

1 IN THE UNITED STATES DISTRICT COURT  
 2 FOR THE EASTERN DISTRICT OF PENNSYLVANIA  
 3  
 4 ---  
 5 IN RE: AVANDIA MARKETING : CIVIL ACTION  
 6 SALES PRACTICES AND PRODUCTS :  
 7 LIABILITY LITIGATION : 07-MD-01871  
 8  
 9  
 10 PHILADELPHIA, PENNSYLVANIA  
 11 TUESDAY, SEPTEMBER 21, 2010  
 12  
 13 BEFORE: THE HONORABLE CYNTHIA M. RUFÉ, J.  
 14 THE HONORABLE SANDRA MAZER MOSS, J.  
 15  
 16 DAUBERT HEARING  
 17  
 18  
 19 SUZANNE R. WHITE, CM  
 20 FEDERAL CERTIFIED REALTIME REPORTER  
 21 FIRST FLOOR U. S. COURTHOUSE  
 22 601 MARKET STREET  
 23 PHILADELPHIA, PA 19106  
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 25  
 PROCEEDINGS RECORDED BY STENOTYPE-COMPUTER,  
 TRANSCRIPT PRODUCED BY COMPUTER-AIDED TRANSCRIPTION

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1 (THE CLERK OPENS COURT.)  
 2 HONORABLE CYNTHIA M. RUFÉ: I THINK SHE  
 3 GOT AN EXTRA NAME TODAY.  
 4 HONORABLE SANDRA MAZER MOSS: IT'S A  
 5 TONGUE TWISTER.  
 6 HONORABLE CYNTHIA M. RUFÉ: GOOD MORNING,  
 7 EVERYONE.  
 8 ALL COUNSEL: GOOD MORNING, YOUR HONORS.  
 9 HONORABLE CYNTHIA M. RUFÉ: I EXPECT THAT  
 10 WE WILL HEAR FROM PLAINTIFFS' WITNESSES. THE FIRST ONE  
 11 BEING YOUR -- WELL, NICHOLAS JEWELL, YOU'RE DR. JEWELL?  
 12 DR. JEWELL: YES, YOUR HONORS.  
 13 HONORABLE CYNTHIA M. RUFÉ: MR. CARTMELL,  
 14 YOU WILL TAKE OVER THE QUESTIONING AND WE WILL, OF  
 15 COURSE, TURN TO CROSS EXAMINATION. AND WHO WILL BE  
 16 CONDUCTING THAT?  
 17 MS. GUSSACK: THOMAS SHEEHAN FROM  
 18 PHILLIPS LYTLE, COUNSEL WILL BE CONDUCTING THE CROSS  
 19 EXAM.  
 20 HONORABLE CYNTHIA M. RUFÉ: WE WILL TAKE  
 21 A BRIEF RECESS AROUND 10 :30 FOR STENOGRAPHIC NEEDS, BUT  
 22 WE WILL TRY TO GET AS MUCH TESTIMONY IN AND BREAK AROUND  
 23 12:15 TODAY. JUDGE MOSS AND I BOTH HAVE OTHER  
 24 COMMITMENTS THAT WE ARE SQUEEZING INTO THE MIDDLE OF ALL  
 25 THESE. HOPEFULLY WE WILL NOT HAVE A VERY LONG LUNCH

1 BREAK SO WE CAN GET ALL OF THE EXPERTS ON THAT ARE  
 2 AVAILABLE TODAY. ALL RIGHT?  
 3 MR. CARTMELL: YOUR HONOR, CHRIS IS GOING  
 4 TO GIVE YOU COPIES OF DR. JEWELL'S REPORT, HIS CV AND  
 5 HIS BIBLIOGRAPHY FOR YOU TO REFER TO. WE WILL BE  
 6 REFERRING TO THOSE PERIODICALLY THROUGHOUT HIS  
 7 EXAMINATION.

8 NICHOLAS P. JEWELL, PH.D., SWORN.  
 9 THE CLERK: STATE AND SPELL YOUR FULL  
 10 NAME FOR THE RECORD, PLEASE.

11 THE WITNESS: NICHOLAS PATRICK JEWELL,  
 12 J-E-W-E-L-L.

13 DIRECT EXAMINATION

14 BY MR. CARTMELL:

15 Q. GOOD MORNING, DR. JEWELL.

16 A. **GOOD MORNING.**

17 Q. I'M GOING TO ASK YOU SOME QUESTIONS ABOUT YOUR  
 18 QUALIFICATIONS. GSK HAS SAID YESTERDAY THAT THEY ARE  
 19 NOT CHALLENGING YOUR QUALIFICATIONS, BUT I THINK WE NEED  
 20 TO TALK A LITTLE BIT ABOUT THOSE TO PUT YOUR OPINIONS IN  
 21 CONTEXT.

22 TELL US, IF YOU WOULD, PLEASE, WHERE YOU  
 23 ARE CURRENTLY EMPLOYED?

24 A. **I'M A PROFESSOR OF BIostatISTICS AND STATISTICS  
 25 AT THE UNIVERSITY OF CALIFORNIA IN BERKELEY.**

1 Q. YOU ARE A STATISTICIAN, IS THAT CORRECT?

2 A. **THAT'S CORRECT.**

3 Q. TELL US PLEASE WHAT A STATISTICIAN IS.

4 A. **WELL, I'M ACTUALLY A BIostatISTICIAN, WHICH IS A  
 5 LITTLE MORE SPECIFIC. I STUDY THE ROLE OF RISK FACTORS  
 6 AND EXPOSURES AS THEY RELATE TO THE OCCURRENCE OF  
 7 DISEASES IN HUMANS, BOTH INFECTIOUS AND NONINFECTIOUS  
 8 DISEASES.**

9 Q. HOW LONG HAVE YOU BEEN A BIostatISTICIAN?

10 A. **FOR ABOUT -- MORE THAN 30 YEARS.**

11 Q. WE HAVE HEARD A LOT ABOUT EPIDEMIOLOGY OR  
 12 EPIDEMIOLOGISTS. TELL US WHAT EPIDEMIOLOGY IS, PLEASE.

13 A. **THE FIELD OF EPIDEMIOLOGY STUDIES THE  
 14 DISTRIBUTION OF DISEASES IN HUMAN POPULATIONS, SOMETIMES  
 15 IN ANIMAL POPULATIONS, IN CONJUNCTION WITH THE  
 16 POPULATION DISTRIBUTION OF RISK FACTORS OR EXPOSURES IN  
 17 ATTEMPTS TO LINK RISK FACTORS TO THE OCCURRENCE OF  
 18 DISEASE AND EXPLAIN WHY CERTAIN INDIVIDUALS GET DISEASES  
 19 AND CERTAIN DON'T.**

20 Q. DURING THE COURSE OF YOUR PRACTICE AS A  
 21 BIostatISTICIAN, DO YOU WORK -- DO WORK RELATED TO  
 22 EPIDEMIOLOGIC STUDIES OR EPIDEMIOLOGY?

23 A. **YES. MY ENTIRE CAREER HAS LARGELY BEEN IN THE  
 24 APPLICATION OF STATISTICS TO EPIDEMIOLOGIC STUDIES.**

25 Q. IF YOU WOULD NOT MIND JUST BRIEFLY, BUT TELL US

1 WHAT IN GENERAL YOUR WORK RELATED TO EPIDEMIOLOGY HAS  
 2 BEEN DURING YOUR CAREER?

3 A. **MY RESEARCH HAS BEEN INVOLVED IN DEVELOPING  
 4 STATISTICAL METHODS TO ATTACK THE PROBLEMS I JUST  
 5 DISCUSSED RELATING RISK FACTORS AND EXPOSURES TO  
 6 DISEASES. MY CAREER HAS BEEN NOT FOCUSED IN ANY  
 7 SPECIFIC AREA OF HUMAN DISEASES, BUT HAS COVERED A VERY  
 8 WIDE RANGE, FROM INFECTIOUS DISEASES WHERE I SPENT A LOT  
 9 OF TIME STUDYING HIV WHEN I FIRST WENT TO CALIFORNIA AND  
 10 -- BUT HAS ALSO COVERED THINGS INCLUDING CANCER, HEART  
 11 DISEASE, ENVIRONMENTAL EPIDEMIOLOGY AND THE LIKE.**

12 Q. IN THIS CASE YOU WERE ASKED BY THE PLAINTIFFS'  
 13 STEERING COMMITTEE TO PERFORM A CAUSATION ANALYSIS  
 14 RELATED TO WHETHER OR NOT AVANDIA CAUSES MYOCARDIAL  
 15 INFARCTS AND MYOCARDIAL ISCHEMIC EVENTS; IS THAT  
 16 CORRECT?

17 A. **THAT'S CORRECT.**

18 Q. AND IS THAT SOMETHING -- THAT TYPE OF CAUSATION  
 19 ANALYSIS, IS THAT SOMETHING THAT YOU HAD DONE PREVIOUSLY  
 20 OR HAVE DONE PREVIOUSLY IN YOUR CAREER OVER THE LAST  
 21 30 YEARS?

22 A. **YES. THAT IS WHAT I DO PRETTY MUCH EVERY DAY OF  
 23 MY LIFE. IT IS CHARACTERIZED -- ALL THE WORK I DO IS  
 24 TRYING TO DEVELOP STATISTICAL METHODS, NOT ONLY TO  
 25 QUANTIFY RELATIONSHIPS BETWEEN RISK FACTORS AND**

1 **OUTCOMES, BUT TO ALSO ASSESS WHAT STATISTICAL TOOLS CAN  
 2 BE BROUGHT TO BEAR ON THE ISSUE OF CAUSATION.**

3 Q. WE HAVE HEARD ABOUT YOUR BOOK. THIS IS YOUR  
 4 BOOK, IS THAT CORRECT?

5 A. **THAT IS MY BOOK, YES.**

6 Q. STATISTICS FOR EPIDEMIOLOGY?

7 A. **THAT IS CORRECT.**

8 Q. MR. ZONIES CATEGORIZED IT AS A BEST SELLER. IS  
 9 IT A BEST SELLER?

10 A. **NOT BY NORMAL -- I DON'T THINK TOO MANY PEOPLE  
 11 ARE READING IT AT BEDTIME. PUT IT THAT WAY.**

12 HONORABLE CYNTHIA M. RUFÉ: SOUNDS LIKE  
 13 SOMETHING I WOULD LIKE TO READ AT BEDTIME.

14 THE WITNESS: IT MIGHT PUT TO YOU SLEEP.

15 BY MR. CARTMELL:

16 Q. THIS BOOK, I WANT TO MAKE SOME REFERENCE TO  
 17 THIS.

18 MR. CARTMELL: PLEASE PULL UP, IF YOU  
 19 WOULD NOT MIND, F, SLIDE F.

20 BY MR. CARTMELL:

21 Q. BY MR. CARTMELL: YOU HAVE MULTIPLE CHAPTERS IN  
 22 THIS BOOK RELATED TO EPIDEMIOLOGIC PRINCIPLES, IS THAT  
 23 CORRECT.

24 A. **YEAH. THE BOOK IS ACTUALLY BASED ON A COURSE  
 25 I'VE TAUGHT AT BERKELEY FOR 30 YEARS AND THE DEVELOPMENT**

1 **OF THOSE MATERIALS, AND SO IT'S A COURSE THAT IS AIMED**  
 2 **ACTUALLY AT EPIDEMIOLOGISTS MORE THAN AT STATISTICIANS**  
 3 **AND TRYING TO TEACH AND EDUCATE THEM ON HOW STATISTICAL**  
 4 **METHODS ARE USED TO TACKLE THE PROBLEMS LIKE THE PROBLEM**  
 5 **WE HAVE HERE OF AN EXPOSURE RELATED TO AN OUTCOME.**

6 **Q.** AS YOU SEE ON THE SLIDE, SOME OF THE CHAPTERS  
 7 INVOLVED IN YOUR BOOK OR INCLUDED IN YOUR BOOK INVOLVE  
 8 STUDY DESIGNS, CAUSAL INFERENCE, CONFOUNDING AND  
 9 INTERACTION, CONTROL OF EXTRANEOUS FACTORS AND  
 10 REGRESSION MODELS, THINGS THAT YOU WERE LOOKING AT WHEN  
 11 YOU PERFORMED YOUR ANALYSIS IN THIS CASE, IS THAT  
 12 CORRECT?

13 **A. YES. THE CHAPTER ON CAUSAL INFERENCE IS**  
 14 **ACTUALLY THE HEART OF THAT BOOK. THAT IS THE KEY**  
 15 **CHAPTER. IF YOU ONLY READ ONE, THAT IS THE ONE YOU NEED**  
 16 **TO READ.**

17 **Q.** YOU MENTIONED I THINK, BUT YOU ACTUALLY TEACH  
 18 EPIDEMIOLOGISTS?

19 **A. I DO. I TEACH ABOUT 100 EPIDEMIOLOGISTS A YEAR**  
 20 **AT THE UNIVERSITY OF CALIFORNIA, BERKELEY. I ALSO HAVE**  
 21 **MY LECTURES ON ITUNES SO I ACTUALLY TEACH A LOT OF**  
 22 **PEOPLE ACROSS THE WORLD WHO LISTEN IN TO THE LECTURES ON**  
 23 **ITUNES.**

24 **Q.** WE HAVE YOUR CV.  
 25 **MR. CARTMELL: YOUR HONORS, YOU HAVE**

1 THAT.

2 BY MR. CARTMELL:

3 **Q.** BUT I THINK YOU'VE PUBLISHED APPROXIMATELY HOW  
 4 MANY --

5 **HONORABLE SANDRA MAZER MOSS: I DON'T**  
 6 **KNOW IF I HAVE THE CV. I HAVE THE BIBLIOGRAPHY, SEVERAL**  
 7 **BIBLIOGRAPHIES. IS IT ATTACHED TO THE REPORT?**

8 **HONORABLE CYNTHIA M. RUFÉ: YES, IT IS.**

9 **HONORABLE SANDRA MAZER MOSS: I SEE IT.**

10 OKAY, NOT A PROBLEM.

11 BY MR. CARTMELL:

12 **Q.** I THINK YOU HAVE PUBLISHED MANY TIMES IN PEER  
 13 REVIEW JOURNALS, IS THAT CORRECT?

14 **A. YES.**

15 **Q.** APPROXIMATELY 145 OR 150?

16 **A. ROUGHLY ABOUT 150 ARTICLES.**

17 **Q.** YOU ARE THE PRESIDENT OF THE SECTION OF  
 18 STATISTICS AND EPIDEMIOLOGY OF THE AMERICAN STATISTICAL  
 19 ASSOCIATION?

20 **A. I AM CURRENTLY, YES.**

21 **Q.** TELL US WHAT THE AMERICAN STATISTICAL  
 22 ASSOCIATION IS, PLEASE.

23 **A. THE AMERICAN STATISTICAL ASSOCIATION IS THE**  
 24 **LARGEST PROFESSIONAL ORGANIZATION FOR STATISTICIANS IN**  
 25 **THE COUNTRY. IT INCLUDES AS MEMBERS ACADEMICS LIKE**

1 **MYSELF, BUT ALSO A LARGE NUMBER FROM THE GOVERNMENT AND**  
 2 **FROM INDUSTRY. AND IT HAS SECTIONS DEVOTED TO THE AREAS**  
 3 **OF INTEREST OF ITS MEMBERS AND THE SECTION ON**  
 4 **EPIDEMIOLOGY IS FOR STATISTICIANS ACROSS THE COUNTRY WHO**  
 5 **ARE INTERESTED IN THESE VERY ISSUES AND THE STATISTICAL**  
 6 **IDEAS.**

7 **Q.** NOW, DURING YOUR REVIEW OF THIS CASE, DID YOU  
 8 COME ACROSS BIOSTATISTICIANS WHO WERE INVOLVED IN THE  
 9 ANALYSIS OF AVANDIA RELATED TO WHETHER OR NOT IT CAUSED  
 10 CARDIOVASCULAR RISK THAT YOU HAVE WORKED WITH IN THE  
 11 PAST, FOR EXAMPLE, STUART POCOCK WHO'S ONE OF THE MAIN  
 12 AUTHORS OF THE RECORD STUDY?

13 **A. I DO KNOW STUART QUITE WELL, YES.**

14 **Q.** AND WERE THERE BIOSTATISTICIANS ON THE FDA  
 15 PANEL, FOR INSTANCE, VOTING MEMBERS OF THE PANEL RELATED  
 16 TO WHETHER OR NOT AVANDIA CAUSES INCREASED  
 17 CARDIOVASCULAR RISK?

18 **A. YES. THERE WERE SEVERAL STATISTICIANS INVOLVED**  
 19 **IN BOTH OF THE ADCOM MEETINGS AND THAT REFLECTS, I THINK**  
 20 **AS YOU MAY HAVE PICKED UP YESTERDAY, THIS IS AS MUCH**  
 21 **ABOUT BIostatISTICS AS IT IS ABOUT EPIDEMIOLOGY. AND**  
 22 **THE TWO FIELDS -- STATISTICS IS AN OLDER FIELD THAN**  
 23 **EPIDEMIOLOGY. EPIDEMIOLOGY STARTED ABOUT 150 YEARS AGO.**  
 24 **WE HEARD ABOUT KOCH YESTERDAY, BUT IT RIGHT FROM THE**  
 25 **VERY BEGINNING IT WORKED HAND-IN-HAND WITH THE FIELD OF**

1 **STATISTICS AND IT'S WORKED SYMBIOTICALLY EVER SINCE. IN**  
 2 **MY OWN DEPARTMENT, OUR TWO GROUPS ARE SIDE-BY-SIDE,**  
 3 **CHEEK TO JOWL BECAUSE WE DEPEND ON EACH OTHER FOR OUR**  
 4 **WORK.**

5 **Q.** NOW YOU UNDERSTAND THAT YOU ARE HERE TODAY  
 6 BECAUSE GSK IS CHALLENGING YOUR METHODOLOGY THAT YOU  
 7 USED IN FORMING YOUR OPINIONS IN THIS CASE, IS THAT  
 8 CORRECT?

9 **A. YES, THAT IS MY UNDERSTANDING.**

10 **Q.** I WANT TO TALK ABOUT THE METHODOLOGY THAT YOU  
 11 USE WHEN YOU ARE DOING A CAUSATION ANALYSIS AND THAT YOU  
 12 HAVE DONE OVER THE 30 YEARS THAT YOU HAVE BEEN A  
 13 BIOSTATISTICIAN. TELL YOUR HONORS, IF YOU WOULD, WHAT  
 14 METHODOLOGY YOU USE WHEN YOU ARE DOING A CAUSATION  
 15 ANALYSIS LIKE YOU HAVE DONE IN THIS CASE.

16 **A. WELL, WHEN I'M ASKED TO LOOK AT A PROBLEM FOR**  
 17 **THE FIRST TIME FOR A PARTICULAR EXPOSURE, IN THIS CASE**  
 18 **IT'S A DRUG EXPOSURE, AVANDIA, AND A SPECIFIC OUTCOME,**  
 19 **IN THIS CASE CARDIOVASCULAR DISEASE AND IN PARTICULAR**  
 20 **HEART ATTACKS OR MYOCARDIAL INFARCTIONS, THE FIRST THING**  
 21 **I DO IS TRY TO, OF COURSE -- IF I'M NOT ACTUALLY**  
 22 **PERSONALLY INVOLVED IN THE STUDY MYSELF, OFTEN MY**  
 23 **WORK IS, I HAVE BEEN INVOLVED IN A STUDY MYSELF FROM ITS**  
 24 **INCEPTION, BUT IN THIS CASE, I WAS ASKED TO REVIEW AND**  
 25 **UNDERSTAND WHAT IS KNOWN ABOUT THE QUESTION, I'LL REVIEW**

1 THE LITERATURE TO THE EXTENT OF MY ABILITY TO GET ALL OF  
 2 THE INFORMATION THAT I CAN FIND.  
 3 NOW THE FIRST THING THAT I LOOK FOR IS  
 4 RANDOMIZED CONTROLLED TRIALS AS WE HEARD OVER AND OVER  
 5 AGAIN YESTERDAY. I HAVE TO SAY THAT IN MANY TIMES IN MY  
 6 EXPERIENCE THERE ARE NO RANDOMIZED CONTROLLED TRIALS.  
 7 THERE NEVER WAS A RANDOMIZED CONTROLLED TRIAL THAT  
 8 ESTABLISHED THAT SMOKING CAUSED LUNG CANCER. IT'S  
 9 INDISPUTABLE NOW THAT THAT IS TRUE, BUT THERE WAS NEVER  
 10 A RANDOMIZED CONTROLLED TRIAL. THERE WERE ONLY  
 11 OBSERVATIONAL STUDIES AT THE BEGINNING AND THAT IS NOT  
 12 ATYPICAL OF EPIDEMIOLOGY. AND THAT IS ONE OF THE  
 13 CHALLENGES IN CAUSATION WITH EPIDEMIOLOGY BECAUSE OFTEN  
 14 THERE ARE NO RANDOMIZED TRIALS, AND THERE CAN'T BE  
 15 RANDOMIZED TRIALS, AS YOU CAN SEE IMMEDIATELY IN THE  
 16 CASE OF SMOKING.  
 17 IN THIS CASE, HOWEVER, WE ARE FORTUNATE  
 18 BECAUSE THERE ARE RANDOMIZED CONTROLLED TRIALS AND SO I  
 19 COLLECTED AS MUCH INFORMATION AS I COULD ABOUT WHO DID  
 20 THOSE TRIALS AND WHERE THEY WERE PUBLISHED AND TRIED TO  
 21 REVIEW THAT LITERATURE.  
 22 SUBSEQUENTLY THEN, I WOULD GO ON AND LOOK  
 23 FOR INFORMATION ABOUT THE OBSERVATIONAL STUDIES.  
 24 SOMETIMES THAT IS ALL YOU HAVE. HERE YOU HAVE BOTH, SO  
 25 THERE ARE A NUMBER OF OBSERVATIONAL STUDIES THAT WE

1 HEARD ABOUT YESTERDAY THAT I ALSO REVIEWED.  
 2 SOMETIMES IN THE -- WHETHER IT'S FOR  
 3 RANDOMIZED CONTROLLED TRIALS OR OBSERVATIONAL STUDIES,  
 4 THERE WILL ALSO BE ATTEMPTS BY PROFESSIONALS TO  
 5 ASSIMILATE THE INFORMATION IN A META-ANALYSIS, THAT WE  
 6 ALSO HEARD THAT TERM REFERRED TO YESTERDAY. THAT IS  
 7 JUST A TECHNIQUE FOR TAKING SIMILAR TRIALS, ASKING  
 8 SIMILAR QUESTIONS AND TRYING TO ASSIMILATE THE  
 9 INFORMATION IN ONE SUMMARY. AND OF COURSE THERE ARE  
 10 SOME OF THOSE IN THIS CASE TOO.  
 11 SO I LOOKED AT ALL OF THOSE, I ALSO  
 12 LOOKED AT SOME TRIALS THAT I THINK ARE ALMOST BELOW THE  
 13 STANDARD OF QUALITY OF OBSERVATIONAL STUDIES. SO I DID  
 14 THE BEST I COULD TO TRY AND REVIEW ALL OF THE LITERATURE  
 15 THAT I COULD FIND.  
 16 Q. NOW, YOU HAVE WITH YOU, AND FEEL FREE TO LOOK AT  
 17 IT WHENEVER YOU NEED TO, A COPY OF YOUR BIBLIOGRAPHY  
 18 THAT WAS SUBMITTED ON YOUR BEHALF TO GSK AND WITH YOUR  
 19 REPORTS IN THIS CASE. JUST TO MAKE IT CLEAR, YOU HAVE  
 20 SUBMITTED TWO EXPERT REPORTS. YOU HAD AN INITIAL REPORT  
 21 AND A SUPPLEMENTAL EXPERT REPORT, IS THAT CORRECT?  
 22 A. THAT IS CORRECT. I HAVE THOSE IN FRONT OF ME,  
 23 ACTUALLY I DON'T HAVE THE BIBLIOGRAPHY IN FRONT OF ME.  
 24 Q. I HAVE IT RIGHT HERE AND ACTUALLY I MAY AS WELL  
 25 GIVE YOU MY COPY.

1 HONORABLE CYNTHIA M. RUFÉ: DO YOU ONE  
 2 CODIFIED? I HAVE THREE SUPPLEMENTALS.  
 3 HONORABLE SANDRA MAZER MOSS: I HAVE  
 4 MANY. I HAVE TWO AMENDED AND SOME SUPPLEMENTALS.  
 5 MR. CARTMELL: I WAS JUST GOING TO GET TO  
 6 THAT. THERE ARE THREE SUPPLEMENTALS AND AN ORIGINAL.  
 7 THE ORIGINAL WENT WITH THE ORIGINAL REPORT AND THEN  
 8 SINCE THEN AS HE HAS CONTINUED TO REVIEW --  
 9 HONORABLE SANDRA MAZER MOSS: WHICH IS  
 10 THE ORIGINAL? I HAVE AN AMENDED BIBLIOGRAPHY, A SECOND  
 11 AMENDED AND THREE SUPPLEMENTALS.  
 12 MR. CARTMELL: THE AMENDED IS THE  
 13 ORIGINAL BECAUSE OF SOME OF THE MATERIALS HE REVIEWED  
 14 BEFORE WRITING HIS REPORT WERE ADDED. IT WAS MADE TO BE  
 15 AN AMENDED. THE KEY IS, IT'S VERY CONFUSING.  
 16 HONORABLE SANDRA MAZER MOSS: THE AMENDED  
 17 IS THE ORIGINAL. OKAY.  
 18 MR. CARTMELL: THAT'S RIGHT.  
 19 BY MR. CARTMELL:  
 20 Q. THERE ARE 18 PAGES OF YOUR BIBLIOGRAPHIES,  
 21 MULTIPLE BIBLIOGRAPHIES, CONTAINING ALL OF THE  
 22 INFORMATION THAT YOU REVIEWED, IS THAT CORRECT?  
 23 A. YES. I MUST SAY I HAVE NEVER READ AS MUCH  
 24 MATERIAL ON ANY QUESTION IN MY ENTIRE 30-YEAR CAREER AS  
 25 I HAVE READ ABOUT AVANDIA AND CARDIOVASCULAR DISEASE.

1 Q. NOW, LET ME ASK YOU THIS, YOU TOLD US WHAT THE  
 2 METHODOLOGY YOU USE IS WHEN YOU DO A CAUSATION ANALYSIS,  
 3 DID YOU USE THAT SAME METHODOLOGY IN THIS CASE?  
 4 A. YES. OF COURSE, IN ADDITION TO COLLECTING THE  
 5 INFORMATION ABOUT THE CLINICAL TRIALS, THERE ARE  
 6 SPECIFIC QUESTIONS YOU WANT TO LOOK ABOUT HOW THOSE  
 7 TRIALS WERE CONDUCTED, WHAT POPULATIONS THEY WERE DONE,  
 8 WHAT DOSES OF THE DRUG WERE GIVEN, WHAT WAS THE  
 9 COMPARATOR GROUP. ALL OF THAT HAS TO BE DONE IN  
 10 ADDITION TO LOOKING AT SOME OF THE QUESTIONS THAT WERE  
 11 REFERRED TO YESTERDAY: IS THERE A DOSE RESPONSE? IS  
 12 THERE CONSISTENCY? IS THERE CONSISTENCY BETWEEN THE  
 13 RANDOMIZED CLINICAL TRIALS AND THE OBSERVATIONAL  
 14 STUDIES. ALL OF THAT HAS TO BE DONE AND THEN YOU TRY TO  
 15 COME TO AN OPINION OR SUMMARIZE IT ALL AT SOME POINT. I  
 16 DID EXACTLY THAT IN THIS STUDY, AS I TEACH AND AS I DO  
 17 IN OTHER WORK COMPLETELY OUTSIDE OF LITIGATION.  
 18 Q. AND DID YOU USE THE SAME AMOUNT OF SCIENTIFIC  
 19 RIGOR THAT YOU USE IN YOUR NORMAL PRACTICE? DID YOU USE  
 20 THAT SAME AMOUNT IN THIS CASE?  
 21 A. I WOULD SAY I ACTUALLY USED A LITTLE BIT MORE  
 22 RIGOR BECAUSE I KNEW I WOULD BE UP HERE ANSWERING  
 23 QUESTIONS.  
 24 Q. LET'S TALK ABOUT THE METHODOLOGY. I WANT TO GO  
 25 INTO MORE DETAIL.

1 MR. CARTMELL: C 1, PLEASE.  
 2 BY MR. CARTMELL:  
 3 Q. FIRST OF ALL, YOU DID WRITE A REPORT, YOUR  
 4 ORIGINAL REPORT.  
 5 MR. CARTMELL: I WANT TO REFER TO THAT  
 6 PERIODICALLY FOR YOUR HONORS.  
 7 BY MR. CARTMELL:  
 8 Q. PAGE TWO, PLEASE. THAT IS A COPY OF YOUR  
 9 GENERIC EXPERT REPORT AND IT'S SMALL, BUT IF YOU COULD  
 10 PULL OUT THE FIRST EXECUTIVE SUMMARY OF YOUR REPORT.  
 11 THAT IS ACTUALLY PAGE TWO OF THE REPORT. YOU NEED TO GO  
 12 BACK ONE PAGE, PLEASE. THERE WE GO, EXECUTIVE SUMMARY  
 13 OF YOUR REPORT. NOW THIS IS YOUR SUMMARY THAT YOU DID  
 14 AFTER DEVELOPING YOUR OPINIONS IN THIS CASE, IS THAT  
 15 CORRECT?  
 16 A. **THAT IS CORRECT.**  
 17 Q. I'M JUST GOING TO HIGHLIGHT WHAT YOU SAY HERE.  
 18 IT SAYS: BASED SOLELY ON RANDOMIZED CLINICAL TRIAL  
 19 DATA, I FIND SIGNIFICANT EVIDENCE OF INCREASED RISK OF  
 20 SERIOUS CARDIOVASCULAR SIDE EFFECTS, IN PARTICULAR, IN  
 21 THE RATE OF OCCURRENCE OF ISCHEMIC HEART DISEASE EVENTS  
 22 AND MYOCARDIAL INFARCTIONS. WERE YOU ASKED TO LOOK BOTH  
 23 AT SERIOUS ISCHEMIC HEART DISEASE EVENTS AND MYOCARDIAL  
 24 INFARCTIONS?  
 25 A. **YES. I WAS ASKED TO LOOK AT BOTH, AND I CAN**

1 **CERTAINLY, IF EITHER PARTY WANTS TO QUESTION ABOUT THE**  
 2 **CHOICE OF THE OUTCOME, I CAN TALK MORE ABOUT THAT**  
 3 **BECAUSE THAT IS, OF COURSE, AN IMPORTANT ISSUE, BUT I**  
 4 **DID LOOK AT BOTH.**  
 5 Q. IN OTHER WORDS, YOU LOOKED NOT ONLY AT DATA  
 6 RELATED TO MYOCARDIAL ISCHEMIA EVENTS AS A COMBINED  
 7 OUTCOME, BUT YOU ALSO LOOKED AT DATA RELATED TO  
 8 MYOCARDIAL INFARCTIONS OR HEART ATTACKS AS WELL, IS THAT  
 9 CORRECT?  
 10 A. **YES. I MADE SPECIFIC EFFORT TO TRY AND LOOK AT**  
 11 **THE MYOCARDIAL INFARCTION DATA SPECIFICALLY WHEN IT WAS**  
 12 **AVAILABLE.**  
 13 Q. YOU GO ON AND YOU SAY: THIS EVIDENCE IS LARGELY  
 14 CONSISTENT ACROSS TRIALS WITH SHORT DURATION AND LONGER  
 15 TERM TRIALS AND ACROSS DIFFERENT POPULATIONS. THE  
 16 REPORTED ESTIMATED INCREASES IN RISK TEND TO BE  
 17 UNDERESTIMATES BECAUSE TRIAL POPULATIONS OFTEN LIMITED  
 18 PARTICIPATION OR EXCLUDED INDIVIDUALS AT HIGH RISK OF  
 19 CARDIOVASCULAR EVENTS, A GROUP THAT IS GENERALLY  
 20 ACCEPTED TO BE AT GREATER RISK OF AN ADVERSE OUTCOME  
 21 WHEN EXPOSED TO ROSIGLITAZONE. AND AGAIN ROSIGLITAZONE  
 22 IS AVANDIA, IS THAT CORRECT?  
 23 A. **THAT IS CORRECT.**  
 24 Q. THE DATA FROM THE OBSERVATIONAL STUDIES OF  
 25 ROSIGLITAZONE PATIENTS IS GENERALLY CONSISTENT WITH THE

1 NEGATIVE ASSESSMENT OF ROSIGLITAZONE PROVIDED BY THE  
 2 RANDOMIZED CLINICAL TRIALS. IS THIS A SUMMARY OPINION  
 3 THAT YOU CAME TO OR PUT AT THE BEGINNING OF YOUR REPORT  
 4 AND BEYOND -- BEHIND THAT ACTUALLY YOU DISCUSSED THE  
 5 METHODOLOGIES AND YOUR SUMMARY OF THE EVIDENCE THAT YOU  
 6 REVIEWED.  
 7 A. **THAT IS A SUMMARY OF MY OPINION. WHAT IT DOES**  
 8 **NOT ACTUALLY SAY AND I DON'T TALK ABOUT IN MY REPORT BUT**  
 9 **I FOUND I THINK MIGHT BE HELPFUL, GIVEN THE DISCUSSION**  
 10 **YESTERDAY IS, THERE IS A CONTEXT THAT THIS QUESTION HAS**  
 11 **ARISEN. AVANDIA OR ROSIGLITAZONE IS A PARTICULAR**  
 12 **CHEMICAL COMPOUND OF A CLASS OF COMPOUNDS CALLED THE**  
 13 **PPAR AGONISTS. PLEASE DON'T ASK ME TO GIVE THE CHEMICAL**  
 14 **NAME BECAUSE I'M A STATISTICIAN, NOT A CHEMIST, BUT IT'S**  
 15 **A CLASS OF COMPOUNDS. THESE COMPOUNDS ARE QUITE**  
 16 **BIOLOGICALLY POWERFUL. THAT HAS BEEN KNOWN. REMEMBER,**  
 17 **THIS IS A STATISTICIAN TALKING SO I'M GOING TO BE FAIRLY**  
 18 **-- SPEAKING IN LAY TERMS. AND AS A RESULT BECAUSE OF**  
 19 **THEIR ABILITY TO HAVE BIOLOGICAL IMPACT IN HUMAN, THEY**  
 20 **HELD PROMISE FOR TREATMENT PARTICULARLY OF DIABETICS.**  
 21 **THERE IS MORE THAN 40 OF THESE DRUGS, AVANDIA.**  
 22 **VERY FEW OF THEM MADE IT TO TESTING IN**  
 23 **HUMANS BECAUSE OF SIDE EFFECTS IN ANIMALS. SO MOST OF**  
 24 **THE PPAR AGONISTS HAVE BEEN DROPPED. THERE WERE SOME**  
 25 **OTHERS THAT DID GET TO DEVELOPMENT IN HUMANS AND THERE**

1 **WAS ONE FROM ASTRAZENECA -- I HAVE FORGOTTEN WHAT THE**  
 2 **NAME OF IT -- SOMETHING LIKE GLISSIDE.**  
 3 Q. TROGLITAZONE?  
 4 A. **THERE IS ANOTHER ONE THAT ASTRAZENECA PRODUCED,**  
 5 **STARTED TESTING AND THEN STOPPED DEVELOPMENT BECAUSE OF**  
 6 **CONCERN ABOUT NEGATIVE SIDE EFFECTS. THREE MADE IT TO**  
 7 **THE MARKET. TROGLITAZONE. I DON'T KNOW THE GENERIC OR**  
 8 **THE TRADE NAME FOR IT.**  
 9 Q. REZULIN.  
 10 A. **SO TROGLITAZONE AND THAN THIS ONE,**  
 11 **ROSIGLITAZONE, AVANDIA, AND PIOGLITAZONE. TROGLITAZONE**  
 12 **WAS ALSO WITHDRAWN FROM THE MARKET IN THE UNITED STATES,**  
 13 **I GUESS WORLDWIDE, I DON'T KNOW FOR SURE, BECAUSE OF --**  
 14 **IT WAS CAUSING HEPATITIS IN HUMANS AND THERE WAS A REAL**  
 15 **CONCERN ABOUT THE SIDE EFFECTS SO IT WAS WITHDRAWN FROM**  
 16 **THE MARKET.**  
 17 **BUT OF COURSE PIOGLITAZONE HAS ALSO GONE**  
 18 **THROUGH ITS OWN ANALYSIS THAT WE ARE NOT REALLY TALKING**  
 19 **ABOUT HERE BECAUSE WE ARE FOCUSING ON ROSIGLITAZONE OR**  
 20 **AVANDIA, BUT IT'S ALSO BEEN TESTED IN RANDOMIZED**  
 21 **CLINICAL TRIALS AND IN OBSERVATIONAL STUDIES. IT IS**  
 22 **WORTH COMPARING THE RESULTS OF THOSE BECAUSE IT'S NOT**  
 23 **THAT AVANDIA WAS PICKED ON PARTICULARLY. THERE IS**  
 24 **ALWAYS BEEN A CONCERN. TO THIS DAY, I BELIEVE, PATIENTS**  
 25 **ON AVANDIA AND PIOGLITAZONE HAVE TO HAVE LIVER ENZYMES**

1 **CHECKED IN THE EARLY PART OF THEIR EXPOSURE TO INSURE**  
 2 **THEY ARE NOT SUFFERING FROM HEPATITIS ISSUES. AND HERE**  
 3 **WITH PIOGLITAZONE, I BELIEVE -- I'M NOT AN EXPERT ON**  
 4 **PIOGLITAZONE, BUT THERE IS A CURRENT CONCERN WITH**  
 5 **PIOGLITAZONE WITH BLADDER CANCER. SO THERE IS A CONTEXT**  
 6 **HERE IN WHICH THESE STUDIES HAVE BEEN CARRIED OUT.**

7 Q. IS THAT PART OF THE --

8 MR. SHEEHAN: WE ARE GOING TO OBJECT TO  
 9 THAT LAST ANSWER. IT REALLY HAS NOTHING TO DO WITH ANY  
 10 OPINION THAT HE EXPRESSED IN EITHER OF HIS REPORTS OR AT  
 11 HIS DEPOSITION. AND FRANKLY I SEE -- I CAN'T SEE ANY  
 12 RELEVANCE TO THE METHODOLOGY THAT HE EMPLOYED TO  
 13 DETERMINE CAUSATION IN THIS CASE.

14 HONORABLE CYNTHIA M. RUFÉ: WOULD YOU  
 15 LIKE TO RESPOND, MR. CARTMELL?

16 MR. CARTMELL: I JUST THINK HE IS GIVING  
 17 INFORMATION AS THE CONTEXT IN THE -- BACKGROUND  
 18 INFORMATION HE HAD AS HE WAS GOING THROUGH THE DATA.

19 HONORABLE CYNTHIA M. RUFÉ: WELL, AS TO  
 20 STUDIES, WHICH IS WHERE HE CAME FROM IN THE TESTIMONY, I  
 21 WOULD SAY I CAN UNDERSTAND STUDIES TO ADDRESS THIS, BUT  
 22 I THINK HIS RESPONSES WENT FURTHER THAN THAT. FOR THE  
 23 FEDERAL COURT I WOULD SUSTAIN THE OBJECTION.

24 HONORABLE SANDRA MAZER MOSS: I WILL  
 25 AGREE.

1 MR. CARTMELL: OKAY. THANK YOU.

2 BY MR. CARTMELL:

3 Q. LET'S TALK ABOUT YOUR METHODOLOGY BECAUSE THAT  
 4 IS WHY WE ARE HERE AND YOU MENTIONED THAT YOU GO TO THE  
 5 RANDOMIZED CONTROLLED TRIALS, AND WERE YOU AWARE OF THE  
 6 NISSEN META-ANALYSIS BEFORE YOU EVER WERE CONTACTED  
 7 ABOUT THIS LITIGATION OR INVOLVED?

8 A. **YES, I WAS, BECAUSE I WAS ACTUALLY VERY**  
 9 **INTERESTED IN THE METHODOLOGY BECAUSE OF OTHER**  
 10 **META-ANALYSES THAT I HAD BEEN INVOLVED IN.**

11 Q. OTHER THAN REVIEWING THE NISSEN META-ANALYSIS,  
 12 YOU HAD NOT DONE ANY OTHER EXTENSIVE RESEARCH RELATED TO  
 13 WHETHER OR NOT AVANDIA CAUSES CARDIOVASCULAR EVENTS  
 14 PRIOR TO THIS CASE, IS THAT FAIR?

15 A. **THAT IS FAIR.**

16 Q. NOW, WHEN YOU GOT INVOLVED IN THIS CASE, DID YOU  
 17 REVIEW THE RANDOMIZED CONTROLLED TRIALS?

18 A. **I DID.**

19 Q. AND THAT INCLUDES -- WE HAVE HEARD A LOT ABOUT  
 20 THE RECORD TRIAL. YOU REVIEWED THE RECORD TRIAL, IS  
 21 THAT CORRECT?

22 A. **THAT IS CORRECT.**

23 Q. WE WILL TALK ABOUT THAT AND YOUR REVIEW -- YOU  
 24 ALSO REVIEWED THE DREAM -- THE LARGE RANDOMIZED CONTROLS  
 25 ARE RECORD AND DREAM AND ADOPT, IS THAT CORRECT?

1 A. **THAT IS CORRECT.**

2 Q. AND THOSE ARE ALL TRIALS THAT YOU AS PART OF  
 3 YOUR METHODOLOGY REVIEWED, IS THAT CORRECT?

4 A. **YES. I ACTUALLY PAID PARTICULAR ATTENTION ALL**  
 5 **OF THE WAY THROUGH TO THE LARGER TRIALS BECAUSE THEY**  
 6 **TEND TO HAVE MORE INFORMATION. I THINK IT'S IMPORTANT**  
 7 **TO LOOK AT THOSE COLLECTIVELY, SEPARATELY AS WELL AS**  
 8 **LOOKING AT THE INFORMATION FROM THE OTHER SMALLER**  
 9 **TRIALS.**

10 Q. THAT IS A QUESTION I WANTED TO ASK YOU.

11 THERE HAS BEEN A DISTINCTION BETWEEN  
 12 SMALLER RANDOMIZED CONTROLLED TRIALS AND THE LARGER  
 13 TRIALS. NOW, YOU REVIEWED THE ICT 42 AND THAT WOULD  
 14 HAVE BEEN MADE UP OF SMALLER RANDOMIZED CONTROLLED  
 15 TRIALS, IS THAT CORRECT?

16 A. **BY AND LARGE MOST OF THOSE WERE AROUND SIX**  
 17 **MONTHS OR SHORTER AND THERE WAS ONE OR TWO THAT I THINK**  
 18 **WERE, IF MY MEMORY IS CORRECT, ABOUT A YEAR IN LENGTH,**  
 19 **BUT THEY WERE SMALLER AND/OR SHORTER THAN THE THREE YOU**  
 20 **MENTIONED.**

21 Q. OKAY. THAT WAS ALSO DATA IN TRIALS THAT YOU  
 22 LOOKED AT DURING THE COURSE OF YOUR REVIEW, IS THAT  
 23 CORRECT?

24 A. **THAT'S CORRECT.**

25 Q. NOW, YOU -- I WANT TO FOLLOW UP ON THAT ONE

1 SECOND.

2 DO YOU LOOK AT THESE SMALL TRIALS OR ARE  
 3 THEY JUST NOT VERY HELPFUL TO YOU BECAUSE THEY DON'T  
 4 HAVE A LOT OF EVENTS? ARE THOSE TRIALS THAT CAN TELL  
 5 YOU INFORMATION?

6 A. **WELL, THEY CERTAINLY CAN TELL YOU INFORMATION.**  
 7 **I THINK IT WOULD BE NOT APPROPRIATE TO IGNORE THEM**  
 8 **BECAUSE THEY ARE SMALL. ON THE OTHER HAND, I CERTAINLY**  
 9 **WANT TO LOOK AT AND -- PULL OUT AND LOOK AT THE LARGER**  
 10 **ONES SEPARATELY BECAUSE YOU WOULD WANT TO BE SURE THAT**  
 11 **YOU WERE NOT -- YOU WERE GETTING A SIMILAR PICTURE AND**  
 12 **BASING YOUR OPINION ON THE COMBINATION OF THE**  
 13 **INFORMATION, SO I LOOK AT BOTH.**

14 Q. NOW, WOULD YOU EXPECT THOSE TRIALS TO HAVE  
 15 STATISTICALLY SIGNIFICANT RESULTS FOR CARDIOVASCULAR  
 16 RISK?

17 A. **THE SMALLER TRIALS YOU ARE REFERRING TO OF**  
 18 **COURSE WERE NOT DESIGNED TO TEST SAFETY. THEY WERE**  
 19 **DESIGNED LARGELY FOR EFFICACY REASONS AND AS A RESULT,**  
 20 **THEY ARE SMALL. THEY ARE SHORT DURATION. SO YOU WOULD**  
 21 **NOT EXPECT TO SEE MANY SERIOUS ADVERSE OUTCOMES, HEART**  
 22 **ATTACKS. IF YOU ARE STUDYING A FEW HUNDRED PEOPLE FOR**  
 23 **THREE MONTHS, THANKFULLY, HOPEFULLY, NONE OF YOUR**  
 24 **PARTICIPANTS WILL HAVE -- EXPERIENCE A HEART ATTACK. SO**  
 25 **MANY OF THOSE TRIALS MAY HAVE NO HEART ATTACKS AT ALL**

1 **UNDER ANY TREATMENT. SO EVEN THE ONES THAT DO, BECAUSE**  
 2 **THEY ARE A LITTLE LONGER, THERE MAY BE A SLIGHTLY HIGHER**  
 3 **RISK POPULATION, YOU MIGHT SEE A FEW, BUT IT WOULD BE --**  
 4 **NO STATISTICIAN WOULD EVER EXPECT TO SEE A SIGNIFICANT**  
 5 **RESULT APPEARING IN A SINGLE ONE OF THESE TRIALS. THEY**  
 6 **ARE JUST TOO SMALL.**

7 **Q.** THANKS.

8 MR. CARTMELL: H, PLEASE.

9 BY MR. CARTMELL:

10 **Q.** I WANT TO GIVE SOME PERSPECTIVE OF HOW YOU ARE  
 11 LOOKING AT THIS INFORMATION. IN OTHER WORDS, WHEN YOU  
 12 COLLECT THIS DATA, THIS IS A SLIDE OF A PUBLICATION FROM  
 13 THE RECORD TRIAL. DO YOU SEE THAT?

14 **A.** I DO.

15 **Q.** AND JUST TELL US HOW -- IS THIS THE SORT OF WAY  
 16 THAT YOU LOOK AT THE INFORMATION? DO YOU GO TO THE  
 17 PUBLISHED LITERATURE? TELL US HOW YOU WOULD PROCEED  
 18 THROUGH A PUBLICATION LIKE THIS.

19 **A.** YES, I WOULD -- ONCE I FIND A PUBLICATION LIKE  
 20 THIS OR KNOW OF IT, I WILL READ THE ARTICLE BECAUSE IT  
 21 WILL DESCRIBE RELATIVELY SUCCINCTLY IN WHAT THEY BELIEVE  
 22 IS IMPORTANT AND HAS BEEN SUBJECT TO PEER REVIEW ABOUT  
 23 THE DESIGN OF THE STUDY AND THE STATISTICAL METHODS  
 24 USED, ANY BIAS ISSUES THAT THEY ARE CONCERNED ABOUT AND  
 25 THEN THE ANALYSIS AND THEIR OWN CONCLUSIONS. SO I WILL

1 **LOOK AT THAT. MANY BIG TRIALS LIKE RECORD ALSO HAVE**  
 2 **PUBLICATIONS THAT PURELY DESCRIBE THE DESIGN OF THE**  
 3 **STUDY SO THAT READERS CAN LOOK AT THAT. BECAUSE OFTEN**  
 4 **THESE LARGE STUDIES HAVE MULTIPLE RESEARCH PAPERS THAT**  
 5 **COME OUT LOOKING AT SLIGHTLY DIFFERENT QUESTIONS. SO I**  
 6 **WILL USUALLY LOOK TO SEE IF THERE IS A PAPER DESCRIBING**  
 7 **THE DESIGN OF THE STUDY ALSO.**

8 **Q.** OKAY. IN THE TOP --

9 HONORABLE SANDRA MAZER MOSS: HOW LONG  
 10 ARE THE LONG RANGE TRIALS, RECORD, DREAM, ADOPT? WHEN  
 11 YOU SAY LONG TERM, WHAT ARE YOU TALKING ABOUT.

12 THE WITNESS: YEARS. WE'RE TALKING ABOUT  
 13 SEVERAL YEARS. IT'S HARD TO DESCRIBE RECORD BECAUSE  
 14 PEOPLE STARTED TO DROPPING OUT SO -- BUT IT WAS I THINK  
 15 THREE, FOUR YEARS IS MY MEMORY. I COULD BE OFF BY SIX  
 16 MONTHS EASILY, BUT THAT IS WHAT I MEAN BY LONG TRIAL,  
 17 AND ALSO A LARGE NUMBER OF PARTICIPANTS, IN THE  
 18 THOUSANDS. SO YOU DO START SEEING SOME CARDIOVASCULAR  
 19 EVENTS BECAUSE THIS PARTICULAR TRIAL WAS A TRIAL OF  
 20 DIABETICS WHO ARE SUBJECT TO HAVE CARDIOVASCULAR EVENTS.

21 HONORABLE SANDRA MAZER MOSS: THANK YOU.

22 BY MR. CARTMELL:

23 **Q.** WHAT WE ARE SHOWING HERE, WE PULLED OUT OF THE  
 24 ARTICLE AND HIGHLIGHTED. THERE IS AN ABSTRACT AT THE  
 25 BEGINNING OF THE ARTICLE AND ONE OF THE THINGS IT DOES

1 IS GIVE A SUMMARY OF THE RESULTS, ALSO OF THE FINDINGS  
 2 AND TELLS YOU METHODS. ARE THE METHODS AND THE DETAIL  
 3 ABOUT THE DESIGN OF THE TRIAL, THINGS LIKE THAT, SPELLED  
 4 OUT TYPICALLY IN DETAIL WITHIN THE ARTICLE?

5 **A.** YES.

6 **Q.** THAT IS SOMETHING THAT YOU ARE LOOKING AT AND  
 7 ANALYZING AS YOU GO THROUGH?

8 **A.** YES. YOU KNOW, I HAVE TO REVIEW ARTICLES LIKE  
 9 THIS AS AN EDITOR OR AS REVIEWER MULTIPLE TIMES A WEEK.  
 10 SO WHEN I'M REVIEWING A MEDICAL ARTICLE IN A MEDICAL  
 11 JOURNAL LIKE THIS, I'M USUALLY RESPONSIBLE, IF I'M GIVEN  
 12 IT TO REVIEW, TO GO STRAIGHT TO THE STATISTICAL METHODS  
 13 BECAUSE THAT IS WHY THEY ARE ASKING ME RATHER THAN A  
 14 CLINICIAN TO LOOK AT THE PAPER.

15 **Q.** NOW, YESTERDAY THERE WAS SOME DISCUSSION ABOUT  
 16 -- I THINK A COMMENT WAS MADE THAT THERE WAS NEVER A  
 17 STATISTICALLY SIGNIFICANT FINDING THAT AVANDIA CAUSES  
 18 MYOCARDIAL INFORMATION (SIC) IN A RANDOMIZED CONTROLLED  
 19 TRIAL. DO YOU RECALL THAT?

20 **A.** I REMEMBER THAT.

21 **Q.** NOW LET ME ASK YOU, DID GSK EVER DO -- HAVE THEY  
 22 -- TO THIS DAY, HAVE THEY EVER DONE A RANDOMIZED  
 23 CLINICAL TRIAL THAT WAS DESIGNED AND POWERED TO  
 24 DETERMINE WHETHER OR NOT AVANDIA CAUSES MYOCARDIAL  
 25 INFARCTION?

1 **A.** NO.

2 **Q.** THAT TEST HAS NEVER BEEN DONE BY GSK?

3 **A.** NOT TO DATE, NO.

4 **Q.** NOW, YOU ALSO MENTIONED THAT A PART OF YOUR  
 5 METHODOLOGY IS TO LOOK AT THE META-ANALYSIS, IS THAT  
 6 CORRECT?

7 **A.** THAT'S CORRECT.

8 **Q.** AND IN FACT IF WE GO TO YOUR REPORT, YOU TALK IN  
 9 DETAIL ABOUT META-ANALYSIS AT --

10 MR. CARTMELL: LET'S GO TO PAGE C FIVE,  
 11 PLEASE.

12 THE LAST PARAGRAPH, PULL THAT OUT,  
 13 PLEASE.

14 BY MR. CARTMELL:

15 **Q.** YOU TALK ABOUT META-ANALYSIS AND YOU IN FACT  
 16 TALK ABOUT SOME OF THE LIMITATIONS TO A META-ANALYSIS.  
 17 WE WILL TALK ABOUT THAT IN A MINUTE. JUST TELL US AGAIN  
 18 WHAT THE PURPOSE IS OF META-ANALYSIS. TELL US WHEN IT'S  
 19 APPROPRIATE TO DO META-ANALYSIS AND SOME OF THE  
 20 STRENGTHS AND THE LIMITATIONS RELATED TO THOSE?

21 **A.** WELL, THERE ARE TWO FUNDAMENTAL REASONS WHY  
 22 PEOPLE DO META-ANALYSIS. ONE IS THE SITUATION YOU JUST  
 23 DESCRIBED WHERE THERE ARE SHORT EFFICACY TRIALS THAT  
 24 WERE NOT DESIGNED TO COLLECT ENOUGH INFORMATION TO  
 25 UNDERSTAND WHETHER AVANDIA CAUSES HEART ATTACK, FOR

1 EXAMPLE. BUT THERE ARE A LARGE NUMBER OF THEM. YOU  
 2 MENTIONED THERE, I THINK, THE ICT 42, CERTAINLY  
 3 MENTIONED YESTERDAY 42 OF THESE TRIALS, MOSTLY SHORT.  
 4 SO ONE PURPOSE OF META-ANALYSIS IS, OKAY, WE SEE SMALL  
 5 VARIATIONS IN THE NUMBERS OF PEOPLE SUFFERING ADVERSE  
 6 EVENTS LIKE A HEART ATTACK IN EACH OF THESE TRIALS. HOW  
 7 CAN WE BEST -- NONE OF WHICH OF COURSE WILL EVER ACHIEVE  
 8 STATISTICAL SIGNIFICANCE. NO ONE WOULD EVER EXPECT THEM  
 9 TO. HOW CAN WE COMBINE THE INFORMATION AND MAKE SURE  
 10 THAT WE ARE NOT SEEING A PERSISTENT PATTERN THAT IS  
 11 OCCURRING CONSISTENTLY IN EACH OF THESE TRIALS THAT WHEN  
 12 YOU LOOK AT THE EVIDENCE AS A WHOLE ADDS UP TO SOMETHING  
 13 THAT IS OF CONCERN OR TECHNICALLY REACHES STATISTICAL  
 14 SIGNIFICANCE. THAT IS ONE PURPOSE OF A META-ANALYSIS,  
 15 COMBINE MANY SHORT TRIALS.

16 EVEN WHEN THERE ARE HOWEVER LONG TRIALS,  
 17 IF THERE ARE SEVERAL OF THEM, AS THERE ARE IN THIS CASE,  
 18 SOMETIMES STATISTICIANS OR EPIDEMIOLOGISTS WILL THEN  
 19 WENT TO SAY, OKAY, LET'S LOOK AT ALL OF THE EVIDENCE  
 20 TOGETHER IN ONE BASKET AND COMBINE THE INFORMATION  
 21 THROUGH A META-ANALYSIS. THAT IS THE STATISTICAL  
 22 APPROACH THAT IS USED TO DO THAT. SO IN BOTH CASES --  
 23 IN THIS CASE YOU SEE BOTH KINDS OF META-ANALYSIS BEING  
 24 DONE AND ULTIMATELY ONCE YOU HAVE ALL THE DATA, YOU MAY  
 25 IN FACT WANT TO COMBINE ALL OF THE STUDIES UNTIL INTO

1 ONE MEGA, GIANT META-ANALYSIS. THE TECHNIQUES ARE  
 2 DESIGNED TO MAKE SURE THAT YOU WEIGHT THE STUDIES  
 3 APPROPRIATELY, SO THEY ARE NOT WEIGHTED EQUALLY. THE  
 4 LITTLE GUYS DON'T HAVE THE SAME WEIGHTS AS THE BIG  
 5 STUDIES. THAT IS WHAT STATISTICIANS HAVE DEVELOPED  
 6 METHODS TO MAKE SURE YOU DON'T MAKE THAT KIND OF MISTAKE  
 7 IN AVERAGING THINGS SO NO STUDY HAS AN UNDUE INFLUENCE.  
 8 BUT META-ANALYSIS CAN BE USED ACROSS ALL THOSE AND HAVE  
 9 BEEN, I THINK IN THIS CASE, USED FOR ALL OF THESE  
 10 PURPOSES.

11 Q. YESTERDAY THE WORD HETEROGENEITY I THINK CAME UP  
 12 AND IS THAT WHAT YOU ARE TALKING ABOUT? THOSE ARE SOME  
 13 OF THE MECHANISMS THAT CAN BE USED OR THERE ARE  
 14 MECHANISMS THAT CAN BE USED TO TAKE CARE OF THAT.

15 A. I WANT TO DEFEND A LITTLE BIT THE STATISTICIAN  
 16 TODAY. THEY TOOK A LITTLE BIT OF A BEATING YESTERDAY.  
 17 META-ANALYSES, THEY ARE NOT LIKE CARRYING OUT A STUDY.  
 18 RECORD TRIAL TAKES A LOT OF EFFORT TO FOLLOW THESE  
 19 INDIVIDUALS FOR THIS MANY YEARS, TO DESIGN THE STUDY, TO  
 20 IMPLEMENT IT AND SO ON. META-ANALYSIS DOES NOT INVOLVE  
 21 THAT BECAUSE IT IS SUMMARIZING STUDIES THAT HAVE ALREADY  
 22 BEEN CARRIED OUT.

23 IT'S NOT, HOWEVER, QUICK AND DIRTY. I  
 24 WANT TO CORRECT THAT MISINTERPRETATION. A WELL  
 25 CONDUCTED META-ANALYSIS CAN TAKE A SUBSTANTIAL AMOUNT OF

1 TIME. MY ESTIMATE WOULD BE THAT GSK SPENT MANY MONTHS  
 2 DEVELOPING, DESIGNING, IMPLEMENTING AND ANALYZING THEIR  
 3 OWN META-ANALYSIS. THIS IS NOT SOMETHING I DO ON THE  
 4 BACK OF AN ENVELOPE ON THE WAY HOME. IT'S NOT QUICK AND  
 5 DIRTY.

6 Q. THE OTHER THING I WANTED TO ASK YOU, IS IT LIKE  
 7 MIXING APPLES AND ORANGES?

8 A. WELL, OF COURSE, A KEY THING IN A WELL CONDUCTED  
 9 META-ANALYSIS, ONE OF THE LIMITATIONS I THINK I REFER TO  
 10 HERE, IS THAT THE CLINICAL TRIALS THAT YOU ARE COMBINING  
 11 OR OBSERVATIONAL STUDIES IF IT'S A META-ANALYSIS OF  
 12 OBSERVATIONAL STUDIES, ARE NOT IDENTICAL. THEY DON'T --  
 13 IN FACT ONE -- YOU CAN VIEW THAT AS A STRENGTH AND A  
 14 WEAKNESS. THEY ARE NOT IDENTICAL POPULATION -- THEY ARE  
 15 NOT SAMPLING FROM EXACTLY THE SAME POPULATION. THE  
 16 ELIGIBILITY CRITERIA FOR THE TRIAL THAT WAS DESIGNED FOR  
 17 AN EFFICACY REASON MAY VARY FROM TRIAL TO TRIAL  
 18 SOMEWHAT. THEY ARE DONE IN DIFFERENT PLACES.

19 AS I SAY, THIS IS A WEAKNESS BECAUSE YOU  
 20 ARE NOW TRYING TO MIX THINGS THAT WERE COLLECTED IN  
 21 DIFFERENT PLACES. IT'S ALSO A STRENGTH BECAUSE AS WE  
 22 HEARD YESTERDAY, ONE OF THE IMPORTANT ISSUES IN  
 23 CAUSATION IS SEEING IS A PHENOMENA -- IS THERE ANY IDEA  
 24 OF A RISK REPLICATED IN DIFFERENT POPULATIONS, BECAUSE  
 25 THAT IS GOING TO STRENGTHEN YOUR BELIEF THAT THIS IS

1 SOMETHING CAUSAL AND NOT PECULIAR TO A PARTICULAR TRIAL  
 2 OR A PARTICULAR POPULATION.

3 SO ONE OF THE LIMITATIONS, AS I SAID, AND  
 4 STRENGTH IS YOU ARE MIXING THESE THINGS. IT'S NOT  
 5 MIXING APPLES AND ORANGES, HOWEVER. IF I CAN USE THAT  
 6 ANALOGY, IT'S MIXING DIFFERENT VARIETIES OF APPLES. ALL  
 7 OF THESE STUDIES HAD THE SAME DRUGS APPLIED TO THE  
 8 TREATMENT ARM. THEY WERE ALL, BY AND LARGE, WITH SOME  
 9 NOTABLE EXCEPTIONS, STUDYING DIABETICS. THEY WERE ALL  
 10 ESSENTIALLY -- AND WHEN THE DATA WAS PULLED OUT ON  
 11 ADVERSE EVENTS, THEY WERE -- ALL THESE INVESTIGATORS  
 12 WERE HONESTLY, I THINK, TRYING TO GET AT THE SAME  
 13 QUESTION. SO THIS WAS NOT REALLY TRYING TO PULL THINGS  
 14 FROM OUT OF A HAT AND SORT OF JAM THEM TOGETHER. THIS  
 15 WAS -- MOST OF THESE META-ANALYSES, NOT ALL OF THEM, BUT  
 16 MOST OF THEM WERE WELL CONDUCTED, THOUGHTFULLY AND  
 17 TRYING TO ANSWER THE QUESTION AND SUMMARIZE THE  
 18 INFORMATION.

19 Q. THIS IS A SLIDE --

20 A. IT TAKES TIME TO DO THAT. IT TAKES TIME TO DO  
 21 THAT WELL.

22 Q. THIS IS A SLIDE, DR. JEWELL, THAT WAS SEEN  
 23 YESTERDAY THAT RELATED TO THE ICT 42. THAT IS A  
 24 META-ANALYSIS THAT GSK DID, IS THAT CORRECT?

25 A. GSK DID THIS ANALYSIS, YES, AND PRESENTED IT TO

1 **THE FDA, IS MY UNDERSTANDING.**  
2 **Q.** AND AS IT SAYS IT INCLUDED 42 STUDIES AND 14,237  
3 PATIENTS, IS THAT CORRECT?  
4 **A.** **THAT IS CORRECT.**  
5 **Q.** ONE OF THE THINGS THAT CAME UP YESTERDAY, I  
6 THINK YOU MENTION THIS IN YOUR REPORT, IS THAT A LARGE  
7 PERCENTAGE OF THESE PATIENTS, I THINK APPROXIMATELY  
8 80 PERCENT, WERE ON -- COMPARED TO PLACEBO, IS THAT  
9 CORRECT?  
10 **A.** **MY MEMORY IS A SIGNIFICANT FRACTION OF THESE**  
11 **TRIALS INVOLVED PLACEBO COMPARISONS AND THAT IS**  
12 **IMPORTANT. WE CAN DISCUSS WHY I THINK THAT IS**  
13 **IMPORTANT, BUT YES, THAT IS MY MEMORY.**  
14 **Q.** IN OTHER WORDS, IN THE RANDOMIZED CONTROLLED  
15 TRIALS SOME OF THE PATIENTS ARE ON AVANDIA AND THEY ARE  
16 CONTROLLED -- THE COMPARATOR DRUG WOULD BE A SUGAR PILL  
17 OR PLACEBO, IS THAT CORRECT?  
18 **A.** **THAT'S CORRECT.**  
19 **Q.** AND YOU MENTIONED IN YOUR REPORT, IS THAT  
20 SOMETHING THAT YOU PAY PARTICULAR ATTENTION TO?  
21 **A.** **YES. I ALWAYS LOOK -- WHEN I'M LOOKING AT THE**  
22 **RANDOMIZED CLINICAL TRIALS, I ALWAYS TRY AND IDENTIFY**  
23 **QUICKLY WHICH ONES ARE PLACEBO COMPARISONS, BECAUSE YOU**  
24 **DON'T HAVE TO WORRY ABOUT WHAT ELSE IS GOING ON WHEN YOU**  
25 **HAVE AN ACTIVE COMPARATOR DRUG.**

1 **Q.** SO IS IT TRUE THAT YOU ARE ABLE TO SEE THE TRUE  
2 RISK OF THAT DRUG BETTER WHEN IT'S VERSUS PLACEBO.  
3 **A.** **YES, COMPARED TO NOTHING, IT'S MUCH BETTER.**  
4 **Q.** NOW, SOME OF THESE PATIENTS IN THE ICT AND THE  
5 OTHER STUDIES THAT YOU LOOKED AT WERE ON AVANDIA AND  
6 THEY HAD COMPARISONS TO ACTIVE CONTROL DRUGS LIKE  
7 METFORMIN, ANOTHER ORAL ANTIDIABETIC, OR SULFONYLUREA,  
8 IS THAT CORRECT?  
9 **A.** **OCCASIONALLY THAT WAS TRUE, CORRECT.**  
10 **Q.** ONE OF THE CRITICISMS THAT GSK HAS OF YOU IS  
11 THAT YOU ARE ACTUALLY USING THOSE COMPARISONS OR THAT  
12 DATA TO SUPPORT YOUR OPINIONS. AND MY QUESTION IS, DO  
13 YOU JUST THROW OUT THE DATA THAT HAS AN ACTIVE  
14 COMPARISON OR THAT IS SOMETHING THAT YOU LOOK AT AS  
15 WELL?  
16 **A.** **NO. AS I MENTION IN MY REPORT, I PAID SPECIFIC**  
17 **ATTENTION AND PULLED OUT THE PLACEBO TRIALS BECAUSE I**  
18 **WANT TO BE SURE THAT THE ESTIMATE OF RISK -- INCREASED**  
19 **RISK THAT I'M GETTING FROM A META-ANALYSIS LIKE THIS**  
20 **WHERE YOU ARE MIXING TRIALS THAT HAVE DIFFERENT**  
21 **COMPARISON GROUPS IS NOT DRIVEN BY -- WHAT IS DRIVING**  
22 **IT -- IF IT DID NOT OCCUR IN THE PLACEBO GROUP, THAT**  
23 **WOULD HAVE GIVEN ME PAUSE. IF I PULLED OUT THE PLACEBO**  
24 **TRIALS AND SAID, OH, I GOT SOMETHING -- I GOT A RELATIVE**  
25 **RISK OF -- AN INCREASE OF 40 PERCENT OVERALL, BUT WHEN I**

1 **LOOK AT THE PLACEBO TRIALS, I GET NOTHING. WELL, THAT**  
2 **WOULD TELL ME THAT THAT RISK MUST BE COMING FROM THE**  
3 **OTHER TRIALS, BUT IT'S NOT COMING FROM PLACEBO AND THAT**  
4 **WOULD HAVE GIVEN ME PAUSE.**  
5 **BUT I DON'T THROW AWAY THE OTHER TRIALS.**  
6 **THEY ARE INFORMATION. EVERY META-ANALYSIS THAT HAVE I**  
7 **HAVE LOOKED AT IN THIS CASE HAS INCLUDED THOSE TRIALS**  
8 **WITH COMPARATORS IN THEIR FINAL RESULTS ALSO.**  
9 **SOMETIMES, SOME OF THE AUTHORS HAVE DONE THE SAME AS I**  
10 **DID AND LOOKED SPECIFICALLY AT SUBGROUPS.**  
11 **ONE OF THE ADVANTAGES, BY THE WAY, OF**  
12 **LOOKING AT DIFFERENT -- LIKE LOOKING AT JUST THE PLACEBO**  
13 **CONTROLS, IS THAT YOU ARE NOW MAKING THOSE VARIETY OF**  
14 **APPLES A LITTLE MORE SIMILAR BECAUSE THESE ARE PATIENT**  
15 **POPULATIONS WHERE THEY FELT IT WAS ETHICAL AND**  
16 **APPROPRIATE TO DO A PLACEBO.**  
17 **IF YOU ARE LOOKING AT OTHER GROUPS OF**  
18 **COMPARATOR DRUGS, THERE'S A CHANCE THAT MAY BE A LITTLE**  
19 **BIT MORE HOMOGENOUS OR MORE SIMILAR. SO THAT IS WHY**  
20 **STATISTICIANS LIKE I DO THAT, BUT YOU WOULD NEVER JUST**  
21 **ERADICATE THE INFORMATION ENTIRELY ON THESE TRIALS.**  
22 **Q.** NOW THE FDA I THINK YOU MENTIONED TOOK THE SAME  
23 42 TRIALS AND THEY DID THEIR OWN ANALYSIS OF THIS DATA,  
24 IS THAT CORRECT?  
25 **A.** **THAT IS CORRECT.**

1 **Q.** AND THE FDA CAME UP WITH A HIGHER STATISTICALLY  
2 SIGNIFICANT RISK THAN GSK, IS THAT CORRECT?  
3 **A.** **THAT IS CORRECT.**  
4 **Q.** YOU LOOKED, I TAKE IT, AT THOSE METHODS AND DO  
5 YOU HAVE AN OPINION REGARDING WHY THAT OCCURRED?  
6 **A.** **WELL, THE GSK STATISTICAL METHODS -- I LOOKED AT**  
7 **THE STATISTICAL METHODS OF COURSE WITH PARTICULAR**  
8 **INTEREST BECAUSE THAT IS MY EXPERTISE. GSK DID A COUPLE**  
9 **OF THINGS IN THE ANALYSIS THAT I DID NOT AGREE WITH AND**  
10 **NEITHER DID THE FDA. AND SO YOU GET SLIGHTLY HIGHER**  
11 **RESULTS WHEN DO YOU, I THINK, A MORE PROPER ANALYSIS,**  
12 **META-ANALYSIS OF THAT -- OF THEIR DATA.**  
13 **Q.** THE ICT -- I'M GOING TO SHOW ONE OF THE SLIDES  
14 THAT WE TALKED ABOUT YESTERDAY. THE ICT META-ANALYSIS  
15 THAT GSK DID AND THEN THE FDA META-ANALYSIS BASED ON THE  
16 SAME INFORMATION, THEY PULLED OUT DATA RELATED  
17 PARTICULARLY TO MI AS WELL, IS THAT CORRECT?  
18 **A.** **YES.**  
19 **Q.** WAS THAT INFORMATION THAT YOU LOOKED AT DURING  
20 THE COURSE OF YOUR REVIEW AS WELL?  
21 **A.** **YES. AND I ACTUALLY REANALYZED FOR MYSELF. I**  
22 **ACTUALLY HAD -- SINCE I -- IN ONE OF THE FDA REPORTS**  
23 **THAT I WAS ABLE TO READ, IT HAD SOME OF THE RAW DATA SO**  
24 **I WAS ACTUALLY ABLE TO RUN THE NUMBERS MYSELF. SO, YES,**  
25 **I LOOKED AT -- WHEN I COULD, I LOOKED AT MI AND THEY**

1 **CERTAINLY DID -- LOOKED AT MI AND MYOCARDIAL ISCHEMIA.**  
 2 **Q.** THIS SLIDE SHOWS THE ICT 42 AND THE FDA 42. AND  
 3 THE GREEN DIAMONDS ARE MYOCARDIAL ISCHEMIC OR MYOCARDIAL  
 4 ISCHEMIA. THAT WAS THE ENDPOINT THAT WAS USED DURING  
 5 THOSE META-ANALYSIS, IS THAT CORRECT?  
 6 **A.** **YEAH. BOTH THE GSK STATISTICIANS AND THE FDA**  
 7 **STATISTICIANS USED THE SAME ENDPOINTS.**  
 8 **Q.** THAT WAS A LARGE ENDPOINT INCLUDING ANGINA AND  
 9 CORONARY THROMBOSIS, LOTS OF THINGS INCLUDING MYOCARDIAL  
 10 INFARCTION, IS THAT CORRECT?  
 11 **A.** **THAT'S CORRECT.**  
 12 **Q.** THEY ALSO TOOK OUT THE MYOCARDIAL INFARCTION  
 13 INFORMATION AND THIS SLIDE IN THE RED FROM THOSE STUDIES  
 14 REFLECTS THE MYOCARDIAL INFARCTION RESULTS AND RELATIVE  
 15 RISK, IS THAT CORRECT?  
 16 **A.** **I'M MORE FAMILIAR WITH THE FDA ANALYSIS, BUT I**  
 17 **THINK THAT LOOKS REASONABLE, YES.**  
 18 **Q.** AND IT LOOKS LIKE THE RELATIVE RISK IS GREATER  
 19 IN MYOCARDIAL INFARCTION IN THE RED VERSUS THE GREEN.  
 20 IN OTHER WORDS IT'S CLOSER, IT'S APPROXIMATELY 1.5.  
 21 WHAT DOES THAT TELL YOU AS A BIOSTATISTICIAN?  
 22 **A.** **THIS COMES BACK TO THE CHOICE OF THE OUTCOME AND**  
 23 **THERE WERE SOME COMMENTS MADE YESTERDAY FROM BOTH**  
 24 **PARTIES ABOUT THE OUTCOME.**  
 25 **SO WHEN I'M -- AS A STATISTICIAN, I WAS**

1 **GIVEN A CHARGE HERE, BUT I'M TRYING TO THINK ABOUT THE**  
 2 **OUTCOME. I HAVE DONE THIS BEFORE IN OTHER**  
 3 **CARDIOVASCULAR SETTINGS IN LOOKING AT META-ANALYSES. SO**  
 4 **CHOOSING THE OUTCOME IS ACTUALLY A SCIENCE IN ITSELF.**  
 5 **IT'S NOT AS EASY AS IT SOUNDS. THERE WERE POINTS MADE**  
 6 **YESTERDAY THAT MYOCARDIAL ISCHEMIA IS A MUCH LARGER**  
 7 **GROUP OF CONDITIONS THAN MYOCARDIAL INFARCTION. NO**  
 8 **QUESTION, MYOCARDIAL INFARCTION IS ONE OF THE SERIOUS**  
 9 **COMPONENTS OF MYOCARDIAL ISCHEMIA. WHEN YOU ARE DOING**  
 10 **AN ANALYSIS OF DATA LIKE THIS, YOU UNFORTUNATELY HAVE**  
 11 **TWO DANGERS. YOU CAN MAKE THE OUTCOME VERY BROAD TO**  
 12 **MAKE SURE YOU CAPTURE ALL OF THE EVENTS THAT -- WHERE**  
 13 **SOMETHING MIGHT BE BEING CAUSED BY A DRUG. YOU CAN MAKE**  
 14 **IT SO BROAD THAT YOU ACTUALLY GO TO ALL CAUSE MORTALITY,**  
 15 **BUT THINKING MORTALITY IS A REALLY HARD ENDPOINT. THE**  
 16 **TROUBLE WITH VERY LARGE, BROAD COMPOSITE OUTCOMES, IS**  
 17 **THAT THE DRUG MAY BE SPECIFIC OR THE EXPOSURE MAY BE**  
 18 **SPECIFIC AND IT MAY ONLY CAUSE SOME OF THE CONDITIONS IN**  
 19 **YOUR VERY BROAD OUTCOME. AND IF YOU HAVE A VERY BROAD**  
 20 **OUTCOME, THE DANGER WITH THAT IS IT DILUTES YOUR ABILITY**  
 21 **TO DETECT THAT BECAUSE IF YOU KEEP ADDING THINGS WHERE**  
 22 **THE DRUG IS NOT CAUSING, LIKE BUS ACCIDENTS, CAR**  
 23 **ACCIDENTS, AND THEY ARE OCCURRING PRESUMABLY EQUALLY THE**  
 24 **SAME IN THE PLACEBO AND THE CONTROL -- AND THE ACTIVE**  
 25 **ARM, YOU WILL GET A DILUTED MEASURE. SO STATISTICIANS**

1 **KNOW THIS AND THEY SAY, OKAY, WE HAVE TO BE CAREFUL.**  
 2 **ON THE OTHER HAND, YOU SAY, OKAY, LET'S**  
 3 **GET TO IT BE REALLY SPECIFIC. LET'S LOOK AT MI'S ONLY**  
 4 **AS IT WAS TALKED ABOUT YESTERDAY. BECAUSE THAT IS WHAT**  
 5 **WE REALLY CARE ABOUT POTENTIALLY. IF THAT IS ALL YOU**  
 6 **CARE ABOUT, LET'S LOOK AT MI'S. WELL, MI IS NOT AS EASY**  
 7 **TO PIN DOWN AS IT MIGHT -- AS YOU MIGHT THINK. MY**  
 8 **UNDERSTANDING, I'M A STATISTICIAN SO YOU SHOULD**  
 9 **CERTAINLY CHECK WITH CLINICIANS. IF I -- THERE'S A**  
 10 **WHOLE RANGE OF DIFFERENT KINDS OF HEART ATTACKS, SILENT**  
 11 **MI'S, SERIOUS MI'S, DEFINITE MI'S, ALL OF THOSE -- YOU**  
 12 **HAVE TO PICK ONE OF THOSE AND PIN THEM DOWN. SO I THINK**  
 13 **THE IDEA OF USING MI'S AND MYOCARDIAL ISCHEMIA SORT OF**  
 14 **COVERS YOUR BASES IN A SENSE, COVERS YOUR BETS A LITTLE**  
 15 **BIT. SO YOU ARE LOOKING A LITTLE BIT BROADLY.**  
 16 **BUT ONE THING YOU MIGHT WANT TO DO IS, IS**  
 17 **THE SIGNAL THAT YOU ARE GETTING FROM -- WHEN YOU LOOK AT**  
 18 **MYOCARDIAL ISCHEMIA, IS THERE NOTHING WHEN YOU LOOK AT**  
 19 **MI'S. THEN YOU SAY OKAY SOMETHING IS GOING ON WITH**  
 20 **MYOCARDIAL ISCHEMIA PERHAPS, BUT IT DOES NOT SEEM TO**  
 21 **HAVE ANYTHING TO DO WITH MI'S. THE SLIDE THERE POINTS**  
 22 **THAT OUT, NO, THAT IS ACTUALLY THE OPPOSITE. THERE ARE**  
 23 **FEWER MI'S BECAUSE IT'S ONLY A SUBPART OF ISCHEMIC HEART**  
 24 **DISEASE, BUT THE EFFECTS ARE BIGGER FOR MYOCARDIAL**  
 25 **INFARCTION. SO THAT GIVES ME A REASON TO BELIEVE THAT**

1 **THE RESULTS WE'RE SEEING THAT WERE STATISTICALLY**  
 2 **SIGNIFICANT FOR MYOCARDIAL ISCHEMIA ARE NOT MASKING OR**  
 3 **UNFAIRLY ATTRIBUTING THE RISK WHERE MYOCARDIAL**  
 4 **INFARCTION IS CONCERNED. THE RISK IS GREATER FOR**  
 5 **MYOCARDIAL INFARCTION.**  
 6 **IN FACT IN ALL OF THE ANALYSES AND**  
 7 **COMPARISONS THAT THE GSK AND FDA DID, SERIOUS MYOCARDIAL**  
 8 **ISCHEMIC DISEASE ALWAYS GAVE A LARGER ESTIMATE OF THE**  
 9 **RELATIVE RISK THAN JUST ISCHEMIC HEART DISEASE IN**  
 10 **GENERAL. THAT GIVES ME REASON TO BELIEVE IT'S THE**  
 11 **SERIOUS EVENTS ARE BEING CAUSED PERHAPS EVEN MORE THAN**  
 12 **JUST THE GENERAL BROAD COMPOSITE OUTCOMES.**  
 13 **Q.** SO IT DOES LOSE STATISTICAL SIGNIFICANCE. WE  
 14 TALKED A LOT ABOUT THAT YESTERDAY, MEANING THAT THE RED  
 15 LINES, THEY CROSS 1 AND ARE YOU TALKING ABOUT THERE IS A  
 16 LITTLE LESS PRECISION BECAUSE THERE IS LESS MI'S, THE  
 17 NUMBERS ARE SMALLER?  
 18 **A.** YOU CAN SEE THAT IN BOTH OF THOSE WHERE THE RED  
 19 ONES ARE WHERE THEY ARE LOOKING AT MI'S, THE CONFIDENCE  
 20 INTERVALS ARE WIDER, THAT IS PURELY STATISTICAL IN  
 21 REFLECTING THE MYOCARDIAL INFARCTION AS A SUBGROUP OF  
 22 MYOCARDIAL ISCHEMIA, AND THERE ARE JUST FEWER EVENTS.  
 23 WHEN THERE ARE FEWER EVENTS, THERE IS LESS PRECISION.  
 24 **OF COURSE, IF YOU LOOK AT THOSE RESULTS,**  
 25 **THEY ARE CONSISTENT. NO STATISTICIAN WOULD LOOK AT**

1 THOSE FOUR LINES AND SAY, GEE, THOSE NUMBERS ARE NOT ALL  
 2 LINED IDENTICALLY BECAUSE LOOK AT THE IMPRECISION THAT  
 3 IS REPRESENTED BY THE CONFIDENCE. THEY ALL FIT OVER --  
 4 TO ME THAT IS JUST ESSENTIALLY GIVING YOU THE SAME  
 5 INFORMATION. PUTTING IT CRUDELY AS A STATISTICIAN, I  
 6 CAN'T TELL THE DIFFERENCE BETWEEN THE GREEN AND THE RED.  
 7 I SHOULD NOT TELL THE DIFFERENCE BECAUSE THE DIFFERENCE  
 8 THERE IS MUCH SMALLER THAN THE RANDOM VARIATION. SO YOU  
 9 SHOULD NOT SWEAT THE SMALL STUFF ABOUT THOSE LITTLE  
 10 DIFFERENCES. THEY ARE REALLY ALL THE SAME. THAT IS ALL  
 11 THE STATISTICIAN CAN TELL YOU.

12 BUT IT'S IMPORTANT THAT THEY ARE ALL THE  
 13 SAME BECAUSE WE ARE SAYING -- WHEN WE LOOK AT MYOCARDIAL  
 14 ISCHEMIA, WE ARE NOT UNFAIRLY MISREPRESENTING WHAT'S  
 15 GOING ON WITH MYOCARDIAL INFARCTION. THAT IS WHAT THAT  
 16 SLIDE REALLY TELLS YOU.

17 MR. CARTMELL: C 14, PLEASE.

18 BY MR. CARTMELL:

19 Q. IN YOUR REPORT YOU ACTUALLY HAVE A FIGURE THAT  
 20 YOU HAVE INCLUDED THAT IS AN EVALUATION FROM AN INTERNAL  
 21 GSK DOCUMENT ABOUT -- IF WE CAN ENLARGE THAT A LITTLE  
 22 BIT, IT'S REAL HARD TO SEE, BUT THIS IS A GSK  
 23 META-ANALYSIS INTERNALLY THAT HAS CONFIDENCE INTERVALS.  
 24 AND TELL US ABOUT THIS AND YOU MENTIONED CONSISTENCY.

25 A. SO I APOLOGIZE ABOUT THIS SLIDE. I HAD TO COPY

1 IT FROM THAT DOCUMENT. THIS IS WHAT IS KNOWN AS A  
 2 FOREST PLOT, LIKE THE TREES. AND WE SAW THIS. IN EACH  
 3 OF THESE LINES THERE IS A LITTLE DOT IN THEM ROUGHLY IN  
 4 THE MIDDLE WHICH REPRESENTS THE BEST ESTIMATE OF THE  
 5 RELATIVE RISK OF -- ASSOCIATED WITH EXPOSURE. AND THEN  
 6 THE LENGTH OF THE LINE IS JUST THE CONFIDENCE INTERVAL.  
 7 SO IT GIVES YOU A FEEL FOR THE PRECISION.

8 THIS FOREST PLOT IS LARGELY OF TRIALS IN  
 9 THE ICT 42. AND THEN AT THE BOTTOM, IT INCLUDES SOME  
 10 THAT WERE NOT INCLUDED IN THE ICT 42, PARTICULARLY  
 11 RECORD, AT THE VERY BOTTOM THERE, THE BIGGER TRIALS.  
 12 YOU CAN SEE THE BIGGER TRIALS AT THE BOTTOM, HOW MUCH  
 13 TIGHTER THE CONFIDENCE INTERVAL IS. THAT IS BECAUSE  
 14 THERE IS MORE EVENTS AND MORE PRECISION.

15 LOOKING -- UNFORTUNATELY YOU CAN'T REALLY  
 16 SEE THE DOTS, PARTICULARLY ON THE SCREEN. ANY  
 17 STATISTICIAN WHO LOOKS AT THIS FOREST PLOT IMMEDIATELY  
 18 SHOULD HAVE CONCERN. WHY? BECAUSE MOST OF THE DOTS  
 19 FALL TO THE RIGHT OF 1. ANY STATISTICIAN KNOWS THAT IF  
 20 THERE IS NOTHING GOING ON WITH AVANDIA, THE CHANCES OF  
 21 THAT DOT FALLING ON THE RIGHT OF 1, MEANING IT'S  
 22 INCREASING THE RISK, OR THE LEFT OF 1, MEANING IT'S  
 23 DECREASING THE RISK, IS 50-50. IT'S JUST LIKE TOSSING A  
 24 COIN.

25 SO WHEN I TOSS A COIN THAT MANY TIMES AND

1 I SEE SO MANY TIMES I GET A HEAD, SO MANY TIMES I SEE IT  
 2 TO THE RIGHT OF 1, IMMEDIATELY, I THINK THIS IS NOT THE  
 3 KIND OF PATTERN THAT YOU WOULD EXPECT FROM MULTIPLE  
 4 TRIALS WHERE YOU HAVE ABSOLUTELY NOTHING GOING ON. SO  
 5 THAT IS RIGHT THERE AN IMPORTANT THING FOR A  
 6 STATISTICIAN. THEN YOUR JOB IS NOT OVER BECAUSE YOU  
 7 HAVE GOT TO TRY TO QUANTIFY -- OKAY, GIVEN ALL THIS  
 8 INFORMATION, GIVEN THE IMPRECISION AND THE LITTLE TRIALS  
 9 AND GIVEN WHAT YOU KNOW ABOUT THE BIG TRIALS, WHAT IS  
 10 YOUR BEST ESTIMATE OF THE INCREASE IN RISK, BECAUSE THAT  
 11 IS GOING TO BE IMPORTANT FOR SCIENTISTS. AND THAT IS  
 12 WHAT YOU DO. BY THE WAY, THIS HERE -- SOME OF THEM  
 13 ARE -- MANY OF THESE LITTLE TRIALS, MOST OF THEM ARE NOT  
 14 STATISTICALLY SIGNIFICANT. SOME OF THE ONES AT THE  
 15 BOTTOM ARE VERY CLOSE TO STATISTICAL SIGNIFICANCE, THE  
 16 ONE -- AND THE OVERALL IS AT THE BOTTOM. THAT IS NOT  
 17 INCONSISTENT. LOOK AT THE LINES. THEY ARE ALL PRETTY  
 18 MUCH LYING ON TOP. THIS IS CONSISTENCY, NOT  
 19 INCONSISTENCY.

20 AND I WANT TO SAY THAT STATISTICIANS HAVE  
 21 DEVELOPED METHODS THAT LOOK AT THESE LINES AND SAY, IS  
 22 THERE ANY STATISTICAL EVIDENCE THAT THERE ARE REALLY  
 23 DIFFERENT THINGS GOING ON HERE, THAT THERE REALLY ARE  
 24 APPLES AND ORANGES AND THAT YOU OUGHT TO HAVE PAUSE  
 25 ABOUT PUTTING ALL THESE TOGETHER.

1 EVERY SINGLE META-ANALYSIS THAT I LOOKED  
 2 AT, GOOD ONES, THE GSK ANALYSIS, THE STATISTICIANS THERE  
 3 USED A STATISTICAL TEST, ARE THESE APPLES AND ORANGES?  
 4 IT WAS QUITE CLEAR THEY ARE ALL APPLES. THEY SAID IT IN  
 5 THEIR REPORT. FDA LOOKED AT THE STATISTICAL TESTS  
 6 SAYING ARE THESE APPLES AND ORANGES? NO, THE P VALUE  
 7 WAS .9 MEANING THERE IS NO EVIDENCE OF THESE  
 8 REPRESENTING VERY DIFFERENT INFORMATION. THE SINGH --  
 9 ALL OF THESE META-ANALYSES PERFORMED THAT KIND OF TEST  
 10 OF CONSISTENCY.

11 Q. YOU MENTIONED SINGH. YOU ALSO LOOKED AT THE  
 12 SINGH META-ANALYSIS. YOU LOOKED AT THE FDA 2010  
 13 META-ANALYSIS. THESE ARE ALL INCLUDED IN YOUR REPORTS  
 14 AND YOU HAVE INCLUDED SUMMARIES OF THOSE?

15 A. THAT IS CORRECT.

16 Q. OKAY. NOW FROM THE META-ANALYSIS AND THE RCT --  
 17 HONORABLE CYNTHIA M. RUFÉ: BEFORE YOU GO  
 18 ON WE NEED TO TAKE THAT BREAK RIGHT NOW FOR THE  
 19 STENOGRAPHER.

20 (RECESS.)

21 THE CLERK: ALL RISE.

22 HONORABLE CYNTHIA M. RUFÉ: GOOD MORNING,  
 23 PLEASE BE SEATED.

24 ALL RIGHT MR. CARTMELL.

25 MR. CARTMELL: THANK YOU, YOUR HONOR.

1 BY MR. CARTMELL:  
 2 Q. DR. JEWELL, WE ARE BACK AFTER A SHORT BREAK, ARE  
 3 YOU READY TO PROCEED?  
 4 A. YES.  
 5 Q. WE WERE TALKING BEFORE THE BREAK ABOUT SOME OF  
 6 THE META-ANALYSES THAT YOU HAD REVIEWED AND YOU OUTLINED  
 7 A SPECIFICALLY MULTIPLE OF THOSE AT LEAST IN YOUR  
 8 REPORT, IS THAT CORRECT?  
 9 A. THAT IS CORRECT.  
 10 Q. THERE WAS A META-ANALYSIS THAT YOU HAVE REVIEWED  
 11 AND OUTLINED IN YOUR REPORT AND IT IS CALLED MANNUCCI.  
 12 WE HEARD THAT YESTERDAY, THAT NAME, THE MANNUCCI  
 13 META-ANALYSIS?  
 14 A. THAT IS CORRECT.  
 15 Q. YOU REVIEWED THAT, CORRECT?  
 16 A. YES.  
 17 Q. LET ME FIND WHERE THAT IS IN YOUR REPORT. AT  
 18 PAGE C 29, PLEASE. NOW, THERE WAS TALK YESTERDAY ABOUT  
 19 THE MANNUCCI META-ANALYSIS BEING THE LARGEST  
 20 META-ANALYSIS. IN FACT, IT INCLUDED 164 TRIALS, IS THAT  
 21 RIGHT?  
 22 A. THAT SOUNDS RIGHT TO ME.  
 23 Q. WE HAD THE ICT 42 WHICH IS 42 STUDIES, I THINK  
 24 THE NISSEN META-ANALYSIS WAS 42 STUDIES. THE FDA  
 25 META-ANALYSIS FROM 2007 WAS 42 STUDIES. NOW, THE SINGH

1 META-ANALYSIS WAS ONLY 4 STUDIES, IS THAT CORRECT?  
 2 A. THAT IS CORRECT.  
 3 Q. AND WAS IT THE LARGER RANDOMIZED CLINICAL  
 4 TRIALS?  
 5 A. THREE OF THEM OF ARE THE LARGE TRIALS AND ONE  
 6 SMALLER TRIAL.  
 7 Q. OKAY.  
 8 NOW, I THINK THERE WAS SOME TALK  
 9 YESTERDAY ABOUT SEVERAL OF THESE META-ANALYSIS WERE  
 10 ESSENTIALLY THE SAME META-ANALYSES. WHAT ARE YOUR  
 11 THOUGHTS ABOUT THAT?  
 12 A. I CERTAINLY LOOKED AT THAT OF COURSE BECAUSE I  
 13 WANTED TO KNOW IF I WAS READING JUST A REANALYSIS OF THE  
 14 SAME DATA OR NOT. THE NISSEN, COINCIDENTALLY HAD 42  
 15 TRIALS AS DID THE GSK AND FDA, ICT 42, BUT THEY ARE NOT  
 16 IDENTICAL TRIALS, THEY OVERLAPPED BY 28, IS MY MEMORY.  
 17 SO AND THEN NISSEN HAD A DIFFERENT 14 AND GSK AND FDA  
 18 HAD ANOTHER DIFFERENT 14. SO THEY WERE NOT IDENTICAL  
 19 AND THE SINGH DIFFERED FROM THE ORIGINAL NISSEN AND ICT  
 20 42 BECAUSE THEY INCLUDED AT THAT POINT INTERIM RESULTS  
 21 FROM THE RECORD TRIAL THAT HAD NOT BEEN COMPLETED AT THE  
 22 TIME THEY DID THAT ANALYSIS. THEY GOT INTERIM RESULTS  
 23 AND OF COURSE NOW WE HAVE FINAL RESULTS FROM RECORD.  
 24 Q. AND THE SINGH META-ANALYSIS BEING THE 4 -- WELL,  
 25 3 OF THE LARGE TRIALS, ADOPT, DREAM AND RECORD AND THEN

1 ONE OF THE LARGE INTERNAL GSK STUDIES, 211 OR DARGIE.  
 2 THAT WAS SOMEWHAT DIFFERENT DATA THAN THE OTHER STUDIES,  
 3 IS THAT CORRECT?  
 4 A. THAT IS CORRECT.  
 5 Q. ONE OF THE THINGS YOU SAY IN YOUR REPORT IS THAT  
 6 IF YOU HAVE REPLICATION OF RESULTS, IN OTHER WORDS  
 7 STATISTICALLY SIGNIFICANT FINDINGS OF AN INCREASED RISK,  
 8 IN DIFFERENT META-ANALYSES THAT THAT CAN INCREASE THE  
 9 EVIDENCE OR THE STRENGTH OF THE ASSOCIATION, IS THAT  
 10 CORRECT?  
 11 A. THAT'S CORRECT.  
 12 Q. TELL US ABOUT THAT.  
 13 A. WELL, YOU REALLY WANT TO SEE THE RESULTS AS YOU  
 14 JUST SAID, REPLICATED IN DIFFERENT SITUATIONS. SO  
 15 REALLY TO ME THE ISSUE IS THE NUMBER OF TRIALS AND WHERE  
 16 THE TRIALS HAVE BEEN DONE AND HAS THIS BEEN INVESTIGATED  
 17 IN A WIDE SET OF SITUATIONS, AND SO THAT IS IMPORTANT TO  
 18 ME.  
 19 Q. NOW, THE MANNUCCI -- BACK TO THAT MANNUCCI  
 20 META-ANALYSIS, IT HAS 164 TRIALS IN IT. DOES THAT MEAN  
 21 IT'S BETTER? IN OTHER WORDS, IS BIGGER BETTER WHEN YOU  
 22 LOOK AT META-ANALYSES?  
 23 A. SURE SOUNDS GOOD, DOESN'T IT? SOUNDS LIKE IT'S  
 24 A MUCH BIGGER META-ANALYSIS. IT'S NOT MUCH BIGGER. I  
 25 LOOKED AT THE DATA FROM THE MANNUCCI META-ANALYSIS. AS

1 YOU SAID, I THINK IT HAD 160 PLUS TRIALS. IN PARTICULAR  
 2 THEY INCLUDED ALL THE NON-GSK TRIALS. THE ORIGINAL  
 3 ONES, THE ICT WERE ALL SPONSORED BY GSK AND PRODUCED BY  
 4 GSK. MANNUCCI CAST THEIR NETS MUCH WIDER AND GOT A LOT,  
 5 102 ADDITIONAL TRIALS THAT WERE NOT GSK TRIALS THAT SOME  
 6 OF THESE OTHER AUTHORS HAD -- NISSEN HAD NOT INCLUDED, I  
 7 THINK WISELY, IN MANY REGARDS, BUT LET ME JUST TELL YOU  
 8 BRIEFLY ABOUT THOSE 102 EXTRA TRIALS. IT'S IN MY  
 9 REPORT. FOR MYOCARDIAL INFARCTIONS, 60 OF THE TRIALS  
 10 HAD NO MYOCARDIAL INFARCTIONS AT ALL IN EITHER ARM OF  
 11 THE STUDY. 60. 39 OF THE STUDIES HAD NO DATA. HE WAS  
 12 NOT ABLE TO GET ANY DATA ON MYOCARDIAL INFARCTIONS.  
 13 SO OF THE 102 EXTRA NON-GSK TRIALS WITH  
 14 REGARD TO MYOCARDIAL INFARCTION, 99 OF THEM HAD NO  
 15 INFORMATION ON MI'S. AND A VERY SIMILAR RESULT, I DON'T  
 16 WANT TO BORE WITH YOU THE NUMBERS, BUT SIMILAR FOR CV  
 17 MORTALITY, ALSO SIMILAR FINDINGS, SO THE MANNUCCI RESULT  
 18 I FELT FAILED SOME OF THE CORE PRINCIPLES THAT I HAVE  
 19 ABOUT DOING A GOOD META-ANALYSIS. IT'S NOT REALLY ANY  
 20 DIFFERENT FROM THE ICT 42. AND I DON'T WANT TO GO INTO  
 21 THIS IN DETAIL, BUT ADDING IN ALL THOSE ZERO TRIALS IS  
 22 WELL-KNOWN TO DILUTE THE ULTIMATE AVERAGE BECAUSE YOU  
 23 KEEP ADDING ZEROS, AND IT DILUTES THE RESULTS. I COULD  
 24 GO ON AT LENGTH, BUT I WOULD BORE EVERYONE. SO I JUST  
 25 DID NOT TRUST THAT ANALYSIS AT ALL. IT DID NOT PROVIDE

1 **TO ME ONE WHIT OF EXTRA PIECE OF INFORMATION, SO I WAS**  
 2 **TRYING TO BE DISCRIMINATING WHEN I WAS LOOKING AT THESE**  
 3 **META-ANALYSES.**

4 **Q.** NOW, YOU MENTIONED ADDING IN ZEROS AND THINGS  
 5 LIKE THAT. YOU ARE LOOKING -- IS THAT LOOKING FOR  
 6 THINGS LIKE BIAS AND CONFOUNDING AND THOSE TYPES OF  
 7 ERRORS THAT MIGHT AFFECT THE RESULT RELATED TO THE RISK?

8 **A.** **ABSOLUTELY. YOU ARE LOOKING FOR -- THAT IS A**  
 9 **BIAS INTRODUCED IN THAT CASE FROM -- BY -- FOR**  
 10 **STATISTICAL REASONS.**

11 **Q.** NOW, GSK IS CRITICAL OF YOU WE FOUND OUT  
 12 YESTERDAY FOR NOT RELYING ON TWO META-ANALYSES THAT GSK  
 13 DID AND I THINK THEY ACTUALLY MAY BE ONE, BUT THEY  
 14 INCLUDE ADJUDICATED ADOPT. IN OTHER WORDS, ADOPT WAS  
 15 PUBLISHED, THERE WAS EVENTS IN THERE, GSK WENT BACK,  
 16 THEY ADJUDICATED ADOPT AGAIN. AND TELL US WHY YOU DID  
 17 NOT RELY ON THE GSK ADJUDICATED ADOPT META-ANALYSES?

18 **A.** **WELL, AS I INDICATED IN MY DEPOSITION, WITH GOOD**  
 19 **REASON, THE FDA WILL NOT ALLOW YOU TO DO THAT IN**  
 20 **EFFICACY TRIALS, TO POST-ADJUDICATE. IN OTHER WORDS,**  
 21 **CHANGE YOUR PROCEDURES FOR DEFINING ENDPOINTS AND FOR**  
 22 **PICKING WHO GOT AN ENDPOINT OR NOT AFTER YOU HAVE LOOKED**  
 23 **AT THE DATA. IT'S JUST TOO -- HUMANS BEING HUMANS IT'S**  
 24 **JUST TOO SUBJECT TO BIAS. SO MY BASIC PRINCIPAL IS NOT**  
 25 **TO RELY ON POST-ADJUDICATED DATA UNLESS IT IS BEEN DONE**

1 **IN A SYSTEMATIC WAY.**  
 2 **I LOOKED AT THE READJUDICATED DATA FOR**  
 3 **ADOPT, WHICH IS ONE OF THESE LARGE TRIALS, AND THEY**  
 4 **CHANGED THE COUNTS A LITTLE BIT AND REDID IT AND I HAD**  
 5 **SOME SUSPICIONS ABOUT THAT. I DID NOT FEEL THAT THE**  
 6 **ADJUDICATION WAS RELIABLE ENOUGH TO CHANGE WHAT I SAW IN**  
 7 **THE PUBLICATION. SO THAT IS WHY I WAS NOT COMFORTABLE**  
 8 **USING THAT AS MUCH OR RELYING ON THAT AS MUCH.**

9 **Q.** NOW, HAVE EITHER OF THOSE META-ANALYSES THAT GSK  
 10 IS TALKING ABOUT BEEN PUBLISHED IN PEER REVIEWED  
 11 LITERATURE, DO YOU KNOW?

12 **A.** **NOT THAT I'M AWARE OF. THERE HAVE BEEN PEOPLE**  
 13 **WHO HAVE LOOKED AT THAT, STATISTICIANS BASICALLY HAVE**  
 14 **LOOKED AT THE DATA, BUT NO. ACTUALLY, THE STATISTICIANS**  
 15 **WHO HAVE LOOKED TO THE DATA CONFIRM THE NISSEN RESULTS**  
 16 **BASICALLY ON THAT. SO, BUT THE NATURE OF THE**  
 17 **READJUDICATION, THE REDEFINING OF ENDPOINTS HAS NOT BEEN**  
 18 **PEER REVIEWED, AS FAR AS I'M AWARE.**

19 **Q.** NOW, YOU SAY IN YOUR REPORT THAT AS A RESULT OF  
 20 YOUR REVIEW OF THE META -- MULTIPLE META-ANALYSES YOU  
 21 FOUND AN ASSOCIATION BETWEEN I BELIEVE AVANDIA AND  
 22 INCREASED CARDIOVASCULAR RISK, INCLUDING MYOCARDIAL  
 23 INFARCTIONS, IS THAT CORRECT?

24 **A.** **YES, THAT IS CORRECT.**

25 **Q.** NOW, DID YOU AT THAT POINT DEVELOP AN OPINION

1 THAT AVANDIA CAUSED MYOCARDIAL INFARCTIONS AND  
 2 MYOCARDIAL ISCHEMIA?

3 **A.** **FROM WHICH?**

4 **Q.** AFTER LOOKING AT THE META-ANALYSIS, BEFORE YOU  
 5 LOOKED AT THE OBSERVATIONAL STUDIES AND COMPLETED YOUR  
 6 REVIEW.

7 **A.** **YES, I DID ACTUALLY COME TO THAT OPINION JUST**  
 8 **FROM LOOKING AT ALL THE RANDOMIZED CLINICAL TRIAL,**  
 9 **RANDOMIZED CONTROLLED TRIAL DATA.**

10 **Q.** NOW YOU THEN, I THINK -- I AM TRYING TO SPEED  
 11 THIS UP A LITTLE BIT, BUT YOU LOOKED AT 20 OBSERVATIONAL  
 12 STUDIES THROUGH PUBLICATIONS AND INFORMATION, IS THAT  
 13 CORRECT?

14 **A.** **THAT SOUNDS ROUGHLY RIGHT.**

15 **Q.** I THINK YOU CALL THEM POPULATION STUDIES, BUT  
 16 TELL US WHAT OBSERVATIONAL STUDIES ARE, PLEASE?

17 **A.** **OBSERVATIONAL STUDIES REALLY REFER TO THE**  
 18 **SITUATION WHERE THE TREATMENT, IN THIS CASE AVANDIA OR**  
 19 **PLACEBO, IS NOT RANDOMLY ALLOCATED SO OTHER PEOPLE,**  
 20 **OFTEN PHYSICIANS, ARE CHOOSING WHETHER YOU TAKE AVANDIA**  
 21 **OR NOT FOR REASONS TO DO WITH YOUR HEALTH. AND AS A**  
 22 **RESULT, YOU MAY BE GETTING A DRUG OR A COMPARATOR DRUG**  
 23 **FOR REASONS BECAUSE YOU ARE IN DECLINING HEALTH OR**  
 24 **IMPROVING HEALTH AND YOU GOT TO SOMEHOW DEAL WITH THAT**  
 25 **ISSUE TO TRY AND BALANCE THOSE ISSUES ACROSS THE ARM.**

1 **SO OBSERVATIONAL STUDIES REALLY ARE KNOWN THAT YOU HAVE**  
 2 **TO PAY A LOT OF ATTENTION TO CONFOUNDING. BY**  
 3 **DEFINITION, A RANDOMIZED CONTROLLED TRIAL HAS NO**  
 4 **CONFOUNDING BECAUSE THE GROUPS ARE BALANCED IMMEDIATELY**  
 5 **ON EVERYTHING AT BASELINE BY THE RANDOMIZATION.**

6 **Q.** NOW --

7 **A.** **I DON'T -- JUST, THE OBSERVATIONAL STUDIES --**  
 8 **WEIGHING OBSERVATIONAL STUDIES VERSUS CLINICAL TRIALS, I**  
 9 **IN MY REPORT BASED IT PRETTY MUCH ENTIRELY ON THE**  
 10 **RANDOMIZED CLINICAL TRIAL. IT WOULD HAVE -- EVEN IF THE**  
 11 **OBSERVATIONAL STUDIES HAD SHOWN DIFFERENT ANSWERS, IT**  
 12 **PROBABLY WOULD NOT HAVE CONVINCED ME -- I JUST WANT TO**  
 13 **BE HONEST, BECAUSE IN MY FIELD, THE RANDOMIZED CLINICAL**  
 14 **TRIAL DATA TRUMPS. AND THE WOMEN'S HEALTH STUDY ABOUT**  
 15 **THE USE OF POSTMENOPAUSAL ESTROGENS AND THE OCCURRENCE**  
 16 **OF HEART DISEASE WHERE YEARS OF OBSERVATIONAL STUDIES**  
 17 **WERE OVERTURNED BY A SINGLE RANDOMIZED TRIAL REFLECT OUR**  
 18 **FEELINGS AS STATISTICIANS ABOUT THOSE, BUT I STILL**  
 19 **LOOKED AT THEM, ABOUT 20, AS YOU SAID.**

20 **Q.** I THINK YOUR REPORT REFLECTS SOME THAT FOUND  
 21 INCREASED RISK WITH MYOCARDIAL INFARCTION OR MYOCARDIAL  
 22 ISCHEMIC OR CV EVENTS AND SOME ALSO THAT DIDN'T, IS THAT  
 23 CORRECT?

24 **A.** **YEAH, SOME FOUND STATISTICALLY SIGNIFICANT**  
 25 **INCREASE IN RISK, SOME DIDN'T FIND IN ANY STATISTICAL**

1 **SIGNIFICANCE, THAT'S CORRECT.**

2 **Q.** NOW, AT THAT POINT, YOU HAD REVIEWED THE TRIAL

3 DATA, THE OBSERVATIONAL STUDIES, THE META-ANALYSES, THE

4 RANDOMIZED CLINICAL TRIAL.

5 DID YOU ALSO LOOK AT BIAS AND CONFOUNDING

6 IN ALL OF THESE STUDIES AND TRY TO DETERMINE WHETHER

7 WHAT YOU WERE SEEING THIS INCREASED RISK WAS THE RESULT

8 OF SOMETHING ELSE, ANOTHER EXPLANATION OTHER THAN

9 AVANDIA?

10 **A.** **ABSOLUTELY. I NEVER HAVE THOUGHT ABOUT BIAS SO**

11 **MUCH AS READING THESE STUDIES. SO I THOUGHT ABOUT IT,**

12 **BOTH THE RANDOMIZED CLINICAL TRIALS, WHICH HAVE**

13 **POTENTIAL FOR OTHER FORMS OF BIAS, BUT PARTICULARLY FOR**

14 **THE OBSERVATIONAL STUDIES AND CONFOUNDING.**

15 **Q.** NOW, BEFORE YOU DID THAT, I WANT TO SHOW THE

16 SLIDE THAT WENT UP YESTERDAY ABOUT THE STATISTICALLY

17 SIGNIFICANT FINDINGS IN STUDIES AND DID YOU LOOK AT

18 MULTIPLE ENDPOINTS FROM VARIOUS STUDIES THAT WERE

19 STATISTICALLY SIGNIFICANT AND FOUND AN INCREASED RISK OF

20 MYOCARDIAL INFARCTION WITH AVANDIA?

21 **A.** **YES.**

22 **Q.** OKAY. MOST OF THE DATA THAT YOU LOOKED AT

23 ACTUALLY, YOU CAN SEE FROM THIS SLIDE THAT WE SAW

24 YESTERDAY, MOST OF THE DATA IS RED, WHICH MEANS

25 MYOCARDIAL INFARCTION, RIGHT?

1 **A.** **CORRECT.**

2 **Q.** THERE IS SOME GREEN AT THE BOTTOM, WHICH ARE THE

3 META-ANALYSES FROM FDA AND ICT AND THAT IS GREEN. THAT

4 IS MYOCARDIAL ISCHEMIA DATA, IS THAT CORRECT?

5 **A.** **YES.**

6 **Q.** THOSE ARE STATISTICALLY SIGNIFICANT, ALTHOUGH

7 THERE ARE SOME META-ANALYSES THAT ARE NOT STATISTICALLY

8 SIGNIFICANT, IS THAT CORRECT?

9 **A.** **NOT QUITE, CORRECT.**

10 **Q.** YOU ALSO LOOKED AT THE NONSTATISTICALLY

11 SIGNIFICANT DATA, IS THAT CORRECT?

12 **A.** **YES, ABSOLUTELY.**

13 **Q.** THIS IS THE FOREST PLOT THAT WE SAW YESTERDAY

14 THAT HAS ALL OF THE RESULTS FROM MULTIPLE STUDIES THAT

15 ARE NOT STATISTICALLY SIGNIFICANT. YOU CAN SEE THAT THE

16 LINES CROSS 1, THAT MEANS THAT THEY ARE NOT

17 STATISTICALLY SIGNIFICANT, CORRECT?

18 **A.** **THIS SLIDE HAS ALL THE RESULTS I THINK BECAUSE**

19 **IT HAS SOME STATISTICALLY SIGNIFICANT ONES ON THERE AS**

20 **WELL.**

21 **Q.** NOW, THESE ARE THE NONSTATISTICALLY SIGNIFICANT

22 FINDINGS FROM THE STUDIES, A LOT OF THE ENDPOINTS THAT

23 YOU SAW, CORRECT?

24 **A.** **CORRECT.**

25 **Q.** THEY ARE ALL, IT LOOKS LIKE TO ME RIGHT OF THE

1 1, WHAT DOES THAT MEAN?

2 **A.** **SO THAT MEANS THESE PARTICULAR STUDIES ALL**

3 **SHOWED THAT THERE WAS AN INCREASED RISK ASSOCIATED WITH**

4 **EXPOSURE TO AVANDIA EVEN THOUGH IT DID NOT ACHIEVE**

5 **STATISTICAL SIGNIFICANCE IN THAT PARTICULAR STUDY.**

6 **Q.** YOU TALK IN YOUR REPORT ABOUT TRENDS. WHAT DO

7 YOU MEAN BY TRENDS? DOES THIS SHOW TRENDS?

8 **A.** **THIS SHOWS THAT THERE'S A LOT OF STUDIES THAT**

9 **EVEN THOUGH NONE OF THESE PARTICULAR ONES ACHIEVE**

10 **STATISTICAL SIGNIFICANT ON THEIR OWN, THEY GET PRETTY**

11 **CONVINCING WHEN YOU SEE THEM ALL.**

12 **Q.** THAT WAS ACTUALLY THE NEXT SLIDE.

13 MS. GUSSACK: YOUR HONOR, FOR THE SAKE OF

14 THOSE WHO ARE PARTICIPATING.

15 HONORABLE SANDRA MAZER MOSS: CAN YOU

16 SPEAK INTO THE MICROPHONE? PULL IT CLOSER TO YOU.

17 MS. GUSSACK: YES, JUDGE. THANK YOU.

18 COULD WE ASK THAT EACH SLIDE BE

19 IDENTIFIED BY A TITLE BECAUSE I FEAR OUR RECORD IS GOING

20 TO BE IMPAIRED AND CERTAINLY FOR THOSE JUDGES WHO ARE

21 INTERESTED IN THESE PROCEEDINGS, THEY WILL WANT TO ALSO

22 HAVE THESE SLIDES IDENTIFIED.

23 HONORABLE CYNTHIA M. RUFÉ: YES.

24 MS. GUSSACK: A COPY OF THEM WOULD

25 ASSIST, BUT CERTAINLY RECOGNIZING THAT THERE MAY BE SOME

1 LOGISTICAL CHALLENGES THAT MR. CARTMELL IS FACING RIGHT

2 NOW IN GIVING US THOSE SLIDES, REFERENCING THEM BY TITLE

3 SO THAT WE KNOW THAT THE TESTIMONY CONNECTS TO THE SLIDE

4 WOULD BE HELPFUL. I WOULD APPRECIATE THAT.

5 MR. CARTMELL: I APOLOGIZE. I WILL

6 DEFINITELY DO THAT. I SHOULD HAVE BEEN DOING THAT.

7 HONORABLE SANDRA MAZER MOSS: COULD WE

8 GET A COPY OF THE SLIDES?

9 MR. CARTMELL: I'M SORRY, DID YOU ASK FOR

10 A PACKET OF EVERYTHING WE USED WITH DR. JEWELL?

11 HONORABLE SANDRA MAZER MOSS: THAT WOULD

12 BE WONDERFUL.

13 MR. CARTMELL: I APOLOGIZE WE DID NOT DO

14 IT BEFORE. WE ARE TRYING TO GET THAT. WE WILL GET

15 THOSE TO YOU.

16 HONORABLE SANDRA MAZER MOSS: I CAN SEE

17 IT PRETTY MUCH, BUT WHEN YOU HAVE A PAGE OF TEXT, IT'S

18 HARD FOR ME TO FOLLOW IT. IT WOULD BE EASIER IF I

19 HAD --

20 MR. CARTMELL: OKAY, WE WILL GET YOU

21 THOSE. I WILL TELL YOU THAT EVERY SLIDE I'M USING WE

22 USED YESTERDAY OR IS IN HIS REPORT, BUT I WILL

23 DEFINITELY -- MAYBE YOU WANT A SMALL PACKET OF JUST WHAT

24 WAS USED?

25 HONORABLE SANDRA MAZER MOSS: I DON'T

1 NEED A SMALL PACKET, I NEED YOU TO DO WHAT MS. GUSSACK  
 2 SAID, YOU HAVE TO IDENTIFY EVERYTHING FOR THE RECORD AND  
 3 COMBINED RISK CHART IS ALL WE NEED FOR THIS.  
 4 BY MR. CARTMELL:  
 5 Q. THIS IS THE COMBINED RISK CHART. AND TELL US  
 6 WHAT YOU SEE ON THIS CHART, DR. JEWELL.  
 7 A. **SO THIS IS AGAIN A LIST OF A LOT OF THE -- MAYBE**  
 8 **ALL OF THE STUDIES, SOME SIGNIFICANT AND SOME NOT. SOME**  
 9 **-- MOST OF THEM MYOCARDIAL INFARCTION AND IT'S -- TO USE**  
 10 **THAT LANGUAGE, IT'S A PRETTY CLEAR TREND.**  
 11 Q. OKAY.  
 12 A. **TO EVERYONE, I DON'T THINK THERE IS ANYONE THAT**  
 13 **DISPUTES THAT.**  
 14 HONORABLE CYNTHIA M. RUFÉ: I NEED TO ASK  
 15 A QUESTION.  
 16 THE WITNESS: SURE.  
 17 HONORABLE CYNTHIA M. RUFÉ: YOU SAY  
 18 TREND. NOW, TREND IN THE WEBSTER'S DICTIONARY  
 19 DEFINITION IS SOMETHING THAT IS OCCURRING MORE AND MORE  
 20 AND MORE. OF COURSE, THIS IS AN UP AND DOWN CHART TO  
 21 ME, NOT GOING Laterally. CAN YOU EXPLAIN TO ME IN THAT  
 22 CONTEXT, PLEASE, WHAT TREND MEANS?  
 23 THE WITNESS: IT'S NOT A GREAT WORD, I  
 24 AGREE. ACTUALLY NOT, BUT WHAT IT MEANS IS IF YOU  
 25 IMAGINE JUST -- IF YOU CAN BLOCK OUT EVERYTHING BUT THE

1 TOP TRIAL AT THE MOMENT AND YOU SEE THE RESULT. IT'S  
 2 THE VERY TOP ONE IS JUST SLIGHTLY TO THE RIGHT OF 1 ON  
 3 THAT SLIDE OF -- COMBINED RISK SLIDE. THEN YOU LOOK AT  
 4 THE NEXT ONE AND THE NEXT ONE AND THE NEXT ONE AND THE  
 5 WORD TREND IS BEING USED. AS YOU KEEP ADDING, IS THERE  
 6 A TENDENCY FOR THE RESULTS TO BE OFF IN ONE DIRECTION  
 7 AND THIS IS BIGGER THAN 1.  
 8 HONORABLE SANDRA MAZER MOSS: ARE YOU  
 9 SAYING THEY ARE MOVING OVER TO THE RIGHT?  
 10 THE WITNESS: NOT NECESSARILY THEY ARE  
 11 MOVING MORE OVER TO THE RIGHT, BUT THEY ARE ALL TRENDING  
 12 ALWAYS -- I WOULD USE THE WORD TENDENCY, THERE'S A  
 13 TENDENCY FOR THEM ALWAYS TO BE ON THE RIGHT SIDE OF 1  
 14 REFLECTING AN INCREASED RISK. IT'S A TERRIBLE WORD, I  
 15 AGREE, BUT THAT IS WHAT -- THAT IS THE WAY WE ARE USING  
 16 IT HERE.  
 17 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.  
 18 THE WITNESS: YOU'RE WELCOME.  
 19 BY MR. CARTMELL:  
 20 Q. THEN JUST FOR CLARIFICATION, THE ONES ON THE  
 21 BOTTOM THAT DO NOT CROSS THAT LINE THAT IS VERTICAL,  
 22 THOSE ARE NOT TRENDS, RIGHT, THOSE ARE STATISTICALLY  
 23 SIGNIFICANT FINDINGS?  
 24 A. **RIGHT. SO IN A SENSE TO KEEP OUR CONVERSATION**  
 25 **GOING, THEY EVEN STRENGTHEN THE TENDENCY BECAUSE NOT**

1 **ONLY ARE THEY IN THE SAME DIRECTION, EXHIBIT THE SAME**  
 2 **TENDENCY, BUT THEY -- EVEN ON THEIR OWN, THEY SAY THIS**  
 3 **CAN'T BE ATTRIBUTABLE TO CHANCE ALONE.**  
 4 Q. I SHOULD HAVE ASKED YOU THAT EARLIER, BUT WHEN  
 5 YOU SAY SOMETHING IS STATISTICALLY SIGNIFICANT, TELL US  
 6 WHAT THAT MEANS?  
 7 A. **THAT MEANS ASSESSING THE PLAY OF CHANCE. SO,**  
 8 **IT'S REMOVING ONE POSSIBLE EXPLANATION OF A RESULT BEING**  
 9 **BIGGER THAN ONE, IT'S JUST RANDOM CHANCE. YOU WIN SOME,**  
 10 **YOU LOSE SOME. SO STATISTICIANS HAVE DEVELOPED**  
 11 **SOPHISTICATED TECHNIQUES IN COMPLICATED TRIALS TO ASSESS**  
 12 **THAT AND THAT IS WHAT SIGNIFICANCE MEANS, YOU HAVE RULED**  
 13 **OUT THE RULE OF CHANCE AT A CERTAIN LEVEL. YOU CAN**  
 14 **NEVER RULE IT OUT 100 PERCENT.**  
 15 Q. AGAIN, I THINK THEY USE A 95 PERCENT CONFIDENCE  
 16 LEVEL TYPICALLY, IS THAT CORRECT?  
 17 A. **FOR EFFICACY TRIALS, 95 PERCENT IS THE STANDARD.**  
 18 **SAFETY TRIALS PEOPLE OFTEN BECOME A LITTLE BIT MORE**  
 19 **LIBERAL AND MAKE IT 90 PERCENT BECAUSE THEY WANT TO BE**  
 20 **PARTICULARLY CONSERVATIVE WITH REGARD TO HUMAN SAFETY.**  
 21 Q. OKAY.  
 22 SO THE LAST BOTTOM THIRD AT LEAST OF  
 23 THOSE RED FINDINGS THAT ARE TO THE RIGHT AND THEIR  
 24 CONFIDENCE INTERVALS ARE NOT CROSSING 1, THOSE ARE  
 25 STATISTICALLY SIGNIFICANT OR THOUGHT BY

1 BIO-STATISTICIANS NOT TO BE DUE TO CHANCE, CORRECT?  
 2 A. **THAT IS CORRECT.**  
 3 Q. OKAY. NOW, WITH RESPECT TO YOUR OPINIONS ABOUT  
 4 -- OR EXCUSE ME, WITH RESPECT TO DID YOU CONSIDER BIAS  
 5 AND CONFOUNDING AND YOU HAVE SEEN THAT GSK CLAIMS THAT  
 6 YOU -- LET'S SEE, THIS IS THEIR BRIEF, A PAGE 2. THIS  
 7 IS GSK'S DAUBERT BRIEF AT PAGE 2 AND IF YOU WILL  
 8 HIGHLIGHT THE SECOND BULLET POINT, PLEASE. GSK STATES  
 9 DR. JEWELL LEAPFROGGED FROM A FINDING OF A PURPORTED  
 10 ASSOCIATION TO A CONCLUSION REGARDING CAUSATION WITHOUT  
 11 CONSIDERING WHETHER THE ASSOCIATION IS REAL OR DUE TO  
 12 CHANCE, CONFOUNDING OR BIAS. DO YOU SEE THAT?  
 13 A. **I DO.**  
 14 Q. DID YOU DO THAT?  
 15 A. **NO.**  
 16 Q. LET'S PUT UP --  
 17 A. **I DID NOT LEAPFROG.**  
 18 Q. LET'S PUT UP C AT PAGE 7 OR EXCUSE ME, PAGE 4,  
 19 AND THIS IS DR. JEWELL'S EXPERT REPORT AND IN PARAGRAPH  
 20 7, IF YOU CAN PULL THAT UP, PLEASE.  
 21 ARE YOU TALKING HERE ABOUT BIAS AND  
 22 CONFOUNDING AND THINGS LIKE THAT?  
 23 A. **IN THIS PARAGRAPH I'M PARTICULARLY DRAWING THE**  
 24 **ATTENTION THAT OBSERVATIONAL STUDIES SUFFER FROM**  
 25 **CONFOUNDING BIAS AS COMPARED TO RANDOMIZED CONTROLLED**

1 TRIALS.

2 Q. PAGE 22, IF YOU CAN PULL UP THE SECOND PARAGRAPH

3 OR THE FIRST FULL PARAGRAPH, PLEASE. HERE YOU ARE

4 TALKING ABOUT STATINS AND THE USE OF STATINS IN SOME OF

5 THE STUDIES. ARE YOU TALKING ABOUT BIAS AND CONFOUNDING

6 IN STUDIES, ARE YOU CONSIDERING THAT?

7 A. THAT IS A SLIGHTLY DIFFERENT -- I WOULD NOT CALL

8 THAT CONFOUNDING. IT'S WHAT'S KNOWN AS A POST

9 RANDOMIZATION BIAS, WHEN GROUPS START TO DIFFER AFTER

10 RANDOMIZATION, AND I WAS WORRIED ABOUT THAT AND AM

11 WORRIED ABOUT THAT IN SOME OF THESE TRIALS.

12 Q. PAGE 28, PLEASE. IF YOU CAN PULL UP THE FIRST

13 FULL PARAGRAPH, PLEASE.

14 YOU ARE TALKING IN THIS SECOND PARAGRAPH

15 -- OR, EXCUSE ME, SENTENCE, YOU SAY: TAKEN TOGETHER

16 WITH THE MULTIPLICITY OF CONCOMITANT BIAS CONCERNS. YOU

17 ARE TALKING ABOUT A STUDY AND YOU ARE ACTUALLY

18 EVALUATING WHETHER OR NOT THERE IS BIAS INVOLVED IN THAT

19 STUDY, IS THAT CORRECT?

20 A. THAT IS CORRECT, THAT'S PARTICULARLY ABOUT THE

21 RECORD TRIAL. I WAS QUITE CONCERNED ABOUT BIAS, EVEN

22 THOUGH IT WAS A RANDOMIZED CONTROLLED TRIAL.

23 Q. AND I THINK YOUR REPORT HAS 3 PAGES OF ANALYSIS

24 RELATED TO THE RECORD TRIAL, IS THAT CORRECT?

25 A. THAT SOUNDS ABOUT RIGHT, YES.

1 Q. TELL US BRIEFLY, BUT IF YOU COULD, WHAT YOUR

2 CONCERNS ABOUT THE RECORD TRIAL ARE?

3 A. BRIEFLY. OKAY. THE RECORD TRIAL, FIRST OF ALL,

4 IT WAS A NONINFERIORITY TRIAL. THAT IS THE CONTEXT. A

5 NONINFERIORITY TRIAL IS QUITE DIFFERENT FROM AN EFFICACY

6 TRIAL. IN AN EFFICACY TRIAL, YOU ARE TRYING TO SHOW THE

7 TWO GROUPS ARE DIFFERENT. THAT IS REALLY YOUR GOAL.

8 YOU MAY NOT SUCCEED, BUT YOU ARE TRYING.

9 IN A NONINFERIORITY TRIAL, YOU ARE TRYING

10 TO SHOW THE TWO GROUPS ARE THE SAME. A NONINFERIORITY

11 SAFETY TRIAL, YOU ARE TRYING TO SHOW THAT THEY ARE THE

12 SAME WITH REGARD TO SAFETY. MOST STATISTICIANS ARE

13 UNCOMFORTABLE WITH NONINFERIORITY TRIALS BECAUSE MOST OF

14 THE BIASES THAT OCCUR IN RANDOMIZED CONTROLLED TRIALS

15 ARE BIASES TOWARD SHOWING THE GROUPS ARE THE SAME.

16 THAT IS NOT SO MUCH OF A CONCERN IN AN

17 EFFICACY TRIAL BECAUSE YOU JUST HAVE WORK HARDER BECAUSE

18 YOU ARE REALLY TRYING TO SHOW THAT THEY ARE DIFFERENT,

19 BUT WHEN YOU ARE TRYING TO SHOW THEM THE SAME AND THE

20 BIASES ARE HELPING YOU, THAT IS A PROBLEM. RECORD WAS

21 AN OPEN LABEL TRIAL, MEANING THAT THE PATIENTS AND THE

22 PHYSICIANS KNEW WHAT TREATMENT THEY WERE GETTING.

23 EVERYBODY KNOWS THAT AN OPEN LABEL TRIAL TENDS TO MAKE

24 THE BIASES BIGGER. SO THE COMBINATION TO ME OF A

25 NONINFERIORITY TRIAL WHERE BIASES TEND TO MAKE THE

1 GROUPS LOOK THE TAME PLUS AN OPEN LABEL TRIAL WILL

2 ALMOST SURELY TEND TO LEAD TO THE CONCLUSION OF

3 NONINFERIORITY. AND THAT IS A GREAT -- TO ME THAT

4 TROUBLED ME GREATLY FROM RECORD FROM THE MOMENT I READ

5 THE DESCRIPTION OF THE DESIGN. THEN THERE ARE SOME

6 OTHER BIASES THAT WORRIED ME ABOUT THE CONDUCT OF THE

7 TRIAL.

8 MANY OF THE INDIVIDUALS ON RECORD, FOR

9 EXAMPLE, STOPPED THEIR TREATMENT AND WENT ON TO ANOTHER

10 TREATMENT. SO THAT IS A COMPLICATION BECAUSE SUDDENLY

11 NOW YOU HAVE GOT PEOPLE CHANGING TREATMENTS IN A SENSE

12 DURING THE TRIAL. SO THERE IS A NUMBER OF OTHERS LIKE

13 THAT, FOR THE SAKE OF BREVITY, THEY ARE IN MY REPORT SO.

14 Q. WE ARE SHOWING A DESIGN BIAS SLIDE FROM

15 YESTERDAY THAT DEALS WITH WHETHER OR NOT THE BIAS WOULD

16 TEND TO BIAS TOWARDS THE NULL OR NOT. TELL US WHAT IT

17 MEANS WHEN YOU SAY BIAS TOWARD THE NULL?

18 A. AGAIN, THAT MEANS THAT YOU ARE ACTUALLY HAVING A

19 TENDENCY TO MAKE THE RESULTS FROM THE TWO GROUPS LOOK

20 THE SAME. SO YOU ARE TENDING TO THINK THE GROUPS LOOK

21 THE SAME WHEN YOU BIAS THINGS TOWARDS THE NULL.

22 Q. WHEN YOU BIAS TO THE NULL, IT MAY PUSH THE

23 RESULTS TO SAFE, THE DRUG BEING SAFE?

24 A. IN THIS CASE, YOU ARE MAKING IT LOOK LIKE

25 AVANDIA IS JUST AS SAFE AS THE -- IN THIS CASE IT WAS AN

1 ACTIVE CONTROL, BUT THE OTHER -- THE GROUPS IN THE OTHER

2 CONTROLS.

3 Q. GSK, ONE OF THEIR CONCERNS IS THAT SEVERAL OF

4 YOUR BIASES THAT YOU INCLUDE IN YOUR REPORT ALL, YOU

5 KNOW, I GUESS GO AGAINST THE DRUG AND DON'T FAVOR ROSI.

6 TELL US, WERE YOU TRYING TO CHERRY-PICK YOUR BIASES OR

7 TELL US ABOUT THAT?

8 A. NO. IN FACT, THERE IS ONLY ONE BIAS THAT WAS

9 IDENTIFIED THAT COULD HELP AVANDIA AND THAT WAS THAT

10 THERE WOULD BE A TENDENCY AMONGST AVANDIA PATIENTS TO

11 OVER-DETECT MI'S OR ISCHEMIC HEART DISEASE BECAUSE IT IS

12 WELL-KNOWN THAT PATIENTS ON AVANDIA HAVE DOUBLE THE RISK

13 OF CONGESTIVE HEART FAILURE AND THAT WAS DISCUSSED

14 YESTERDAY. SO THAT WAS THE ONE BIAS I FOUND OR HEARD

15 ABOUT THAT COULD HURT AVANDIA. EVERY OTHER ONE HELPS IT

16 LOOK LIKE AVANDIA IS AS SAFE AS ITS COMPARATORS.

17 Q. AND IN THIS SLIDE, DR. MARCINIAK AT THE FDA

18 ADCOM RECENTLY IN 2010, THIS IS A SLIDE FROM THAT AND

19 THERE IS MULTIPLE BIASES THAT HE INDICATES AND JUST SO

20 IT IS CLEAR, WHEN YOU WROTE YOUR REPORT IN THIS CASE

21 ABOUT THE MULTIPLE CONCERNS YOU HAD ABOUT THE RECORD

22 TRIAL, YOU HAD NOT SEEN THIS, IN OTHER WORDS, YOU HAD

23 NEVER HEARD FROM DR. MARCINIAK, CORRECT?

24 A. YES, THIS WAS MAYBE SIX MONTHS AFTER I HAD

25 FINISHED MY REPORT AND FILED IT.

1 Q. AND DID DR. MARCINIAK THROUGH HIS EVALUATION AND  
2 LOOK AT THE TRIAL ACTUALLY CONFIRM YOUR CONCERNS?

3 A. **ABSOLUTELY.**

4 Q. NOW, ANOTHER CRITICISM THAT GSK HAS AGAINST YOU  
5 IS THAT YOU DID NOT APPLY THE BRADFORD-HILL CRITERIA,  
6 HAVE YOU SEEN THAT?

7 A. **YES.**

8 Q. I THINK YOU SAID DURING YOUR DEPOSITION AND THEY  
9 PLAYED THIS YESTERDAY THAT WHEN YOU WERE ASKED, DO YOU  
10 KNOW THE BRADFORD-HILL CRITERIA YOU SAID SOMEWHAT,  
11 SOMETHING LIKE THAT.

12 A. **I THINK I SAID I'M FAMILIAR OR VAGUELY FAMILIAR  
13 WITH THEM, YES.**

14 Q. ARE YOU FAMILIAR WITH THE BRADFORD-HILL  
15 CRITERIA?

16 A. **YES, I ACTUALLY KNEW BRADFORD-HILL AND -- TONY  
17 HILL, AS HE WAS KNOWN. SIR AUSTIN BRADFORD-HILL, I KNEW  
18 HIM. IN FACT, THE PERSON WHO TOOK BRADFORD-HILL'S JOB  
19 AT THE LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE,  
20 SIR PETER ARMITAGE, WAS THE PERSON WHO FIRST BROUGHT ME  
21 INTO THE FIELD OF BIOSTATISTICS WHEN I WAS YOUNG AND  
22 HANDSOME. NOW THAT I'M OLD AND UGLY IT SEEMS IN THE  
23 PAST, BUT YES, I KNEW TONY HILL AND I KNOW HIS METHOD  
24 AND HIS CRITERIA QUITE WELL.**

25 Q. FOR THE SAKE OF MOVING ALONG, I WON'T IDENTIFY

1 IT, BUT YOU IN YOUR REPORT IN MULTIPLE PLACES USED THE  
2 WORD CONSISTENCY, CORRECT?

3 A. **CORRECT.**

4 Q. THAT IS ONE OF THE BRADFORD-HILL CRITERIA,  
5 CORRECT?

6 A. **YES.**

7 Q. YOU USED THE WORD REPLICATION OR REPEATED  
8 RESULTS, THAT IS ONE OF THE BRADFORD-HILL CRITERIA,  
9 CORRECT?

10 A. **THAT IS THE CONSISTENCY, BRADFORD-HILL. BY THE  
11 WAY, YESTERDAY'S DESCRIPTION OF BRADFORD-HILL LEFT OUT  
12 THREE OF HIS CRITERIA.**

13 Q. THERE IS ALSO ONE OF THE -- OR SOME OF THE  
14 CRITERIA ARE TAKEN CARE OF BY RANDOMIZATION, AREN'T  
15 THEY?

16 A. **YES. TONY HILL WAS COMING FROM A CONTEXT OF  
17 DOING OBSERVATIONAL STUDIES. HE WAS THE MAIN  
18 STATISTICIAN ON THE STUDY THAT DETERMINED THAT SMOKING  
19 CAUSED LUNG CANCER, WITH SIR RICHARD DOLL. AND SO THAT  
20 WAS A TIME WHEN INTEREST IN OBSERVATIONAL STUDIES WAS  
21 EXPLODING AND HE WROTE DOWN THESE METHODS. MANY OF THEM  
22 ARE AUTOMATICALLY DEALT WITH BY -- IN RANDOMIZED  
23 CONTROLLED TRIALS.**

24 Q. IS THE BRADFORD-HILL A CHECKLIST THAT YOU GO  
25 THROUGH AND YOU HAVE TO MAKE SURE THAT YOU SATISFY ALL

1 OF THE CRITERIA, OF THE BRADFORD-HILL CRITERIA BEFORE  
2 YOU FIND THAT A DRUG CAUSES AN ADVERSE EVENT?  
3 A. **NO. TONY HILL WAS OPPOSED TO USING THAT LIST AS  
4 A CHECKLIST. HE IS QUOTED AS SAYING IT SHOULD NOT BE  
5 USED AS A CHECKLIST AND HE ALSO SAID YOU SHOULD NEVER  
6 NOT ESTABLISH CAUSATION. NONE OF THE CRITERIA SHOULD BE  
7 USED SINE QUA NON. SO HE KNEW THAT THESE WERE THINGS  
8 THAT YOU SHOULD LOOK AT WHEN YOU ARE LOOKING AT  
9 CAUSATION, HE DID NOT MEAN TO SAY YOU HAVE PASS EVERY  
10 SINGLE ONE. IN MANY SITUATIONS, THEY ARE NOT  
11 APPLICABLE, ALL OF THEM.**

12 Q. YOU WERE ASKED IN YOUR DEPOSITION WHETHER OR NOT  
13 YOU LOOKED AT THE ICT 42, SOMETHING TO THE EFFECT OF,  
14 DOES THAT SHOW YOU CAUSATION. IN OTHER WORDS, THAT  
15 AVANDIA CAUSES MYOCARDIAL INFARCTIONS. DO YOU RECALL  
16 THAT?

17 A. **YES.**

18 Q. WHAT DID YOU MEAN BY THAT?

19 A. **WELL, I THINK I WAS ASKED THE QUESTION IF THERE  
20 WAS ONE ANALYSIS THAT YOU WANTED TO TELL SOMEONE THAT  
21 SUPPORTED MY OPINION. I THINK THE ONE I WOULD GO TO  
22 WOULD HAVE BEEN THE ICT 42. THIS WAS GSK'S OWN  
23 EVIDENCE. NOW IT'S ICT 52, SO THERE IS MORE EVIDENCE,  
24 BUT I CERTAINLY DID NOT MEAN BY THAT THAT IS THE ONLY  
25 THING I USED TO BASE MY EVIDENCE. AS WE HAVE DISCUSSED**

1 **NOW AND AT SOME LENGTH, I USE ALL OF THE CLINICAL TRIALS  
2 AND THEN LOOKED AT THE OBSERVATIONAL STUDIES.**

3 Q. DID YOU USE A SCIENTIFICALLY RELIABLE  
4 METHODOLOGY IN FORMING YOUR OPINIONS IN THIS CASE?

5 A. **YES.**

6 Q. IS THAT A WELL-ACCEPTED SCIENTIFIC METHODOLOGY  
7 THAT YOU USED IN THIS CASE?

8 A. **YES.**

9 Q. AND YOUR OPINION IS THAT AVANDIA CAUSES HEART  
10 ATTACKS AND IT CAUSES MYOCARDIAL ISCHEMIC EVENTS, IS  
11 THAT CORRECT?

12 A. **YES.**

13 **MR. CARTMELL: THANK YOU, DR. JEWELL.**

14 **HONORABLE CYNTHIA M. RUFÉ: WE ARE READY  
15 TO ENTERTAIN CROSS EXAMINATION OF DR. JEWELL. AT THIS  
16 POINT, THOUGH, JUDGE MOSS AND I HAVE DISCUSSED THE LUNCH  
17 HOUR BREAK AND HOW WE CAN SHORTEN IT AND STILL GIVE  
18 EVERYBODY A CHANCE TO SUSTAIN THEIR ENERGY LEVEL. WE  
19 WOULD LIKE TO BREAK AT 12:15 AND RECONVENE AT 1:30. AND  
20 I HOPE THAT THAT FITS IN WITH THE TESTIMONY. I'M NOT  
21 SUGGESTING THAT YOU HAVE TO BE THROUGH YOUR CROSS  
22 EXAMINATION, MR. SHEEHAN, BUT EVERYONE TO KEEP IN MIND  
23 THAT THERE ARE TWO OTHER WITNESSES THAT NEED TO BE  
24 DIRECTED AND CROSSED TODAY. SO I THINK WE DO HAVE TO  
25 MOVE ALONG. ALL RIGHT?**

1 MR. SHEEHAN: I WILL DO MY VERY BEST.

2 CROSS EXAMINATION

3 BY MR. SHEEHAN:

4 Q. GOOD MORNING, DR. JEWELL.

5 A. **GOOD MORNING.**

6 Q. WE HAVE NOT MET BEFORE. MY NAME IS TOM SHEEHAN.

7 I REPRESENT GLAXOSMITHKLINE. I'M GOING TO ASK YOU A FEW

8 QUESTIONS.

9 A. **SURE.**

10 Q. BEFORE I START INTO MY OUTLINE HERE, I JUST

11 WANTED TO CLARIFY A FEW THINGS THAT YOU TESTIFIED TO ON

12 DIRECT EXAMINATION. I BELIEVE MR. CARTMELL ASKED YOU A

13 QUESTION ABOUT THE ADVISORY COMMITTEE VOTES AND WITHIN

14 THAT QUESTION WAS THE IMPLICATION THAT THE ADVISORY

15 COMMITTEE MEMBERS IN 2007 AND IN 2010 VOTED ON WHETHER

16 AVANDIA CAUSES MYOCARDIAL INFARCTION. YOU ARE AWARE

17 THAT THAT WAS ACTUALLY NOT THE VOTE THAT WAS TAKEN,

18 CORRECT?

19 A. **HE DID NOT ASK ME THAT QUESTION, AND I'M AWARE**

20 **OF THAT, TOO.**

21 Q. I MAY HAVE MISHEARD. I JUST WANTED TO CLARIFY.

22 THERE WAS ALSO SOME TESTIMONY WITH REGARD

23 TO GSK'S 42 STUDY META-ANALYSIS, THE ICT 42. I BELIEVE

24 THE TESTIMONY WAS THAT THERE WAS AVANDIA ON ONE SIDE AND

25 SOME OTHER DRUG ON THE OTHER. AND NOW, YOU ARE AWARE

1 THAT MANY OF THE STUDIES IN THE ICT 24 INCLUDED NOT ONLY

2 AVANDIA ON ONE SIDE OF THE RANDOMIZED TRIAL, BUT AVANDIA

3 PLUS SULFONYLUREA, FOR INSTANCE?

4 A. **YES, I'M AWARE OF THAT. AND THAT IS WHAT I WAS**

5 **MEANING WHEN I SAID THERE WERE ACTIVE COMPARATORS IN**

6 **SOME OF THE CLINICAL TRIALS, YES.**

7 Q. SO THERE COULD HAVE BEEN AVANDIA ALONE AS

8 MONOTHERAPY, FOR INSTANCE, AND THERE COULD HAVE BEEN

9 AVANDIA PLUS SULFONYLUREA, IS THAT CORRECT?

10 A. **THERE COULD HAVE BEEN, YES.**

11 Q. DO YOU KNOW ONE WAY OR THE OTHER?

12 A. **WELL, I WOULD HAVE TO LOOK BACK. THERE WAS --**

13 **THERE WERE SEVERAL POSSIBLE COMPARATOR DRUGS, METFORMIN**

14 **WAS ANOTHER. SOME OF THE TRIALS USED METFORMIN, FOR**

15 **EXAMPLE, AS WHAT THEY CALLED A RUN-IN THERAPY SO THE**

16 **PATIENTS WERE ON THAT BEFORE THEY WERE RANDOMIZED ON**

17 **BOTH SIDES OF THE ARM AND THEN SOME OF THEM, THEY WERE**

18 **RANDOMIZED TO AVANDIA AFTER NOTHING, THAT IS WHAT WE**

19 **WOULD THROW IN AS THE PLACEBO BECAUSE THEY DIDN'T GET**

20 **ANYTHING IN COMPARISON. SO I CAN'T TELL YOU EXACTLY ALL**

21 **OF THE DIFFERENT COMPARATOR DRUGS OFF THE TOP OF MY**

22 **HEAD.**

23 Q. BUT YOU WOULD AGREE THAT SOME OF THOSE TRIALS

24 INVOLVED COMPARISONS OF AVANDIA PLUS OTHER ORAL

25 ANTIDIABETIC MEDICATIONS COMPARED TO SOME OTHER

1 COMPARATOR THERAPY?

2 A. **CORRECT, THERE WAS OFTEN MORE THAN ONE**

3 **MEDICATION INVOLVED, CORRECT.**

4 Q. I BELIEVE YOU TESTIFIED AT YOUR DEPOSITION THAT

5 PRIOR TO FORMING YOUR OPINIONS IN THIS CASE YOU HAD NOT

6 DONE ANY RESEARCH TO DETERMINE THE CARDIOVASCULAR

7 EFFECTS OF OTHER ORAL ANTIDIABETIC MEDICATIONS, OTHER

8 THAN AVANDIA?

9 A. **THAT IS CORRECT.**

10 Q. YOU DON'T KNOW IF THERE IS ANY INTERACTION

11 BETWEEN AVANDIA AND OTHER ORAL ANTIDIABETIC DRUGS, IS

12 THAT ACCURATE?

13 A. **I CERTAINLY DID NOT KNOW THAT GOING IN, THAT IS**

14 **CORRECT.**

15 Q. THERE WAS SOME TESTIMONY ABOUT LUNG CANCER AND

16 SMOKING WHERE YOU SAID THAT IT'S WELL-ESTABLISHED IN THE

17 ABSENCE OF RANDOMIZED CLINICAL TRIALS THAT SMOKING

18 CAUSES LUNG CANCER, DO YOU RECALL THAT TESTIMONY?

19 A. **I DO.**

20 Q. WHAT IS THE RELATIVE RISK OF LUNG CANCER WITH

21 SMOKING?

22 A. **IT'S PROBABLY AROUND TEN.**

23 Q. SO IT'S A VERY LARGE MAGNITUDE EFFECT, IS THAT

24 RIGHT?

25 A. **THAT IS CORRECT.**

1 Q. AND OBSERVATIONAL STUDIES ARE APPROPRIATE FOR

2 ESTABLISHING ASSOCIATIONS WHERE THE EFFECT IS OF LARGE

3 MAGNITUDE, WOULD YOU AGREE WITH THAT?

4 A. **WELL, THEY ARE APPROPRIATE FOR EXAMINING ANY**

5 **ASSOCIATION, OF COURSE, BUT THEY ARE MORE LIKELY TO**

6 **PRODUCE A CAUSAL INTERPRETATION. THE STRONGER THE**

7 **EFFECT THE MORE LIKELY YOU ARE TO HAVE A REASONABLE**

8 **CONCLUSION OF CAUSALITY AND THAT IS ONE OF THE**

9 **BRADFORD-HILL CRITERIA, THE STRENGTH OF THE ASSOCIATION**

10 **IS IMPORTANT, ABSOLUTELY.**

11 Q. JUST SO I'M CLEAR, ARE YOU TESTIFYING THAT ONE

12 STUDY, ONE EPIDEMIOLOGIC STUDY STANDING ALONE CAN

13 ESTABLISH CAUSATION?

14 A. **IT DID FOR LUNG CANCER AND SMOKING, YES.**

15 Q. WAS THAT WITHOUT REGARD TO ANY OF

16 BRADFORD-HILL'S CRITERIA, JUST THE STUDY ITSELF?

17 A. **BRADFORD-HILL CRITERIA WERE NOT WRITTEN AT THE**

18 **TIME THOSE STUDIES WERE DONE. HILL WAS ONE OF THE**

19 **AUTHORS, SO WHAT WAS YOUR QUESTION?**

20 Q. MY QUESTION IS THIS: CAN THE STUDY ITSELF, THE

21 RELATIONSHIP THAT IS IDENTIFIED IN THE STUDY ESTABLISH

22 CAUSATION WITHOUT REGARD TO OTHER INFORMATION?

23 A. **NO. NO, AS I SAID IN MY TESTIMONY, YOU SHOULD**

24 **TRY AND MAKE USE OF ALL AVAILABLE INFORMATION AT THAT**

25 **TIME AND SOMETIMES YOU WANT TO COLLECT MORE AND THERE**

1 **WERE MORE STUDIES DONE, OF COURSE, LATER ABOUT LUNG**  
 2 **CANCER AND SMOKING.**  
 3 Q. I WAS A LITTLE BIT UNCLEAR WITH REGARD TO YOUR  
 4 TESTIMONY ABOUT OBSERVATIONAL STUDIES. ARE YOU OR ARE  
 5 YOU NOT RELYING ON OBSERVATIONAL STUDIES FOR YOUR  
 6 OPINION THAT AVANDIA CAUSES MYOCARDIAL INFARCTION?  
 7 A. **IF YOU GO BACK TO MY EXECUTIVE SUMMARY, I SAY**  
 8 **BASED ON THE RANDOMIZED CONTROLLED TRIAL DATA ALONE I**  
 9 **COME TO MY OPINION, BUT I WANT TO ASSURE EVERYONE THAT I**  
 10 **LOOKED AT THE OBSERVATIONAL STUDIES.**  
 11 Q. AND I BELIEVE YOU SAID REGARDLESS OF HOW THEY  
 12 CAME OUT, YOU WOULD NOT HAVE CHANGED YOUR MIND?  
 13 A. **WELL, I DID NOT QUITE SAY THAT. I SAID A**  
 14 **PRIORI. I WAS OF THE OPINION IT WOULD TAKE A VERY WEIRD**  
 15 **SET OF OBSERVATIONAL STUDIES TO MAKE ME CHANGE MY MIND**  
 16 **BECAUSE OF THE STRENGTH THAT WE PLACE ON THE RANDOMIZED**  
 17 **CONTROLLED TRIAL. AS IT HAPPENED, THE OBSERVATIONAL**  
 18 **STUDIES I THINK BY AND LARGE CONFIRM WHAT WE SEE IN THE**  
 19 **RANDOMIZED CONTROLLED TRIAL, BUT THEY ARE MORE VARIABLE**  
 20 **BECAUSE OF THE NATURE OF THE BIASES THAT GO WITH THOSE**  
 21 **STUDIES.**  
 22 Q. IS IT YOUR TESTIMONY THAT THE OBSERVATIONAL  
 23 STUDIES DEMONSTRATE A CONSISTENT STATISTICALLY  
 24 SIGNIFICANT ASSOCIATION BETWEEN AVANDIA AND MYOCARDIAL  
 25 INFARCTION?

1 A. **I HAVE NEVER DONE A META-ANALYSIS OF THE**  
 2 **OBSERVATIONAL STUDIES TO SUMMARIZE THEM AS ONE COMPLETE.**  
 3 **I THINK SOME STUDIES SHOW THE STATISTICALLY SIGNIFICANT**  
 4 **EFFECT. WE ALL AGREE ON THAT, SOME DON'T AND THAT IS**  
 5 **WHERE I WOULD SAY MY OPINION IS AT THE MOMENT.**  
 6 Q. WOULD YOU CHARACTERIZE THEM AS CONSISTENT?  
 7 A. **I WOULD NOT CHARACTERIZE THEM AS CONSISTENT AS**  
 8 **THE CLINICAL TRIALS, WHICH IS WHAT I BASE MY CAUSATION**  
 9 **OPINION ON.**  
 10 Q. THERE WAS SOME TESTIMONY AS WELL WITH REGARD TO  
 11 OVERLAPPING META-ANALYSES. YOU WOULD AGREE THAT THE GSK  
 12 ICT 42 COMPLETELY OVERLAPS WITH THE FDA ANALYSIS OF THE  
 13 ICT 42, CORRECT?  
 14 A. **THEY USE THE SAME DATA, THAT IS CORRECT. THEY**  
 15 **DID NOT QUITE USE THE SAME METHOD OF ANALYSIS.**  
 16 Q. THEY ARE NOT SEPARATE SOURCES OF INFORMATION?  
 17 A. **CORRECT.**  
 18 Q. AND THE GSK ICT 52 COMPLETELY OVERLAPS WITH THE  
 19 FDA 52?  
 20 A. **THAT IS MY UNDERSTANDING.**  
 21 Q. AND OBVIOUSLY THE ICT 42 PERFORMED BY GSK AND  
 22 FDA ARE COMPLETELY SUBSUMED WITHIN THE ICT 52?  
 23 A. **THAT IS MY UNDERSTANDING.**  
 24 Q. AND THE SINGH META-ANALYSIS IS SUBSUMED WITHIN  
 25 NISSEN'S UPDATED META-ANALYSIS OF 56 TRIALS, RIGHT?

1 A. **IT WAS NOT SUBSUMED WITHIN THE ORIGINAL NISSEN**  
 2 **ANALYSIS AND THE UPDATED NISSEN META-ANALYSIS WAS NOT**  
 3 **AVAILABLE AT THE TIME I WROTE MY REPORT. THAT HAS NOW**  
 4 **APPEARED I THINK IN JULY OF THIS YEAR AND NOW HE HAS**  
 5 **INCLUDED RECORD, FOR EXAMPLE, THAT SINGH ALSO INCLUDED**  
 6 **THAT WAS NOT IN THE ORIGINAL NISSEN META-ANALYSIS THAT**  
 7 **STARTED ALL THIS IN 2007.**  
 8 Q. I GUESS MY QUESTION IS, DO YOU AGREE THAT THE  
 9 SINGH META-ANALYSIS IS COMPLETELY SUBSUMED WITHIN THE  
 10 NISSEN 56 META-ANALYSIS?  
 11 A. **I THINK IT IS NOW IN THE NEW ONE. I THINK IT'S**  
 12 **IMPORTANT THAT -- WHAT DID YOU CALL IT, THE UPDATED OR**  
 13 **NEW? YES, THE NEW ONE.**  
 14 Q. 2010?  
 15 A. **YES.**  
 16 Q. WE ARE ON THE SAME PAGE?  
 17 A. **YES.**  
 18 Q. AND I BELIEVE YOU SAID THERE WAS AT LEAST 8  
 19 TRIALS THAT OVERLAPPED BETWEEN NISSEN'S 42 STUDY  
 20 META-ANALYSIS IN 2007 AND THE FDA AND GSK 42 STUDY  
 21 META-ANALYSIS?  
 22 A. **THAT IS NOT CORRECT. THEY AGREED ON THE -- THEY**  
 23 **HAD THE SAME 28 STUDIES AND DIFFERED IN 14.**  
 24 Q. THERE WAS SOME TESTIMONY ABOUT TRENDS, AND I  
 25 BELIEVE THERE WAS ACTUALLY A QUESTION FROM THE BENCH

1 ABOUT TRENDS.  
 2 I WANT TO KNOW, IS THERE ANY TEXTBOOK  
 3 THAT DEFINES TRENDING DATA?  
 4 A. **NO. I MEAN, AS I SAID, I DON'T LIKE THAT WORD.**  
 5 **I DON'T USE IT MYSELF VERY MUCH. IT'S REALLY KIND OF A**  
 6 **LOOSELY USED WORD TO SAY WHEN YOU WANT TO SUMMARIZE A**  
 7 **SET OF TRIALS AND SAY DO THEY TEND TO HAVE A TENDENCY TO**  
 8 **GIVE A CERTAIN PICTURE OR NOT, DOES IT TEND TO BE A**  
 9 **LITTLE BIT RED OR A LITTLE BIT BLUE. AND SO THE TREND**  
 10 **THERE IS VERY INFORMAL, JUST SAYING DO THESE TRIALS HAVE**  
 11 **A TENDENCY OR A TREND TOWARDS BEING NEGATIVE OR POSITIVE**  
 12 **WITH REGARD TO A COMPARISON. THAT IS THE ONLY WAY I**  
 13 **HAVE SEEN THAT WORD USED. IT'S NOT A WORD I USE A LOT**  
 14 **MYSELF.**  
 15 Q. OKAY. SO YOU WOULD AGREE THAT THERE IS NO  
 16 GENERALLY ACCEPTED DEFINITION WITHIN THE PROFESSION OF  
 17 BIostatISTICS FOR THE WORD TREND?  
 18 A. **I DON'T THINK THERE IS A FORMAL DEFINITION, NO.**  
 19 Q. THANK YOU.  
 20 YOU ARE NOT A MEDICAL DOCTOR, CORRECT?  
 21 A. **NO.**  
 22 Q. SO YOU ARE NOT A CARDIOLOGIST OR  
 23 ENDOCRINOLOGIST?  
 24 A. **NO.**  
 25 Q. AND YOU DON'T CONSIDER YOURSELF AN EXPERT IN THE

- 1 FIELD OF CARDIOVASCULAR MEDICINE OR DISEASE, CORRECT?
- 2 **A. NOT MEDICALLY, NO.**
- 3 **Q.** YOU DON'T CLAIM TO BE AN EXPERT IN THE FIELD OF
- 4 ATHEROSCLEROSIS?
- 5 **A. NOT MEDICALLY.**
- 6 **Q.** OR LIPIDS?
- 7 **A. NO.**
- 8 **Q.** LP-PLA2?
- 9 **A. NO.**
- 10 **Q.** YOU DO NOT HAVE ANY EXPERTISE REGARDING HOW
- 11 ATHEROSCLEROSIS RELATES TO MYOCARDIAL INFARCTION OR
- 12 MYOCARDIAL ISCHEMIC DISEASE, CORRECT?
- 13 **A. JUST AS A LAY PERSON.**
- 14 **Q.** YOU HAVE NOT DONE ANY CARDIOVASCULAR RESEARCH
- 15 RELATED TO PHARMACEUTICAL PRODUCTS OUTSIDE OF
- 16 LITIGATION, CORRECT?
- 17 **A. NOT OUTSIDE OF LITIGATION. I HAVE DONE A LOT IN**
- 18 **LITIGATION.**
- 19 **Q.** YOU HAVE NEVER PUBLISHED A RANDOMIZED CONTROLLED
- 20 TRIAL INVESTIGATING THE RELATIONSHIP BETWEEN ANY KIND OF
- 21 EXPOSURE AND A CARDIOVASCULAR ENDPOINT?
- 22 **A. NO.**
- 23 **Q.** YOU HAVE NEVER PUBLISHED A SCIENTIFIC PAPER OR
- 24 CONDUCTED AN EPIDEMIOLOGIC STUDY ON DIABETES?
- 25 **A. I AM JUST ABOUT TO PUBLISH ONE ON DIABETES, IT'S**

- 1 **IN PRESS.**
- 2 **Q.** IT IS NOT PUBLISHED YET?
- 3 **A. NOT YET.**
- 4 **Q.** IT WILL BE YOUR FIRST ONE?
- 5 **A. FIRST ONE, YES. NOT TO DO WITH THIS, BY THE**
- 6 **WAY.**
- 7 **Q.** THANK GOODNESS.
- 8 YOU HAVE NEVER DESIGNED, CONDUCTED OR
- 9 ANALYZED RANDOMIZED CONTROLLED TRIALS IN WHICH
- 10 CARDIOVASCULAR EFFECTS WERE AN OUTCOME -- I ALREADY
- 11 ASKED THAT QUESTION, FORGET IT.
- 12 YOU HAVE NEVER WORKED ON AN OBSERVATIONAL
- 13 STUDY INVOLVING A PHARMACEUTICAL PRODUCT AND A
- 14 CARDIOVASCULAR ENDPOINT OUTSIDE OF THE LITIGATION
- 15 CONTEXT, CORRECT?
- 16 **A. I DON'T THINK SO, NO. MOST OF MY INTERESTS HAVE**
- 17 **BEEN IN NONPHARMACEUTICAL EXPOSURES.**
- 18 **Q.** YOU HAVE NEVER PUBLISHED A META-ANALYSIS, IS
- 19 THAT RIGHT?
- 20 **A. NEVER PUBLISHED ONE, NO.**
- 21 **Q.** AND I JUST WANT TO BE REAL CLEAR NOW ABOUT
- 22 ASSOCIATION AND CAUSATION. I THINK YOU ARE GOING TO
- 23 AGREE WITH MUCH OF THIS, WE HAVE TALKED ABOUT IT A BUNCH
- 24 YESTERDAY AND TODAY.
- 25 BUT AS WE HEARD YESTERDAY IN THE

- 1 PRESENTATIONS, BOTH FROM THE DEFENSE AND THE PLAINTIFFS,
- 2 ASSOCIATION AND CAUSATION ARE NOT THE SAME THING,
- 3 CORRECT?
- 4 **A. CORRECT.**
- 5 **Q.** SOMETIMES THERE IS AN ASSOCIATION THAT IS CAUSAL
- 6 AND SOMETIMES THERE IS AN ASSOCIATION THAT IS NOT
- 7 CAUSAL?
- 8 **A. CORRECT.**
- 9 **Q.** AND ASSOCIATIONS HAVE TO BE EVALUATED TO
- 10 DETERMINE WHETHER THEY MIGHT BE DUE TO CHANCE, BIAS AND
- 11 CONFOUNDING, CORRECT?
- 12 **A. CORRECT.**
- 13 **Q.** AND STATISTICALLY EVEN -- WELL, STATISTICAL
- 14 SIGNIFICANCE IS A WAY OF EVALUATING WHETHER THE FINDINGS
- 15 MAY BE DUE TO CHANCE, CORRECT?
- 16 **A. THAT IS ROUGHLY CORRECT.**
- 17 **Q.** AND EVEN STATISTICALLY SIGNIFICANT FINDINGS MUST
- 18 BE EVALUATED FOR BIAS AND CONFOUNDING, CORRECT?
- 19 **A. CORRECT.**
- 20 **Q.** IN FACT, BIAS AND CONFOUNDING MUST BE RULED OUT
- 21 BEFORE A STATISTICALLY SIGNIFICANT ASSOCIATION IS
- 22 CONSIDERED A VALID ASSOCIATION, ISN'T THAT CORRECT?
- 23 **A. WELL, YOU HAVE TO ASSESS HOW BIG THE BIAS MIGHT**
- 24 **BE TO REASSESS WHAT YOUR ESTIMATE OF RELATIVE RISK IS**
- 25 **BECAUSE IT MAY BE -- BIAS MEANS IT'S EITHER OVER OR**

- 1 **UNDER ESTIMATED. SO USUALLY WHEN YOU ARE ASSESSING**
- 2 **BIAS, YOU WOULD LIKE TO MAKE A QUANTITATIVE ASSESSMENT**
- 3 **OF HOW BIG THE BIAS CAN BE. IT'S A LITTLE BIT EASY TO**
- 4 **JUST SAY IT'S BIASED, BECAUSE IF THE BIAS IS TINY, IT'S**
- 5 **NOT A CONCERN. SO THAT IS REALLY WHAT YOU ARE DOING**
- 6 **WHEN YOU ARE EVALUATING BIAS, YOU ARE TRYING TO ASSESS**
- 7 **QUANTITATIVELY HOW LARGE THE BIAS COULD BE.**
- 8 **Q.** IF YOU IDENTIFY A BIAS, YOU WANT TO THEN
- 9 QUANTITATIVELY EVALUATE THAT BIAS TO DETERMINE THE
- 10 IMPACT THAT BIAS MAY HAVE HAD ON THE RESULTS OF THE
- 11 STUDY, CORRECT?
- 12 **A. FIRST OF ALL, YOU'D LIKE TO QUALITATIVELY ASSESS**
- 13 **THE DIRECTION OF THE BIAS. WE TALKED ABOUT THAT EARLIER**
- 14 **THIS MORNING, DOES IT BIAS TOWARD THE NULL OR AGAINST,**
- 15 **AND IF -- IN A CERTAIN DIRECTION YOU MAY WISH TO GO**
- 16 **FURTHER AND TRY TO QUANTIFY IT BECAUSE IT MAY CHANGE**
- 17 **YOUR OPINION.**
- 18 **Q.** IT WOULD BE IMPORTANT TO DO THAT, RIGHT?
- 19 **A. IF YOU CAN. YOU VERY RARELY HAVE DATA TO DO**
- 20 **THAT, BUT SOMETIMES YOU DO.**
- 21 **Q.** DOCTOR, YOU DO NOT HAVE ANY EXPERTISE IN THE
- 22 MECHANISMS THROUGH WHICH MYOCARDIAL INFARCTION DEVELOPS,
- 23 IS THAT CORRECT?
- 24 **A. THAT IS CORRECT.**
- 25 **Q.** IN FACT, YOU HAVE A VAGUE LAY PERSON'S

1 UNDERSTANDING OF ISCHEMIC HEART DISEASE, CORRECT?

2 **A. THAT'S CORRECT. I'M NOT A PHYSICIAN.**

3 **Q.** I'M JUST GOING TO SHOW UP A SLIDE HERE OF

4 MYOCARDIAL ISCHEMIC EVENTS. IF WE COULD BRING THAT UP.

5 HOW AM I GOING TO IDENTIFY THIS FOR THE

6 RECORD?

7 HONORABLE SANDRA MAZER MOSS: CAN YOU

8 ENLARGE IT AT ALL?

9 MR. SHEEHAN: I ASSUME WE CAN FOCUS IN ON

10 IT. THIS IS A SLIDE OF THE DEFINITION OF MYOCARDIAL

11 ISCHEMIC EVENTS THAT WAS UTILIZED IN THE ICT ANALYSIS,

12 ICT 42.

13 HONORABLE CYNTHIA M. RUFÉ: IT IS ALSO IN

14 YOUR EXHIBIT BOOK FROM ORAL ARGUMENT.

15 MR. SHEEHAN: THAT'S CORRECT. IT'S THE

16 SAME SLIDE.

17 BY MR. SHEEHAN:

18 **Q.** NOW, YOU ARE NOT AN EXPERT IN THE DIAGNOSIS OR

19 CLASSIFICATION OF ACUTE CORONARY SYNDROME, CORRECT, DR.

20 JEWELL?

21 **A. CORRECT.**

22 **Q.** SO YOU ARE NOT AN EXPERT IN THE DIAGNOSIS OR

23 CLASSIFICATION OF PRINZMETAL ANGINA?

24 **A. CORRECT.**

25 **Q.** YOU DO NOT ASSESS ELECTROCARDIOGRAMS?

1 **A. NOT FOR A LIVING, NO.**

2 **Q.** SO YOU WOULD NOT BE ABLE TO DIAGNOSE OR CLASSIFY

3 EVENTS THAT ARE DEPENDENT ON READING ELECTROCARDIOGRAMS,

4 RIGHT?

5 **A. THAT IS CORRECT.**

6 **Q.** YOU DON'T KNOW WHETHER CHEST PAIN IS ALWAYS

7 CAUSED BY CARDIAC ISCHEMIA, DO YOU?

8 **A. NO. I'M NOT A PHYSICIAN.**

9 **Q.** AND, IN FACT, YOU ARE NOT AN EXPERT IN THE

10 DIAGNOSIS OR CLASSIFICATION OF MYOCARDIAL INFARCTION?

11 **A. THAT IS CORRECT.**

12 **Q.** YOU ARE NOT AN EXPERT IN THE WAYS IN WHICH MI OR

13 ANY OF THE OTHER TERMS THAT ARE INCLUDED IN MYOCARDIAL

14 ISCHEMIC EVENTS MAY BE MISDIAGNOSED OR MISCLASSIFIED,

15 CORRECT?

16 **A. NOT AN EXPERT IN THAT, NO.**

17 **Q.** THAT IS BECAUSE YOU ARE NOT A CARDIOLOGIST, YOU

18 ARE NOT QUALIFIED TO DIAGNOSE OR CLASSIFY CARDIOVASCULAR

19 EVENTS, RIGHT?

20 **A. CORRECT.**

21 **Q.** YOU NEVER COLLABORATED WITH AN ADJUDICATION

22 COMMITTEE IN ANY TYPE OF STUDY FOR CARDIOVASCULAR

23 EVENTS, IS THAT CORRECT?

24 **A. NOT FOR CARDIOVASCULAR EVENTS, NO.**

25 **Q.** SO YOU WOULD NOT CONSIDER YOURSELF AN EXPERT ON

1 THE ADJUDICATION OF CARDIOVASCULAR EVENTS, CORRECT?

2 **A. NO. NOT WHEN IT IS USING SPECIFIC DIAGNOSTIC**

3 **CRITERIA, NO.**

4 **Q.** YOU DON'T KNOW WHAT METHODS, IF ANY, WERE USED

5 TO ADJUDICATE MYOCARDIAL INFARCTION EVENTS IN NISSEN'S

6 42 STUDY META-ANALYSIS, IS THAT ACCURATE?

7 **A. THAT IS CORRECT.**

8 **Q.** AND IN FACT, YOU DON'T KNOW THE METHODS, IF ANY,

9 THAT WERE USED TO ADJUDICATE MYOCARDIAL INFARCTION

10 EVENTS IN ANY OF THE META-ANALYSES, IS THAT RIGHT?

11 **A. OTHER THAN WHAT I READ IN THE PUBLISHED PAPERS,**

12 **YES, I'M NOT AN EXPERT ON THAT.**

13 **Q.** SO YOU DID NOT DO ANY ASSESSMENT OF WHETHER

14 MYOCARDIAL INFARCTION EVENTS IN ANY OF THE META-ANALYSES

15 WERE CLASSIFIED CORRECTLY, IS THAT RIGHT?

16 **A. I DID A LITTLE BIT, BUT JUST AS A STATISTICIAN**

17 **USING DATA, NOT QUESTIONING THE NATURE OF THE CRITERIA**

18 **OR HOW IT WAS DONE.**

19 **Q.** YOU WOULD NOT BE ABLE TO DO THAT, IS THAT RIGHT?

20 **A. NOT CRITICIZE OR CRITIQUE THE CRITERIA USED FOR**

21 **THE ACTUAL CLASSIFICATION ITSELF, CORRECT.**

22 **Q.** IN FACT, DIFFERENTIAL MISCLASSIFICATION, IF IT

23 EXISTS, CAN BIAS A TRIAL TOWARD FINDING AN ASSOCIATION,

24 IS THAT RIGHT?

25 **A. THAT IS WHAT I MEANT AND TOLD MR. CARTMELL, YES.**

1 **Q.** THERE CAN BE MISCLASSIFICATION OF CARDIOVASCULAR

2 EVENTS IF EVENTS -- ANY OF THE EVENTS THAT ARE UNDER THE

3 TERM MYOCARDIAL ISCHEMIC EVENTS ARE MISCLASSIFIED AS MI,

4 IS THAT RIGHT?

5 **A. THAT IS POSSIBLE.**

6 **Q.** AND SINCE YOU ARE NOT AN EXPERT IN THE DIAGNOSIS

7 OR MISDIAGNOSIS OF MYOCARDIAL INFARCTION, YOU HAVE NO

8 EXPERTISE TO DETERMINE WHEN OR IF MISCLASSIFICATION BIAS

9 EXISTS IN A STUDY?

10 **A. THAT IS NOT CORRECT. I CAN DO THAT BY LOOKING**

11 **AT DIFFERENT CLASSIFICATIONS AS A STATISTICIAN. AND**

12 **THAT IS WHAT I DID FOR THE ICT 42 TO DETERMINE THAT**

13 **THERE WAS NO NONDIFFERENTIAL MISCLASSIFICATION. THAT IS**

14 **WHAT I WAS REFERRING TO WITH MR. CARTMELL THIS MORNING.**

15 **THAT I CAN DO, BUT I CAN'T QUESTION THE NATURE OF THE**

16 **DEFINITIONS USED OR THE ABILITY OF THE CLASSIFIERS IN**

17 **CARRYING OUT THE ADJUDICATION.**

18 **Q.** WELL, DR. JEWELL, IF YOU ARE NOT ABLE TO

19 DETERMINE WHETHER OR NOT THE MI EVENTS THAT ARE RECORDED

20 AS ADVERSE EVENTS IN THESE -- IN THE ICT 42 ARE ACTUALLY

21 MI EVENTS, HOW DO YOU DETERMINE WHETHER OR NOT THEY ARE

22 MISCLASSIFIED?

23 **A. BY LOOKING AT THE EXPERTS WHO READJUDICATED THE**

24 **ICT 42 DATA AGAIN AND SEEING THE DIFFERENCES**

25 **STATISTICALLY WITH THE PREVIOUS ADJUDICATION AND THE NEW**

1 **ADJUDICATION, THEN I CAN DETERMINE STATISTICALLY IF**  
 2 **THERE WAS DIFFERENTIAL MISDIAGNOSIS. AND WE GOT THAT**  
 3 **DATA FROM GSK AND THERE WASN'T ANY IN THE DATA THEY**  
 4 **PROVIDED.**  
 5 **Q.** YOU ARE RELYING ON THE READJUDICATION THEN FOR  
 6 THE PURPOSES OF -- I BELIEVE THERE WAS SOME TESTIMONY IN  
 7 YOUR DIRECT EXAM WHERE YOU DID NOT TRUST THE DATA FROM  
 8 THE READJUDICATION, IS THAT CORRECT?  
 9 **A.** **IN THE ADOPT STUDY, THAT IS CORRECT.**  
 10 **Q.** YOU TRUSTED THE READJUDICATION IN THE ICT?  
 11 **A.** **I DID NOT -- IT WAS NOT A QUESTION OF TRUST, I**  
 12 **JUST WAS ABLE TO COMPARE THE ADJUDICATION -- THE RESULTS**  
 13 **OF THE EVENTS BEFORE, UNDER THE ORIGINAL ADJUDICATION,**  
 14 **AND AFTER AND SEE IF THERE WAS A STATISTICAL DIFFERENCE**  
 15 **OR NOT. THAT IS ALL I DID. AND THERE WAS NOT FOR THE**  
 16 **ICT 42. THERE WERE FAR FEWER EVENTS IN THE**  
 17 **READJUDICATION BUT IT WAS NOT DIFFERENTIAL. IN ADOPT IT**  
 18 **WAS DIFFERENTIAL AND THAT I DID NOT TRUST.**  
 19 **Q.** SO YOU TRUSTED IT WHEN IT DID NOT IMPACT YOUR  
 20 OPINION, BUT YOU DID NOT TRUST IT WHEN IT DID IMPACT  
 21 YOUR OPINION?  
 22 **A.** **ABSOLUTELY NOT. THAT IS NOT WHAT I SAID AT ALL.**  
 23 **I SAID IN -- IS THERE EVIDENCE OF**  
 24 **DIFFERENTIAL MISCLASSIFICATION OR NOT? AND THERE WAS**  
 25 **NOT IN THE ICT READJUDICATION. THERE WAS IN THE ADOPT.**

1 **Q.** DR. JEWELL, THE SAME DOCTORS WHO BLINDLY  
 2 READJUDICATED THE EVENTS IN THE ICT 42 BLINDLY  
 3 ADJUDICATED THE EVENTS FROM ADOPT, CORRECT?  
 4 **A.** **ABSOLUTELY. I BELIEVE WAS TWO DOCTORS AND THEY**  
 5 **DID BOTH, I THINK, IF MY MEMORY IS CORRECT.**  
 6 **Q.** THAT WAS BLINDED ADJUDICATION, RIGHT?  
 7 **A.** **ABSOLUTELY.**  
 8 **Q.** AND YOU TRUST THAT BLINDED ADJUDICATION FOR  
 9 PURPOSES OF EVALUATING DIFFERENTIAL MISCLASSIFICATION IN  
 10 THE ICT 42, BUT YOU DO NOT TRUST THAT ADJUDICATION FOR  
 11 PURPOSES OF ASSESSING DIFFERENTIAL MISCLASSIFICATION IN  
 12 ADOPT?  
 13 **A.** **THERE WASN'T ANY DIFFERENCE IN THE ICT SO THE --**  
 14 **Q.** THE EVENTS CHANGED, RIGHT, YOU SAID?  
 15 **A.** **THE EVENTS WENT DOWN SUBSTANTIALLY IN THE**  
 16 **READJUDICATION BECAUSE THEY CHANGED THE DEFINITION. IT**  
 17 **DID NOT DO IT DIFFERENTIALLY IN THE ICT 42.**  
 18 **Q.** WHAT DEFINITION DID THEY CHANGE?  
 19 **A.** **THE DEFINITION -- WELL, THEY READJUDICATE AND**  
 20 **THERE WERE HALF THE NUMBER OF EVENTS COUNTED AFTER THE**  
 21 **READJUDICATION. IF YOU ARE NOT FAMILIAR WITH IT, I**  
 22 **CAN --**  
 23 **Q.** THE EVENTS WERE ADVERSE EVENTS, RIGHT? THEY  
 24 WERE COLLECTED BY INVESTIGATORS IN THE ICT 42.  
 25 **A.** **CORRECT.**

1 **Q.** THEY WERE NEVER ADJUDICATED TO BEGIN WITH,  
 2 RIGHT?  
 3 **A.** **WELL, THEY WERE COLLECTED, WHATEVER SEMANTICS**  
 4 **YOU WANT TO USE, BUT THEY WERE THEN LOOKED AT AGAIN AND**  
 5 **THEY WENT DOWN BECAUSE THEY USED PRESUMABLY A STRICTER**  
 6 **DEFINITION, BUT THEY DID NOT GO DOWN DIFFERENTIALLY.**  
 7 **Q.** WELL, THERE WAS NO DEFINITION, WAS THERE, IN THE  
 8 ICT 42 TO ACTUALLY ADJUDICATE MYOCARDIAL INFARCTION?  
 9 **A.** **THERE WAS A DEFINITION BECAUSE SOMEBODY COUNTED**  
 10 **MI'S. SO THERE WAS A DEFINITION THAT WENT IN THERE.**  
 11 **AND THERE WAS A DEFINITION OF ISCHEMIC HEART DISEASE,**  
 12 **THIS IS THE GSK ONE, THAT SOMEBODY COUNTED THE EVENTS.**  
 13 **Q.** TAKEN FROM ADVERSE EVENT REPORTS, RIGHT?  
 14 **A.** **THAT WAS THE DEFINITION, PRESUMABLY FROM ADVERSE**  
 15 **EVENTS.**  
 16 **Q.** AND THERE WAS NO ADJUDICATION, CORRECT?  
 17 **A.** **YES. I DID NOT SAY THERE WAS ADJUDICATION.**  
 18 **WHEN IT WAS READJUDICATED SUBSEQUENTLY BY THESE TWO**  
 19 **PHYSICIANS, FOR ICT THE NUMBER OF EVENTS WENT DOWN**  
 20 **PRESUMABLY BECAUSE THEY WERE USING STRICTER CRITERIA.**  
 21 **BUT IT DIDN'T CHANGE DIFFERENTIALLY. SO THEY BASICALLY**  
 22 **GOT OUT THE SAME ESTIMATE WITH THE RELATIVE RISK.**  
 23 **THAT IS NOT WHAT HAPPENED WITH ADOPT.**  
 24 **AND THAT MADE ME SUSPICIOUS AND THE REASON -- SOMETHING**  
 25 **NONRANDOM HAPPENED IN ADOPT. THE ORIGINAL STUDIES WERE**

1 **BLINDED WHENEVER THEY DETERMINED THE NUMBER OF EVENTS.**  
 2 **THE READJUDICATION, AS YOU POINTED OUT, WAS BLINDED. SO**  
 3 **SOMETHING HAPPENED THAT WAS NOT BLINDED BECAUSE**  
 4 **SOMETHING NONRANDOM HAPPENED. THAT IS WHAT A**  
 5 **STATISTICIAN IS TRAINED TO LOOK FOR. WHAT COULD**  
 6 **POSSIBLY HAVE HAPPENED? THE ONLY THING THAT -- I DON'T**  
 7 **KNOW, OF COURSE, BECAUSE I WAS NOT IN THE ROOM. THE**  
 8 **ONLY THING THAT COULD HAVE HAPPENED WAS THE NATURE OF**  
 9 **THE DEFINITION BECAUSE THE DEFINITION -- THE NEW**  
 10 **DEFINITIONS USED IN THE READJUDICATION WERE CREATED**  
 11 **AFTER PEOPLE HAD SEEN THE DATA. THAT IS EXACTLY WHY THE**  
 12 **FDA DOES NOT ALLOW YOU TO READJUDICATE THINGS ONCE THE**  
 13 **DATA HAS BEEN ANALYZED BECAUSE THERE IS A TENDENCY TO**  
 14 **START CHANGING THE DEFINITION. I DON'T KNOW THAT FOR**  
 15 **SURE, BUT THAT IS WHY I DID NOT TRUST THE READJUDICATION**  
 16 **OF THE ADOPT. IT'S NOT THAT MANY EVENTS. ADOPT, OF**  
 17 **COURSE, IS ONLY ONE OF THE PIECES OF EVIDENCE. I JUST**  
 18 **STUCK WITH THE ORIGINAL DATA.**  
 19 **Q.** JUST TO BE CLEAR, THERE WAS NO PRESPECIFIED  
 20 DEFINITION OR ADJUDICATION OF MYOCARDIAL INFARCTION  
 21 EVENTS IN ADOPT, CORRECT?  
 22 **A.** **WELL, THERE WAS A DEFINITION. AS I SAID, I'M**  
 23 **NOT AN EXPERT IN HOW THEY ADJUDICATED THE EVENTS, BUT**  
 24 **THERE WAS CERTAINLY A DEFINITION BECAUSE PEOPLE COUNTED**  
 25 **THE EVENTS SO I THINK -- I'M MISSING WHAT YOU ARE SAYING**

1 **ABOUT THERE NOT BEING A DEFINITION.**  
2 Q. THEY WERE INVESTIGATOR REPORTED EVENTS OF MI,  
3 RIGHT?  
4 A. **AND SOMEBODY --**  
5 Q. ARE YOU SAYING THAT THE INVESTIGATORS HAD A  
6 DEFINITION BY WHICH THEY CHECKED OFF A BOX AND SAID THIS  
7 WAS AN MI ACROSS ALL THOSE STUDY SITES?  
8 A. **AS I INDICATED, I'M NOT AN EXPERT IN HOW THE**  
9 **EVENTS WERE CREATED IN THE ORIGINAL DATA SET, NOR THE**  
10 **SKILLS OF THE PEOPLE DOING THAT OR FOR THAT MATTER IN**  
11 **ANY POST DATA ADJUDICATION EITHER.**  
12 Q. OKAY. SO YOU DON'T KNOW?  
13 A. **I'M NOT AN EXPERT, NO.**  
14 Q. I WOULD LIKE TO SWITCH. THERE WAS SOME  
15 TESTIMONY ABOUT THE BRADFORD-HILL CRITERIA.  
16 AND YOU DID NOT FORMALLY GO THROUGH A  
17 LIST OF THE BRADFORD-HILL CRITERIA IN EITHER OF YOUR  
18 REPORTS AND ASSESS THOSE CRITERIA INDIVIDUALLY, IS THAT  
19 ACCURATE?  
20 A. **NOT AS A CHECK LIST. AS I'VE INDICATED, THAT IS**  
21 **NOT THE WAY I BELIEVE THEY SHOULD BE USED. OF COURSE I**  
22 **LOOKED AT MANY OF THE BRADFORD-HILL CRITERIA AND I DON'T**  
23 **EVEN CALL THEM THAT BECAUSE THEY ARE SUCH INGRAINED IN A**  
24 **STATISTICIAN NOW 50 YEARS AFTER BRADFORD-HILL THAT -- SO**  
25 **MANY OF THEM --**

1 Q. YOU CALL THEM TONY'S CRITERIA?  
2 A. **I DON'T CALL THEM THAT EITHER, NO.**  
3 Q. DO YOU AGREE THAT BIAS CAN CREATE THE APPEARANCE  
4 OF AN ASSOCIATION WHEN NONE EXISTS?  
5 A. **THAT IS POSSIBLE. THAT IS A BIAS AWAY FROM THE**  
6 **NULL.**  
7 Q. EVEN WHEN CHANCE, BIAS AND CONFOUNDING CAN BE  
8 RULED OUT, THE ASSOCIATION STILL MAY OR MAY NOT BE  
9 CAUSAL, CORRECT?  
10 A. **IF CHANCE IS RULED OUT?**  
11 Q. IF CHANCE, BIAS AND CONFOUNDING ARE ALL RULED  
12 OUT AND YOU HAVE A STATISTICALLY SIGNIFICANT ASSOCIATION  
13 BETWEEN TWO VARIABLES THAT IS NOT DUE TO CHANCE, NOT DUE  
14 TO CONFOUNDING, IT STILL MAY OR MAY NOT BE CAUSAL,  
15 CORRECT?  
16 A. **WELL, THAT IS A RATHER OPEN-ENDED QUESTION**  
17 **BECAUSE FOR EXAMPLE IN THE BRADFORD-HILL CRITERIA, ONE**  
18 **OF THE FIRST ONES IS TEMPORALITY. I THINK THAT WAS**  
19 **MENTIONED YESTERDAY. THAT MEANS THE EXPOSURE TO THE**  
20 **DRUG HAS TO HAPPEN BEFORE THE EVENT. IF I HAVE A HEART**  
21 **ATTACK TODAY, SURVIVE AND THEN GET GIVEN AVANDIA YOU**  
22 **CAN'T POSSIBLY CLAIM THAT THE AVANDIA CAUSED THE HEART**  
23 **ATTACK. THAT IS WHAT TEMPORALITY MEANS. SO WHEN YOU**  
24 **HAVE AN ASSOCIATION YOU HAVE RULED OUT CHANCE, YOU HAVE**  
25 **RULED OUT BIAS IN THE WAY YOU HAVE COLLECTED THE DATA,**

1 **INCLUDING CONFOUNDING, YOU STILL HAVE TO PAY ATTENTION**  
2 **IN AN OBSERVATIONAL STUDY TO TEMPORALITY AND SOME OF THE**  
3 **OTHER CRITERIA. TEMPORALITY IS NEVER A PROBLEM OF**  
4 **COURSE IN RANDOMIZED CONTROLLED TRIALS BECAUSE YOU**  
5 **CONTROL THE EXPOSURE.**  
6 Q. IS IT YOUR TESTIMONY THAT DATA FROM RANDOMIZED  
7 CONTROLLED TRIALS DEMONSTRATING A STATISTICALLY  
8 SIGNIFICANT ASSOCIATION BETWEEN TWO VARIABLES IS  
9 NECESSARILY CAUSAL?  
10 A. **WELL, YOU HAVE TO RULE OUT OTHER SOURCES OF**  
11 **BIAS. THERE IS NO CONFOUNDING BECAUSE YOU TOLD ME IT'S**  
12 **A RANDOMIZED CONTROLLED TRIAL, BUT THERE ARE OTHER FORMS**  
13 **OF BIAS. I MENTIONED SOME TO DO WITH RECORD EARLIER.**  
14 **SO YOU HAVE TO RULE THOSE OUT, TOO.**  
15 Q. SO BIAS CAN EXIST IN A RANDOMIZED CONTROLLED  
16 TRIAL?  
17 A. **NOT CONFOUNDING BIAS, BUT OTHER FORMS OF BIAS,**  
18 **YES. AND WE TALKED ABOUT ONE. MISCLASSIFICATION WOULD**  
19 **BE ONE.**  
20 Q. WOULD YOU AGREE THAT IT IS NOT PRUDENT TO  
21 CONCLUDE AN ASSOCIATION IS CAUSAL WITHOUT SATISFYING  
22 ADDITIONAL CRITERIA SUCH AS THE BRADFORD-HILL CRITERIA?  
23 A. **AGAIN THAT IS SUCH AN OPEN-ENDED QUESTION. IF**  
24 **YOU GIVE ME A SPECIFIC CASE --**  
25 Q. WELL, LET'S BRING UP DR. AUSTIN'S REPORT.

1 A. **SURE.**  
2 Q. LET'S TAKE A LOOK AT DR. AUSTIN'S REPORT, PAGE  
3 TEN, SECTION C. SEE THE SECOND LINE THERE?  
4 A. **I DO.**  
5 Q. IT IS NOT PRUDENT TO CONCLUDE THAT THE FIFTH  
6 REASON, A CAUSAL ASSOCIATION IS THE EXPLANATION WITHOUT  
7 SOME POSITIVE EVIDENCE. FORTUNATELY SOME CRITERIA FOR  
8 POSITIVE EVIDENCE EXIST, FIRST DESCRIBED BY AUSTIN  
9 BRADFORD-HILL. THE BRADFORD-HILL CRITERIA PROVIDE A  
10 WELL ACCEPTED METHOD FOR ASSESSING CASUALTY. DO YOU  
11 AGREE WITH DR. AUSTIN?  
12 A. **LARGELY, I AGREE WITH THAT, YES. YOU HAVE TO**  
13 **LOOK AT ALL THE INFORMATION YOU HAVE. YOU WANT TO --**  
14 **AND ONE OF THE BRADFORD-HILL CRITERIA IS YOU WANT -- IS**  
15 **IT PLAUSIBLE THAT THE ASSOCIATION COULD BE CAUSAL? AND**  
16 **YOU WANT TO THINK ABOUT THAT. BUT IT'S SUCH AN**  
17 **OPEN-ENDED QUESTION. THERE ARE MANY CAUSAL**  
18 **ASSOCIATIONS. FOR EXAMPLE, A VIRUS CAUSING ULCERS IN**  
19 **THE STOMACH. MOST PEOPLE WHEN THEY FIRST HEARD OF THAT**  
20 **HYPOTHESIS THOUGHT IT WAS IMPLAUSIBLE AND WAS AN**  
21 **ASSOCIATION THAT WAS NOT CAUSAL. OF COURSE IT'S BEEN**  
22 **PROVEN NOW THAT IT IS CAUSAL. SO YOU CAN'T ASK ME A**  
23 **DEFINITIVE QUESTION ABOUT IS THIS ALWAYS PLAYED OUT THIS**  
24 **WAY. THESE ARE REASONABLE THINGS THAT ALL SCIENTISTS**  
25 **WILL ADDRESS AS THEY CAN IN THE CONTEXT OF A SPECIFIC**

1 **QUESTION.**  
 2 **Q.** I THINK ALL I ASKED YOU WAS WHETHER YOU AGREE  
 3 WITH DR. AUSTIN.  
 4 **A.** **I SAID ROUGHLY, I DO.**  
 5 **Q.** OKAY. GREAT, THANKS.  
 6 DOSE RESPONSE IS ONE OF THE BRADFORD-HILL  
 7 CRITERIA, RIGHT?  
 8 **A.** **THAT IS CORRECT.**  
 9 **Q.** IN FACT YOU AGREED AT YOUR DEPOSITION THAT IT'S  
 10 STANDARD TO EXAMINE DOSE RESPONSE IN A CAUSATION  
 11 ANALYSIS, RIGHT?  
 12 **A.** **WHEN YOU CAN, YES.**  
 13 **Q.** AND YOU DID NOT DO AN INDEPENDENT STATISTICAL  
 14 ANALYSIS REGARDING DOSE RESPONSE IN THIS CASE, RIGHT?  
 15 **A.** **YES, I DID.**  
 16 **Q.** LET'S BRING UP YOUR DEPOSITION TRANSCRIPT.  
 17 MR. SHEEHAN: 129, PAGE 24 TO 25 AND THEN  
 18 130, LINES 1 TO 3.  
 19 BY MR. SHEEHAN:  
 20 **Q.** NOW WITH REGARD TO QUESTION TWO:  
 21 QUESTION: DID YOU DO ANY STATISTICAL  
 22 ANALYSIS, YOUR OWN INDEPENDENT STATISTICAL ANALYSIS, TO  
 23 CALCULATE WHETHER THERE WAS A DOSE RESPONSE?  
 24 ANSWER: I DID NOT.  
 25 **A.** **YES, I DID NOT PUT IT IN THE REPORT, BUT I DID**

1 -- I HAD IT IN MY NOTES. I WENT BACK AFTER THE  
 2 DEPOSITION AND DID LOOK AT THE ANALYSIS.  
 3 **Q.** WHAT DOES THIS QUESTION TO HAVE DO WITH YOUR  
 4 REPORT?  
 5 **A.** **WELL, THIS WAS ASKING ME ABOUT MY REPORT, WASN'T**  
 6 **IT?**  
 7 **Q.** IT'S ASKING YOU WHETHER YOU HAVE DONE ANY  
 8 INDEPENDENT STATISTICAL ANALYSIS TO CALCULATE WHETHER  
 9 THERE IS A DOSE RESPONSE, AND YOU SAY NO.  
 10 **A.** **WELL, I HAVE DONE IT NOW.**  
 11 **Q.** YOU HAVE DONE IT NOW?  
 12 **A.** **I WENT BACK AND LOOKED IN MY NOTES AFTER THE**  
 13 **DEPOSITION AND PULLED IT OUT. I DO NOT BELIEVE -- THE**  
 14 **REASON THAT YOU CONTINUE THAT RESPONSE, YOU WILL SEE,**  
 15 **THE REASON WHY I DID NOT PUT IT IN MY REPORT OR TALK**  
 16 **ABOUT IT IS THERE IS REALLY NOT A LOT OF INFORMATION IN**  
 17 **THE VARIOUS CLINICAL TRIALS.**  
 18 **Q.** WE WILL GET TO THAT. WHY DON'T I ASK A  
 19 QUESTION.  
 20 YOU ALSO TESTIFIED THAT YOU DID NOT  
 21 PERFORM ANY MEANINGFUL ASSESSMENT OF DOSE RESPONSE,  
 22 CORRECT?  
 23 **A.** **I DON'T BELIEVE THERE IS SUFFICIENT DATA TO DO**  
 24 **THE KIND OF ANALYSIS OF THE QUALITY THAT IS COVERED**  
 25 **ELSEWHERE IN THE REPORT, THAT IS CORRECT.**

1 **Q.** SO THERE IS NOT SUFFICIENT DATA TO ADEQUATELY  
 2 ASSESS DOSE RESPONSE?  
 3 **A.** **NOT AT THE SAME LEVEL OF QUALITY AS THE REST OF**  
 4 **THE INFORMATION IN MY REPORT, THAT IS CORRECT.**  
 5 **Q.** OKAY.  
 6 MR. SHEEHAN: LET'S TAKE A LOOK AT YOUR  
 7 DEPOSITION TRANSCRIPT, PAGE 136 LINES 20 TO 25 AND 137  
 8 LINES 1 TO 6.  
 9 BY MR. SHEEHAN:  
 10 **Q.** QUESTION: SO I GUESS I HAVE TO ASK IT  
 11 THIS WAY. ARE YOU OFFERING AN OPINION TO A REASONABLE  
 12 DEGREE OF SCIENTIFIC CERTAINTY THAT THERE IS A DOSE  
 13 RESPONSE BETWEEN AVANDIA AND MYOCARDIAL ISCHEMIC EVENTS  
 14 OR MYOCARDIAL INFARCTION?  
 15 ANSWER: YES.  
 16 QUESTION: YOU ARE OFFERING AN OPINION  
 17 THAT THERE IS A DOSE RESPONSE?  
 18 ANSWER: YES.  
 19 QUESTION: TO A REASONABLE DEGREE OF  
 20 SCIENTIFIC CERTAINTY?  
 21 ANSWER: ABSOLUTELY.  
 22 AND THAT TESTIMONY COMES AFTER YOU  
 23 ACKNOWLEDGED THAT YOU HAD INADEQUATE DATA TO PERFORM ANY  
 24 MEANINGFUL ASSESSMENT OF DOSE RESPONSE, CORRECT?  
 25 **A.** **NOT A FORMAL ANALYSIS OF DOSE RESPONSE, BUT THIS**

1 **OPINION WAS NOT BASED SOLELY ON THAT, OF COURSE.**  
 2 **Q.** DO YOU AGREE THAT SPECIFICITY OF EXPOSURE AND  
 3 OUTCOME IS ONE OF THE BRADFORD-HILL CRITERIA?  
 4 **A.** **YES.**  
 5 **Q.** WHEN YOU ADD ANOTHER ANTIDIABETIC DRUG TO  
 6 AVANDIA IN A STUDY, IT REDUCES SPECIFICITY, CORRECT?  
 7 **A.** **POSSIBLY, YES.**  
 8 **Q.** AND WHEN YOU LUMP ALL DOSES TOGETHER IN A STUDY,  
 9 IT REDUCES SPECIFICITY, CORRECT?  
 10 **A.** **YES.**  
 11 **Q.** AND WHEN YOU LUMP ALL DURATIONS TOGETHER, THAT  
 12 REDUCES SPECIFICITY?  
 13 **A.** **CORRECT.**  
 14 **Q.** WHEN YOU LUMP NUMEROUS OUTCOMES TOGETHER, THAT  
 15 REDUCES SPECIFICITY, RIGHT?  
 16 **A.** **YES, I TALKED ABOUT THAT EARLIER THIS MORNING**  
 17 **ABOUT CHOOSING THE OUTCOME.**  
 18 **Q.** DR. JEWELL, MYOCARDIAL ISCHEMIC EVENTS ARE NOT  
 19 THE SAME THING AS MYOCARDIAL INFARCTION, CORRECT?  
 20 **A.** **THEY INCLUDE MYOCARDIAL INFARCTION, BUT THERE**  
 21 **ARE OTHER CLINICAL EVENTS THAT ARE DIFFERENT.**  
 22 **Q.** AND YOU DON'T KNOW WHETHER THEY ARE DIFFERENT  
 23 PATHOPHYSIOLOGICALLY BECAUSE YOU ARE NOT AN EXPERT IN  
 24 THAT, CORRECT?  
 25 **A.** **I'M NOT AN EXPERT. I UNDERSTAND THAT THEY ARE**

1 **LUMPED TOGETHER FOR SOME REASON, THAT YOU DON'T PUT**  
2 **STROKE FOR EXAMPLE NECESSARILY INTO THAT GROUP. OTHER**  
3 **THAN THAT, I'M JUST A LAYPERSON.**  
4 Q. WELL, LET ME ASK YOU, DO YOU THINK STROKE  
5 PROVIDES ANY INFORMATION WITH REGARD TO MYOCARDIAL  
6 INFARCTION?  
7 A. **I JUST SAID I'M NOT AN EXPERT. NOT IN**  
8 **MYOCARDIAL INFARCTION. BUT YOU WILL HAVE TO TALK TO THE**  
9 **CLINICIANS.**  
10 Q. NOW DR. AUSTIN TESTIFIED AND WE SAW THIS  
11 YESTERDAY, THAT IF MY ANALYSIS IS ON MI, THE MYOCARDIAL  
12 ISCHEMIC EVENTS REALLY DOESN'T PROVIDE MUCH INFORMATION  
13 FOR THAT. DO YOU DISAGREE WITH DR. AUSTIN?  
14 A. **I DO A LITTLE BIT, YES. AS I INDICATED THIS**  
15 **MORNING, THAT I THINK WHEN YOU ARE LOOKING AT OUTCOMES,**  
16 **AND YOU MAY HAVE A SPECIFIC ONE IN MIND, FINDING EXACTLY**  
17 **THE RIGHT COMPOSITE OUTCOME THAT CAPTURES THE SIGNAL YOU**  
18 **ARE TRYING TO DETECT OR DETERMINE IS A DIFFICULT SCIENCE**  
19 **AND IT'S NOT EASY TO DO. SO SOMETIMES YOU HAVE TO USE A**  
20 **COMPOSITE OUTCOME THAT INCLUDES THE ONE YOU ARE REALLY**  
21 **AFTER AND SOMETIMES -- SOMETIMES YOU GO DOWN AND TRY TO**  
22 **MAKE IT MORE SPECIFIC, AS YOU SAY, BUT YOU RUN OUT OF**  
23 **DATA OF COURSE IF YOU MAKE IT TOO SPECIFIC.**  
24 Q. DR. AUSTIN ALSO TESTIFIED THAT I DON'T THINK  
25 ANYONE WOULD DRAW A CONCLUSION ABOUT MI FROM THAT BROAD

1 OF A TERM. I TAKE IT YOU DISAGREE WITH DR. AUSTIN?  
2 A. **WELL, I WOULDN'T SAY I DISAGREE WITH HIM**  
3 **ENTIRELY BECAUSE I DID NOT DRAW MY OPINION FROM DOING**  
4 **THAT. I DREW MY OPINION ON MI'S FROM LOOKING AT DATA ON**  
5 **MI'S. BUT I ALSO LOOKED AT DATA ON COMPOSITE OUTCOMES**  
6 **THAT I THINK ARE RELEVANT TO THAT OPINION, AS DID EVERY**  
7 **OTHER STATISTICIAN WHO ANALYZED ALL OF THESE**  
8 **META-ANALYSES. ALL OF THESE COMPOSITE OUTCOMES WERE**  
9 **USED INCLUDING BY GSK REPEATEDLY. SO I DID PRETTY MUCH**  
10 **WHAT EVERYONE ELSE DID IN LOOKING AT COMPOSITE OUTCOMES**  
11 **AND THEN TRYING TO LOOK AT MI'S SPECIFICALLY WHEN THERE**  
12 **WAS DATA AVAILABLE. SO THAT MY OPINION WAS BASED ON**  
13 **THAT AND THE BROADER INFORMATION.**  
14 Q. BUT YOU ACTUALLY TESTIFIED THAT THE ICT 42 --  
15 WELL, LET ME ASK IT THIS WAY. THE ICT 42 DID NOT FIND  
16 ANY STATISTICALLY SIGNIFICANT ASSOCIATION BETWEEN  
17 AVANDIA AND MI, RIGHT?  
18 A. **IT DOES NOW. IT DID NOT IN THE ICT 42.**  
19 Q. THAT WAS MY QUESTION, THE ICT 42.  
20 A. **WELL, I THINK -- DON'T YOU WANT TO LOOK AT**  
21 **MORE -- ALL OF THE DATA IN THE ICT 52 NOW?**  
22 Q. WE WILL GET THERE.  
23 A. **OKAY. IT DIDN'T THEN JUST ON MYOCARDIAL**  
24 **INFARCTION. IT DID SHOW STATISTICALLY SIGNIFICANCE FOR**  
25 **ISCHEMIC HEART DISEASE AND THEN IT SHOWS SIGNIFICANCE**

1 **FOR BOTH NOW.**  
2 Q. I THINK -- YOU WENT OVER THIS WITH MR. CARTMELL,  
3 BUT I THINK YOU TESTIFIED THAT THE BEST PIECE OF  
4 INFORMATION THAT YOU WOULD PROPOSE TO SOMEBODY WAS THE  
5 ICT 42.  
6 A. **AT THAT POINT WHEN I WROTE THE REPORT THAT IS**  
7 **CORRECT.**  
8 Q. RIGHT. AND THAT IS WHAT ALLOWED YOU TO DRAW  
9 YOUR CAUSAL CONCLUSION WITH REGARD TO MI?  
10 A. **NO. I SAID -- IF YOU FORCE ME TO PICK ONE**  
11 **PIECE, THAT IS THE ONE THAT I THINK IS THE ONE I WOULD**  
12 **LIKE TO TELL PEOPLE ABOUT, BUT I USED ALL OF THE**  
13 **INFORMATION, AS I HAVE SAID IN MY REPORT AND THIS**  
14 **MORNING, IN DRAWING MY CONCLUSIONS ABOUT MI.**  
15 Q. SO YOU THINK EVEN THE ICT IS BETTER THAN  
16 NISSEN'S META-ANALYSIS, FOR EXAMPLE?  
17 A. **I DID NOT SAY I THOUGHT IT WAS BETTER. I JUST**  
18 **SAID IF I HAD ONE META-ANALYSIS THAT I WANTED TO SHOW**  
19 **YOU, I WOULD SHOW YOU THE ICT 52 NOW, BUT THE NISSEN**  
20 **ANALYSIS --**  
21 Q. THE TESTIMONY WAS ABOUT ICT 42. I WANT TO STICK  
22 WITH YOUR TESTIMONY.  
23 A. **AT THAT TIME I WROTE THE REPORT I WOULD HAVE**  
24 **SAID THAT IS THE ONE I WOULD HAVE SHOWN, BUT AS YOU**  
25 **POINTED OUT EARLIER, THE 28 STUDIES OVERLAP SO THERE IS**

1 **NOT A HUGE --**  
2 Q. JUST SO WE ARE CLEAR, JUST SO THE RECORD IS  
3 CLEAR, THE ONE STUDY THAT YOU WOULD HAVE PULLED OUT DID  
4 NOT DEMONSTRATE A STATISTICALLY SIGNIFICANT ASSOCIATION  
5 BETWEEN AVANDIA AND MYOCARDIAL INFARCTION?  
6 A. **NO. ITS P VALUE WAS AROUND -- I FORGET EXACTLY,**  
7 **BUT IT WAS VERY CLOSE TO SIGNIFICANCE. BUT IT DID NOT**  
8 **ACHIEVE STATISTICAL SIGNIFICANCE, CORRECT.**  
9 Q. THANK YOU.  
10 NOW CONSISTENCY IS ONE OF THE  
11 BRADFORD-HILL CRITERIA, RIGHT?  
12 A. **YES.**  
13 Q. AND WE HAVE SEEN A SLIDE UP THERE SHOWING LOTS  
14 OF POINT ESTIMATES. DID YOU ASSIST THE PLAINTIFFS'  
15 COUNSEL IN PREPARING ANY OF THOSE SLIDES?  
16 A. **NO.**  
17 Q. DO YOU KNOW WHETHER THEY ARE ACCURATE?  
18 A. **WHAT DO YOU MEAN BY ACCURATE?**  
19 Q. IS THE DATA REPRESENTED ON THE SLIDE CORRECT?  
20 A. **AS FAR AS I'M AWARE, YES, THE ONES -- THE**  
21 **STUDIES THAT I'M MOST FAMILIAR WITH LOOK ACCURATE TO ME.**  
22 **I HAVE NO REASON TO BELIEVE OTHERWISE.**  
23 Q. IS IT COMPREHENSIVE?  
24 A. **IT LOOKED PRETTY COMPREHENSIVE TO ME. I**  
25 **CAN'T -- OBVIOUSLY, YOU CAN SEE THAT THE DETAIL ON THOSE**

1 **SLIDES, I COULDN'T POSSIBLY GIVE YOU 100 PERCENT**  
 2 **GUARANTEE. I HAVE NO REASON TO BELIEVE IT WAS NOT**  
 3 **COMPREHENSIVE.**  
 4 **Q.** IF THERE WERE PARTICULAR STUDIES THAT REPORTED  
 5 MULTIPLE POINT ESTIMATES FOR MI, BUT ONLY THE  
 6 STATISTICALLY SIGNIFICANT ASSOCIATION WAS PULLED OUT AND  
 7 REPORTED IN THOSE SLIDES, YOU WOULD NOT AGREE WITH THAT,  
 8 RIGHT?  
 9 **A.** **WELL, IT DEPENDS THE PURPOSE OF THE SLIDE. BUT**  
 10 **ALL OF THESE TRIALS HAD MULTIPLE ENDPOINTS. THERE WOULD**  
 11 **BE -- YOU WOULD NOT BELIEVE HOW MANY RELATIVE RISKS**  
 12 **THERE ARE. THERE IS ONE FOR ISCHEMIC HEART DISEASE.**  
 13 **THERE'S ONE FOR MI. THERE IS ONE FOR -- SO THERE IS A**  
 14 **WHOLE BUNCH OF THEM.**  
 15 MR. SHEEHAN: PULL UP SLIDE 30. COMBINED  
 16 RISK.  
 17 BY MR. SHEEHAN:  
 18 **Q.** ALL STUDIES, ALL RESULTS. AND WE DON'T EVEN  
 19 HAVE THE NAMES OF THE STUDIES ON THE SLIDE SO YOU CAN'T  
 20 REALLY EVEN TELL WHAT IS THERE. BUT IS IT YOUR  
 21 TESTIMONY THAT THAT PRESENTS EVERY POINT ESTIMATE FOR  
 22 MYOCARDIAL ISCHEMIA, EVERY POINT ESTIMATE FOR MYOCARDIAL  
 23 INFARCTION AND EVERY POINT ESTIMATE FOR OTHER  
 24 CARDIOVASCULAR EVENTS THAT IS AVAILABLE FOR EVALUATION  
 25 WITH REGARD TO THE CARDIOVASCULAR RISK OF AVANDIA?

1 **A.** **WELL, I CAN'T POSSIBLY -- I DID NOT CREATE THE**  
 2 **SLIDE, SO I CAN'T POSSIBLY TESTIFY TO ITS --**  
 3 **Q.** IF THERE IS DATA MISSING, THAT WOULD BE  
 4 MISLEADING, RIGHT?  
 5 **A.** **DEPENDS WHICH DIRECTION. IF IT WAS JUST MISSING**  
 6 **AT RANDOM, IT WOULD NOT MATTER AT ALL, OF COURSE.**  
 7 **Q.** IF THERE'S DATA THAT IS BELOW 1, THAT WOULD BE  
 8 MISLEADING.  
 9 **A.** **I'M FINDING IT HARD TO THINK ABOUT A**  
 10 **HYPOTHETICAL. WHEN YOU ASK ME A HYPOTHETICAL ABOUT**  
 11 **SOMEBODY ELSE'S SLIDE AND SAY IF THEY MISS -- WAS IT**  
 12 **MISLEADING OR NOT? I DON'T REALLY KNOW.**  
 13 **Q.** WELL, I'M ASKING A HYPOTHETICAL. IF IN FACT  
 14 THERE IS POINT ESTIMATES THAT ARE BELOW 1 THAT ARE NOT  
 15 REPRESENTED ON THIS SLIDE, THAT WOULD BE MISLEADING,  
 16 RIGHT?  
 17 **A.** **AND IF THERE ARE ONES THAT ARE BIGGER THEN 1, IT**  
 18 **WOULD BE MISLEADING. I DON'T KNOW OBVIOUSLY. IT LOOKS**  
 19 **VERY SIMILAR IN TONE AND INFORMATION TO THE ONE THAT IS**  
 20 **IN MY REPORT THAT WAS FROM GSK. SO -- ON THE CLINICAL**  
 21 **TRIALS, THIS HAS I THINK BOTH CLINICAL AND OBSERVATIONAL**  
 22 **STUDIES.**  
 23 **Q.** LET'S JUST TAKE A LOOK AT ONE. WHY DON'T WE  
 24 TAKE A LOOK AT STOCKL.  
 25 **A.** **WHICH STUDY?**

1 **Q.** ARE YOU FAMILIAR WITH STOCKL? THAT IS AN  
 2 OBSERVATIONAL STUDY.  
 3 **A.** **WELL, I CAN'T TELL YOU THE NAMES OF ALL 20**  
 4 **OBSERVATIONAL STUDIES THAT I LOOKED AT. I WOULD HAVE TO**  
 5 **GO BACK TO MY BIBLIOGRAPHY, WHICH IS QUITE LONG, AS YOU**  
 6 **CAN SEE.**  
 7 HONORABLE SANDRA MAZER MOSS: MANY  
 8 AMENDED ONES.  
 9 THE WITNESS: EXACTLY, MANY AMENDED ONES.  
 10 BY MR. SHEEHAN:  
 11 **Q.** YOU REVIEWED THEM ALL FOR CONSISTENCY, RIGHT?  
 12 **A.** **REVIEWED WHAT?**  
 13 **Q.** ALL THE OBSERVATIONAL STUDIES?  
 14 **A.** **I LOOKED AT ABOUT 20 OF THEM.**  
 15 **Q.** YOU REVIEWED THEM FOR CONSISTENCY, RIGHT?  
 16 **A.** **I LOOK AT THE RESULTS OF ALL 20 TO SEE WHAT**  
 17 **INFORMATION THEY PROVIDED AND HOW IT COMPARED WITH THE**  
 18 **INFORMATION WE HAD ALREADY OBTAINED FROM THE RANDOMIZED**  
 19 **CONTROLLED TRIALS, YES.**  
 20 **Q.** IS IT YOUR TESTIMONY THAT THEY WERE CONSISTENT?  
 21 **A.** **YOU'VE ALREADY ASKED ME THAT QUESTION. I SAID**  
 22 **THEY ARE NOT AS CONSISTENT AS THE RESULTS FROM THE**  
 23 **RANDOMIZED CONTROLLED TRIALS.**  
 24 **Q.** LET'S TAKE A LOOK AT TABLE TWO ON STOCKL --  
 25 MR. SHEEHAN: IF YOU CAN PULL THAT UP.

1 BY MR. SHEEHAN:  
 2 **Q.** THIS IS THE -- ACTUALLY LET'S TAKE A LOOK AT  
 3 THIS SLIDE HERE. THEY IDENTIFY STOCKL HERE, AND IT'S  
 4 EXTREMELY DIFFICULT TO READ. I WILL WALK UP HERE, BUT  
 5 THIS IS -- THIS IS FOR RECENT USE, RIGHT, A  
 6 STATISTICALLY SIGNIFICANTLY INCREASED RISK OF MYOCARDIAL  
 7 INFARCTION WITH RECENT USE. NOW STOCKL REPORTED ANY  
 8 USE, REMOTE USE, CURRENT USE?  
 9 **A.** **I THINK HE REPORTED ABOUT PAST USE IS MY MEMORY.**  
 10 **MY MEMORY WAS THAT IT WAS NOT STATISTICALLY SIGNIFICANT,**  
 11 **BUT DON'T ASK ME TO QUOTE THE NUMBERS.**  
 12 **Q.** LET'S TAKE A LOOK.  
 13 MR. SHEEHAN: LET'S PULL UP TABLE TWO  
 14 FROM STOCKL.  
 15 BY MR. SHEEHAN:  
 16 **Q.** HERE IS TABLE TWO FROM STOCKL. IT'S A LITTLE  
 17 BIT BUSY, BUT WE CAN EASILY SEE DOWN AT THE BOTTOM WE  
 18 HAVE GOT -- THE LAST THREE ARE ROSIGLITAZONE CURRENT  
 19 EXPOSURE, ROSIGLITAZONE RECENT EXPOSURE, ROSIGLITAZONE  
 20 REMOTE EXPOSURE. WE CAN SEE THE STATISTICALLY  
 21 SIGNIFICANT POINT ESTIMATE THAT IS REPORTED ON THE CHART  
 22 THAT PLAINTIFFS HANDED UP TO THE JUDGE AT 1.69. BUT I  
 23 COULD NOT FIND THE .93 OR THE 1.00 FOR CURRENT EXPOSURE  
 24 AND REMOTE EXPOSURE. I CERTAINLY COULD NOT FIND THE  
 25 ROSIGLITAZONE EXPOSURE FOR ANY USE THAT IS ACTUALLY UP

- 1 ABOVE OF 1.09. NOW, DOES THAT STUDY REPRESENT A  
 2 CONSISTENT -- WITHIN THE STUDY ITSELF, DOES IT REPRESENT  
 3 A CONSISTENT ASSOCIATION BETWEEN AVANDIA AND MYOCARDIAL  
 4 INFARCTION?  
 5 **A. I WOULD LIKE TO READ THE PAPER. I DON'T DO**  
 6 **QUICK AND DIRTY ASSESSMENTS OF CONSISTENCY ON THE CUFF,**  
 7 **LET ALONE ON THE WITNESS STAND.**  
 8 **Q.** YOU CAN'T SAY ANYTHING ABOUT IT JUST LOOKING AT  
 9 THE --  
 10 **A. WELL, I DON'T LIKE TO DO THAT. I DON'T LIKE TO**  
 11 **DO STATISTICS SLOPPILY. I HAVE SEEN TOO MUCH OF IT.**  
 12 **WHAT I SEE FROM THERE IS THERE'S A SIGNIFICANT**  
 13 **ASSOCIATION FOR ONE MEASURE OF THE EXPOSURE WHICH IS**  
 14 **RECENT EXPOSURE TO AVANDIA HAS A STATISTICALLY**  
 15 **SIGNIFICANT AND FAIRLY ELEVATED RISK. IT'S NOT**  
 16 **CONFIRMED BY THE CURRENT EXPOSURE OR THE REMOTE**  
 17 **EXPOSURE, BUT TO DO --**  
 18 **Q.** THAT POINT ESTIMATE, THE ONE THAT IS ELEVATED,  
 19 IS THE ONE THAT WAS ON THE SLIDE THAT YOU WERE TALKING  
 20 ABOUT BEFORE WITH REGARD TO CONSISTENCY?  
 21 **A. I DID NOT CREATE THE SLIDE SO I HAVE TO TAKE**  
 22 **YOUR WORD FOR THAT.**  
 23 **Q.** WHAT ABOUT THE TZOULAKI STUDY? IS THAT ONE THAT  
 24 YOU ARE FAMILIAR WITH?  
 25 **A. A LITTLE BIT. YES, I RECOGNIZE IT.**

- 1 **Q.** DID THAT FIND A STATISTICALLY SIGNIFICANT  
 2 ASSOCIATION BETWEEN AVANDIA AND MYOCARDIAL INFARCTION?  
 3 **A. NO, IT DID NOT. I ASSESSED THAT STUDY SUFFERED**  
 4 **FROM QUITE EXTREME BIAS. HAPPY TO TALK ABOUT IT BUT I**  
 5 **WOULDN'T PUT MUCH WEIGHT ON THAT STUDY.**  
 6 **Q.** YOU TALKED ABOUT THE GRAHAM STUDY IN YOUR  
 7 SUPPLEMENTAL REPORT, RIGHT?  
 8 **A. GRAHAM?**  
 9 **Q.** GRAHAM.  
 10 **A. YES, I DID.**  
 11 **Q.** AND GRAHAM STATED THAT: WE WERE UNABLE TO  
 12 DETERMINE WHETHER ONE OR BOTH THIAZOLIDINEDIONES  
 13 INCREASE OR DECREASE THE ABSOLUTE RISK OF ANY OUTCOME,  
 14 CORRECT? DO YOU RECALL THAT LANGUAGE?  
 15 **A. I DON'T RECALL THE DETAILS OF THE --**  
 16 **MR. SHEEHAN: DO WE HAVE GRAHAM?**  
 17 **A. -- OF THE STUDY.**  
 18 **MR. SHEEHAN: JAMIE, CAN WE PULL UP**  
 19 **GRAHAM?**  
 20 **BY MR. SHEEHAN:**  
 21 **Q.** WELL, IF YOU ARE COMPARING -- I THINK YOU GAVE  
 22 SOME TESTIMONY ABOUT THIS ACTUALLY. IF YOU ARE  
 23 COMPARING ROSIGLITAZONE TO SOME OTHER ORAL ANTIDIABETIC  
 24 DRUG, YOU DON'T KNOW WHAT THE ABSOLUTE RISK IS, YOU ONLY  
 25 KNOW WHAT THE RISK IS IN COMPARISON TO THE DRUG THAT YOU

- 1 ARE COMPARING TO, IS THAT RIGHT?  
 2 **A. IF YOU ONLY HAVE THAT INFORMATION, THAT IS**  
 3 **CORRECT. OF COURSE GRAHAM WAS ROSIGLITAZONE VERSUS**  
 4 **PIOGLITAZONE AND THERE IS MORE INFORMATION ABOUT**  
 5 **PIOGLITAZONE'S CARDIOVASCULAR PROFILE THAN IS IN THE**  
 6 **GRAHAM STUDY, AS I INDICATED THIS MORNING. IT'S ALSO**  
 7 **BEEN STUDIED QUITE INTENSELY.**  
 8 **Q.** YOU DON'T KNOW WHAT PIOGLITAZONE'S EFFECT ON  
 9 BLADDER CANCER IS BY ANY CHANCE, DO YOU?  
 10 **A. I THINK THEY JUST ANNOUNCED THAT THEY ARE TRYING**  
 11 **TO -- I MENTIONED THAT I THINK THIS MORNING AND SOMEBODY**  
 12 **OBJECTED TO ME TALKING ABOUT IT, BUT --**  
 13 **Q.** I THINK I MADE THAT OBJECTION.  
 14 **A. YOU MADE THE OBJECTION. I THINK THEY JUST**  
 15 **LAUNCHED -- THEY ARE TRYING TO LAUNCH STUDIES OF THE**  
 16 **ROLE OF PIOGLITAZONE IN BLADDER CANCER.**  
 17 **Q.** I WANT TO FINISH UP ON BRADFORD-HILL AND THEN  
 18 MOVE TO SOMETHING ELSE. BIOLOGICAL PLAUSIBILITY, THAT  
 19 IS A BRADFORD-HILL CRITERIA, RIGHT?  
 20 **A. CORRECT.**  
 21 **Q.** AS WE NOTED EARLIER, YOU ARE NOT AN EXPERT IN  
 22 THE FIELD OF ATHEROSCLEROSIS?  
 23 **A. THAT IS CORRECT.**  
 24 **Q.** OR LIPIDS OR LP-PLA2 OR ANY LIPID SUBFRACTION,  
 25 CORRECT?

- 1 **A. THAT IS CORRECT.**  
 2 **Q.** YOU ACTUALLY TESTIFIED THAT YOU DON'T HAVE AN  
 3 OPINION ABOUT THE MECHANISM OF ACTION BY WHICH AVANDIA  
 4 INCREASES CARDIOVASCULAR RISK, CORRECT?  
 5 **A. THAT'S CORRECT. I HAVE HEARD SEVERAL PLAUSIBLE**  
 6 **EXPLANATIONS, BUT I DON'T HAVE THE ABILITY OR EXPERTISE**  
 7 **TO JUDGE THEM.**  
 8 **Q.** ARE YOU -- YOU KNOW, WE HAVE BEEN TALKING ABOUT  
 9 POST-STUDY ADJUDICATIONS. I JUST WANT TO KNOW, ARE YOU  
 10 RELYING ON DR. MARCINIAK'S POST HOC ADJUDICATION FOR  
 11 YOUR OPINIONS IN THIS CASE?  
 12 **A. NO, BECAUSE IT CAME AFTER MY OPINION WHICH YOU**  
 13 **PUT UP EARLIER.**  
 14 **Q.** IT WAS IN YOUR SUPPLEMENTAL REPORT. I'M JUST  
 15 ASKING YOU.  
 16 **A. YEAH.**  
 17 **Q.** ARE YOU RELYING ON HIS POST HOC ADJUDICATION OF  
 18 EVENTS IN RECORD TO SUPPORT YOUR OPINION THAT AVANDIA  
 19 CAUSES MYOCARDIAL INFARCTION?  
 20 **A. NO.**  
 21 **Q.** YOU ARE NOT, OKAY.  
 22 **A. NO.**  
 23 **Q.** OKAY, I THINK THAT WE CAN AGREE THAT LARGE  
 24 RANDOMIZED CONTROLLED TRIALS IF THEY ARE DONE WELL  
 25 PROVIDE FOR THE BEST ESTIMATES OF RISK AND ARE

1 CONSIDERED THE GOLD STANDARD WITH REGARD TO DETERMINING  
 2 THE RELATIONSHIP BETWEEN MEDICATIONS AND CARDIOVASCULAR  
 3 EFFECTS?  
 4 **A. I WOULD MUCH PREFER THEM TO OBSERVATIONAL  
 5 STUDIES, CORRECT.**  
 6 **Q.** AND OF ALL OF THE INDIVIDUAL RCT'S CONDUCTED  
 7 WITH AVANDIA, NOT ONE OF THEM FINDS A STATISTICALLY  
 8 SIGNIFICANT INCREASED RISK OF MYOCARDIAL INFARCTIONS, IS  
 9 THAT RIGHT?  
 10 **A. NOT ONE OF THEM --**  
 11 **Q.** INDIVIDUALLY?  
 12 **A. INDIVIDUALLY. THEY ALL CONFIRM THE  
 13 META-ANALYSIS RESULTS, HOWEVER.**  
 14 **Q.** NOW, YOU AGREE AND I THINK YOU GAVE SOME  
 15 TESTIMONY ABOUT THIS EARLIER, THAT AVANDIA AS  
 16 MONOTHERAPY COMPARED TO PLACEBO IS THE MOST INFORMATIVE  
 17 TO ASSESS THE CARDIOVASCULAR SAFETY PROFILE OF THE DRUG,  
 18 RIGHT?  
 19 **A. ANY VERSION OF THE PLACEBO CONTROLLED TRIAL IS  
 20 USUALLY BETTER, YES.**  
 21 **Q.** LET'S BRING UP DEPOSITION TRANSCRIPT 184, 10 TO  
 22 14. I THINK THIS IS YOUR ANSWER, BUT I JUST WANT TO  
 23 CONFIRM. WE CAN SEE FROM 10 TO 14, WELL, AS I INDICATE,  
 24 I THINK THE INFORMATION FOR ROSIGLITAZONE AS A  
 25 MONOTHERAPY COMPARED TO PLACEBO IS MOST INFORMATIVE

1 INITIALLY TO ACCESS THE CARDIOVASCULAR SAFETY PROFILE OF  
 2 THE DRUG. IS THAT CORRECT?  
 3 **A. I BELIEVE THAT IS THE QUESTION YOU JUST ASKED  
 4 ME, YES.**  
 5 **Q.** NOW, DR. AUSTIN TESTIFIED THAT IF YOU ARE  
 6 LOOKING AT AVANDIA VERSUS METFORMIN, FOR EXAMPLE, AND  
 7 YOU FIND AN INCREASED RISK FOR AVANDIA, IT COULD BE  
 8 BECAUSE BOTH ARE PROTECTIVE, BUT METFORMIN IS JUST MORE  
 9 PROTECTIVE THAN AVANDIA. WE TALKED A LITTLE BIT ABOUT  
 10 THAT AND I THINK YOU AGREE WITH THAT, RIGHT?  
 11 **A. IN GENERAL. I DON'T KNOW THAT I NECESSARILY  
 12 AGREE WITH YOUR CLASSIFICATION OF METFORMIN, BUT IN  
 13 GENERAL, THAT IS CORRECT. IF YOU KNOW NOTHING ELSE AND  
 14 YOU COMPARE TWO DRUGS, ALL YOU KNOW IS THE COMPARISON  
 15 BETWEEN THOSE TWO DRUGS, NOTHING MORE.**  
 16 **Q.** YOU DID NOT DO ANY RESEARCH -- AS WE STATED  
 17 EARLIER, YOU DID NOT DO ANY RESEARCH ON ANY OTHER ORAL  
 18 ANTIDIABETIC DRUGS, OTHER THAN AVANDIA, PRIOR TO FORMING  
 19 YOUR OPINIONS IN THIS CASE?  
 20 **A. I DID NOT DO IT COMING IN TO IT AND I DID NOT  
 21 BASE MY OPINION ON THAT, THAT'S CORRECT. I HAVE NOW  
 22 READ A FAIR BIT ABOUT PIOGLITAZONE.**  
 23 **Q.** SO FOR INSTANCE, IF YOU HAD A RANDOMIZED TRIAL  
 24 AND ONE ARM HAD AVANDIA PLUS SULFONYLUREA AND THE OTHER  
 25 ARM YOU HAD JUST SULFONYLUREA, BUT THE SULFONYLUREA WAS

1 NOT A FIXED DOSE, IT WAS ALLOWED TO FLUCTUATE IN EITHER  
 2 ARM, THAT WOULD NOT BE A PLACEBO CONTROLLED TRIAL,  
 3 RIGHT?  
 4 **A. THAT WOULD NOT BE A PLACEBO CONTROLLED TRIAL --  
 5 ACTIVE CONTROL.**  
 6 **Q.** THE SAME WOULD BE TRUE IF YOU HAD A TRIAL TO  
 7 COMPARE AVANDIA AND METFORMIN TO METFORMIN, BUT THE DOSE  
 8 OF METFORMIN WAS ALLOWED TO FLUCTUATE, THAT WOULD NOT BE  
 9 A PLACEBO CONTROLLED TRIAL?  
 10 **A. THAT'S CORRECT. ACTIVE CONTROLLED TRIAL.**  
 11 **Q.** THERE ARE PLACEBO CONTROLLED MONOTHERAPY TRIALS  
 12 WITH AVANDIA, RIGHT?  
 13 **A. THERE ARE, I BELIEVE, YES.**  
 14 **MR. SHEEHAN:** LET'S TAKE A LOOK AT TABLE  
 15 24 OF THE FDA 52 META-ANALYSIS. WE CAN BLOW THAT UP A  
 16 LITTLE BIT -- NOT THE PIOGLITAZONE STUFF, BUT THE ROSI  
 17 STUFF DOWN AT THE BOTTOM. ACTUALLY, LET'S JUST LOOK AT  
 18 THE TITLE FIRST SO WE CAN IDENTIFY IT.  
 19 **BY MR. SHEEHAN:**  
 20 **Q.** THIS IS TABLE 24 FROM THE ICT 52 FDA'S ANALYSIS,  
 21 MONOTHERAPY ADD ON GROUP, SUMMARY OF TRIALS IN THE  
 22 MONOTHERAPY TRIAL GROUP BY META-ANALYSIS. ON THE TOP WE  
 23 CAN SEE THERE IS PIOGLITAZONE --  
 24 **MR. SHEEHAN:** IF WE GO DOWN BELOW, JAMIE.  
 25 **BY MR. SHEEHAN:**

1 **Q.** -- WE SEE THERE IS ROSIGLITAZONE. THERE IS A  
 2 NUMBER OF TRIALS THERE THAT ARE MONOTHERAPY TRIALS --  
 3 THESE ARE ALL MONOTHERAPY TRIALS -- COMPARED TO PLACEBO.  
 4 YOU WOULD AGREE WITH THAT, RIGHT?  
 5 **A. WELL, I CAN'T SEE THE TITLE OF THE TABLE OR THE  
 6 CONTEXT, BUT IT DOES SAY PLACEBO, I AGREE WITH THAT. I  
 7 ASSUME THAT IF THEY FLASH BACK UP, IS THAT SAYING THAT  
 8 IS THE CONTROL GROUP?**  
 9 **Q.** YES. THAT'S RIGHT, YEAH.  
 10 **A. IT'S HARD FOR ME TO READ THESE TABLES ON THE FLY  
 11 WHEN YOU CHOP OFF THE TITLE.**  
 12 **Q.** I'M DOING THE BEST I CAN WITH WHAT WE GOT.  
 13 **A. ME, TOO.**  
 14 **Q.** YOU DID NOT ASSESS THE MONOTHERAPY PLACEBO  
 15 CONTROLLED TRIALS REGARDING WHETHER THOSE TRIALS  
 16 DEMONSTRATE A STATISTICALLY SIGNIFICANT INCREASED RISK  
 17 OF MI, DID YOU?  
 18 **A. IN WHICH META-ANALYSIS?**  
 19 **Q.** DID YOU DO IT? DID YOU ASSESS WHETHER THE  
 20 MONOTHERAPY PLACEBO CONTROLLED TRIALS --  
 21 **A. WHAT I DID -- I CAN'T TELL YOU WHAT I DIDN'T DO.  
 22 BUT WHAT I DID WAS, IN THE ICT 42 --**  
 23 **Q.** I'M NOT SURE I UNDERSTAND. YOU CAN'T TELL ME  
 24 WHAT YOU DIDN'T DO?  
 25 **MR. CARTMELL:** YOUR HONOR, I JUST ASK MR.

1 SHEEHAN TO --  
 2 HONORABLE CYNTHIA M. RUFÉ: WE ARE GOING  
 3 TO GO BACK, GOING TO REASK YOUR QUESTION BECAUSE YOU  
 4 ACTUALLY STOPPED AS YOU WERE ASKING THE QUESTION AND  
 5 THEN HE STARTED TO ANSWER SOMETHING THAT WAS NOT EVEN  
 6 YOUR QUESTION. SO LET'S GO BACK. ALL RIGHT. STRIKE  
 7 THE LAST ANSWER AND YOU MAY PROCEED.  
 8 BY MR. SHEEHAN:  
 9 **Q.** DID YOU ASSESS THE MONOTHERAPY PLACEBO  
 10 CONTROLLED TRIALS REGARDING WHETHER THOSE TRIALS  
 11 DEMONSTRATE A STATISTICALLY SIGNIFICANT INCREASED RISK  
 12 OF MYOCARDIAL INFARCTION?  
 13 **A.** **IN THE ICT 42 I USED THE SUBGROUP COMPARISON**  
 14 **THAT THE FDA DID TO LOOK AT PLACEBO CONTROLLED TRIALS**  
 15 **AND LOOKED AT THAT -- RESULTS FROM THAT SEPARATELY FROM**  
 16 **THE ENTIRE META-ANALYSIS. THAT IS WHAT I DID.**  
 17 **Q.** WERE THOSE MONOTHERAPY PLACEBO CONTROLLED  
 18 TRIALS?  
 19 **A.** **I WOULD HAVE TO GO BACK AND LOOK AT THE FDA**  
 20 **REPORT TO GIVE A PRECISE DEFINITION OF WHAT THEY CALLED**  
 21 **PLACEBO COMPARISONS. I DON'T WANT TO DO IT ON THE FLY,**  
 22 **IF YOU BEAR WITH ME.**  
 23 HONORABLE CYNTHIA M. RUFÉ: WE DON'T WANT  
 24 YOU TO EITHER. IT'S 12:15.  
 25 MR. SHEEHAN: I'M SORRY. WE CAN STOP AT

1 ANY TIME.  
 2 HONORABLE CYNTHIA M. RUFÉ: WE ARE GOING  
 3 TO TAKE THE LUNCH RECESS AND WE WILL SEE YOU BACK HERE  
 4 AT 1:30.  
 5 MR. MELLON: THANK YOU.  
 6 (RECESS.)  
 7 THE CLERK: ALL RISE.  
 8 HONORABLE CYNTHIA M. RUFÉ: GOOD  
 9 AFTERNOON.  
 10 ALL COUNSEL: GOOD AFTERNOON, YOUR HONOR.  
 11 HONORABLE CYNTHIA M. RUFÉ: PLEASE BE  
 12 SEATED.  
 13 MR. MELLON: YOUR HONOR, WE HAVE GOOD  
 14 NEWS, I BELIEVE. MS. GUSSACK.  
 15 HONORABLE SANDRA MAZER MOSS: THERE IS  
 16 NOT GOING TO BE ANY MORE TESTIMONY?  
 17 MR. MELLON: NO TESTIMONY.  
 18 HONORABLE SANDRA MAZER MOSS: THAT WOULD  
 19 BE THE BEST POSSIBLE NEWS.  
 20 MR. MELLON: OUR RESPECTIVE LITIGATORS  
 21 HAVE AGREED AND MS. GUSSACK HAS AGREED AS WELL, WE ARE  
 22 GOING TO BREAK THIS DOWN INTO 40-MINUTE SEGMENTS, DIRECT  
 23 40 MINUTES, CROSS 40 MINUTES.  
 24 HONORABLE CYNTHIA M. RUFÉ: GREAT.  
 25 MR. MELLON: SECOND WITNESS, DIRECT 40

1 MINUTES, CROSS 40 MINUTES. HOWEVER, THERE IS ALWAYS A  
 2 FOOTNOTE. MS. GUSSACK.  
 3 MS. GUSSACK: YES.  
 4 HONORABLE CYNTHIA M. RUFÉ: IF THE COURT  
 5 DARES INTERRUPT WITH A QUESTION, YOU GET EXTENDED.  
 6 MS. GUSSACK: IT'S VERY FORTHCOMING OF  
 7 YOU TO INTRODUCE MY FOOTNOTE, WHICH IS THE CAUTIONARY  
 8 FOOTNOTE, YOUR HONOR, THAT IT'S VERY HARD TO DO CROSS IN  
 9 40 MINUTES IF THE WITNESS IS NOT BEING RESPONSIVE TO YES  
 10 AND NO QUESTIONS AND APPROPRIATELY ENGAGING. SO WITH  
 11 YOUR HONORS' COLLECTIVE GUIDANCE, I WOULD HOPE THAT WE  
 12 COULD ARRANGE FOR THAT AND I THINK WE WILL BE ABLE TO  
 13 MOVE PROMPTLY THROUGH THE CROSS.  
 14 HONORABLE CYNTHIA M. RUFÉ: IT'S A GOOD  
 15 GUIDELINE AND I THINK WE SHOULD STICK TO THE PLAN IF AT  
 16 ALL POSSIBLE AND SEE HOW DIFFICULT WITNESSES MAY BE. WE  
 17 DON'T KNOW THAT YET.  
 18 MS. GUSSACK: THANK YOU. AND IF I MAY  
 19 TURN BACK TO DR. JEWELL BEFORE WE CONCLUDE WITH HIS  
 20 CROSS EXAMINATION, I WOULD LIKE TO ASK THE COURT --  
 21 HONORABLE SANDRA MAZER MOSS: CAN YOU  
 22 SPEAK INTO THE MICROPHONE?  
 23 MS. GUSSACK: I'M SORRY, JUDGE MOSS. WE  
 24 MOVE TO STRIKE FROM THE DIRECT TESTIMONY OF DR. JEWELL 4  
 25 SLIDES THAT I AM REFERRING TO AS BEST I CAN FROM

1 RECOLLECTION, SLIDES TITLED COMBINED RISKS, ALL  
 2 STATISTICALLY SIGNIFICANT RESULTS, SUPPORTIVE TREND, ALL  
 3 STUDIES ALL RESULTS, BECAUSE AS YOU HEARD FROM DR.  
 4 JEWELL THIS MORNING, HE CAN'T VOUCH FOR THEM. WE OBJECT  
 5 FOR LACK OF FOUNDATION. HE HAD NO PARTICIPATION NOR  
 6 COULD HE CONFIRM THE CONTENTS OF THOSE SLIDES. AND SO  
 7 WE ASK THAT THEY BE STRICKEN FROM HIS DIRECT TESTIMONY.  
 8 HONORABLE CYNTHIA M. RUFÉ: YOU DON'T  
 9 HAVE ANY OBJECTION TO THAT, DO YOU?  
 10 MR. CARTMELL: OBJECTION TO THEM BEING  
 11 STRICKEN?  
 12 HONORABLE CYNTHIA M. RUFÉ: YES.  
 13 MR. CARTMELL: YES.  
 14 HONORABLE CYNTHIA M. RUFÉ: GIVEN DR.  
 15 JEWELL'S TESTIMONY.  
 16 MR. CARTMELL: HE WAS NOT INVOLVED IN IT.  
 17 HE DID NOT CREATE IT, I THINK HIS TESTIMONY WAS. HE DID  
 18 NOT CREATE IT, WAS MY UNDERSTANDING.  
 19 HONORABLE CYNTHIA M. RUFÉ: HE DIDN'T SAY  
 20 THAT HE USED IT IN FORMULATING HIS OPINION EITHER.  
 21 MR. CARTMELL: THAT'S RIGHT.  
 22 MS. GUSSACK: TO BE CLEAR, HE ALSO SAID  
 23 HE CAN'T SPEAK TO WHAT IS IN THERE OR ISN'T. HE DOES  
 24 NOT KNOW IF THEY ARE ACCURATE.  
 25 HONORABLE SANDRA MAZER MOSS: THEY ARE IN

1 FOR OTHER PURPOSES ANYHOW.  
2 HONORABLE CYNTHIA M. RUFÉ: I'M GRANTING  
3 THE MOTION.  
4 MS. GUSSACK: WITH THAT, YOUR HONOR, I  
5 THINK THAT --  
6 HONORABLE SANDRA MAZER MOSS: WE WILL DO  
7 THE SAME FOR STATE COURT.  
8 MR. SHEEHAN: I DON'T HAVE ANY FURTHER  
9 QUESTIONS OF DR. JEWELL.  
10 HONORABLE CYNTHIA M. RUFÉ: THEN REDIRECT  
11 IS BRIEF?  
12 MR. CARTMELL: I DON'T HAVE ANY REDIRECT,  
13 BUT IF YOUR HONORS WOULD LIKE TO ASK ANY QUESTIONS --  
14 HONORABLE SANDRA MAZER MOSS: OH, NO.  
15 MR. CARTMELL: -- WE WILL HAVE HIM  
16 AVAILABLE AND WE WILL KEEP HIM.  
17 HONORABLE SANDRA MAZER MOSS: HE LEFT ME  
18 SPEECHLESS.  
19 HONORABLE CYNTHIA M. RUFÉ: I, ON THE  
20 OTHER HAND, HAVE BEEN SHOPPING ALL LUNCHTIME, BUT NO,  
21 I'M GOING TO GO ON THE RECORD AND I THINK THAT THERE WAS  
22 QUITE A BIT OF TIME DEVOTED TO THE QUESTIONS AND DIRECT  
23 AND CROSS. I'M READY FOR THE NEXT, SO THANK YOU, DR.  
24 JEWELL. YOU MAY REMAIN IF YOU CHOOSE, YOU MAY ALSO BE  
25 EXCUSED.

1 NEXT.  
2 MR. ZONIES: OUR NEXT WITNESS WILL BE DR.  
3 ELIOT BRINTON, YOUR HONOR.  
4 (DR. ELIOT BRINTON, PLAINTIFF'S WITNESS,  
5 SWORN.)  
6 THE CLERK: STATE AND SPELL YOUR FULL  
7 NAME FOR THE RECORD, PLEASE?  
8 THE WITNESS: ELIOT ASHBY BRINTON,  
9 B-R-I-N-T-O-N.  
10 HONORABLE CYNTHIA M. RUFÉ: PLEASE BE  
11 SEATED. MR. ZONIES.  
12 MR. ZONIES: THANK YOU, YOUR HONOR.  
13 DIRECT EXAMINATION  
14 BY MR. ZONIES:  
15 Q. GOOD AFTERNOON, DR. BRINTON.  
16 A. **GOOD AFTERNOON.**  
17 Q. DR. BRINTON, ARE YOU A PHYSICIAN?  
18 A. **YES.**  
19 Q. WHAT TYPE OF PHYSICIAN?  
20 A. **MY SPECIALTY IS LIPIDOLOGY AND DIABETOLOGY.**  
21 Q. WHY DON'T WE DEFINE EACH OF THOSE RATHER  
22 QUICKLY.  
23 HONORABLE SANDRA MAZER MOSS: IS THAT A  
24 SUBSPECIALTY OF CARDIOLOGY OR IT'S NOT?  
25 THE WITNESS: LIPIDOLOGY CAN CO-EXIST

1 WITH CARDIOLOGY OR ENDOCRINOLOGY OR POSSIBLY OTHER  
2 SUBSPECIALTIES. I AM TRAINED IN ENDOCRINOLOGY AND MY  
3 FOCUS IN MY RESEARCH AND CLINICAL PRACTICE IS LIPIDOLOGY  
4 AND DIABETOLOGY.  
5 HONORABLE SANDRA MAZER MOSS: BUT IT'S  
6 ENDOCRINOLOGY AS OPPOSED TO CARDIOLOGY?  
7 THE WITNESS: YES.  
8 HONORABLE SANDRA MAZER MOSS: OKAY, THANK  
9 YOU.  
10 MR. ZONIES: THANK YOU, YOUR HONOR.  
11 BY MR. ZONIES:  
12 Q. DR. BRINTON, WHERE ARE YOU CURRENTLY WORKING?  
13 A. **UNIVERSITY OF UTAH.**  
14 Q. WHAT IS YOUR POSITION THERE?  
15 A. **I AM THE DIRECTOR OF THE METABOLISM SECTION,**  
16 **ASSOCIATE PROFESSOR.**  
17 Q. AND DO YOU PARTICIPATE IN CLINICAL RESEARCH?  
18 A. **YES.**  
19 Q. AND HAVE YOU DESIGNED RANDOMIZED CLINICAL  
20 TRIALS?  
21 A. **YES.**  
22 Q. HAVE YOU DESIGNED LARGE AND SMALL RANDOMIZED  
23 CLINICAL TRIALS?  
24 A. **I HAVE ASSISTED IN THE DESIGN OF LARGE TRIALS.**  
25 **I HAVE CONDUCTED THE DESIGN OF SMALLER TRIALS.**

1 Q. HAVE YOU ALSO PARTICIPATED AS A STEERING  
2 COMMITTEE MEMBER ON RANDOMIZED CONTROLLED TRIALS?  
3 A. **YES.**  
4 Q. HAVE THOSE TRIALS HAD CARDIOVASCULAR ENDPOINTS?  
5 A. **YES.**  
6 Q. HAVE THEY HAD LIPID ENDPOINTS?  
7 A. **YES.**  
8 Q. ARE YOU CURRENTLY WORKING ON A LIPID  
9 OBSERVATIONAL STUDY IN THE VADT STUDY?  
10 A. **YES.**  
11 Q. AND WHAT DRUG WAS USED IN THAT STUDY?  
12 A. **THERE WERE MANY DRUGS USED. IT IS NOTEWORTHY**  
13 **THAT ONE OF THE DRUGS USED WAS ROSIGLITAZONE.**  
14 Q. IN ADDITION TO YOUR CLINICAL RESEARCH DUTIES, DO  
15 YOU ALSO SEE PATIENTS IN A CLINICAL SETTING?  
16 A. **YES.**  
17 Q. AND YOU DO THAT AS A DIABETOLOGIST, IS THAT  
18 CORRECT?  
19 A. **YES, AND LIPIDOLOGIST.**  
20 Q. AND AT THE UNIVERSITY OF UTAH, ARE YOU THE  
21 DIRECTOR OF SOME CLINICS THERE?  
22 A. **YES. I MEAN WE HAVE ONE SMALL CLINIC THAT WE**  
23 **SEE OUR PATIENTS IN AND I'M NOT ACTUALLY THE DIRECTOR OF**  
24 **THE CLINIC, BUT I'M ONE OF TWO ATTENDING PHYSICIANS IN**  
25 **THAT CLINIC.**

1 Q. ARE YOU BOARD CERTIFIED IN LIPIDOLOGY?  
 2 A. YES.  
 3 MR. ZONIES: NOW, YOUR HONORS, DR.  
 4 BRINTON'S RESUME IS ATTACHED AT THE END OF HIS INITIAL  
 5 REPORT. I BELIEVE WE DELIVERED THAT TO YOU YESTERDAY.  
 6 IF YOU NEED ANOTHER COPY, I'VE GOT EVERYTHING RIGHT  
 7 HERE.

8 HONORABLE CYNTHIA M. RUFÉ: I DON'T THINK  
 9 THAT WAS DELIVERED, BUT I HAVE MY COPY.

10 HONORABLE SANDRA MAZER MOSS: I DON'T  
 11 HAVE A COPY.

12 MR. ZONIES: DO YOU HAVE COPIES OF HIS  
 13 THREE REPORTS?

14 HONORABLE SANDRA MAZER MOSS: I HAVE YOUR  
 15 RESPONSE. IS IT ATTACHED TO YOUR RESPONSE?

16 MR. ZONIES: MAY I APPROACH AND I WILL  
 17 DELIVER YOU FRESH COPIES, YOUR HONOR.

18 HONORABLE SANDRA MAZER MOSS: I JUST HAVE  
 19 THE MOTIONS, I DON'T HAVE HIS REPORT.

20 MR. ZONIES: THEY WERE DELIVERED. THAT  
 21 IS THE NOTEBOOK, CORRECT. IT SHOULD BE -- DR. BRINTON  
 22 IS THE FIRST TAB OR FIRST TAB.

23 HONORABLE CYNTHIA M. RUFÉ: I THINK IT IS  
 24 UP THERE.

25 HONORABLE SANDRA MAZER MOSS: YES, I DO.

1 I'M SORRY.

2 BY MR. ZONIES:

3 Q. AS YOU CAN SEE IN THAT NOTEBOOK --

4 HONORABLE SANDRA MAZER MOSS: I DO HAVE  
 5 IT NOW.

6 MR. ZONIES: GREAT. IN THAT NOTEBOOK,  
 7 THE FIRST TAB IS HIS INITIAL EXPERT REPORT AND FAR AT  
 8 THE END, I BELIEVE IT'S ACTUALLY PAGE 99, IT'S NOT  
 9 PAGINATED, IS HIS RESUME. I DO NOT WANT TO TAKE A BUNCH  
 10 OF TIME GOING THROUGH THAT, PARTICULARLY SINCE THE  
 11 DEFENDANTS HAVE STIPULATED TO HIS QUALIFICATIONS AS AN  
 12 EXPERT WITNESS.

13 BUT IF THE COURT HAS ANY PARTICULAR  
 14 QUESTIONS ABOUT ANY OF HIS BACKGROUND, SUCH AS A WHAT IS  
 15 A DIABETOLOGIST, OBVIOUSLY --

16 HONORABLE CYNTHIA M. RUFÉ: I THINK NOT  
 17 EVERYONE MAY HAVE THE BENEFIT OF ALL OF THE PAPER.  
 18 EVENTUALLY THEY WILL IF THEY NEED TO HEAR THIS. I THINK  
 19 THAT THE LIPIDOLOGY ASPECTS OF IT ARE BETTER KNOWN THAN  
 20 THE DIABETOLOGY. I CAN GUESS AT WHAT IT IS, BUT I DON'T  
 21 WANT ANYONE ELSE TO GUESS, SO IF YOU JUST EXPLAIN THE  
 22 STUDY OF -- IT'S OF DIABETES, NO DOUBT?

23 THE WITNESS: YES. AND THE STUDY OF  
 24 DIABETES AND SPECIFICALLY CLINICAL, FROM A CLINICAL  
 25 STANDPOINT AND ALSO FROM A SCIENTIFIC STANDPOINT, IT CAN

1 BE USED IN EITHER SENSE. AND IT IS THE STUDY OF  
 2 DIABETES AS A DISEASE PROCESS, THE DISEASES THAT ARE  
 3 RELATED TO DIABETES AND THEN USUALLY ALSO IMPLIES THE  
 4 TREATMENT, ALTHOUGH I THINK YOU COULD SAY THAT SOMEONE  
 5 WHO'S NOT A PHYSICIAN MIGHT BE A DIABETOLOGIST, BUT I'M  
 6 A CLINICIAN AND SCIENTIST DIABETOLOGIST SO I DO BOTH  
 7 SIDES OF THAT.

8 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.  
 9 BY MR. ZONIES:

10 Q. DO YOU ACTIVELY SEE PATIENTS WITH DIABETES ON A  
 11 REGULAR BASIS?

12 A. YES.

13 Q. AND DO YOU TREAT NOT ONLY THEIR DIABETES, BUT  
 14 THE CARDIOVASCULAR COMPLICATIONS ASSOCIATED WITH HAVING  
 15 DIABETES?

16 A. YES. LET ME CLARIFY THIS, I'M NOT A  
 17 CARDIOLOGIST, BUT I CONSIDER MYSELF TO BE A PREVENTIVE  
 18 CARDIOLOGIST, AND THE DISTINCTION THERE IS THAT I AM NOT  
 19 THE PRIMARY TREATER OF CORONARY EVENTS, BUT MY JOB IS TO  
 20 HELP PREVENT THOSE EVENTS. AND I SEE PATIENTS WHO HAVE  
 21 HAD RECENT OR DISTANT EVENTS AND SO TO SOME DEGREE I'M  
 22 INVOLVED IN THAT, BUT I'M INVOLVED AS AN OUTSIDER IN  
 23 TERMS OF THE TREATMENT OF THOSE EVENTS, BUT MY JOB AS I  
 24 SEE IT IS TO PREVENT THOSE EVENTS AS BEST I CAN.

25 Q. DO YOU RUN A CLINIC AT THE UNIVERSITY OF UTAH OR

1 ARE YOU CO-DIRECTOR OF THE CLINIC THERE THAT DEALS WITH  
 2 THAT IN PARTICULAR?

3 A. YES. THAT IS OUR FOCUS.

4 MR. ZONIES: ANY OTHER QUESTIONS, YOUR  
 5 HONORS?

6 HONORABLE CYNTHIA M. RUFÉ: NO.

7 HONORABLE SANDRA MAZER MOSS: NO.

8 BY MR. ZONIES:

9 Q. IN YOUR ROLE AS A DIABETOLOGIST AND LIPIDOLOGIST  
 10 AND ENDOCRINOLOGY, YOU HAVE BEEN FAMILIAR WITH THE  
 11 THIAZOLIDINEDIONE CLASS OF DRUGS FOR SOME TIME, IS THAT  
 12 CORRECT?

13 A. YES.

14 Q. AND WE WILL REFER TO THOSE FOR PRIMARILY THE  
 15 COURT REPORTER'S SAKE AS TZD'S, IS THAT OKAY?

16 A. YES.

17 Q. THERE HAVE BEEN A NUMBER OF TZD'S THAT HAVE  
 18 ATTEMPTED TO MAKE IT TO THE MARKET, IS THAT CORRECT?

19 A. YES.

20 Q. AND MANY HAVE NOT?

21 A. YES. IT'S MORE TRUE IF ONE TAKES THE LARGER  
 22 TERM, WHICH IS PPAR-GAMMA AGONIST, BUT YES.

23 Q. WHAT WAS THE PRIMARY REASON THAT MANY OF THESE  
 24 PPAR-GAMMA AGONISTS DID NOT MAKE IT TO MARKET?

25 A. THERE HAVE BEEN SEVERAL TYPES OF TOXICITY, IN

1 **LARGE PART CARDIO TOXICITY, BUT OTHERS AS WELL.**  
2 Q. AVANDIA IS A PPAR-GAMMA AGONIST, CORRECT?  
3 A. **YES.**  
4 Q. WERE YOU INVOLVED WITH -- WE HAVE HEARD THAT  
5 THREE TZD'S HAVE ACTUALLY RECEIVED APPROVAL AT ONE POINT  
6 IN TIME FROM THE FDA, CORRECT?  
7 A. **YES.**  
8 Q. WHAT IS THE INDICATION FOR WHICH TZD'S ARE  
9 APPROVED?  
10 A. **GLYCEMIC CONTROL IN A DIABETIC PATIENT.**  
11 Q. WHAT DOES THAT MEAN?  
12 A. **ONE OF THE PRINCIPAL FINDINGS IN DIABETES,**  
13 **INDEED YOU COULD SAY PERHAPS THE DEFINING CHARACTERISTIC**  
14 **IS AN ELEVATED LEVEL OF BLOOD SUGAR. AND SO NATURALLY**  
15 **ONE OF THE APPROACHES, A PRINCIPAL APPROACH TO TREATMENT**  
16 **OF DIABETES IS TO LOWER THE BLOOD SUGAR AS BEST ONE CAN**  
17 **WITH THE IDEA THAT THIS SHOULD REDUCE SOME OF THE**  
18 **COMPLICATIONS AND THERE IS EVIDENCE FOR THAT, AND SO**  
19 **DIABETES DRUGS ARE APPROVED OR NOT APPROVED PRIMARILY ON**  
20 **THE BASIS OF WHETHER OR NOT THEY CAN LOWER BLOOD GLUCOSE**  
21 **LEVELS.**  
22 Q. AND IS THAT KNOWN AS A SURROGATE ENDPOINT BLOOD  
23 GLUCOSE LEVEL?  
24 A. **SURROGATE'S KIND OF A LOADED QUESTION, BUT**  
25 **CERTAINLY THAT TERM HAS BEEN USED FOR THAT ENDPOINT AND**

1 **IN THE SENSE THAT THERE IS RELATIVELY LITTLE DIRECT**  
2 **MORBIDITY FROM HYPERGLYCEMIA. WHEREAS THE MAJOR**  
3 **COMORBIDITIES OF DIABETES ARE NOT HYPERGLYCEMIA PER SE,**  
4 **IT'S IN THAT SENSE A SURROGATE.**  
5 Q. AND WE HAVE HEARD THAT DIABETES ITSELF CARRIES A  
6 SIGNIFICANT CARDIOVASCULAR RISK?  
7 A. **YES, IT DOES.**  
8 Q. IS THERE ANY EVIDENCE THAT TZD OR IN PARTICULAR  
9 THAT AVANDIA ACTUALLY DECREASES CARDIOVASCULAR RISK,  
10 SUCH AS MYOCARDIAL INFARCTIONS AND ISCHEMIA?  
11 A. **IS THERE ANY EVIDENCE THAT IT DECREASES IT?**  
12 **THERE ARE PIECES OF EVIDENCE THAT SUGGEST THAT, YES.**  
13 Q. AND YOU REVIEWED THOSE PIECES OF EVIDENCE IN  
14 YOUR WORK IN THIS CASE, CORRECT?  
15 A. **YES.**  
16 Q. YOU REVIEWED EVIDENCE THAT SHOWED THE OPPOSITE  
17 OF THAT, CORRECT?  
18 A. **YES.**  
19 Q. NOW, WERE YOU HERE FOR DR. JEWELL -- YOU WERE  
20 HERE IN THE COURTROOM FOR DR. JEWELL'S TESTIMONY?  
21 A. **YES.**  
22 Q. DO YOU RECALL DR. JEWELL BEING ASKED ABOUT THE  
23 STOCKL MATTER?  
24 A. **YES.**  
25 Q. AND IN PARTICULAR, DR. JEWELL WAS ASKED ABOUT A

1 SLIDE THAT SHOWED STATISTICALLY SIGNIFICANT RESULTS. IT  
2 HAD STOCKL ON THAT SLIDE FOR STATISTICALLY SIGNIFICANT  
3 INCREASED RISK?  
4 A. **YES.**  
5 **MS. BENNES: EXCUSE ME, I JUST WANT TO**  
6 **OBJECT. I DON'T BELIEVE --**  
7 **HONORABLE SANDRA MAZER MOSS: WHAT IS**  
8 **YOUR NAME?**  
9 **MS. BENNES: CINDY BENNES. I DON'T THINK**  
10 **THE STOCKL ARTICLE WAS DISCUSSED IN DR. BRINTON'S**  
11 **REPORT.**  
12 **HONORABLE SANDRA MAZER MOSS: CAN YOU**  
13 **SPEAK INTO THE MICROPHONE?**  
14 **MS. BENNES: I'M SORRY. TO BE CLEAR,**  
15 **YOUR HONORS, DR. BRINTON DISCUSSED HIS OBSERVATIONAL**  
16 **STUDIES, A FEW OBSERVATIONAL STUDIES ON PAGES 35 AND 36**  
17 **OF HIS REPORT. STOCKL IS NOT ONE OF THEM.**  
18 **MR. ZONIES: I'M NOT ACTUALLY INQUIRING**  
19 **ABOUT THAT, YOUR HONOR. IF I MAY JUST BE GIVEN TWO**  
20 **MINUTES OF LEEWAY ON THIS, I WILL SHOW YOU WHERE I'M**  
21 **GOING WITH THIS.**  
22 **HONORABLE CYNTHIA M. RUFÉ: WELL, AS LONG**  
23 **AS YOU CONNECT IT TO HIS FINDINGS AND HIS METHODOLOGY.**  
24 **BY MR. ZONIES:**  
25 Q. DR. BRINTON, WHO CREATED THESE SLIDES?

1 A. **YOU DID.**  
2 Q. THANK YOU. AND YOU HEARD TESTIMONY ABOUT DR.  
3 JEWELL AND THIS SLIDE AND HOW IT DIDN'T PROPERLY  
4 REPRESENT THE STOCKL ENDPOINTS, DO YOU RECALL THAT?  
5 A. **YES.**  
6 Q. AND HAVE YOU AND I ACTUALLY GONE OVER THESE  
7 SLIDES?  
8 A. **YES.**  
9 Q. AND PARTICULARLY OVER THE LUNCH BREAK, DID YOU  
10 REVIEW THE ALL STUDIES ALL RESULTS SLIDE WITH ME?  
11 A. **YES.**  
12 Q. PARTICULARLY FOR THE ENDPOINTS AT THE TOP THAT  
13 ARE NONSTATISTICALLY SIGNIFICANT?  
14 A. **YES.**  
15 Q. DID YOU REVIEW THE STOCKL RESULTS?  
16 A. **YES, I REVIEWED THEM WITH YOU, AND JUST TO**  
17 **CLARIFY, STOCKL WAS IN MY BIBLIOGRAPHY AND PART OF MY**  
18 **ANALYSIS.**  
19 Q. AND DID YOU CONFIRM WITH ME THAT THE ALL  
20 STUDIES, ALL RESULTS ACCURATELY REPRESENTS THE RESULTS  
21 FROM THE STOCKL STUDY?  
22 A. **YES. THESE -- DURING THE LUNCH BREAK, I**  
23 **REREVIEWED THE TABLE FROM THE PAPER, AND THIS SLIDE, IN**  
24 **COMPARING THE TWO, THEY ARE TOGETHER -- THEY ARE -- THIS**  
25 **SLIDE IS A FAITHFUL REPRESENTATION OF THE PRIMARY**

1 **RESULTS OF THE STOCKL STUDY WITH REGARD TO MI.**  
2 Q. NOW, DR. BRINTON, AS WE DISCUSSED, YOU HAVE BEEN  
3 INVOLVED WITH THE TZD CLASS OF DRUGS FOR SOME TIME?  
4 A. **YES.**  
5 Q. AND DID YOU AT SOME POINT IN YOUR CAREER HAVE  
6 THE OPPORTUNITY TO PRESCRIBE REZULIN, FOR EXAMPLE?  
7 A. **YES.**  
8 Q. TROGLITAZONE?  
9 A. **YES.**  
10 Q. REZULIN WAS THEN WITHDRAWN FROM THE MARKET?  
11 A. **YES.**  
12 Q. DID YOU HAVE TIME IN YOUR CAREER WHERE YOU  
13 PRESCRIBED AVANDIA?  
14 A. **YES.**  
15 Q. AND ALSO ACTOS?  
16 A. **YES.**  
17 Q. AND THOSE ARE THE THREE TZD'S THAT HAVE BEEN  
18 APPROVED BY THE FDA, CORRECT?  
19 A. **YES, ACTOS IS PIOGLITAZONE.**  
20 Q. HAVE YOU CONSULTED FOR PHARMACEUTICAL COMPANIES  
21 RELATED TO ANY TZD'S?  
22 A. **YES.**  
23 Q. TELL THE COURT ABOUT THAT.  
24 A. **I HAVE BEEN A CONSULTANT FOR ALL THREE OF THE**  
25 **MEDICATIONS AND I HAVE BEEN A SCIENTIFIC CONSULTANT FOR**

1 **THEM ON SEVERAL OCCASIONS.**  
2 Q. SO YOU HAVE BEEN A SCIENTIFIC CONSULTANT  
3 HISTORICALLY FOR GSK ON THE DRUG AVANDIA?  
4 A. **YES.**  
5 Q. WHAT WAS YOUR ROLE, WERE YOU ON THE AVANDIA  
6 SPEAKERS BUREAU?  
7 A. **YES.**  
8 Q. WHAT DID THAT MEAN?  
9 A. **WELL, I WAS TRAINED IN SPEAKING TO OTHER**  
10 **PHYSICIANS ABOUT AVANDIA. I WAS ALSO A CONSULTANT TO**  
11 **THEM REGARDING THEIR DESIRE FOR INPUT FROM A PHYSICIAN**  
12 **SCIENTIST, SUCH AS MYSELF.**  
13 Q. HAVE YOU ALSO CONSULTED FOR PHARMACEUTICAL  
14 COMPANIES REGARDING LABELING ISSUES?  
15 A. **YES.**  
16 Q. WERE YOU A CONSULTANT FOR THE LABELING ISSUES  
17 RELATED TO WHAT IS NOW KNOWN AS LOVAZA, GSK'S DRUG?  
18 A. **YES, I HAVE CONSULTED ON THAT DRUG, SPECIFIC TO**  
19 **THE LABELING QUESTION AS AN INVITED CONSULTANT.**  
20 Q. WHEN REZULIN WAS REMOVED FROM THE MARKET AND  
21 THERE WERE TWO TZD'S LEFT, WAS THAT ROUGHLY 1999, 2000?  
22 A. **IT WAS NOT '99, IT WAS 2000 OR SO.**  
23 Q. YOU HAD TWO TZD'S OF CHOICE. AT THE POINT IN  
24 2000, DID YOU HAVE ANY REASON OR TO FAVOR ONE OVER THE  
25 OTHER?

1 A. **NOT INITIALLY.**  
2 Q. DID YOU EVENTUALLY BEGIN TO HAVE A REASON IN  
3 YOUR MIND TO FAVOR ONE OVER THE OTHER?  
4 A. **AS A LIPIDOLOGIST, I WAS VERY INTERESTED IN**  
5 **REPORTS THAT CAME OUT EARLY AFTER 2000 OF LIPID**  
6 **DIFFERENCES BETWEEN THE TWO DRUGS, DIFFERENCES IN THEIR**  
7 **EFFECTS ON LIPID LEVELS.**  
8 Q. WHAT DOES THAT MEAN?  
9 A. **IT BECAME CLEAR THAT THERE WERE DIFFERENCES**  
10 **BETWEEN THESE TWO DRUGS. THEY WERE BOTH IN THE SAME**  
11 **CLASS AND SEEMED TO BE FAIRLY SIMILAR, BUT THERE WERE**  
12 **DIFFERENCES WITH REGARD TO LDL IN PARTICULAR, THAT WAS**  
13 **THE FIRST, I THINK, DISCOVERY AND THEN ALSO HDL AND**  
14 **TRIGLYCERIDES.**  
15 Q. AND WHAT WERE THOSE DIFFERENCES AND WHICH DRUG  
16 DID YOU FAVOR?  
17 A. **THE DIFFERENCES WERE ALL IN FAVOR OF**  
18 **PIOGLITAZONE OVER ROSIGLITAZONE. BOTH DRUGS HAD A**  
19 **TENDENCY TO INCREASE LDL, WHEREAS FOR PIOGLITAZONE,**  
20 **THERE WAS VERY LITTLE EFFECT, BUT PERHAPS A SLIGHT**  
21 **INCREASE. FOR ROSIGLITAZONE, THERE WAS A FAIRLY STRONG**  
22 **INCREASE AND QUITE CONSISTENT INCREASE IN LDL. FOR HDL**  
23 **THERE WAS AN INCREASE WITH BOTH DRUGS, BUT MUCH STRONGER**  
24 **FOR PIOGLITAZONE, THEREFORE BEING FAVORABLE SINCE HDL IS**  
25 **A FAVORABLE FACTOR.**

1 HONORABLE SANDRA MAZER MOSS: YOU ARE  
2 SAYING ONE INCREASED HDL A LOT AND LDL A LITTLE BIT?  
3 THE WITNESS: AND THAT WAS PIOGLITAZONE.  
4 HONORABLE SANDRA MAZER MOSS: RIGHT, AND  
5 ROSIGLITAZONE INCREASED LDL A LOT AND HDL A LITTLE BIT?  
6 THE WITNESS: LESS, YES. AND THEN FOR  
7 TRIGLYCERIDES, IT WAS MORE OR LESS THE SAME STORY.  
8 PIOGLITAZONE DECREASED TRIGLYCERIDES CONSISTENTLY. AND  
9 ROSIGLITAZONE HAD EITHER AN INCONSISTENT EFFECT OR IN  
10 MANY STUDIES AN INCREASE IN TRIGLYCERIDES. SO ALL THREE  
11 OF THE DIFFERENCES FAVORED PIOGLITAZONE OVER  
12 ROSIGLITAZONE AND THAT WAS OF CONCERN TO ME AS A  
13 LIPIDOLOGIST.  
14 BY MR. ZONIES:  
15 Q. DURING THIS PERIOD OF TIME, DID YOU CONTINUE TO  
16 SPEAK ON BEHALF OF GSK ABOUT AVANDIA?  
17 A. **I DID.**  
18 Q. AND HOW WOULD YOU HANDLE YOUR CONCERNS?  
19 A. **IT WAS WITH SOME DIFFICULTY BECAUSE AS A**  
20 **LIPIDOLOGIST I WAS CONCERNED ABOUT THAT, BUT THERE**  
21 **CERTAINLY WERE REASSURANCES THAT WERE GIVEN TO US BOTH**  
22 **DIRECTLY BY GSK AND INDIRECTLY BY INDIVIDUALS WHO WERE**  
23 **RESEARCHING THEIR DRUG, IN MANY CASES SPONSORED BY GSK.**  
24 **SPECIFIC TO THE LDL QUESTION WAS THE ISSUE OF LDL**  
25 **PARTICLE SIZE. AND IT WAS CLEAR THAT BOTH DRUGS**

1 **INCREASED LDL PARTICLE SIZE, ALTHOUGH EVENTUALLY IT**  
2 **BECAME CLEAR THAT AGAIN PIOGLITAZONE HAD MORE OF A**  
3 **FAVORABLE EFFECT AND HERE LDL PARTICLE SIZE,**  
4 **COUNTER-INTUITIVELY IS GOOD. THE MORE THE BETTER. SO**  
5 **THE INCREASE IN PARTICLE SIZE WAS GREATER WITH**  
6 **PIOGLITAZONE THAN IT WAS WITH ROSIGLITAZONE.**  
7 **Q.** IS IT FAIR TO SAY THAT THE SCIENCE ON THESE  
8 DRUGS WAS IN SOME SENSE DEVELOPING DURING THE PERIOD OF  
9 TIME FROM 2000 UNTIL 2007?  
10 **A.** **YES. THE SCIENCE HAS EVOLVED FROM THE VERY**  
11 **BEGINNING AND YES.**  
12 **Q.** IN 2000, IT WAS A VERY BUSY YEAR WITH REGARD TO  
13 TZD PUBLICATIONS AND SCIENCE, FAIR?  
14 **A.** **YES.**  
15 **Q.** IN 2007, DREAM, ADOPT, INTERIM RECORD, THE FDA  
16 ADCOM IN 2007, THE AMERICAN HEART ASSOCIATION MEETING IN  
17 2007?  
18 **A.** **AMERICAN DIABETES ASSOCIATION.**  
19 **Q.** SORRY, AMERICAN DIABETES ASSOCIATION. ALL OF  
20 THESE EVENTS WERE OCCURRING DURING THE PERIOD AND, IN  
21 FACT, THE NISSEN META-ANALYSIS. ALL OF THESE EVENTS  
22 WERE OCCURRING DURING THE 2007 PERIOD OF TIME?  
23 **A.** **YES.**  
24 **Q.** DURING THE 2007 PERIOD OF TIME, AS YOU SIT HERE  
25 TODAY, DO YOU ROUGHLY RECALL IF YOUR OPINIONS WERE BEING

1 MODIFIED EVEN MORE AS NEW EVIDENCE CAME OUT?  
2 **A.** **I WAS CONSTANTLY EVALUATING NEW EVIDENCE AND MY**  
3 **OPINIONS WERE INDEED IN A STATE OF FLUX AND IT'S A**  
4 **LITTLE DIFFICULT TO RECALL ALL OF THE DETAILS OF IT, BUT**  
5 **I THINK I CAN ANCHOR THE CHANGES IN MY OPINION TO**  
6 **CERTAIN EVENTS THAT HAPPENED WHERE THERE WAS AN**  
7 **INFLECTION POINT IN MY OPINION RELATED TO A PARTICULAR**  
8 **EVENT OR PERHAPS SOME EVIDENCE OF MY OPINION AT A GIVEN**  
9 **POINT AS WELL.**  
10 **Q.** AND BY THE END OF 2007, DID YOU START TO HAVE  
11 CONCERNS ABOUT NOT JUST THE LIPID EFFECTS OF THIS DRUG,  
12 BUT MORE BROADLY ITS CARDIOVASCULAR EFFECTS?  
13 **A.** **2007 WAS NOT THE FIRST TIME WE HAD EVIDENCE.**  
14 **THAT HAD OCCURRED EARLIER WITH PROACTIVE TRIAL, WHICH**  
15 **WAS THE FIRST TIME WE ACTUALLY HAD CLINICAL EVENT DATA**  
16 **WITH REGARD TO THIS CLASS OF DRUGS, BUT IN 2007 DREAM**  
17 **AND ADOPT CAME OUT. I LOOKED AT THESE AND WAS CONCERNED**  
18 **TO SEE AN UPWARD TREND INSTEAD OF THE EXPECTED DOWNWARD**  
19 **TREND, SO THAT STOOD OUT. THAT WAS ALSO SEEN WITH**  
20 **NISSEN META-ANALYSIS. IT WAS NOT SEEN WITH RECORD**  
21 **INTERIM, BUT THEN LATER IN THE YEAR THERE WERE TWO**  
22 **META-ANALYSES, TWO ADDITIONAL META-ANALYSES THAT CAME**  
23 **OUT, ONE WITH THE FIRST AUTHOR OF SINGH AND THE OTHER**  
24 **LINCOFF AND THESE WERE TWO STUDIES THAT LOOKED AT THE**  
25 **TWO SEPARATE COMPOUNDS AND CAME TO OPPOSITE CONCLUSIONS.**

1 **Q.** SO YOU ARE SAYING YOU -- THIS IS YOUR DAILY  
2 PRACTICE?  
3 **A.** **YES.**  
4 **Q.** THESE ARE NOT STUDIES THAT YOU REVIEWED FOR THE  
5 FIRST TIME FOR THIS LITIGATION?  
6 **A.** **NO.**  
7 **Q.** YOU WERE LIVING THESE AND BREATHING THESE  
8 STUDIES ON A REGULAR BASIS?  
9 **A.** **THIS WAS VERY IMPORTANT TO ME AS A LIPIDOLOGIST**  
10 **AND DIABETOLOGIST AND PREVENTATIVE CARDIOLOGIST.**  
11 **Q.** YOU DISCUSSED THE LINCOFF. WHAT IS THAT  
12 META-ANALYSIS?  
13 **A.** **THIS IS A META-ANALYSIS OF RANDOMIZED CLINICAL**  
14 **TRIALS OF PIOGLITAZONE.**  
15 **Q.** OF ACTOS?  
16 **A.** **YES.**  
17 **Q.** THE LINCOFF META-ANALYSIS CAME OUT IN THE FALL  
18 OF 2007?  
19 **A.** **YES.**  
20 **Q.** AND AS DID THE SINGH META-ANALYSIS?  
21 **A.** **YES.**  
22 **Q.** AND THAT WAS IMPORTANT IN YOUR CLINICAL OPINION,  
23 NOT YOUR LITIGATION OPINION, THAT YOU WERE SEEING A  
24 DIFFERENCE BETWEEN THESE TWO AGENTS?  
25 **A.** **YES.**

1 **Q.** AND I'M JUST GOING TO PUT UP A SLIDE FROM YOUR  
2 REPORT. IN YOUR SUPPLEMENTAL REPORT AT PAGE 10, YOU  
3 ACTUALLY HAD A SLIDE THAT REFLECTS -- THIS SLIDE IS  
4 ENTITLED BRINTON SUPPLEMENT AT 10. TELL THE COURT WHAT  
5 THIS SLIDE REPRESENTS.  
6 **A.** **THIS IS A FOREST PLOT SUCH AS WE HAVE SEEN**  
7 **BEFORE LOOKING AT THESE TWO META-ANALYSES IN THE SAME**  
8 **FIGURE. NOW, THIS IS NOT SINGH AND LINCOFF, BUT IT'S**  
9 **NISSEN AND LINCOFF. I THINK I ACTUALLY HAVE A FIGURE**  
10 **WITH SINGH AND LINCOFF AS WELL. BUT NISSEN AND SINGH**  
11 **CAME TO FAIRLY SIMILAR CONCLUSIONS SO THIS IS FINE AS A**  
12 **SURROGATE. WHAT ONE SEES HERE IS ON THE RIGHT-HAND**  
13 **SIDE, ROSIGLITAZONE WITH A BOX INSTEAD OF A POINT FOR**  
14 **THE POINT ESTIMATE. THE BOX REPRESENTING -- THE SIZE OF**  
15 **THE BOX REPRESENTING THE NUMBER OF EVENTS ON WHICH THE**  
16 **ESTIMATE IS BASED. SO ONE GETS A GRAPHIC FEEL FOR THE**  
17 **WEIGHT OF EVIDENCE THERE. AND THEN ONE SEES THE**  
18 **95 PERCENT CONFIDENCE INTERVALS WHICH DO NOT TOUCH 1 AND**  
19 **SO IN THE NISSEN META-ANALYSIS, THERE WAS A**  
20 **STATISTICALLY SIGNIFICANT INCREASE IN CARDIOVASCULAR**  
21 **EVENTS; ABOUT 40 PERCENT, A LITTLE OVER 40 PERCENT. FOR**  
22 **PIOGLITAZONE WITH LINCOFF, THERE IS A FIGURE TO THE**  
23 **LEFT, A LARGER BOX MEANING MORE EVENTS. THERE IS A**  
24 **TOUCHING OF THE 95 PERCENT CONFIDENCE INTERVAL OF 1 SO**  
25 **NOT QUITE STATISTICALLY SIGNIFICANT IN THIS PARTICULAR**

1 **ENDPOINT, ALTHOUGH THERE WAS WITH SOME OF THE OTHER**  
 2 **ENDPOINTS IN THAT STUDY. AND THE POINT OF THIS IS THAT**  
 3 **THERE IS A RATHER STRIKING CONTRAST AND THESE ARE DRUGS**  
 4 **WHICH INITIALLY APPEARED TO BE IDENTICAL. AND THEN AS**  
 5 **TIME HAD GONE ON, THE LIPID EFFECTS SEEM TO DIVERGE THEN**  
 6 **CARDIOVASCULAR EVENTS DIVERGING AND SO I'M LOOKING AT**  
 7 **THIS AND THINKING THIS IS IMPORTANT. THIS IS OF**  
 8 **CLINICAL AND SCIENTIFIC IMPORTANCE.**

9 Q. AND THIS WAS PART OF YOUR OPINION MOVING FORWARD  
 10 THROUGH TIME IN THE YEAR 2007?

11 A. YES.

12 Q. WHEN NISSEN CAME OUT, YOU DIDN'T -- WHAT DID YOU  
 13 THINK?

14 A. ONE EVENT THAT OCCURRED IN 2007 WAS THE ADA  
 15 MEETING AT WHICH STEVE NISSEN AND PHILIP HOME DEBATED --

16 Q. AND PHILIP HOME IS THE PRIMARY AUTHOR ON RECORD?

17 A. ON RECORD. SO PHILIP HOME CAME TO PRESENT THE  
 18 INTERIM RESULTS OF RECORD, STEVE NISSEN PRESENTED HIS  
 19 RESULTS AND THERE WAS AN AUDITORIUM FILLED WITH  
 20 ENDOCRINOLOGISTS ATTENDING THAT MEETING AND I HAVE TO  
 21 SAY IT WAS A LITTLE HOSTILE FOR DR. NISSEN. HE BEING AN  
 22 OUTSIDER, A CARDIOLOGIST BASICALLY COMING TO TELL US AS  
 23 ENDOCRINOLOGISTS HOW TO PRACTICE DIABETOLOGY. HE WAS  
 24 NOT WELL RECEIVED. WE WERE NOT APPRECIATIVE OF HIS  
 25 APPROACH, I THINK, IN MANY WAYS AND WE WERE GLAD TO SEE

1 **THAT ONE OF THE DRUGS THAT WE HAD USED FOR MANY YEARS**  
 2 **AND HAD EXPERIENCE WITH AND APPRECIATED THAT IT WAS**  
 3 **BEING DEFENDED BY DR. HOME.**

4 Q. AND SUBSEQUENT OR AROUND THAT SAME TIME FRAME  
 5 THERE WAS ALSO THE FDA ADVISORY COMMITTEE MEETING?

6 A. YES.

7 Q. WHERE THE FDA ADVISORY COMMITTEE VOTED IN FAVOR  
 8 OF THE FOLLOWING, WHICH WAS THAT THE EVIDENCE  
 9 DEMONSTRATED THAT AVANDIA SUPPORTED A CONCLUSION OF  
 10 INCREASE IN CARDIOVASCULAR ISCHEMIC EVENTS?

11 A. YES.

12 Q. WHEN YOU HEARD THAT FDA ADVISORY COMMITTEE VOTE,  
 13 AND I'M TALKING ABOUT WHEN YOU FIRST HEARD IT IN JULY OF  
 14 '07, WHAT WERE YOUR THOUGHTS ABOUT THAT?

15 A. WELL, THIS WAS JUST A MONTH AFTER THE ADA  
 16 MEETING, AND CERTAINLY I WAS BEGINNING TO BE CONCERNED  
 17 ABOUT THE DIVERGENCE OF THE DATA FOR THESE TWO DRUGS,  
 18 BUT I THINK I WAS STILL CONCERNED ABOUT DR. NISSEN'S  
 19 INTRUSION INTO OUR FIELD. AND I THINK MY INITIAL  
 20 IMPRESSION WAS THAT IT WAS PROBABLY A GOOD VOTE, THAT I  
 21 WAS NOT READY TO TOTALLY RELINQUISH AVANDIA FROM THE  
 22 ARMAMENTARIUM, AND THAT I INITIALLY WOULD AGREE WITH  
 23 THEM.

24 Q. BECAUSE I MEAN AT THE TIME THEY DID NOT VOTE TO  
 25 REMOVE AVANDIA FROM THE MARKET, CORRECT?

1 A. RIGHT.

2 Q. SO SUBSEQUENT TO THAT FDA ADVISORY COMMITTEE  
 3 MEETING, THIS DATA CAME OUT IN THE FALL OF '07?

4 A. YES. THE LINCOFF CAME OUT.

5 Q. BY THE END OF YEAR IN '07, YOUR OPINION HAD  
 6 FRANKLY SWUNG MORE TOWARD AGREEING WITH DR. NISSEN?

7 A. IT HAD. THERE WAS THE LINCOFF ANALYSIS FOR  
 8 PIOGLITAZONE. THERE WAS ALSO THE SINGH ANALYSIS FOR  
 9 ROSIGLITAZONE, WHICH WAS IN LARGE PART, ALTHOUGH NOT  
 10 COMPLETELY, INDEPENDENT OF THE NISSEN META-ANALYSIS AND  
 11 THE FDA AND GSK META-ANALYSIS. SO THERE WERE ACTUALLY  
 12 FOUR META-ANALYSES LOOKING AT THREE SOMEWHAT OVERLAPPING  
 13 BUT SOMEWHAT DISTINCT BODIES OF RANDOMIZED CLINICAL  
 14 TRIAL DATA.

15 ALL FOUR OF THOSE META-ANALYSES CAME TO  
 16 THE SAME CONCLUSION, THAT THERE WAS INDEED AN INCREASE  
 17 IN CARDIOVASCULAR EVENTS WITH -- ASSOCIATED WITH  
 18 ROSIGLITAZONE, WHEREAS ON THE SIDE OF PIOGLITAZONE, WE  
 19 ALREADY HAD THE PROACTIVE TRIAL AS A SINGLE LARGE  
 20 RANDOMIZED TRIAL WHICH CAME VERY CLOSE TO PROVIDING  
 21 STATISTICALLY SIGNIFICANT EVIDENCE, AND THEN THE  
 22 META-ANALYSIS WHICH BASICALLY CONFIRMED WITH A BROADER  
 23 PATIENT SAMPLE AND MORE STUDIES THE SAME FINDING OF THE  
 24 PROACTIVE AS A SINGLE TRIAL. SO IT WAS BECOMING AT THAT  
 25 POINT INCREASINGLY CLEAR THAT THIS DIVERGENCE BETWEEN

1 **THE TWO DRUGS WAS REPRODUCIBLE AND THAT IT WAS**  
 2 **CONSISTENT AMONG VARIOUS TRIALS. SO THIS WAS SOMETHING**  
 3 **THAT WAS NOT SIMPLY A PLAY OF CHANCE OR PERHAPS SOME**  
 4 **OTHER THING THAT WOULD NOT BE OF CLINICAL OR SCIENTIFIC**  
 5 **IMPORTANCE.**

6 Q. EVENTUALLY YOU RESIGNED YOUR ROLE AS SPEAKER ON  
 7 THE AVANDIA SPEAKER BUREAU?

8 A. I DID, ALTHOUGH THAT TOOK A WHILE. WHAT  
 9 HAPPENED WAS GSK, IN THE FACE OF CONSIDERABLE ONSLAUGHT  
 10 AND RELABELING AND VARIOUS THINGS THAT WERE HAPPENING IN  
 11 2007, BASICALLY STOPPED -- AS FAR AS I WAS AWARE, AS FAR  
 12 AS I WAS BEING INVITED, THEY STOPPED DOING THE PROGRAM.  
 13 SO I WAS NO LONGER BEING INVITED TO SPEAK FOR THEM AND  
 14 THAT WAS FINE AND THAT WAS THE CASE FOR A COUPLE OF  
 15 YEARS.

16 Q. EVENTUALLY YOU WERE ASKED BY MEMBERS OF THE PSC  
 17 TO SEE IF YOU WOULD BE INTERESTED IN ACTING AS AN EXPERT  
 18 IN THIS LITIGATION?

19 A. YES.

20 Q. THAT WAS IN OR AROUND 2009?

21 A. YES.

22 HONORABLE SANDRA MAZER MOSS: WHAT YEAR  
 23 DID YOU STOP SPEAKING FOR GSK?

24 THE WITNESS: THEY WERE NO LONGER

25 INVITING ME AS OF THE END OF 2007. SO I DID NOT SPEAK

1 IN 2008 AT ALL. NOW WHAT HAPPENED IN 2009 WAS A LITTLE  
 2 BIT OF A SWING BACK IN THE OTHER DIRECTION AND THAT WAS  
 3 WITH THE PUBLICATION OF THE FULL RESULTS OF RECORD AND  
 4 THEN A STATEMENT BY THE AMERICAN ASSOCIATION OF CLINICAL  
 5 ENDOCRINOLOGY, WHICH CAME OUT REALLY QUITE STRONGLY  
 6 ENDORSING ROSIGLITAZONE, NOT OVER PIOGLITAZONE, BUT  
 7 ENDORSING THE TWO EQUALLY, WHICH TO ME WAS OF SOME  
 8 INTEREST AND SOME SIGNIFICANCE AS AN ENDOCRINOLOGIST.  
 9 SO THOSE TWO THINGS IN A RECORD -- THE FULL RESULTS OF  
 10 RECORD COMING OUT, THIS HOPEFULLY PRESUMABLY DEFINITIVE  
 11 TRIAL OF CARDIOVASCULAR DISEASE IN ROSIGLITAZONE,  
 12 APPEARING TO EXONERATE IT. THERE WAS A SHORT PERIOD OF  
 13 TIME IN WHICH I DID ACTUALLY RESUME AT THE INVITATION OF  
 14 GSK TO SPEAK FOR THEM.

15 NOW PART OF THE SUBTEXT OF THIS IS THAT I  
 16 WAS ALSO -- IN THE TIME BETWEEN 2007 AND 2009 I HAD  
 17 BEGUN TO SPEAK FOR THEM AND TO BE ADVISOR FOR THEM ON  
 18 THEIR PRODUCT, A LIPID PRODUCT CALLED LOVAZA,  
 19 L-O-V-A-Z-A, WHICH IS A CONCENTRATED FISH OIL PRODUCT.  
 20 SO I WAS CONTINUING MY RELATIONSHIP WITH GSK AS A  
 21 CONSULTANT AND AS A SPEAKER DURING THE TIME IN WHICH  
 22 AVANDIA HAD BEEN BASICALLY PUT ON THE SHELF BY THEM IN  
 23 TERMS OF VERY LITTLE IF ANY ACTIVITY. AND THEN WITH  
 24 THESE NEW DATA THAT CAME OUT IN THE MIDDLE OF 2009, I  
 25 LOOKED AT THIS AND THOUGHT, WELL, PERHAPS I CAN GO BACK

1 TO MY PRIOR ROLE TO SPEAK ON BEHALF OF AVANDIA. EVEN  
 2 THOUGH I WAS NO LONGER PRESCRIBING IT, I THOUGHT WELL,  
 3 PERHAPS MAYBE THIS IS SOMETHING THAT COULD WORK. THEY  
 4 WERE VERY ENTHUSIASTIC ABOUT IT AND REALIZING THE  
 5 IMPORTANCE OF GLYCEMIC CONTROL AND THE MANY PRESUMED AND  
 6 IN SOME CASES PROVEN BENEFITS OF THIS CLASS OF DRUGS,  
 7 THE THOUGHT WAS THAT PERHAPS IT WOULD BE REASONABLE  
 8 AGAIN TO ADVOCATE FOR AVANDIA.

9 HONORABLE SANDRA MAZER MOSS: THIS WAS IN  
 10 2008 OR 2009?

11 THE WITNESS: MIDDLE OF 2009. AND THAT  
 12 FELL FLAT IN MY OPINION BECAUSE I JUST COULDN'T FEEL  
 13 GOOD ABOUT THAT. I AT THAT POINT LOOKED MORE CAREFULLY  
 14 AT RECORD. I HAD NOT LOOKED AT IT AS CAREFULLY AS I  
 15 NEEDED TO, AND I BEGAN TO LOOK MORE CAREFULLY AT THE  
 16 AACE STATEMENT. I SPOKE WITH SOME OF THE PEOPLE WHO HAD  
 17 WRITTEN THE STATEMENT AND REALIZED THAT THEY HAD  
 18 ACTUALLY NOT DONE A VERY CAREFUL ASSESSMENT OF THAT  
 19 PARTICULAR QUESTION. THEIR GUIDELINES WERE VERY BROAD.  
 20 THEY COVERED TEN DIFFERENT CLASSES OF DIABETES DRUGS OF  
 21 WHICH TZD'S WERE ONLY ONE. BUT THE SPECIFIC REFERENCE  
 22 TO THE TZD'S AND TO PIO AND ROSI HAD BEEN NOT EXACTLY AN  
 23 AFTERTHOUGHT, BUT HAD NOT RECEIVED MUCH FOCUS.

24 SO I THEN IN LOOKING MORE CAREFULLY AT  
 25 RECORD AT THAT POINT IN TIME AND LOOKING MORE CAREFULLY

1 AT THESE NEW GUIDELINES JUST FELT THAT THIS REALLY HAD  
 2 FALLEN SHORT AND THAT THE LONG ANTICIPATED FINAL RESULTS  
 3 OF RECORD, EVEN THOUGH BY MANY PEOPLE CONSIDERED TO BE  
 4 COMPLETE EXONERATION OF ANY HARM ON THE PART OF  
 5 ROSIGLITAZONE, I COULD NOT AGREE WITH THAT.

6 SO IT WAS IN THAT SETTING THAT I WAS  
 7 APPROACHED BY THE PLAINTIFFS TO CONSIDER BEING AN EXPERT  
 8 WITNESS FOR THEM. AND I EXPLAINED TO THEM AT THE OUTSET  
 9 THAT I HAD MIXED FEELINGS ABOUT THIS, THAT I WASN'T  
 10 100 PERCENT CONVINCED THAT ROSIGLITAZONE IN FACT DID  
 11 CAUSE CARDIOVASCULAR EVENTS, BUT THAT THAT WAS MY  
 12 INCLINATION, THAT I HAD STOPPED SPEAKING COMPLETELY  
 13 PERMANENTLY FOR GSK ON THIS DRUG, THAT I HAD STOPPED  
 14 USING IT ACTUALLY SEVERAL YEARS EARLIER, AND THAT I WAS  
 15 INTERESTED IN THE OPPORTUNITY TO STUDY MORE CAREFULLY  
 16 THE QUESTION. I WAS ACTUALLY DOING THAT ON MY OWN, BUT  
 17 TO BE WILLING TO ASSIST THEM IN THIS PROCESS BECAUSE IT  
 18 WAS ONE THAT HAD INTERESTED ME FOR MANY YEARS.

19 HONORABLE SANDRA MAZER MOSS: THANK YOU.

20 HONORABLE CYNTHIA M. RUFÉ: BUT THERE IS  
 21 CONFUSION IN MY MIND. DID GSK ACTUALLY ASK YOU TO  
 22 RESUME SPEAKING FOR AVANDIA ON OR ABOUT 2009?

23 THE WITNESS: YES. THEY APPROACHED ME.

24 I DID NOT APPROACH THEM. REMEMBER THAT I HAD THIS  
 25 RELATIONSHIP WITH THE SAME REPRESENTATIVES BECAUSE I WAS

1 SPEAKING REGULARLY ON THEIR BEHALF WITH REGARD TO  
 2 LOVAZA, SO I WAS HAVING REGULAR INTERACTION WITH THEM.  
 3 AND THEY -- MAYBE BEG IS TOO STRONG A WORD, BUT THEY  
 4 WERE VERY STRONG AND INSISTENT IN THEIR REQUEST THAT I  
 5 SPEAK FOR THEM. AND I VALUE MY RELATIONSHIPS WITH ALL  
 6 OF THE PEOPLE THAT I HAVE EVER KNOWN AT GSK AND IT WAS A  
 7 DIFFICULT THING FOR ME TO SAY NO TO THEM.

8 HONORABLE SANDRA MAZER MOSS: WHEN IN  
 9 2009 DID THEY APPROACH YOU?

10 THE WITNESS: IT WAS RIGHT AROUND THE  
 11 MIDPOINT OF THAT YEAR. I DON'T RECALL THE EXACT DATE.

12 HONORABLE SANDRA MAZER MOSS: MID IS  
 13 FINE.

14 HONORABLE CYNTHIA M. RUFÉ: SO YOU  
 15 REFUSED, BUT DID YOU CONTINUE TO SPEAK FOR THEM ON  
 16 LOVAZA?

17 THE WITNESS: YES AND I HAVE TO THIS  
 18 DATE.

19 HONORABLE CYNTHIA M. RUFÉ: ALL RIGHT.  
 20 THANK YOU.

21 MR. ZONIES: YOUR HONORS, IN DR.  
 22 BRINTON'S FIRST REPORT, HE DOES DISCUSS SOME OF THIS ON  
 23 PAGES 1 THROUGH 3 IN HIS INTRODUCTION, AND IN PARTICULAR

24 --

25 HONORABLE SANDRA MAZER MOSS: WE ARE

1 STILL ON THE REPORT?  
 2 MR. ZONIES: YES. AND IN PARTICULAR, IN  
 3 THE FIRST PARAGRAPH OF THE INTRODUCTION ON PAGE ONE  
 4 WHERE HE SAYS IT IS WITH SOME RELUCTANCE THAT HE  
 5 APPROACHED THIS TASK.  
 6 BY MR. ZONIES:  
 7 Q. WHEN YOU AGREED TO LOOK AT THE DATA AND STUDIES  
 8 AND WHATEVER INFORMATION YOU REQUESTED OF THE PSC OR THE  
 9 PSC COULD PROVIDE TO YOU, DID YOU START TO DEVELOP A  
 10 FULLER UNDERSTANDING OF THESE ISSUES?  
 11 A. YES.  
 12 Q. DID YOU IN FACT REQUEST PATIENT LEVEL DATA?  
 13 A. YES.  
 14 Q. FROM THE STUDIES?  
 15 A. YES.  
 16 Q. WOULD THOSE THINGS NORMALLY BE AVAILABLE TO  
 17 PEOPLE, AS YOU WERE EARLIER, IN CLINICAL PRACTICE?  
 18 A. NO.  
 19 Q. SO YOU HAD, THROUGH YOUR ROLE AS AN EXPERT,  
 20 ACCESS TO MORE INFORMATION THAN YOU DID IN YOUR  
 21 CLINICIAN SETTING?  
 22 A. CERTAINLY AND EVEN MORE THAN I WOULD ORDINARILY  
 23 HAVE IN MY ROLE AS A SCIENTIST. I MEAN, IT WOULD BE  
 24 SOMEWHAT EXTRAORDINARY CIRCUMSTANCES THAT ONE WOULD  
 25 OBTAIN PATIENT LEVEL DATA FROM A STUDY THAT ONE HAD NOT

1 DIRECTLY PARTICIPATED IN.  
 2 Q. AND IN FORMULATING YOUR OPINIONS, AND WE WILL  
 3 GET TO IT QUICKLY, YOU RELY ON SOME OF THAT PATIENT  
 4 LEVEL DATA THAT YOU WERE PROVIDED TO REACH YOUR  
 5 OPINIONS?  
 6 A. YES.  
 7 Q. THAT WAS AN IMPORTANT INFORMATION THAT YOU DID  
 8 NOT PREVIOUSLY HAVE AT YOUR FINGERTIPS OR AVAILABLE?  
 9 A. YES.  
 10 Q. AND IT'S ONLY AVAILABLE EITHER DIRECTLY FROM THE  
 11 INVESTIGATORS OR THROUGH A LITIGATION, SAY?  
 12 A. YES.  
 13 Q. NOW, DR. BRINTON, WE ARE HERE ABOUT METHODOLOGY  
 14 IN PARTICULAR. SO I WOULD LIKE TO DIRECT YOUR ATTENTION  
 15 TO YOUR REPORT AT PAGE THREE AND YOUR SUMMARY  
 16 CONCLUSIONS, WHICH ARE ON THE BOARD. DID YOU REACH YOUR  
 17 OPINIONS IN THIS CASE BASED SOLELY UPON YOUR CLINICAL  
 18 EXPERIENCE? AND NOW I'M TALKING APART FROM SCIENTIFIC  
 19 EXPERIENCE.  
 20 A. NO.  
 21 Q. HOW DID YOU APPLY YOUR CLINICAL EXPERIENCE AND  
 22 JUDGMENT?  
 23 A. I APPLIED IT, I GUESS, IN SEVERAL WAYS.  
 24 CERTAINLY THE CONTEXT HERE IS WE HAVE A DRUG THAT WE ARE  
 25 USING IN HUMAN BEINGS. SO THAT IS AN IMPORTANT FACT IN

1 ANY CONSIDERATION REGARDING ROSIGLITAZONE. CERTAINLY MY  
 2 CLINICAL EXPERIENCE WITH ROSIGLITAZONE AND PIOGLITAZONE  
 3 WAS IMPORTANT. BUT TRULY IN COMING TO THE CONCLUSION, I  
 4 WAS PRIMARILY RELYING UPON SCIENCE AND SCIENTIFIC METHOD  
 5 THAT WOULD GO BEYOND THAT THAT A CLINICIAN WOULD USE.  
 6 Q. YOU HAVE, AS WE DISCUSSED EARLIER, VAST  
 7 EXPERIENCE IN CLINICAL TRIALS AS A SCIENTIST?  
 8 A. I HAVE CONSIDERABLE EXPERIENCE IN THAT, YES.  
 9 Q. AS YOU SAID IN YOUR REPORT, YOUR OPINIONS WERE  
 10 BASED UPON YOUR PROFESSIONAL EDUCATION, YES?  
 11 A. YES.  
 12 Q. YOUR TRAINING?  
 13 A. YES.  
 14 Q. YOUR EXPERIENCE AS A CLINICAL RESEARCHER?  
 15 A. YES.  
 16 Q. AND AS A CLINICIAN?  
 17 A. YES.  
 18 Q. AND LASTLY, YOUR REVIEW OF THE RELEVANT  
 19 SCIENTIFIC INVESTIGATIONS?  
 20 A. YES.  
 21 Q. DID YOU REVIEW A SIGNIFICANT NUMBER OF STUDIES  
 22 AND DOCUMENTS IN THIS CASE?  
 23 A. YES, HUNDREDS.  
 24 Q. HAVE YOU EVER MADE SUCH AN IN DEPTH REVIEW OF A  
 25 DRUG IN YOUR LIFE?

1 A. NO.  
 2 Q. YOUR CONCLUSION AGAIN IN YOUR REPORT AT PAGE  
 3 FOUR, DO YOU CONSIDER THAT YOUR CONCLUSION WAS CAREFULLY  
 4 CONSIDERED?  
 5 A. YES.  
 6 Q. AND IT WAS BASED UPON SCIENTIFIC AND CLINICAL  
 7 OPINIONS?  
 8 A. YES.  
 9 Q. AND THE TOTALITY OF THE EVIDENCE?  
 10 A. YES.  
 11 Q. DID YOU IN FACT SOLELY RELY UPON WHAT THE PSC  
 12 PROVIDED TO YOU?  
 13 A. NO. MUCH OF WHAT I HAVE INCLUDED IN MY  
 14 BIBLIOGRAPHY WAS ALREADY SOMETHING I WAS FAMILIAR WITH.  
 15 DURING THE TIME THAT I WAS SERVING, HAD BEGUN TO SERVE  
 16 AS AN EXPERT WITNESS FOR COUNSEL, I WAS NOT RELYING UPON  
 17 THE PLAINTIFFS FOR -- AS A SOLE SOURCE OF INFORMATION.  
 18 I WAS MYSELF LOOKING AT LITERATURE AS BEST I COULD AND I  
 19 WAS READING EVERYTHING THAT CAME MY WAY AND EVALUATING  
 20 IT AS PART OF THE QUESTION OF WHETHER OR NOT I COULD  
 21 COME TO A CONCLUSION REGARDING THE RELATIONSHIP OF  
 22 ROSIGLITAZONE TO CARDIOVASCULAR EVENTS.  
 23 Q. AND THE EVENTS THAT YOU DESCRIBED IN YOUR  
 24 CONCLUSION ARE MYOCARDIAL ISCHEMIC EVENTS INCLUDING  
 25 MYOCARDIAL INFARCTION?

- 1 **A. YES.**  
 2 **Q.** AND YOU'RE COMFORTABLE -- WE HAVE HEARD A LOT OF  
 3 TESTIMONY ABOUT THIS AND PRESENTATIONS, YOU ARE  
 4 COMFORTABLE THAT BOTH OF THOSE ENDPOINTS WERE IMPORTANT  
 5 FOR YOU TO REVIEW?  
 6 **A. YES.**  
 7 **Q.** AND YOUR CONCLUSIONS IN THIS CASE ARE BASED UPON  
 8 BOTH OF THOSE ENDPOINTS?  
 9 **A. YES.**  
 10 **Q.** NOW, I JUST WANT TO TURN TO YOUR METHODOLOGY AND  
 11 AT PAGE 22 OF YOUR INITIAL REPORT YOU DISCUSS THE  
 12 STRONGEST EVIDENCE IS THE MOST DIRECT EVIDENCE WHICH YOU  
 13 CITE TO THE STUDIES. SO YOU DID REVIEW THE STUDIES, NOT  
 14 ONLY FOR PURPOSES OF THIS LITIGATION, BUT YOU'D REVIEWED  
 15 MANY OF THEM IN YOUR PRACTICE?  
 16 **A. YES.**  
 17 **Q.** AND DID YOU REVIEW RANDOMIZED CONTROLLED TRIALS?  
 18 **A. YES.**  
 19 **Q.** PAGE 22 OF YOUR INITIAL REPORT -- I'M SORRY,  
 20 PAGE 25 OF YOUR INITIAL REPORT YOU DISCUSSED THREE TYPES  
 21 OF EVIDENCE REGARDING THE EFFECTS OF ROSIGLITAZONE ON  
 22 CARDIOVASCULAR DISEASE EVENTS. WHAT ARE THOSE THREE  
 23 TYPES OF EVIDENCE THAT YOU REVIEWED?  
 24 **A. CAN WE SEE PAGE 25 JUST TO MAKE SURE?**  
 25 **Q.** WELL, DID YOU REVIEW RANDOMIZED CONTROLLED

- 1 TRIALS?  
 2 **A. RANDOMIZED CLINICAL TRIALS, INDIVIDUAL TRIALS.**  
 3 **Q.** DID YOU ALSO REVIEW -- AT PAGE 22 OF YOUR  
 4 REPORT, I THINK THAT IS ACTUALLY 27 OF YOUR REPORT, DID  
 5 YOU ALSO REVIEW META-ANALYSES?  
 6 **A. YES.**  
 7 **Q.** DID YOU ALSO REVIEW OBSERVATIONAL STUDIES?  
 8 **A. YES.**  
 9 **Q.** AND WHEN YOU WERE REVIEWING ALL OF THESE  
 10 STUDIES, AS IT SAYS ON THIS SLIDE ENTITLED BRINTON, AT  
 11 22, DID YOU REVIEW THESE FOR CONFOUNDING AND BIAS?  
 12 **A. YES.**  
 13 **Q.** DID YOU REVIEW ALL OF THE EVIDENCE AND APPLY A  
 14 CONFOUNDING AND BIAS ANALYSIS?  
 15 **A. YES.**  
 16 **Q.** DID YOU REACH AN OPINION WITHIN A REASONABLE  
 17 DEGREE OF MEDICAL CERTAINTY WHETHER OR NOT THIS DRUG WAS  
 18 ASSOCIATED WITH AN INCREASED RISK OF MYOCARDIAL ISCHEMIC  
 19 EVENTS AND INFARCTION?  
 20 **A. YES.**  
 21 **Q.** WHAT WAS THAT OPINION?  
 22 **A. THAT OPINION WAS AND REMAINS THAT THERE IS, TO A**  
 23 **REASONABLE DEGREE OF CERTAINTY, A -- THAT ROSIGLITAZONE**  
 24 **TO A REASONABLE DEGREE OF MEDICAL CERTAINTY IS INDEED**  
 25 **BETTER THAN ABLE TO CAUSE OR CONTRIBUTE TO CAUSE -- DOES**

- 1 **I GUESS IS ABLE, DOES INDEED CAUSE OR CONTRIBUTE TO**  
 2 **CAUSE MYOCARDIAL INFARCTION AND MYOCARDIAL ISCHEMIA.**  
 3 **Q.** DID YOU REACH THAT OPINION ON CAUSATION AFTER  
 4 FINDING AN ASSOCIATION AND AFTER DISCUSSING THE  
 5 BRADFORD-HILL FACTORS WE ARE ABOUT TO GO INTO?  
 6 **A. ABSOLUTELY.**  
 7 **Q.** I DO WANT TO GET TO THE MULTIPLE BRADFORD-HILL  
 8 FACTORS, BUT THE ONE I'LL FOCUS ON IS BIOLOGICAL  
 9 MECHANISM. DID YOU FIND CONSISTENCY ACROSS THE STUDIES?  
 10 **A. YES.**  
 11 **Q.** DID YOU SEE THAT THE RESULTS WERE REPLICATED?  
 12 **A. YES.**  
 13 **Q.** DID YOU SEE THEY WERE REPLICATED ACROSS VARIOUS  
 14 POPULATIONS?  
 15 **A. YES.**  
 16 **Q.** WITH VARIOUS COMBINATIONS?  
 17 **A. YES.**  
 18 **Q.** IN VARIOUS INVESTIGATORS IN VARIOUS CLINICAL  
 19 CENTERS ACROSS THE WORLD?  
 20 **A. YES.**  
 21 **Q.** DID YOU EXAMINE THE ISSUE OF WHETHER OR NOT  
 22 THERE WAS A BIOLOGICALLY PLAUSIBLE MECHANISM BY WHICH  
 23 THIS DRUG COULD CAUSE EVENTS?  
 24 **A. YES.**  
 25 **Q.** ON YOUR REPORT AT PAGE EIGHT YOU DISCUSS SOME OF

- 1 THESE MECHANISMS, THE PRIMARY ONES BEING LIPID EFFECTS,  
 2 IS THAT RIGHT?  
 3 **A. YES.**  
 4 **Q.** YOU DISCUSS LDL CHOLESTEROL?  
 5 **A. YES.**  
 6 **Q.** YOU DISCUSS APO-B AT PAGE EIGHT.  
 7 **A. YES.**  
 8 **Q.** YOU DISCUSS NONHDL AT PAGE NINE?  
 9 **A. YES.**  
 10 **Q.** YOU DISCUSS LDL PARTICLE NUMBER AT PAGE TEN?  
 11 **A. YES.**  
 12 **Q.** AND DID YOU CONCLUDE THAT -- WELL, ARE EACH OF  
 13 THESE FACTORS, AN INCREASE IN LDL-C, AN INCREASE IN  
 14 APO-B, AN INCREASE IN NONHDL AND AN INCREASE IN LDL  
 15 PARTICLE NUMBER, ARE EACH OF THOSE ASSOCIATED WITH  
 16 INCREASED RISK IN MYOCARDIAL ISCHEMIC EVENTS AND  
 17 MYOCARDIAL INFARCTIONS?  
 18 **A. YES.**  
 19 **Q.** THAT IS WELL-KNOWN AND WELL ACCEPTED IN THE  
 20 SCIENTIFIC COMMUNITY?  
 21 **A. YES. YEAH, I THINK THERE IS QUITE A CONSENSUS**  
 22 **AMONG LIPIDOLOGISTS, SCIENTISTS WHO STUDY THESE, THAT**  
 23 **THESE ARE ALL ASSOCIATED AND A CONSENSUS THAT THEY ARE**  
 24 **CAUSALLY ASSOCIATED. SO THIS IT'S NOT JUST AN**  
 25 **ASSOCIATION, BUT THIS IS A CAUSE AND EFFECT ASSOCIATION.**

1 Q. SO, IT'S NOT JUST THE ASSOCIATION. IT'S  
 2 ASSOCIATION SOMEBODY HAS DONE A BIAS AND CONFOUNDING,  
 3 AND IT'S ALL THE WAY TO CAUSATION. AN INCREASE IN THESE  
 4 FACTORS, IT'S WELL ACCEPTED CAUSALLY -- IS RELATED  
 5 CAUSALLY AND CAUSES MYOCARDIAL ISCHEMIC EVENTS AND  
 6 INFARCTIONS?  
 7 A. YES.  
 8 Q. WHAT DOES AVANDIA DO TO EACH OF THESE MEASURES?  
 9 A. ELEVATES THEM ALL.  
 10 Q. THE EVALUATION IN LDL IN PARTICULAR, YOU  
 11 EXAMINED AND REQUESTED PATIENT LEVEL DATA FROM US?  
 12 A. YES.  
 13 Q. WHY DID YOU REQUEST PATIENT LEVEL DATA?  
 14 A. BECAUSE IT'S ALWAYS GOOD TO LOOK AT PATIENT  
 15 LEVEL DATA, BUT SPECIFICALLY THERE WAS A QUESTION  
 16 REGARDING THE RATIO OF BAD TO GOOD CHOLESTEROL OR BAD TO  
 17 GOOD PARTICLES. AND ONE OF THE QUESTIONS WAS, WAS ANY  
 18 INCREASE IN LDL CHOLESTEROL OR THINGS RELATED TO LDL  
 19 CHOLESTEROL COUNTERBALANCED BY AN INCREASE IN HDL  
 20 CHOLESTEROL. SO ONE OF THE QUESTIONS THAT I WAS ASKING  
 21 IN MY MIND WAS, IS THERE AN ASSOCIATION BETWEEN THESE  
 22 CHANGES? IN OTHER WORDS, COULD ONE PREDICT THE HDL  
 23 INCREASE BASED ON THE LDL INCREASE OR VICE VERSA, AND  
 24 THEREFORE COULD ONE SAY THAT IN A LARGE PERCENTAGE OF  
 25 THE MAJORITY OF INDIVIDUAL PATIENTS THAT THE ONE WOULD

1 DIRECTLY COUNTERBALANCE THE OTHER. AND THE REASON FOR  
 2 THAT IS, IT'S ONE THING TO LOOK AT THE AVERAGE DATA, BUT  
 3 IT'S MUCH MORE IMPORTANT TO LOOK AT INDIVIDUAL PATIENTS.  
 4 Q. SO ON THIS PAGE TEN OF YOUR REPORT, YOU DISCUSS  
 5 THE AVERAGE DATA SHOWING A RANGE OF 15 TO 20 PERCENT  
 6 INCREASE IN LDL CHOLESTEROL?  
 7 HONORABLE SANDRA MAZER MOSS: WHAT  
 8 PARAGRAPH IS THAT ON PAGE TEN? I'M SORRY.  
 9 MR. ZONIES: THAT IS QUITE ALL RIGHT.  
 10 HONORABLE SANDRA MAZER MOSS: THE LAST  
 11 PARAGRAPH.  
 12 MR. ZONIES: YES, IT IS, THE LAST  
 13 PARAGRAPH:  
 14 BY MR. ZONIES:  
 15 Q. AND THAT IS BECAUSE MOST OF THE STUDIES OR ALL  
 16 OF THE STUDIES IN THE LABEL ACTUALLY ONLY REPORT THE  
 17 AVERAGE, WHAT IS CALLED THE MEAN?  
 18 A. YES.  
 19 Q. SO YOU ARE GETTING ACROSS AN ENTIRE POPULATION  
 20 WHAT DOES THEIR LDL INCREASE AVERAGE?  
 21 A. YES.  
 22 Q. AND YOU WANTED TO LOOK AT THE PATIENT LEVEL  
 23 DATA?  
 24 A. YES.  
 25 Q. AND YOU DID IN FACT DO THAT?

1 A. YES.  
 2 Q. AND IN YOUR SUPPLEMENTAL REPORT AT PAGE TWO.  
 3 MR. ZONIES: TIMES UP? THREE MORE  
 4 SLIDES.  
 5 HONORABLE CYNTHIA M. RUFÉ: ALL RIGHT.  
 6 WE DID INTERRUPT SO WE ARE GOING TO GIVE JUST A FEW MORE  
 7 MINUTES.  
 8 HONORABLE SANDRA MAZER MOSS: MY BAD, AS  
 9 THEY SAY.  
 10 BY MR. ZONIES:  
 11 Q. IN YOUR SUPPLEMENTAL REPORT WHICH IS TAB TWO, AT  
 12 PAGE TWO, YOU DISCUSS SOME OF THE PATIENT LEVEL DATA  
 13 THAT YOU REVIEWED.  
 14 A. YES.  
 15 Q. AND IN THE PATIENT LEVEL DATA FOR LDL  
 16 CHOLESTEROL, WHAT DID YOU FIND? WHAT PERCENTAGE OF  
 17 PATIENTS WERE HAVING AN INCREASE IN THAT LETHAL  
 18 CHOLESTEROL?  
 19 A. NEARLY 3 QUARTERS, 72 PERCENT.  
 20 Q. WAS THAT DISCLOSED IN THE LABEL ANYWHERE?  
 21 A. NO.  
 22 Q. AND OF THOSE PEOPLE WHO HAD AN INCREASE, OF  
 23 THOSE PATIENTS WHO HAD AN INCREASE OF LDL, WHAT WAS  
 24 THEIR ACTUAL AVERAGE INCREASE?  
 25 A. IT WAS JUST BELOW 30 PERCENT.

1 Q. SO THE AVERAGE INCREASE IN THE PATIENTS WHO HAD  
 2 AN INCREASE WAS 30 PERCENT. WOULD THAT BE IMPORTANT TO  
 3 YOU AS A LIPIDOLOGIST?  
 4 A. YES.  
 5 Q. THAT WAS NOT REPORTED TO YOU BY GSK IN THE  
 6 LABEL?  
 7 A. NO.  
 8 Q. DID YOU THEN ALSO LOOK AT WHETHER OR NOT -- THE  
 9 CORRELATION BETWEEN THE INCREASE IN LDL AND HDL?  
 10 A. YES.  
 11 Q. AND WHAT DID YOU FIND?  
 12 A. THERE WAS NO CORRELATION WHATSOEVER.  
 13 Q. THAT IS DISCUSSED IN YOUR SUPPLEMENTAL REPORT AT  
 14 PAGE THREE?  
 15 A. YES.  
 16 Q. AND WHAT DOES NO CORRELATION MEAN?  
 17 A. IT MEANS THAT ONE CANNOT PREDICT THE CHANGE OF  
 18 THE ONE WITH THE CHANGE OF THE OTHER, SO THAT  
 19 INDIVIDUALS WHO HAVE A STRIKING INCREASE IN LDL MAY HAVE  
 20 EITHER AN INCREASE IN HDL OR POSSIBLY EVEN A DECREASE IN  
 21 HDL.  
 22 Q. WERE YOU SEEING -- WHEN YOU LOOKED AT THE  
 23 PATIENT LEVEL DATA IN YOUR SUPPLEMENTAL REPORT AT 3, YOU  
 24 DISCUSSED THAT YOU WERE ACTUALLY FINDING A PORTION OF  
 25 THE PATIENT POPULATIONS WHO WERE HAVING A DECREASE IN

1 HDL?

2 **A. YES.**

3 **Q. AND WHAT PORTION WAS THAT POPULATION AT MOST?**

4 **A. LET'S SEE, IT'S ON HERE. A QUARTER.**

5 **Q. SO ABOUT 25 PERCENT OF THE PATIENTS WERE HAVING**

6 **A DECREASE IN THEIR HDL?**

7 **A. YES.**

8 **Q. WAS THAT REPORTED IN THE AVANDIA LABEL?**

9 **A. NO. THERE HAD BEEN IN THE LITERATURE SOME CASE**

10 **REPORTS OF PEOPLE -- EXTREME DROPS IN HDL, BUT THIS WAS**

11 **THE FIRST TIME THAT I HAD ACCESS TO DATA TO SHOW IN A**

12 **BROAD POPULATION THAT AS MANY AS A QUARTER OF THEM MIGHT**

13 **HAVE A DECREASE IN HDL.**

14 **Q. I WANT TO BE CLEAR AND OPEN WITH THIS. DID YOU**

15 **ACTUALLY INDEPENDENTLY CREATE THE EXCEL SPREADSHEET THAT**

16 **HAD THE DATA IN IT?**

17 **A. A PLAINTIFF COUNSEL ENTERED THE DATA, CREATED**

18 **THE SPREADSHEET, DID THE CALCULATION. I DID THE**

19 **ANALYSIS OF THE DATA.**

20 **Q. AND SO YOU ARE COMFORTABLE THAT YOUR OPINION IS**

21 **BASED UPON YOUR ANALYSIS?**

22 **A. IT IS DEFINITELY MY ANALYSIS, NOT PLAINTIFF**

23 **COUNSEL, AND I DID CHECK TO SEE IF THERE WAS EVIDENCE**

24 **FOR ADEQUACY OF THE DATA, BASED ON REVIEW OF THE PRIMARY**

25 **NUMBERS THAT HAD BEEN ENTERED AND THEN REVIEW OF THE**

1 **FIGURES THAT CAME OUT TO MAKE SURE THAT THERE WAS IN**

2 **FACT EVIDENCE FOR QUALITY CONTROL.**

3 **Q. AND HAVE YOU SUBSEQUENT TO THAT ACTUALLY HAD NOW**

4 **ACCESS TO THE UNDERLYING ACTUAL GSK DATA SETS?**

5 **A. YES.**

6 **Q. AND HAVE YOU HAD A BIOSTATISTICIAN RUN THOSE**

7 **NUMBERS?**

8 **A. YES.**

9 **Q. DID THAT BIOSTATISTICIAN'S RESULTS CONFIRM YOUR**

10 **ORIGINAL RESULTS LARGELY?**

11 **A. YES.**

12 **Q. YOU ALSO DISCUSS IN YOUR SUPPLEMENTAL REPORT AT**

13 **PAGE 4 APOLIPOPROTEIN B?**

14 **A. YES.**

15 **Q. AND AVANDIA INCREASES THAT?**

16 **A. YES.**

17 **Q. AND AGAIN IN A LARGE PERCENTAGE OF THE**

18 **POPULATION?**

19 **A. MORE THAN HALF, CLOSE TO TWO-THIRDS.**

20 **Q. WELL SETTLED THAT THAT INCREASES RISK OF**

21 **MYOCARDIAL ISCHEMIA AND RISK OF MYOCARDIAL INFARCTION?**

22 **A. IT IS PROBABLY THE SINGLE STRONGEST CAUSAL**

23 **FACTOR FOR ATHEROGENESIS.**

24 **Q. WHEN YOU LOOKED AT THE HDL DATA, DID YOU LOOK AT**

25 **THE DATA FOR -- HDL BEING THE HAPPY CHOLESTEROL, DID YOU**

1 **ALSO LOOK AT THE DATA FOR APOLIPOPROTEIN A 1 WHICH IS**

2 **RELATED TO HDL?**

3 **A. APO-A 1 IS THE MAJOR PROTEIN IN THE HDL**

4 **PARTICLE. IT APPEARS IN MANY STUDIES TO BE A STRONGER**

5 **PREDICTOR OF RISK THAN IS HDL CHOLESTEROL. AND I WAS**

6 **CONCERNED TO LEARN IN THE PROCESS OF INVESTIGATION OF MY**

7 **STUDIES FOR THIS CASE THAT APO-A 1 LEVELS DECREASED. I**

8 **HAD NOT BEEN AWARE OF THAT PREVIOUSLY.**

9 **Q. AND IS THE APO-B TO APO-A 1 RATIO A GOOD**

10 **PREDICTOR OF RISK?**

11 **A. IN MANY STUDIES IT'S A MUCH STRONGER THAN THE**

12 **LDL CHOLESTEROL OR TOTAL CHOLESTEROL TO HDL CHOLESTEROL**

13 **RATIO.**

14 **Q. AND AVANDIA IMPACTS THAT RATIO IN A POSITIVE OR**

15 **NEGATIVE WAY?**

16 **A. IN THIS CASE, IN THE VAST MAJORITY OF CASES**

17 **ADVERSELY.**

18 **Q. AND THEN THE LAST BIOMARKER AND THEN WE WILL BE**

19 **FINISHED THAT I WILL TALK ABOUT, BUT THERE ARE OTHERS IN**

20 **YOUR REPORT, BUT IN YOUR MAIN REPORT AT PAGE 18, YOU**

21 **DISCUSS LP-PLA-I.**

22 **A. YES.**

23 **Q. AND I PRESENT SOME BASIC INFORMATION ON THAT,**

24 **BUT WHAT IS YOUR UNDERSTANDING OF WHAT AVANDIA DOES TO**

25 **THIS CARDIAC INFLAMMATORY MARKER?**

1 **A. IT INCREASES THE LEVELS.**

2 **Q. AND IN YOUR REPORT AT PAGE 18 YOU DISCUSS THAT**

3 **LP-PLA2 DESTABILIZES ATHEROSCLEROTIC PLAQUES?**

4 **A. IT IS A PROINFLAMMATORY AND PRO-OXIDATIVE FACTOR**

5 **AND THERE IS EVIDENCE THAT IT DOES DESTABILIZE PLAQUES.**

6 **Q. AND IF A PLAQUE RUPTURES BECAUSE OF**

7 **DESTABILIZATION, WHAT IS THE RUPTURE OF A PLAQUE? WHAT**

8 **DOES THAT MEAN?**

9 **A. WELL, THERE IS GROWTH -- THERE IS THICKENING OF**

10 **THE WALL AND THEN THERE IS THE CREATION OF THE**

11 **ATHEROSCLEROTIC PLAQUE, MEANING THAT THERE IS LIPID AND**

12 **NECROTIC DEAD MATERIAL IN THE MIDDLE OF THIS WALL**

13 **THICKENING. AND THEN THERE IS A TENDENCY FOR A BREAK IN**

14 **THIS PLAQUE. AND AS THE BREAK OCCURS, THEN THERE IS A**

15 **LARGE CLOT. AND IT APPEARS THAT THE CLOT IS ACTUALLY**

16 **THE CAUSE OF THE VAST MAJORITY OF CARDIOVASCULAR EVENTS.**

17 **SO IT'S -- THE INITIAL STAGES, THE CREATION OF THE**

18 **PLAQUE, THE ADVANCEMENT OF THE PLAQUE, THE RUPTURE OF**

19 **THE PLAQUE, THAT ALL PRECEDE THE CLINICAL EVENT.**

20 **Q. SO IF WE THINK OF A CORONARY ARTERY AS A HOSE, A**

21 **PLAQUE IS A SORT OF LIKE A SOFT BAKED POTATO ON THE SIDE**

22 **-- OF THE INSIDE OF THE HOSE?**

23 **A. IT'S A COLLECTION OF DEAD MATERIAL IN THE WALL,**

24 **AND SO IT'S DISTINCT FROM WALL THICKENING.**

25 **Q. IF THAT RUPTURES, WHAT EVENT OCCURS?**

1 **A. IT'S USUALLY EITHER UNSTABLE ANGINA, MYOCARDIAL**  
2 **INFARCTION OR SUDDEN DEATH.**  
3 **Q.** SO IT'S EITHER A MYOCARDIAL ISCHEMIC EVENT OR  
4 MYOCARDIAL INFARCTION OR DEATH?  
5 **A. OR SUDDEN CARDIAC DEATH.**  
6 HONORABLE SANDRA MAZER MOSS: WE DON'T  
7 GET TO CHOOSE.  
8 THE WITNESS: NO.  
9 BY MR. ZONIES:  
10 **Q.** IN YOUR FINDINGS AND IN YOUR OPINION, AVANDIA  
11 INCREASES THIS CARDIAC ENZYME?  
12 **A. YES.**  
13 **Q.** AND IT'S A BIOLOGICALLY PLAUSIBLE MECHANISM?  
14 **A. YES.**  
15 **Q.** BY WHICH AVANDIA COULD CAUSE MYOCARDIAL ISCHEMIC  
16 EVENTS AND MYOCARDIAL INFARCTIONS?  
17 **A. YES. AND IT IS WELL ESTABLISHED WITH SCIENTIFIC**  
18 **STUDIES AND THERE IS A GOOD CONSENSUS AMONG**  
19 **LIPIDOLOGISTS AND PREVENTIVE CARDIOLOGISTS THAT THIS IS**  
20 **INDEED A CAUSAL FACTOR FOR CARDIOVASCULAR EVENTS.**  
21 **Q.** AND BASED UPON ALL THESE BIOLOGICAL MECHANISMS  
22 AND YOUR RESEARCH ON THE VARIOUS STUDIES AND FINDING AN  
23 ASSOCIATION, DID YOU REACH A CONCLUSION TO A REASONABLE  
24 DEGREE OF MEDICAL PROBABILITY ABOUT WHETHER OR NOT THE  
25 USE OF AVANDIA CAUSES MYOCARDIAL ISCHEMIC EVENTS AND

1 MYOCARDIAL INFARCTION?  
2 **A. YES.**  
3 **Q.** DOES IT?  
4 **A. YES, IT DOES.**  
5 **Q.** THANK YOU, DOCTOR.  
6 HONORABLE CYNTHIA M. RUFÉ:  
7 CROSS-EXAMINE. I NOTE THAT THE STENOGRAPHER NEEDS A  
8 BREAK, SO I'M GOING TO JUST SIT HERE AND --  
9 (RECESS.)  
10 MS. BENNES: GOOD AFTERNOON, YOUR HONORS.  
11 MY NAME IS CINDY BENNES. I'M WITH THE LAW FIRM OF  
12 PHILLIPS LYTTLE.  
13 HONORABLE SANDRA MAZER MOSS: GOOD  
14 AFTERNOON.  
15 CROSS EXAMINATION  
16 BY MS. BENNES:  
17 **Q.** GOOD AFTERNOON, DR. BRINTON.  
18 **A. GOOD AFTERNOON.**  
19 **Q.** WE MET BEFORE, CORRECT?  
20 **A. YES.**  
21 **Q.** AND WE SPENT A LONG DAY WHEN -- DURING YOUR  
22 DEPOSITION, CORRECT?  
23 **A. YES.**  
24 **Q.** HOPEFULLY THIS WILL BE MUCH, MUCH SHORTER.  
25 DID I UNDERSTAND -- DID I HEAR YOU TO

1 TESTIFY THAT THERE IS A CLEAR CAUSAL ASSOCIATION BETWEEN  
2 INCREASING LDL AND HEART ATTACK?  
3 **A. YES.**  
4 **Q.** THAT IS NOT WHAT YOU TESTIFIED TO AT YOUR  
5 DEPOSITION, IS IT, SIR?  
6 **A. I WOULD BE GLAD TO REVIEW WHAT I SAID IN MY**  
7 **DEPOSITION.**  
8 **Q.** ISN'T IT TRUE THAT DURING YOUR DEPOSITION YOU  
9 TESTIFIED THAT JUST BECAUSE SOMETHING INCREASES LDL, IT  
10 DOES NOT MEAN IT INCREASES CARDIOVASCULAR RISK?  
11 **A. THERE IS A CLEAR ASSOCIATION, BUT IT'S NOT**  
12 **ALWAYS THE CASE.**  
13 **Q.** I'M CONFUSED.  
14 ARE YOU SAYING THAT THERE IS A CAUSAL, A  
15 CLEAR CAUSAL ASSOCIATION BETWEEN INCREASING LDL AND  
16 HEART ATTACK LIKE YOU TESTIFIED IN RESPONSE TO MR.  
17 ZONIES' QUESTION OR IS YOUR TESTIMONY WHAT YOU TOLD ME  
18 IN APRIL, THAT JUST BECAUSE SOMETHING INCREASES LDL, IT  
19 DOES NOT MEAN IT INCREASES CARDIOVASCULAR RISK?  
20 **A. NOT NECESSARILY.**  
21 **Q.** SO YOU ARE GOING TO TAKE BACK WHAT YOU SAID TO  
22 MR. ZONIES, IT'S NOT -- THERE ISN'T A CLEAR CAUSAL  
23 ASSOCIATION BETWEEN INCREASING LDL AND INCREASING HEART  
24 ATTACK?  
25 **A. THERE IS A CLEAR ASSOCIATION IN THE VAST**

1 **MAJORITY OF CASES.**  
2 **Q.** BUT IT'S NOT NECESSARILY CAUSAL?  
3 **A. NOT ALWAYS. THERE CAN BE EXCEPTIONS TO THAT**  
4 **RULE.**  
5 **Q.** AND YOU AGREE AS YOU TESTIFIED IN APRIL THAT  
6 THERE IS NO RANDOMIZED TRIAL, NO RANDOMIZED CLINICAL  
7 TRIAL WHICH FINDS A STATISTICALLY SIGNIFICANT INCREASE  
8 IN PROGRESSION OF ATHEROSCLEROSIS WITH AVANDIA, CORRECT?  
9 **A. YES.**  
10 **Q.** AND YOU ALSO AGREE THAT THERE IS NO RANDOMIZED  
11 CLINICAL TRIAL THAT REPORTS A STATISTICALLY SIGNIFICANT  
12 ASSOCIATION BETWEEN AVANDIA AND MI, IS THAT RIGHT?  
13 **A. YES, THAT IS CORRECT. MAY I JUST QUALIFY MY**  
14 **PRIOR ANSWER JUST TO SAY THAT --**  
15 **Q.** I HAVE LIMITED TIME AND I WOULD REALLY LIKE TO  
16 STICK TO THE REQUEST FROM THE COURT TO KEEP TO MY TIME.  
17 **A. CERTAINLY. ATHEROSCLEROSIS AS DEFINED.**  
18 **Q.** NOW, YOU APPEARED BEFORE THE UTAH STATE MEDICAID  
19 PHARMACY AND THERAPEUTICS COMMITTEE IN OCTOBER OF 2007,  
20 IS THAT CORRECT?  
21 **A. YES.**  
22 **Q.** AND PHARMACY AND THERAPEUTICS, THE ABBREVIATION  
23 FOR THAT IS P&T, RIGHT?  
24 **A. YES.**  
25 **Q.** SO IF I SAY P&T MEETING, YOU WILL UNDERSTAND

1 WHAT I'M TALKING ABOUT, RIGHT?

2 **A. YES.**

3 **Q.** AND THE TOPIC FOR DISCUSSION AT THAT MEETING IN

4 OCTOBER 2007 WAS AVANDIA AND ACTOS, CORRECT?

5 **A. YES.**

6 **Q.** AND YOU HAVE BEEN REFERRING TO AVANDIA AS

7 ROSIGLITAZONE AND YOU HAVE BEEN REFERRING TO ACTOS AS

8 PIOGLITAZONE, CORRECT?

9 **A. YES.**

10 **Q.** AND GENERALLY SPEAKING -- YOU'VE BEEN A MEMBER

11 OF OTHER P&T COMMITTEES OVER THE COURSE OF YOUR CAREER,

12 CORRECT?

13 **A. YES.**

14 **Q.** AND IS IT FAIR TO SAY THAT A P&T COMMITTEE

15 REVIEWS INFORMATION ABOUT MEDICATIONS TO DETERMINE WHAT

16 MEDICATIONS SHOULD BE AVAILABLE TO PATIENTS SERVED BY

17 THE PARTICULAR P&T COMMITTEE?

18 **A. YES.**

19 **Q.** AND A HOSPITAL P&T COMMITTEE WOULD HELP

20 DETERMINE WHAT MEDICATIONS WILL BE USED IN THE HOSPITAL,

21 RIGHT?

22 **A. YES.**

23 **Q.** AND LIKEWISE THE UTAH MEDICAID P&T COMMITTEE

24 DETERMINES WHICH MEDICATIONS WILL BE COVERED BY MEDICAID

25 IN THE STATE OF UTAH, RIGHT?

1 **A. YES.**

2 **Q.** A FORMULARY IS THE LIST OF MEDICATIONS THAT ARE

3 APPROVED FOR USE BY A P&T COMMITTEE, CORRECT?

4 **A. YES.**

5 **Q.** SO WE HAVE THE TERMINOLOGY DOWN.

6 WHEN YOU APPEARED BEFORE THE UTAH P&T

7 COMMITTEE IN OCTOBER OF 2007, YOU SPOKE ABOUT AVANDIA

8 AND ACTOS, TRUE?

9 **A. YES.**

10 **Q.** AND IS IT FAIR TO SAY THAT PHYSICIANS WHO APPEAR

11 BEFORE P&T COMMITTEES SHOULD BRING ALL OF THEIR TRAINING

12 AND EXPERTISE TO BEAR AND MAKE RECOMMENDATIONS BASED ON

13 THEIR BEST SCIENTIFIC JUDGMENTS?

14 **A. YES.**

15 **Q.** IS IT FAIR TO SAY THAT WHEN YOU APPEARED BEFORE

16 THE UTAH P&T COMMITTEE, YOU TOLD THE TRUTH?

17 **A. YES.**

18 **Q.** YOU GAVE YOUR HONEST OPINIONS BASED ON YOUR BEST

19 ASSESSMENT OF THE SCIENTIFIC LITERATURE?

20 **A. YES.**

21 **Q.** AND YOU WERE VERY FAMILIAR WITH THE LITERATURE

22 CONCERNING AVANDIA AND ACTOS AS OF OCTOBER 2007?

23 **A. NOWHERE NEAR AS FAMILIAR AS I AM TODAY BUT**

24 **SOMEWHAT FAMILIAR, YES.**

25 **Q.** I BELIEVE IN RESPONSE TO QUESTIONS FROM MR.

1 ZONIES YOU INDICATED THAT YOU FOLLOWED THE LITERATURE AS

2 A DIABETOLOGIST BECAUSE IT'S SO RELEVANT AND CRITICAL TO

3 YOUR PRACTICE, CORRECT?

4 **A. YES.**

5 **Q.** IS IT FAIR TO SAY THAT YOU ARE AN EXPERT IN

6 DIABETES AND YOU MAKE IT YOUR BUSINESS TO STAY CURRENT

7 WITH THE LITERATURE?

8 **A. YES.**

9 **Q.** WOULD YOU ALSO AGREE THAT YOU WOULD NEVER

10 RECOMMEND THAT A MEDICATION BE AVAILABLE FOR USE BY

11 PATIENTS IN UTAH OR ANYWHERE IF YOU BELIEVED THAT THE

12 BENEFITS WERE OUTWEIGHED BY THE RISKS OF THAT

13 MEDICATION?

14 **A. YES.**

15 **Q.** WOULD YOU ALSO AGREE THAT YOU WOULD NEVER

16 RECOMMEND THAT A DIABETES MEDICATION BE AVAILABLE FOR

17 USE BY PATIENTS IF YOU HONESTLY BELIEVED THAT THE

18 MEDICATION CAN CAUSE HEART ATTACK?

19 **A. NO.**

20 **Q.** CAN YOU GIVE ME AN EXAMPLE OF A MEDICATION THAT

21 YOU WOULD RECOMMEND FOR USE BY PATIENTS WHEN IT'S

22 CAPABLE OF CAUSING HEART ATTACK?

23 **A. AVANDIA.**

24 **Q.** SO YOU WOULD RECOMMEND THAT A P&T COMMITTEE

25 ENDORSE THE USE OF AVANDIA KNOWING THAT IT CAN CAUSE

1 HEART ATTACK?

2 **A. AT THE TIME I TESTIFIED TO THAT GROUP, THERE WAS**

3 **EVIDENCE AVAILABLE THAT AVANDIA HAD THE POTENTIAL TO**

4 **CAUSE HEART ATTACK. THERE WAS EVIDENCE. THE EVIDENCE**

5 **WAS NOT CONVINCING IN MY MIND. I DID NOT BELIEVE AT**

6 **THAT POINT IN TIME THAT AVANDIA DID INDEED CAUSE HEART**

7 **ATTACK, BUT THERE WAS THAT POTENTIAL. THE REASON THAT I**

8 **SPOKE IN FAVOR OF THAT DRUG TO STAY ON THE FORMULARY WAS**

9 **BECAUSE AT THAT TIME I WAS UNCERTAIN WHETHER OR NOT**

10 **AVANDIA DID INDEED CAUSE AN INCREASE IN HEART ATTACK AND**

11 **I WAS WELL AWARE OF OTHER BENEFICIAL EFFECTS OF THAT**

12 **DRUG.**

13 **Q.** DR. BRINTON, I REALLY HAVE LIMITED TIME. AND I

14 WOULD PLEASE ASK YOU TO RESPOND VERY DIRECTLY TO MY

15 QUESTIONS.

16 YOU DID NOT BELIEVE IN OCTOBER 2007 THAT

17 AVANDIA WAS CAPABLE OF CAUSING HEART ATTACK, TRUE?

18 **A. I BELIEVED THAT IT WAS CAPABLE OF CAUSING. I**

19 **DID NOT BELIEVE THAT IT CAUSED BUT CAPABLE, YES.**

20 **CAUSING, NO. THERE IS A DIFFERENCE.**

21 **Q.** YOU DID NOT BELIEVE IN OCTOBER OF 2007 THAT

22 AVANDIA CAUSES HEART ATTACK?

23 **A. CORRECT, I DID NOT.**

24 **Q.** IF YOU DID BELIEVE THAT AVANDIA CAUSES HEART

25 ATTACK, YOU WOULD NOT HAVE RECOMMENDED THAT THE P&T

- 1 COMMITTEE PERMIT ITS USE IN RESIDENTS IN UTAH, CORRECT?
- 2 **A. CORRECT.**
- 3 **Q.** WOULD YOU AGREE THAT IN YOUR STATEMENTS TO THE
- 4 UTAH MEDICAID P&T COMMITTEE IN OCTOBER 2007 YOU SAID
- 5 RANDOMIZED CONTROLLED TRIALS ARE AT THE TOP OF THE
- 6 HIERARCHY OF SCIENTIFIC DATA?
- 7 **A. YES.**
- 8 **Q.** WOULD YOU AGREE THAT YOU TOLD THE UTAH P&T
- 9 COMMITTEE THAT THE RECORD TRIAL, WHICH AT THE TIME WAS
- 10 THE INTERIM RECORD TRIAL, WAS THE SINGLE BEST PIECE OF
- 11 EVIDENCE WITH REGARD TO CORONARY ATHEROSCLEROTIC EVENTS
- 12 WITH AVANDIA?
- 13 **A. YES.**
- 14 **Q.** AND CORONARY ATHEROSCLEROTIC EVENTS, WHICH IS A
- 15 MOUTHFUL, HEART ATTACK IS A CORONARY ATHEROSCLEROTIC
- 16 EVENT, CORRECT?
- 17 **A. YES.**
- 18 **Q.** WOULD YOU AGREE THAT WHEN YOU SPOKE BEFORE THE
- 19 UTAH P&T COMMITTEE, YOU SAID TO YOUR PEERS, THAT YOU
- 20 WERE, QUOTING, A LITTLE PERPLEXED, CLOSE QUOTE, ABOUT
- 21 WHY THE 2007 FDA ADVISORY COMMITTEE THOUGHT THERE WAS AN
- 22 INCREASED RISK OF CARDIOVASCULAR EVENTS WITH AVANDIA
- 23 BECAUSE YOUR OPINION AT THE TIME WAS THAT THE SINGLE
- 24 BEST PIECE OF EVIDENCE, INTERIM RECORD, SUGGESTS IT'S
- 25 NOT THE CASE?

- 1 **A. THAT IS CORRECT.**
- 2 **Q.** AND YOUR OPINION AS EXPRESSED TO THE UTAH P&T
- 3 COMMITTEE IN OCTOBER 2007 WAS THAT AVANDIA HAD CERTAIN
- 4 ADVANTAGES OVER ACTOS FOR SOME PATIENTS. TRUE?
- 5 **A. THEORETICAL ADVANTAGES, YES.**
- 6 **Q.** AND YOUR OPINION AS EXPRESSED TO THE UTAH P&T
- 7 COMMITTEE IN OCTOBER OF 2007 WAS THAT AVANDIA PROBABLY
- 8 WAS NO DIFFERENT THAN ANY OTHER ANTIDIABETIC AGENT IN
- 9 TERMS OF ITS EFFECT ON CORONARY ATHEROSCLEROSIS, TRUE?
- 10 **A. ANY OTHER EXCEPT FOR PIOGLITAZONE, YES.**
- 11 **Q.** SIR, THAT IS NOT WHAT YOU SAID AND I'M HAPPY TO
- 12 PULL UP THE -- YOUR STATEMENT IF YOU LIKE?
- 13 **A. OKAY.**
- 14 MS. BENNES: COULD YOU PULL UP THE UTAH
- 15 TAPE, PAGE SEVEN, LINE 20.
- 16 (VIDEO PLAYED.)
- 17 DR. BRINTON: AND MY OWN TAKE ON THIS IS
- 18 THAT ROSIGLITAZONE IS PROBABLY NO DIFFERENT, PROBABLY NO
- 19 DIFFERENT THAN ANY OTHER ANTIDIABETIC AGENT IN TERMS OF
- 20 ITS EFFECT ON CORONARY ATHEROSCLEROSIS.
- 21 (VIDEO ENDED.)
- 22 BY MS. BENNES:
- 23 **Q.** THAT WAS YOUR TESTIMONY -- THAT WAS YOUR
- 24 STATEMENT BEFORE THE COMMITTEE, CORRECT?
- 25 **A. IT WAS.**

- 1 **Q.** AND WHILE YOU EXPRESSED WHAT YOU DESCRIBED AS
- 2 SOME CAVEATS, YOUR BOTTOM LINE WAS: BUT I THINK THAT
- 3 ACROSS THE BOARD IT, REFERRING TO AVANDIA, PROBABLY HAS
- 4 THE SAME EFFECT ON CARDIOVASCULAR EVENTS AS DO NEARLY
- 5 ALL THE OTHER DIABETIC DRUGS, WHICH IS GENERALLY FAIRLY
- 6 NEUTRAL. THAT WAS YOUR STATEMENT TO THE P&T COMMITTEE
- 7 IN OCTOBER 2007, WASN'T IT?
- 8 **A. NEARLY REFERS TO PIOGLITAZONE AS AN EXCEPTION.**
- 9 **Q.** SIR, WAS THAT YOUR STATEMENT TO THE P&T
- 10 COMMITTEE IN OCTOBER 2007?
- 11 **A. YES.**
- 12 **Q.** THANK YOU.
- 13 AND YOU KNEW AT THE TIME, AS YOU JUST
- 14 TESTIFIED TO MR. ZONIES IN RESPONSE TO HIS QUESTIONS,
- 15 THAT AVANDIA INCREASED LDL, CORRECT?
- 16 **A. YES.**
- 17 **Q.** AND YOU KNEW AT THAT TIME THAT THE COMPARABLE
- 18 LIPID PROFILE BETWEEN ACTOS AND AVANDIA WITH REGARD TO
- 19 HDL, WITH REGARD TO LDL, AND WITH REGARD TO
- 20 TRIGLYCERIDES BASED ON YOUR TESTIMONY HAD AVANDIA COME
- 21 OUT NOT AS GOOD AS ACTOS ON ALL THOSE PARAMETERS,
- 22 CORRECT?
- 23 **A. THAT IS CORRECT.**
- 24 **Q.** YOU KNEW THAT WHEN YOU TESTIFIED, WHEN YOU SPOKE
- 25 BEFORE THE UTAH P&T COMMITTEE, DIDN'T YOU?

- 1 **A. AND THAT IS WHY I SAID THAT PIOGLITAZONE WOULD**
- 2 **BE MY CHOICE.**
- 3 **Q.** YOUR OPINION THAT YOU EXPRESSED TO THE UTAH P&T
- 4 COMMITTEE WAS THAT YOU RECOMMENDED THAT AVANDIA SHOULD
- 5 BE ON THE FORMULARY BECAUSE IT WOULD BE ADVANTAGEOUS FOR
- 6 BOTH CLINICIANS AND PATIENTS IN UTAH, CORRECT?
- 7 **A. AS AN ALTERNATIVE TO PIOGLITAZONE, YES.**
- 8 MS. BENNES: COULD YOU PLEASE BRING UP
- 9 THE, HIS TESTIMONY -- NOT TESTIMONY, I KEEP SAYING THAT,
- 10 PAGE TEN, LINE NINE.
- 11 (VIDEO PLAYED.)
- 12 DR. BRINTON: BUT I WOULD HOPE THAT YOU
- 13 WOULD GIVE US BOTH BECAUSE I THINK THAT'S ADVANTAGEOUS
- 14 TO THE CLINICIAN AND THE PATIENT AND THAT WOULD BE MY
- 15 RECOMMENDATION.
- 16 (VIDEO ENDED.)
- 17 BY MS. BENNES:
- 18 **Q.** BY BOTH, SIR, YOU MEAN ACTOS AND AVANDIA,
- 19 CORRECT?
- 20 **A. YES.**
- 21 **Q.** WHEN YOU PRESENTED YOUR INFORMED OPINIONS TO THE
- 22 UTAH P&T COMMITTEE IN OCTOBER 2007, YOU KNEW ABOUT THE
- 23 INTERIM RECORD RESULTS, TRUE?
- 24 **A. I WAS AWARE OF THE RECORD RESULTS, YES.**
- 25 **Q.** YOU KNEW ABOUT THE DESIGN OF THE RECORD STUDY

- 1 BECAUSE THE DESIGN OF THE RECORD STUDY HAD BEEN  
 2 PUBLISHED YEARS EARLIER, CORRECT?  
 3 **A. I HAD NOT FULLY CONSIDERED THE DESIGN OF RECORD.**  
 4 **Q.** THEY WERE AVAILABLE FOR YOU TO CONSIDER, RIGHT,  
 5 SIR?  
 6 **A. I HAD NOT FULLY CONSIDERED THEM, BUT YES, THEY**  
 7 **WERE AVAILABLE TO ME.**  
 8 **Q.** THANK YOU.  
 9 YOU KNEW ABOUT THE DREAM STUDY, CORRECT?  
 10 **A. YES.**  
 11 **Q.** AND I'M NOT SURE IF I HEARD YOUR RESPONSES TO  
 12 MR. ZONIES' QUESTIONS CORRECTLY BEFORE, BUT DREAM WAS  
 13 PUBLISHED IN 2006, CORRECT?  
 14 **A. PROBABLY, I DON'T RECALL EXACTLY WHEN.**  
 15 **Q.** I THINK THE SUGGESTION IN YOUR QUESTIONING AND  
 16 RESPONSES BEFORE WAS THAT DREAM WAS PUBLISHED IN 2007.  
 17 **A. THAT MIGHT HAVE BEEN THE CASE. I BECAME MORE**  
 18 **CLEARLY AWARE OF IT IN 2007. THAT IS WHEN I FIRST**  
 19 **MENTIONED THIS TO A GSK REPRESENTATIVE AND I SUPPOSE IT**  
 20 **WAS AT THE TIME OF THE PUBLICATION OF THE OTHER STUDY.**  
 21 **Q.** YOU WON'T DISAGREE WITH ME THAT DREAM WAS  
 22 PUBLISHED IN 2006?  
 23 **A. NO, I WON'T DISAGREE.**  
 24 **Q.** YOU WON'T DISAGREE WITH ME THAT ADOPT WAS ALSO  
 25 PUBLISHED IN 2006?

- 1 **A. OKAY.**  
 2 **Q.** AND PROACTIVE WAS PUBLISHED IN 2005, CORRECT?  
 3 **A. OKAY.**  
 4 MR. BENNES: FOR THE BENEFIT OF YOUR  
 5 HONORS, PROACTIVE WAS THE STUDY WITH ACTOS.  
 6 BY MS. BENNES:  
 7 **Q.** CORRECT?  
 8 **A. YES.**  
 9 **Q.** AND AS OF THE TIME YOU SPOKE BEFORE THE UTAH P&T  
 10 COMMITTEE, YOU ABOUT THE JULY 30TH, 2007 FDA ADVISORY  
 11 COMMITTEE PROCEEDINGS, CORRECT?  
 12 **A. YES.**  
 13 **Q.** IN FACT YOU TALKED ABOUT THEM AT THE P&T  
 14 MEETING?  
 15 **A. YES.**  
 16 **Q.** YOU KNEW ABOUT THE VOTES, CORRECT?  
 17 **A. YES.**  
 18 **Q.** YOU KNEW THAT AT THE FDA ADVISORY COMMITTEE  
 19 MEETING THAT THEY PRESENTED DATA FROM GSK AND FDA'S  
 20 META-ANALYSIS, DIDN'T YOU?  
 21 **A. YES.**  
 22 **Q.** AND WHEN YOU SPOKE BEFORE THE UTAH P&T  
 23 COMMITTEE, YOU KNEW ABOUT THE NISSEN META-ANALYSIS,  
 24 CORRECT?  
 25 **A. YES.**

- 1 **Q.** YOU KNEW THAT AVANDIA WAS ASSOCIATED WITH HEART  
 2 FAILURE, CORRECT?  
 3 **A. YES.**  
 4 **Q.** AND YOU KNEW THAT AVANDIA INCREASED LDL AS WE  
 5 TALKED ABOUT BEFORE?  
 6 **A. YES.**  
 7 **Q.** AND YOU KNEW ABOUT THE GOLDBERG STUDY WHICH WAS  
 8 PUBLISHED IN 2005, MAYBE THE MOST WELL-KNOWN STUDY  
 9 COMPARING THE LIPID PROFILE OF ACTOS TO AVANDIA,  
 10 CORRECT?  
 11 **A. YES.**  
 12 **Q.** THE GOLDBERG STUDY, I WOULD EXPECT IN YOUR VIEW  
 13 MAKES IT CLEAR THAT THE LIPID PROFILE FOR AVANDIA IS  
 14 MUCH LESS FAVORABLE THAN THE LIPID PROFILE FOR ACTOS?  
 15 **A. YES.**  
 16 **Q.** YOU KNEW ABOUT THAT WHEN YOU SPOKE TO THE UTAH  
 17 P&T COMMITTEE, CORRECT?  
 18 **A. YES.**  
 19 **Q.** YOU KNEW ALL OF THESE THINGS THAT I JUST  
 20 MENTIONED IN THE SUMMER OF 2007, DIDN'T YOU, SIR?  
 21 **A. YES.**  
 22 **Q.** NOW, UPON QUESTIONING FROM MR. ZONIES, YOU  
 23 TALKED ABOUT THE SINGH META-ANALYSIS AND THE LINCOFF  
 24 META-ANALYSIS, CORRECT?  
 25 **A. YES.**

- 1 **Q.** AND ARE YOU AWARE, SIR, THAT THOSE META-ANALYSES  
 2 WERE PUBLISHED IN JAMA, THE JOURNAL OF THE AMERICAN  
 3 MEDICAL ASSOCIATION, IN SEPTEMBER OF 2007?  
 4 **A. YES.**  
 5 **Q.** SO YOU WERE AWARE OF BOTH THE SINGH  
 6 META-ANALYSIS AND THE LINCOFF META-ANALYSIS MORE THAN A  
 7 MONTH BEFORE YOU SPOKE AT THE UTAH P&T MEDICAID  
 8 COMMITTEE?  
 9 **A. I'M NOT CERTAIN WHEN I FIRST BECAME AWARE OF**  
 10 **THOSE TWO STUDIES.**  
 11 **Q.** FAIR TO SAY, DR. BRINTON, THAT IN 2007, THERE  
 12 WAS A LOT OF INTEREST AND PUBLICITY CONCERNING AVANDIA  
 13 AND THE POSSIBLE ASSOCIATION WITH MYOCARDIAL ISCHEMIC  
 14 EVENTS, TRUE?  
 15 **A. YES.**  
 16 **Q.** THERE WAS INFORMATION COMING OUT VERY FREQUENTLY  
 17 WITH REGARD TO THAT ISSUE, CORRECT?  
 18 **A. YES.**  
 19 **Q.** AND YOU ARE SAYING THAT THE LINCOFF ARTICLE AND  
 20 THE SINGH META-ANALYSIS WHICH CAME OUT IN SEPTEMBER OF  
 21 2007 AND RECEIVED A LOT OF PUBLICITY, YOU WERE NOT AWARE  
 22 OF THEM BEFORE THE UTAH P&T COMMITTEE?  
 23 **A. I'M NOT CERTAIN WHEN I FIRST BECAME AWARE OF**  
 24 **THEM AND MORE IMPORTANT TO THE QUESTION, I'M NOT CERTAIN**  
 25 **WHEN IT WAS THAT I FIRST WAS ABLE TO TAKE THE TIME TO**

**1 STUDY THEM CAREFULLY. IT'S ONE THING TO READ THE TOP  
2 LINE OF A MEDICAL NEWS BULLETIN. IT'S ANOTHER THING TO  
3 LOOK AT THE STUDY IN GREATER DEPTH AND WITH GREATER  
4 DETAIL AND IN A SCIENTIFIC MANNER.**

**5 Q.** DR. BRINTON, I WOULD LIKE TO ASK YOU -- WELL, WE  
**6** CAN PULL UP YOUR REPORT, YOU RAISED MULTIPLE CRITICISMS  
**7** OF THE RECORD TRIAL IN YOUR REPORT, CORRECT?

**8 A. YES.**

**9 Q.** I'M REFERRING TO YOUR INITIAL REPORT FROM  
**10** JANUARY 15TH, 2010.

**11 A. YES.**

**12 Q.** AND I WOULD LIKE TO ASK FIRST IF YOU COULD TURN  
**13** TO PAGE 29.

**14** MS. BENNES: I WILL NEVER SEE THAT. IS  
**15** THERE SOMETHING ON THE SCREEN?

**16** BY MS. BENNES:

**17 Q.** OKAY. SO ON PAGE 29 OF YOUR REPORT, THE FIRST  
**18** PARAGRAPH THAT BEGINS IN THE MIDDLE OF THE PAGE:

**19** PERHAPS THE SINGLE LARGEST SINGLE DEFICIENCY -- LET ME  
**20** GO BACK AND TRY THAT AGAIN.

**21** PERHAPS THE LARGEST SINGLE DEFICIENCY OF  
**22** RECORD IS THE LACK OF SPECIFICITY IN ITS PRIMARY  
**23** ENDPOINT.

**24 A. YES.**

**25 Q.** DO YOU SEE THAT?

**1 A. YES.**

**2 Q.** AND THAT STILL PERMITTED YOU TO TELL THE UTAH  
**3** P&T COMMITTEE THAT IT WAS A GOOD STUDY?

**4 A. AT THE TIME THAT I SPOKE TO THEM IN OCTOBER, I  
5 WAS UNDER THE IMPRESSION THAT RECORD EXONERATED AVANDIA.**

**6 Q.** THAT REALLY WAS NOT MY QUESTION, SIR.

**7** YOU CRITICIZED RECORD BECAUSE IT LACKED

**8** SPECIFICITY IN THE PRIMARY ENDPOINT. THAT WAS ALSO

**9** KNOWN TO YOU BASED ON THE INTERIM RECORD STUDY ABOUT  
**10** WHICH YOU SPOKE TO THE UTAH P&T MEDICAID COMMITTEE IN  
**11** OCTOBER 2007, TRUE?

**12 A. NOT AT THE LEVEL AT WHICH I STATED HERE.**

**13 Q.** DR. BRINTON --

**14 A. NO.**

**15 Q.** DR. BRINTON, THE PRIMARY ENDPOINT IN RECORD IS A  
**16** COMBINATION OF CARDIOVASCULAR HOSPITALIZATION AND  
**17** CARDIOVASCULAR DEATH, CORRECT?

**18 A. YES.**

**19 Q.** IS THAT A LEVELED UNDERSTANDING YOU HAVE? THAT  
**20** IS THE PRIMARY ENDPOINT.

**21 A. I'M NOT AWARE THAT I KNEW THAT AS OF OCTOBER OF  
22 2007. I HAD NOT PAID A LOT OF ATTENTION TO RECORD.**

**23 WHAT -- MY PRIMARY LOOK AT RECORD WAS THE FACT THAT  
24 HEART ATTACK AND STROKE WENT IN OPPOSITE DIRECTIONS.**

**25 THAT WAS PART OF MY TESTIMONY IN OCTOBER. I HAD NOT**

**1 A. WHAT PAGE IS IT AGAIN?**

**2 Q.** I'M SORRY. PAGE 29 OF YOUR FIRST REPORT.

**3 A. OKAY.**

**4 Q.** AND THE FIRST FULL PARAGRAPH THAT BEGINS IN THE  
**5** MIDDLE OF THE PAGE?

**6 A. YES.**

**7 Q.** SO YOU SAY THAT THE LARGEST SINGLE DEFICIENCY OF  
**8** RECORD IS THE LACK OF SPECIFICITY IN ITS PRIMARY  
**9** ENDPOINT, CORRECT?

**10 A. THAT IS WHAT I SAID, YES.**

**11 Q.** WHAT THAT -- WHAT YOU ARE REFERRING TO IS THE  
**12** FACT THAT THE PRIMARY ENDPOINT IN RECORD WAS A COMPOSITE  
**13** OF CARDIOVASCULAR HOSPITALIZATION AND CARDIOVASCULAR  
**14** DEATH, CORRECT?

**15 A. YES.**

**16 Q.** SO WOULD YOU AGREE, BY THE WAY, THAT IF THERE IS  
**17** LACK OF SPECIFICITY IN THE PRIMARY ENDPOINT IN RECORD,  
**18** THERE IS ALSO LACK OF SPECIFICITY IN THE GROUPED TERM  
**19** MYOCARDIAL ISCHEMIC EVENTS?

**20 A. THERE IS A LACK OF SPECIFICITY IN BOTH, BUT I  
21 WOULD NOT SAY THAT THEY ARE EXACTLY THE SAME.**

**22 Q.** NOW YOU WOULD AGREE, DR. BRINTON, THAT THIS  
**23** CRITICISM OF THE RECORD TRIAL THAT YOU MENTION ON PAGE  
**24** 29, LACK OF SPECIFICITY IN ITS PRIMARY ENDPOINT, WAS  
**25** ALSO TRUE FOR THE RECORD INTERIM TRIAL, CORRECT?

**1 FOCUSED ON THE SPECIFICITY OF THE PRIMARY COMPOSITE.**

**2 Q.** THE SECOND CRITICISM THAT YOU POSE IN YOUR  
**3** EXPERT REPORT ON PAGE 29, THE LAST FULL PARAGRAPH, IS  
**4** THE USE OF STATINS CAUSES MAJOR PROBLEMS WITH STUDY  
**5** INTERPRETATION.

**6 A. WHERE ARE WE HERE?**

**7** HONORABLE CYNTHIA M. RUFÉ: YOU MEAN A  
**8** DIFFERENT PAGE.

**9** BY MS. BENNES:

**10 Q.** I'M SORRY, PAGE 29. PAGE 29 OF YOUR REPORT, THE  
**11** LAST PARAGRAPH.

**12 A. THE VERY LAST PARAGRAPH, YES.**

**13 Q.** SO RIGHT AT THE BOTTOM OF THE PAGE --

**14** HONORABLE SANDRA MAZER MOSS: NOT A FULL  
**15** PARAGRAPH.

**16** MS. BENNES: THANK YOU.

**17** BY MS. BENNES:

**18 Q.** SECOND: USE OF STATINS CAUSES MAJOR PROBLEMS  
**19** WITH STUDY INTERPRETATION?

**20 A. YES.**

**21 Q.** YOU WOULD AGREE THAT THAT WAS KNOWABLE BASED ON  
**22** REVIEWING THE INTERIM RECORD STUDY, TRUE?

**23 A. I'M NOT CERTAIN.**

**24** MS. BENNES: COULD YOU PLEASE BRING UP

**25** PAGE 293 OF DR. BRINTON'S DEPOSITION TESTIMONY, THAT IS.

1 I'M SORRY, PAGE 293 LINE 24.  
 2 BY MS. BENNES:  
 3 Q. DO YOU SEE THAT QUESTION, DR. BRINTON?  
 4 QUESTION: USE OF STATINS WAS ENCOURAGED  
 5 DURING THE TRIAL. THIS WAS ALSO SOMETHING THAT WAS  
 6 KNOWABLE BASED ON REVIEWING THE INTERIM RECORD STUDY,  
 7 CORRECT?  
 8 A. I SAID YES.  
 9 Q. AND DO YOU DISAGREE?  
 10 A. I DON'T RECALL. I WOULD HAVE TO LOOK AT IT.  
 11 Q. DO YOU HAVE A REASON TO DISAGREE, AS YOU SIT  
 12 HERE TODAY?  
 13 A. NO.  
 14 Q. TURNING BACK TO YOUR EXPERT REPORT ON PAGE 30.  
 15 THE FIRST FULL PARAGRAPH --  
 16 HONORABLE SANDRA MAZER MOSS: ANOTHER  
 17 MAJOR PROBLEM?  
 18 MS. BENNES: YES.  
 19 BY MS. BENNES:  
 20 Q. ANOTHER MAJOR PROBLEM IS THE LACK OF BLINDING,  
 21 DO YOU SEE THAT?  
 22 A. YES.  
 23 Q. THAT TOO WAS KNOWABLE BY REVIEWING THE RECORD  
 24 INTERIM ANALYSIS; ISN'T THAT TRUE, DR. BRINTON?  
 25 A. YES, AND THAT IS SOMETHING THAT I WAS AWARE OF

1 IN OCTOBER.  
 2 Q. AND YOUR NEXT CRITICISM OF THE RECORD TRIAL ON  
 3 PAGE 30 OF YOUR EXPERT REPORT, THE SECOND FULL  
 4 PARAGRAPH, ARE YOU WITH ME?  
 5 A. YES.  
 6 Q. ANOTHER MAJOR PROBLEM IS THE LACK OF STUDY  
 7 POWER. DO YOU SEE THAT?  
 8 A. YES.  
 9 Q. THAT IS NOT WHAT YOU TOLD YOUR PEERS IN UTAH, IS  
 10 IT, DR. BRINTON?  
 11 A. THAT IS CORRECT, AND THAT WAS A MISPERCEPTION ON  
 12 MY PART. I HAD NOT FULLY CONSIDERED THE  
 13 NONINFERIORITY -- THE IMPACT OF THE NONINFERIORITY  
 14 NATURE OF THE STUDY AND THE FACT THAT THAT MAKES IT  
 15 UNIQUELY SUSCEPTIBLE TO LACK OF POWER.  
 16 Q. THAT IS NOT WHAT YOU TOLD YOUR PEERS IN UTAH,  
 17 CORRECT?  
 18 A. THAT IS CORRECT BECAUSE I WAS NOT AWARE OF THAT  
 19 AT THAT TIME.  
 20 Q. I WOULD LIKE TO NOW ASK YOU TO TURN TO PAGE 7 OF  
 21 YOUR EXPERT REPORT AND NOW THE THIRD FULL PARAGRAPH THAT  
 22 BEGINS: INITIALLY --  
 23 A. YES.  
 24 Q. YOU STATE: INITIALLY WHEN ROSI AND PIO FIRST  
 25 WERE APPROVED -- THAT WOULD BE 1999, CORRECT?

1 A. YES.  
 2 Q. -- I USED THEM APPROXIMATELY EQUALLY. SOON  
 3 THEREAFTER HOWEVER I BECAME AWARE OF DIFFERENCES IN  
 4 LIPID EFFECTS FAVORING PIO AND SO I BEGAN TO USE IT  
 5 SIGNIFICANTLY MORE. STILL LATER I BECAME MORE ACUTELY  
 6 AWARE OF THESE DIFFERENCES, AND THEN SAW PROACTIVE --  
 7 THAT WOULD BE 2005, RIGHT. YES?  
 8 A. YES. SORRY.  
 9 Q. -- WITH ITS STRONG SUGGESTION OF CARDIOVASCULAR  
 10 DISEASE BENEFITS, IN SHARP CONTRAST TO ADOPT AND DREAM,  
 11 WHICH SUGGESTED CARDIOVASCULAR DISEASE HARM BY ROSI. I  
 12 HAD NEARLY ALREADY STOPPED USING ROSI IN THE CLINIC AT  
 13 THE TIME OF THE NISSEN META-ANALYSIS. SOON THEREAFTER I  
 14 AGREED WITH THE FDA PANEL THAT ROSI DID INCREASE  
 15 MYOCARDIAL ISCHEMIC EVENTS.  
 16 I WOULD LIKE TO STOP RIGHT THERE FOR A  
 17 MINUTE. DO YOU UNDERSTAND, DR. BRINTON, THAT THE  
 18 QUESTION VOTED ON BY THE 2007 FDA ADCOM WAS NOT WHETHER  
 19 ROSIGLITAZONE INCREASES MYOCARDIAL ISCHEMIC EVENTS, BUT  
 20 RATHER WAS WHETHER OR NOT ROSIGLITAZONE, WHETHER THERE  
 21 WAS A SUGGESTION OF AN INCREASE IN MYOCARDIAL ISCHEMIC  
 22 EVENTS?  
 23 A. YES.  
 24 Q. SO THIS IS AN INCORRECT STATEMENT OF THE FDA  
 25 PANEL AND WHAT IT CONSIDERED IN 2007, ISN'T IT?

1 A. I WOULD REWORD THAT TO SAY AGREED WITH THE  
 2 IMPLICATIONS OF THE FDA PANEL VOTE.  
 3 Q. AND THEN YOU GO ON TO SAY, ACKNOWLEDGING THE --  
 4 THAT THE FDA VOTE, THAT YOU WERE PUZZLED THAT THE SAME  
 5 PANEL VOTED TO KEEP ROSIGLITAZONE ON THE MARKET WHEN YOU  
 6 COULD SEE ABSOLUTELY NO MEANINGFUL ADVANTAGE OF ROSI  
 7 OVER PIO AND MANY IN THE REVERSE, THAT IS WHAT YOU WROTE  
 8 IN YOUR EXPERT REPORT AS AN EXPERT IN THIS LITIGATION,  
 9 CORRECT?  
 10 A. YES.  
 11 Q. THAT IS NOT WHAT YOU TESTIFIED -- OH, I'M SORRY,  
 12 START AGAIN. AND YOU TESTIFIED UNDER OATH AT YOUR  
 13 DEPOSITION THAT YOUR OPINION IN THE SUMMER OF 2007 WAS  
 14 THAT AVANDIA CAN CAUSE HEART ATTACK, TRUE?  
 15 A. YES.  
 16 Q. SO YOU TOLD YOUR PEERS IN UTAH IN OCTOBER OF  
 17 2007 THAT THE SINGLE BEST STUDY WAS RECORD AND IT SHOWED  
 18 NO INCREASED RISK, YET AS A PAID LITIGATION EXPERT, YOU  
 19 TESTIFIED UNDER OATH THAT YOUR OPINION IN THE SUMMER OF  
 20 2007 WAS THAT AVANDIA CAN CAUSE HEART ATTACK, CORRECT?  
 21 A. YES.  
 22 Q. IT WAS, IN FACT, NOT YOUR OPINION IN THE SUMMER  
 23 OF 2007 THAT AVANDIA CAN CAUSE HEART ATTACKS, WAS IT?  
 24 A. IT WAS.  
 25 Q. IT WAS -- AND YOU DIDN'T TELL THAT TO THE UTAH

1 P&T COMMITTEE?

2 **A. THAT WAS NOT THE QUESTION THEY WERE ASKING ME.**

3 **Q.** THEY WERE ASKING YOU WHETHER OR NOT AVANDIA

4 SHOULD BE AVAILABLE FOR PATIENTS TO USE IN UTAH. YOUR

5 OPINION WAS THAT AVANDIA CAN CAUSE HEART ATTACK AND YOU

6 DIDN'T BOTHER TO MENTION IT TO THEM?

7 **A. MY OPINION WAS THAT IT HAD THE POTENTIAL TO**

8 **CAUSE HEART ATTACK AND THE REASON THAT I SUGGESTED THAT**

9 **THEY CONTINUE TO MAKE AVANDIA AVAILABLE AS AN**

10 **ALTERNATIVE TO ACTOS WAS THAT THERE ARE -- THAT THERE IS**

11 **POTENTIALLY THEORETICALLY PATIENTS FOR WHOM THE**

12 **METABOLIC PATHWAY OF ACTOS WOULD INTERFERE WITH ITS USE**

13 **SUCH THAT AVANDIA WOULD BE NECESSARY.**

14 **Q.** DR. BRINTON, I WOULD JUST PLEASE AGAIN ASK YOU

15 IF YOU WOULD JUST STICK TO MY QUESTIONS. I COULD TALK

16 WITH YOU FOR HOURS AS WE DID THE FIRST TIME, BUT I'M NOT

17 GOING TO BE ALLOWED TO SO, IF YOU WOULD PLEASE DO YOUR

18 BEST.

19 **A. THAT IS THE SHORTEST I COULD ANSWER THAT**

20 **QUESTION, THANK YOU.**

21 **Q.** NOW, IN CONTRAST TO WHAT YOU TOLD YOUR PEERS IN

22 UTAH IN OCTOBER OF 2007 WHEN YOU SAID YOU WERE PERPLEXED

23 THAT THE 2007 FDA ADVISORY COMMITTEE THOUGHT THERE WAS

24 AN INCREASED RISK, AS A PAID LITIGATION EXPERT YOU

25 TESTIFIED UNDER OATH THAT IN THE SUMMER OF 2007 YOU WERE

1 PUZZLED THAT THE VERY SAME PANEL VOTED TO KEEP AVANDIA

2 ON THE MARKET, CORRECT?

3 **A. YES.**

4 **Q.** IN FACT, YOU WERE NOT PUZZLED IN THE SUMMER OF

5 2007 THAT THE ADVISORY COMMITTEE VOTED TO KEEP AVANDIA

6 ON THE MARKET, WERE YOU?

7 **A. THIS STATEMENT WAS MADE BY ME BASED ON MY BEST**

8 **RECOLLECTION AT THAT MOMENT IN TIME, THAT IT WAS IN THE**

9 **SUMMER WHEN, IN FACT, IT WAS LATE IN THE FALL.**

10 **Q.** SO YOUR TESTIMONY THAT THIS WAS YOUR OPINION IN

11 THE SUMMER OF 2007 IS INCORRECT?

12 **A. THAT IS CORRECT.**

13 HONORABLE SANDRA MAZER MOSS: IT'S

14 CORRECT THAT IT'S INCORRECT?

15 THE WITNESS: IT'S CORRECT THAT IT IS

16 INCORRECT, YES. IN BEING QUIZZED ON THIS, I WAS UNDER

17 OATH BUT THAT WAS THE BEST -- MY BEST RECOLLECTION AT

18 THE TIME AND GOING BACK LATER TO RETHINK WHAT EXACTLY

19 HAD HAPPENED DURING THIS VERY INTERESTING AND BUSY YEAR

20 OF 2007, IT BECAME MORE CLEAR TO ME THAT THAT WAS NOT

21 CORRECT. THAT, IN FACT, AS OF THE SUMMER, I HAD NOT

22 COME TO THAT CONCLUSION, THAT THAT WAS ACTUALLY LATER IN

23 THE YEAR.

24 BY MS. BENNES:

25 **Q.** IT APPEARS TO BE THERE IS ANOTHER THING THAT YOU

1 HAD MISRECOLLECTED. YOU TOLD YOUR PEERS IN UTAH IN

2 OCTOBER OF 2007 THAT AVANDIA HAD ADVANTAGES OVER ACTOS

3 AND SHOULD BE AVAILABLE IN UTAH, CORRECT?

4 **A. YES.**

5 **Q.** AND AS A PAID LITIGATION EXPERT, YOU TESTIFIED

6 UNDER OATH THAT IN THE SUMMER OF 2007, YOUR VIEW WAS

7 THAT AVANDIA HAD NO MEANINGFUL ADVANTAGE OVER ACTOS,

8 CORRECT?

9 **A. I'M NOT SURE THAT I'D SAY SUMMER OF 2007, BUT**

10 **YES, THERE IS A DIFFERENCE AND THAT HAD TO DO WITH THE**

11 **EVOLUTION OF MY OPINION.**

12 **Q.** YOUR OPINION IN 2007 WAS NOT AS YOU STATE ON

13 PAGE 7 OF YOUR EXPERT REPORT, SIR. ISN'T THAT FAIR?

14 **A. WHICH LINE ARE WE LOOKING AT ON PAGE 7?**

15 **Q.** WELL, IT WAS NOT YOUR OPINION IN THE SUMMER OF

16 2007 THAT THERE WAS NO MEANINGFUL ADVANTAGE OF ROSI OVER

17 PIO, TRUE?

18 **A. THAT IS CORRECT. I DON'T SEE SUMMER OF 2007 ON**

19 **THAT PAGE.**

20 **Q.** I CAN BRING UP OTHER TESTIMONY, SIR, WHERE YOU

21 ARE DESCRIBING THAT YOUR OPINIONS ABOUT -- IN THIS

22 PARAGRAPH RELATE TO WHAT YOU HAD FORMULATED IN THE

23 SUMMER OF 2007.

24 **A. IN MY DEPOSITION, I MISRECOLLECTED THAT THIS**

25 **OCCURRED IN THE SUMMER OF 2007. WHAT I SAY IN MY**

1 **STATEMENT ON PAGE 7 IS SOON, I USE THE WORD SOON TWICE.**

2 **THE FIRST USE IS ABOUT 5 YEARS, THE SECOND USE IS ABOUT**

3 **10 MONTHS. NO, 7 OR 8 MONTHS, SOMETHING LIKE THAT. SO**

4 **I'M USING THE WORD SOON IN A WAY THAT PERHAPS SOMEONE**

5 **DISAGREED WITH BUT SOON, SOON THEREAFTER. THE FIRST OF**

6 **THAT PARAGRAPH WAS SEVERAL YEARS LATER, SOON THEREAFTER**

7 **IN THE MIDDLE OF THAT SAME PARAGRAPH WAS SEVERAL MONTHS**

8 **LATER.**

9 **Q.** DR. BRINTON, ISN'T IT TRUE THAT IF WE DIDN'T

10 HAVE A TAPE RECORDING OF THE OPINIONS YOU EXPRESSED TO

11 YOUR PEERS IN OCTOBER OF 2007, THAT WE WOULD HAVE NO

12 IDEA HOW MUCH YOU HAVE ATTEMPTED TO REWRITE HISTORY BY

13 YOUR TESTIMONY IN THIS LITIGATION?

14 MR. ZONIES: YOUR HONOR.

15 THE WITNESS: I WAS NOT ATTEMPTING TO

16 REWRITE HISTORY.

17 MR. ZONIES: OBJECTION.

18 HONORABLE CYNTHIA M. RUFÉ: HOLD ON.

19 THE WITNESS: I WAS TRYING TO CORRECT --

20 HONORABLE CYNTHIA M. RUFÉ: HOLD ON, HOLD

21 ON, DOCTOR. I'M GOING TO OVERRULE THE OBJECTION. YOU

22 CAN -- NOW YOU MAY ANSWER.

23 HONORABLE SANDRA MAZER MOSS: I JOIN IN

24 STATE.

25 THE WITNESS: I MISRECOLLECTED DURING MY

1 DEPOSITION, A LONG AND GRUELING DAY, AS MS. BENNES HAS  
 2 SUGGESTED, THAT IT WAS IN THE SUMMER OF 2007 THAT I CAME  
 3 TO CERTAIN OPINIONS WHEN IN FACT IT WAS LATER THAT YEAR.  
 4 HONORABLE SANDRA MAZER MOSS: IN THE  
 5 FALL?  
 6 THE WITNESS: IT WAS IN THE FALL. SO IT  
 7 WAS AFTER THE OCTOBER VISIT WITH THE MEDICAID OPINION  
 8 AND YET -- OR MEDICAID P&T COMMITTEE AND YES, IT IS TRUE  
 9 WITHOUT THAT RECORDING THE TIME WOULD HAVE BEEN  
 10 INCORRECT. SO I'M OFF BY ABOUT 4 OR 5 MONTHS AND I  
 11 APOLOGIZE FOR THAT.  
 12 BY MS. BENNES:  
 13 Q. WHAT PUBLISHED ARTICLE DID YOU KNOW ABOUT BY THE  
 14 FALL OF 2007 THAT YOU DIDN'T KNOW ABOUT IN THE SUMMER OF  
 15 2007?  
 16 A. **FIRST OF ALL, IT WAS THE CAREFUL REVIEW, WHICH I**  
 17 **DID NOT HAVE A CHANCE TO DO BEFORE OCTOBER, OF THE SINGH**  
 18 **AND LINCOFF META-ANALYSES, AND A MORE CAREFUL REVIEW OF**  
 19 **RECORD THAT BEGAN TO CHANGE MY OPINION MORE CLEARLY.**  
 20 **AND PLEASE REALIZE THAT YOU ARE MISCHARACTERIZING MY**  
 21 **TESTIMONY BY CHERRY-PICKING MY STATEMENT ABOUT**  
 22 **PIOGLITAZONE AND ROSIGLITAZONE. I TOLD THEM**  
 23 **PIOGLITAZONE WAS MY FIRST CHOICE, ROSIGLITAZONE WAS A**  
 24 **SECOND CHOICE THAT MAY BE ADVANTAGEOUS IN THE SETTING OF**  
 25 **THE METABOLIC ABNORMALITY.**

1 Q. DR. BRINTON, AT THE TIME WE TOOK YOUR  
 2 DEPOSITION, YOU HAD NOT GONE TO THE UNIVERSITY OF UTAH  
 3 HOSPITAL TO ASK THEM TO REMOVE AVANDIA FROM THE HOSPITAL  
 4 FORMULARY, DID YOU?  
 5 A. **CORRECT.**  
 6 Q. AND EVEN THOUGH YOU BELIEVE THAT AVANDIA CAUSES  
 7 HEART ATTACK, YOU TESTIFIED THAT GOING TO THE UNIVERSITY  
 8 OF -- UTAH UNIVERSITY HOSPITAL AND ASKING THEM TO REMOVE  
 9 AVANDIA FROM THE HOSPITAL FORMULARY WAS A VERY LOW  
 10 PRIORITY?  
 11 A. **YES. AND I STATED THE REASON FOR THAT WAS THAT**  
 12 **IT IS RARELY USED AS AN IN PATIENT. WHEN I FOUND OUT**  
 13 **THAT IT IS USED IN AN APPRECIABLE NUMBER, I WENT**  
 14 **IMMEDIATELY TO THEM AND HAVE HAD THEM TAKE IT OFF THE**  
 15 **FORMULARY. SO IT IS NOW OFF THE FORMULARY.**  
 16 Q. AFTER I ASKED YOU THAT QUESTION AND YOU GAVE  
 17 THAT ANSWER AT YOUR DEPOSITION, TRUE?  
 18 A. **I HAD BEEN UNDER THE IMPRESSION IT WAS RARELY**  
 19 **USED AND I FOUND OUT IT WAS COMMONLY USED AND SO I SAID**  
 20 **IT NEEDS TO BE DONE IMMEDIATELY.**  
 21 Q. IT BECAME A HIGHER PRIORITY, DIDN'T IT, SIR?  
 22 A. **WHEN I REALIZED IT WAS A SIGNIFICANT ISSUE, YES.**  
 23 Q. DR. BRINTON, YOU AGREE THAT RANDOMIZED CLINICAL  
 24 TRIALS ARE AT THE TOP OF THE HIERARCHY OF SCIENTIFIC  
 25 STUDIES, CORRECT?

1 A. **YES.**  
 2 Q. AND YOU AGREE THAT RECORD IS A RANDOMIZED  
 3 CLINICAL TRIAL?  
 4 A. **YES.**  
 5 Q. AND YOU AGREE THAT RECORD STANDS HEAD AND  
 6 SHOULDERS ABOVE THE OTHER CLINICAL TRIALS BECAUSE IT WAS  
 7 RANDOMIZED, THE PRIMARY PRESPECIFIED OUTCOME WAS A  
 8 CARDIOVASCULAR OUTCOME AND THE CARDIOVASCULAR EVENTS  
 9 WERE ADJUDICATED?  
 10 A. **YES.**  
 11 Q. RECORD DID NOT FIND A STATISTICALLY SIGNIFICANT  
 12 ASSOCIATION BETWEEN AVANDIA AND THE PRIMARY OUTCOME,  
 13 WHICH WE TALKED ABOUT, OF CARDIOVASCULAR HOSPITALIZATION  
 14 OR CARDIOVASCULAR DEATH, TRUE?  
 15 A. **CORRECT.**  
 16 Q. RECORD DID NOT FIND A STATISTICALLY SIGNIFICANT  
 17 ASSOCIATION BETWEEN AVANDIA AND ALL CAUSE DEATH, TRUE?  
 18 A. **CORRECT.**  
 19 Q. IT DID NOT FIND A STATISTICALLY SIGNIFICANT  
 20 ASSOCIATION BETWEEN AVANDIA AND CARDIOVASCULAR DEATH,  
 21 TRUE?  
 22 A. **YES.**  
 23 Q. AND IT DID NOT FIND A STATISTICALLY SIGNIFICANT  
 24 ASSOCIATION BETWEEN AVANDIA AND HEART ATTACK?  
 25 A. **CORRECT.**

1 Q. OR BETWEEN AVANDIA AND STROKE?  
 2 A. **CORRECT.**  
 3 Q. OR BETWEEN CARDIOVASCULAR DEATH AND HEART ATTACK  
 4 AND STROKE AS A COMPOSITE, TRUE?  
 5 A. **CORRECT.**  
 6 Q. IT DID NOT FIND A STATISTICALLY SIGNIFICANT  
 7 ASSOCIATION BETWEEN AVANDIA AND ATHEROSCLEROTIC EVENTS,  
 8 DID IT?  
 9 A. **CORRECT.**  
 10 Q. DESPITE THESE FINDINGS IN RECORD, YOUR TESTIMONY  
 11 IS THAT RECORD AFFIRMATIVELY SUPPORTS YOUR CONCLUSION  
 12 THAT AVANDIA CAUSES HEART ATTACK BECAUSE IT REPORTS A  
 13 14 PERCENT INCREASED RISK OF HEART ATTACK, TRUE?  
 14 A. **IT SUPPORTS THAT CONCLUSION, YES.**  
 15 Q. THE REASON IT SUPPORTS THAT CONCLUSION,  
 16 ACCORDING TO YOUR TESTIMONY, IS BECAUSE OF THE 14  
 17 PERCENT INCREASED RISK OF HEART ATTACK, THAT IS THE  
 18 HEART ATTACK FINDING IN THE STUDY, CORRECT?  
 19 A. **GIVEN THE EXTRAORDINARY DESIGN AND EXECUTION**  
 20 **PROBLEMS OF THE STUDY, THE 14 PERCENT FINDING IS**  
 21 **ACTUALLY QUITE SIGNIFICANT.**  
 22 Q. AND THAT IS SOMETHING THAT YOU HAVE NEVER  
 23 PUBLISHED TO YOUR PEERS, IS IT, SIR?  
 24 A. **NO.**  
 25 Q. AND YOU REACHED A CAUSATION OPINION, ALTHOUGH

1 NOT TO A REASONABLE DEGREE OF CERTAINTY, AFTER YOU SAW  
 2 THE RESULTS OF THE FINAL RECORD STUDY, CORRECT?  
 3 **A. AFTER I REVIEWED THE DESIGN AND THE RESULTS,**  
 4 **YES.**  
 5 **Q.** THE DESIGN THAT HAD BEEN AVAILABLE SEVERAL YEARS  
 6 EARLIER?  
 7 **A. THAT'S RIGHT. I HAD NOT LOOKED AT IT SO**  
 8 **CAREFULLY.**  
 9 **Q.** OKAY. AND I WOULD LIKE TO TAKE A LOOK, IF YOU  
 10 CAN BRING UP THE RECORD STUDY. I'M LOOKING FOR TABLE 4,  
 11 THE FINAL RECORD, TABLE 4. THERE YOU GO.  
 12 DO YOU HAVE IT IN FRONT OF YOU, SIR?  
 13 **A. I'M LOOKING AT IT ON THE SCREEN.**  
 14 **Q.** THAT IS WHAT I MEANT.  
 15 **A. YES.**  
 16 **Q.** SO THAT -- CAN YOU HIGHLIGHT THE MYOCARDIAL  
 17 INFARCTION LINE SO THAT WE ARE FOCUSING ON THE SAME  
 18 THING? SO THIS PARTICULAR FINDING IS THE REASON THAT  
 19 YOU CAME TO THE CONCLUSION IN THE SUMMER OF 2009,  
 20 ACCORDING TO YOUR TESTIMONY, THAT AVANDIA CAUSES HEART  
 21 ATTACK?  
 22 **A. NO, IT IS NOT THE REASON. IT IS ONE OF MANY**  
 23 **REASONS.**  
 24 **Q.** CAN YOU PULL UP DR. BRINTON'S DEPOSITION  
 25 TESTIMONY, PAGE 286, LINE 23?

1 QUESTION: AND WHAT FINDING IN THE RECORD  
 2 TRIAL AFFIRMATIVELY SUPPORTS THE CONCLUSION THAT AVANDIA  
 3 CAUSES HEART ATTACK?  
 4 AND YOUR ANSWER WAS, A 14 PERCENT  
 5 INCREASE IN MYOCARDIAL INFARCTION. GRANTED, NOT  
 6 STATISTICALLY SIGNIFICANT, BUT A POINT ESTIMATE OF 1.14  
 7 IN THE SETTING OF SIGNIFICANT DISPARITY IN DROP IN LIPID  
 8 LOWERING THERAPY. DO YOU SEE THAT?  
 9 **A. YES.**  
 10 **Q.** SO THIS IS THE FINDING IN THE RECORD TRIAL THAT  
 11 SUPPORTS YOUR CAUSATION OPINION THAT YOU REACHED AS OF  
 12 THE SUMMER OF 2009, CORRECT?  
 13 **A. IT IS SUPPORTIVE OF THAT CONCLUSION, YES.**  
 14 **Q.** AND JUST TO BE CLEAR, BECAUSE WE HEARD AN AWFUL  
 15 LOT ABOUT STATISTICAL SIGNIFICANCE YESTERDAY, IF YOU  
 16 COULD PUT TABLE 4 BACK UP. THAT IS A NONSTATISTICALLY  
 17 SIGNIFICANT FINDING, CORRECT?  
 18 **A. YES, AND THE UPPER CONFIDENCE INTERVAL IS 1.63.**  
 19 **Q.** AND THE LOWER BOUND OF THE CONFIDENCE INTERVAL  
 20 IS 0.8, CORRECT?  
 21 **A. YES.**  
 22 **Q.** SO YOUR OPINION THAT AVANDIA CAUSES HEART ATTACK  
 23 IS BASED IN PART ON THIS NONSTATISTICALLY SIGNIFICANT  
 24 FINDING FROM THE RECORD TRIAL, CORRECT?  
 25 **A. IN PART, YES.**

1 **Q.** NOW, WHEN YOU SPOKE TO THE UTAH P&T COMMITTEE,  
 2 YOU SPOKE ABOUT INTERIM RECORD, CORRECT?  
 3 **A. YES.**  
 4 **Q.** AND YOUR COMMENTS TO THE UTAH P&T COMMITTEE  
 5 WERE THAT INTERIM RECORD SHOWED NO INCREASED RISK AND  
 6 THERE WAS CLEARLY A LACK OF TREND IN EITHER DIRECTION,  
 7 THAT IS WHAT YOU SAID, CORRECT?  
 8 **A. THAT IS REFERRING TO THE OVERALL COMPOSITE. NO**  
 9 **TREND IN THE OVERALL COMPOSITE.**  
 10 **Q.** CAN WE BRING UP THE INTERIM RECORD ARTICLE?  
 11 COULD YOU TURN TO TABLE 2? COULD YOU HIGHLIGHT THE  
 12 THIRD FROM THE BOTTOM LINE, ACUTE MYOCARDIAL INFARCTION.  
 13 THANK YOU.  
 14 THIS IS THE INTERIM RECORD TRIAL. DO YOU  
 15 RECOGNIZE IT, DR. BRINTON?  
 16 **A. YES, I DO.**  
 17 **Q.** AND THIS IS THE FINDING FROM THE INTERIM RECORD  
 18 TRIAL. AND AGAIN, AT THE TIME YOU SPOKE BEFORE THE UTAH  
 19 P&T COMMITTEE, YOUR STATEMENT WAS THAT INTERIM RECORD  
 20 SHOWED NO INCREASED RISK AND THERE WAS CLEARLY A LACK OF  
 21 TREND IN EITHER DIRECTION, RIGHT?  
 22 **A. THAT IS WHAT I SAID, YES.**  
 23 **Q.** AND THERE IS NO QUESTION, THOUGH, IS THERE, SIR,  
 24 THAT THE -- THERE WAS A 23 PERCENT RISK OF HEART ATTACK  
 25 REPORTED IN TABLE TWO OF THE INTERIM RECORD TRIAL,

1 CORRECT? YES OR NO, SIR?  
 2 **A. 1.23, YES.**  
 3 **Q.** THAT IS 23 PERCENT INCREASED RISK, CORRECT?  
 4 **A. YES.**  
 5 **Q.** IT'S ALSO NOT STATISTICALLY SIGNIFICANT,  
 6 CORRECT?  
 7 **A. YES.**  
 8 **Q.** AND THE UPPER BOUND OF THIS CONFIDENCE INTERVAL  
 9 IS EVEN HIGHER THAN THE OTHER, IT'S 1.86, CORRECT?  
 10 **A. YES.**  
 11 **Q.** AND THE LOWER BOUND IS ABOUT THE SAME, 0.81,  
 12 CORRECT?  
 13 **A. YES.**  
 14 **Q.** THIS FINDING WAS IN THE INTERIM RECORD TRIAL  
 15 WHEN YOU TESTIFIED -- WHEN YOU TOLD THE UTAH P&T  
 16 COMMITTEE THAT THERE WAS NO INCREASED RISK OF AVANDIA,  
 17 TRUE?  
 18 **A. I DIDN'T SAY THAT THERE WAS NO INCREASED RISK, I**  
 19 **SAID THAT THERE WERE TRENDS GOING IN BOTH DIRECTIONS. I**  
 20 **WAS REFERRING TO STROKE, WHICH WAS TURNING DOWNWARD,**  
 21 **HEART ATTACK TURNING UPWARD. IN THAT SETTING BASED ON**  
 22 **THE ANALYSIS THAT I HAD DONE TO THAT POINT OF RECORD,**  
 23 **THAT TO ME MEANT THAT THERE WAS LESS CERTAINTY OF A**  
 24 **CARDIOVASCULAR HARM FROM RECORD. WHEN I CAME LATER TO**  
 25 **THIS ISSUE FOCUSING PRIMARILY ON MYOCARDIAL INFARCTION,**

1 **BECOMING MORE AWARE OF THE VARIOUS DEFICIENCIES OF THE**  
 2 **DESIGN, I CAME TO A VERY DIFFERENT CONCLUSION.**  
 3 Q. CAN YOU PLEASE BRING UP THE UTAH TRANSCRIPT PAGE  
 4 6 LINE 14. I JUST WANT TO BE CLEAR, DR. BRINTON, SO  
 5 THERE IS NO CONFUSION.  
 6 (VIDEO PLAYED.)  
 7 ANSWER: BUT THE RECORD STUDY, I THINK,  
 8 IN TERMS OF THE INTERIM ANALYSIS THAT ARE THERE, SHOWS A  
 9 LACK OF TREND IN EITHER DIRECTION. AND THAT TO ME, IS  
 10 IMPORTANT BECAUSE THAT, I THINK, NEGATES THE ARGUMENT  
 11 AGAINST THE POWER QUESTION, BECAUSE IF THERE IS VERY  
 12 CLEARLY A LACK OF TREND AND I THINK THERE IS CLEARLY A  
 13 LACK OF TREND IN EITHER DIRECTION THERE, THERE -- SOME  
 14 OF THE ENDPOINTS ARE TRENDING UPWARD SLIGHTLY AND SOME  
 15 ARE TRENDING DOWNWARD SLIGHTLY, BUT THE BEST, THE POOLED  
 16 ENDPOINTS ARE REALLY RIGHT ON THE MARK SUGGESTING THAT  
 17 THERE IS NO INCREASE.  
 18 (VIDEO ENDED.)  
 19 BY MS. BENNES:  
 20 Q. THAT WAS WHAT YOU SAID TO THE UTAH P&T  
 21 COMMITTEE, RIGHT?  
 22 A. YES.  
 23 Q. WHAT YOU SAID TO THE UTAH P&T COMMITTEE ALSO  
 24 APPLIES TO THE FINAL RECORD STUDY WHICH ALSO SHOWED NO  
 25 INCREASED RISK ON THE PRIMARY OUTCOME, CORRECT?

1 A. **WHEN I WAS SPEAKING TO THE UTAH P&T COMMITTEE**  
 2 **WAS MY VERY SUPERFICIAL ANALYSIS OF RECORD AND THE FACT**  
 3 **THAT STROKE WAS DOWN AND HEART ATTACK WAS UP. AND THAT,**  
 4 **TO ME, WAS NOT A PROBLEM, NOT AN ISSUE SIGNIFICANT**  
 5 **ENOUGH FOR ME TO REQUEST THAT THEY TAKE IT OFF THE**  
 6 **MARKET, OFF THE FORMULARY.**  
 7 Q. HAVE YOU CONTACTED THE UTAH P&T COMMITTEE AND  
 8 TOLD THEM THAT YOU DID A SUPERFICIAL ANALYSIS BEFORE YOU  
 9 SPOKE TO THEM IN OCTOBER OF 2007?  
 10 A. **I HAVE DRAFTED A RESPONSE TO THEM ON THAT POINT**  
 11 **AND HAVE NOT YET HAD A CHANCE TO SUBMIT IT TO THEM.**  
 12 **THEY DO NOT MEET VERY OFTEN AND I NEED TO AWAIT AN**  
 13 **OPPORTUNITY TO GIVE THEM THAT INFORMATION.**  
 14 Q. IT'S BEEN THREE YEARS.  
 15 A. **IT HAS NOT BEEN THREE YEARS SINCE I HAVE**  
 16 **REANALYZED RECORD AND HAVE UNDERSTOOD THE PROBLEMS WITH**  
 17 **ITS DESIGN.**  
 18 Q. CAN YOU BRING UP SLIDE 11, PLEASE? SO JUST TO  
 19 BE CLEAR, SINCE WE ARE TALKING A LOT ABOUT STATISTICS  
 20 AND NUMBERS FOR A LONG TIME NOW. DR. BRINTON, THIS IS  
 21 THE FINAL RECORD RESULT WITH REGARD TO HEART ATTACK. DO  
 22 YOU SEE THAT?  
 23 A. YES.  
 24 Q. AND YOUR TESTIMONY IS THAT THIS IS PART OF THE  
 25 BASIS FOR YOUR OPINION THAT AVANDIA CAUSES HEART ATTACK,

1 CORRECT?  
 2 A. **THIS IS ONE SMALL PART, YES.**  
 3 Q. NOW, COULD YOU BRING UP THE SECOND LINE, PLEASE?  
 4 AND THE INTERIM RECORD STUDY WAS THE SUBJECT OF YOUR  
 5 COMMENTS TO THE UTAH P&T COMMITTEE IN 2007 AND THIS  
 6 HEART ATTACK FINDING IS ACTUALLY A HIGHER RISK, CORRECT?  
 7 A 23 PERCENT RISK AS OPPOSED TO A 14 PERCENT RISK,  
 8 CORRECT?  
 9 A. **THE POINT ESTIMATE IS HIGHER.**  
 10 Q. AND WHAT YOU TOLD THE UTAH P&T COMMITTEE ABOUT  
 11 THIS FINDING WAS THAT THERE WAS NO INCREASED RISK AND  
 12 LACK OF TREND IN EITHER DIRECTION?  
 13 A. **THIS MISCHARACTERIZES MY TESTIMONY BECAUSE IN**  
 14 **THE TOP LINE, THIS IS ONE SMALL ELEMENT OF A MUCH LARGER**  
 15 **ANALYSIS THAT I HAD DONE AND THE BOTTOM LINE IS A MAJOR**  
 16 **ELEMENT OF A MUCH MORE SUPERFICIAL ANALYSIS THAT I HAD**  
 17 **DONE, AND THAT WHY IS THE DISCREPANCY.**  
 18 Q. CAN WE AGREE THAT NO INCREASED RISK AND LACK OF  
 19 TREND IN EITHER DIRECTION AS YOU DESCRIBED THE INTERIM  
 20 RECORD STUDY APPLIES TO THE FINAL RECORD STUDY?  
 21 A. **YES AND NO. IN THE UTAH P&T TESTIMONY THAT I**  
 22 **GAVE, I WAS REFERRING TO THE OVERALL CARDIOVASCULAR**  
 23 **ENDPOINTS. STROKE WAS CLEARLY TRENDING DOWNWARD, HEART**  
 24 **ATTACK WAS CLEARLY TRENDING UPWARD. THAT IS WHAT I**  
 25 **REFERRED TO IN THE LOWER RIGHT-HAND CORNER OF THIS**

1 **SLIDE. IN THE UPPER PORTION, I AM NOT REFERRING IN ANY**  
 2 **WAY TO STROKE, I'M REFERRING TO MYOCARDIAL EVENTS,**  
 3 **MYOCARDIAL INFARCTION AND IT'S A VERY DIFFERENT**  
 4 **QUESTION. THIS IS TRULY MIXING OF APPLES AND ORANGES.**  
 5 Q. CAN YOU PLEASE BRING BACK UP FINAL RECORD, TABLE  
 6 4? THERE IT IS.  
 7 HONORABLE SANDRA MAZER MOSS: I THINK HE  
 8 HAS AN OBJECTION. ARE YOU STANDING BECAUSE YOU NEED TO  
 9 STRETCH OR DO YOU HAVE AN OBJECTION?  
 10 MR. ZONIES: BOTH, YOUR HONOR, THANK YOU.  
 11 HONORABLE CYNTHIA M. RUFÉ: IT'S ABOUT  
 12 THE TIME, ISN'T IT?  
 13 MR. ZONIES: IT'S BEEN CLOSE TO AN HOUR.  
 14 HONORABLE CYNTHIA M. RUFÉ: YES.  
 15 MS. BENNES: 1 OR 2 MORE QUESTIONS AND I  
 16 WILL FINISH. I'M SORRY.  
 17 HONORABLE CYNTHIA M. RUFÉ: YOU HAVE THAT  
 18 BY MS. BENNES:  
 19 Q. THIS IS THE FINAL RECORD RESULT, CORRECT, DR.  
 20 BRINTON?  
 21 A. YES.  
 22 Q. AND JUST AS YOU SAID WITH REGARD TO INTERIM  
 23 RECORD, STROKE TRENDS DOWNWARD, DOESN'T IT?  
 24 A. YES.  
 25 Q. AND JUST LIKE IS TRUE FOR INTERIM RECORD, THE

1 PRIMARY ENDPOINT IS -- COULDN'T BE MUCH CLOSER TO NO  
 2 INCREASED EFFECT AT ALL, CORRECT?  
 3 **A. CORRECT.**  
 4 **Q.** AND THE INCREASED EVENT RATE WITH MYOCARDIAL  
 5 INFARCTION IS ACTUALLY LESS IN FINAL RECORD THAN IT WAS  
 6 IN INTERIM RECORD, TRUE?  
 7 **A. YES.**  
 8 MS. BENNES: THANK YOU. I HAVE NO  
 9 FURTHER QUESTIONS. THANK YOU, YOUR HONORS.  
 10 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.  
 11 HONORABLE SANDRA MAZER MOSS: DO YOU HAVE  
 12 REDIRECT?  
 13 MR. ZONIES: SHORT REDIRECT, IF I MIGHT,  
 14 YOUR HONORS.  
 15 REDIRECT EXAMINATION  
 16 BY MR. ZONIES:  
 17 **Q.** DR. BRINTON, THIS IS THE FINAL RECORD  
 18 PUBLICATION. IT'S A SLIDE FROM THE PRESENTATION FROM  
 19 YESTERDAY ENTITLED RECORD, NOT POWERED TO ANSWER MI  
 20 QUESTION. WAS RECORD POWERED TO ANSWER THE QUESTION  
 21 ABOUT WHETHER OR NOT THIS DRUG CAUSES MYOCARDIAL  
 22 INFARCTIONS?  
 23 **A. TWOFOLD UNDER POWERED. ONE IS THAT BY THEIR OWN**  
 24 **POWER CALCULATIONS THEY DID NOT HAVE ENOUGH EVENTS. THE**  
 25 **OTHER POINT, WHICH I BELIEVE IS NOT ADEQUATELY DISCUSSED**

1 **IN THIS PUBLICATION, IS THE FACT THAT BY THE VERY NATURE**  
 2 **OF THE DESIGN OF RECORD, IT WAS VIRTUALLY IMPOSSIBLE TO**  
 3 **POWER IT ADEQUATELY. AS WE HEARD EARLIER TODAY, BY**  
 4 **VIRTUE OF IT BEING A NONINFERIORITY OPEN LABEL STUDY,**  
 5 **THE POWER IS IN SERIOUS QUESTION AND ESPECIALLY GIVEN**  
 6 **BOTH THE DESIGN -- THE EVIDENCE FOR BIAS IN DESIGN AND**  
 7 **BIAS IN THE EXECUTION OR CONDUCT OF THE STUDY.**  
 8 **FURTHERMORE, LET ME JUST STATE THAT AN**  
 9 **IMPORTANT PART OF THIS WHOLE QUESTION IS THE FACT THAT**  
 10 **RECORD WAS NEVER A LARGE PART OF MY DECISION MAKING**  
 11 **BECAUSE THE MORE I STUDIED RECORD, THE MORE IT SHRANK,**  
 12 **IN MY VIEW. IT IS STILL THE STRONGEST SINGLE PIECE OF**  
 13 **EVIDENCE, BUT AS WE HAVE HEARD EARLIER TODAY, THE**  
 14 **EVIDENCE IS REALLY NEGLIGIBLE WHEN IT COMES TO**  
 15 **INDIVIDUAL CLINICAL TRIALS. SO ONLY IN THE CONTEXT OF**  
 16 **META-ANALYSIS DOES RECORD RISE TO THE POINT OF BEING**  
 17 **SUBSTANTIAL IN TERMS OF INFORMING MY OPINION. RECORD**  
 18 **ALL BY ITSELF IS A VERY WEAK PIECE OF EVIDENCE AND ONLY**  
 19 **WITH THE OTHER STUDIES WITH WHICH IT HAS BEEN JOINED AND**  
 20 **UNDERSTANDING CLEARLY THE IMPLICATIONS OF THE**  
 21 **NONINFERIORITY OPEN LABEL DESIGN DOES ONE COME TO THE**  
 22 **CONCLUSION THAT I HAVE COME TO. SO IT'S NOT THE**  
 23 **14 PERCENT INCREASE, IT'S THE FACT THAT ONE COULD STILL**  
 24 **SEE A SMALL INCREASE IN THE SETTING OF THE BIASES THAT**  
 25 **WOULD BIAS STRONGLY AGAINST THAT 14 PERCENT. IT'S**

1 **ANALOGOUS TO HAVING A RACE BETWEEN A FAST RUNNER AND A**  
 2 **SLOW RUNNER AND THE SLOW RUNNER GETS A RIDE ON THE BACK**  
 3 **OF THE PICKUP TRUCK AND THE FAST RUNNER BEATS HIM BY A**  
 4 **FEW SECONDS. AND THE QUESTION IS WHO IS THE BETTER**  
 5 **RUNNER AND IN THIS CASE THE FAST RUNNER IS REMARKABLE.**  
 6 **Q.** ABOUT THE UTAH P&T, WHEN YOU WROTE YOUR REPORT,  
 7 IT WAS JANUARY OF 2009?  
 8 **A. YEAH. MY WRITTEN REPORT IS 2010.**  
 9 **Q.** 2010?  
 10 **A. YES.**  
 11 **Q.** I'M SORRY. 2001 IS ANOTHER YEAR. SO -- AND THE  
 12 P&T MEETING WAS WHEN?  
 13 **A. OCTOBER OF 2007.**  
 14 **Q.** SO TWO PLUS YEARS LATER?  
 15 **A. YES.**  
 16 **Q.** AND THE DIFFERENCE THAT MS. BENNES IS DISCUSSING  
 17 IS A COUPLE OF MONTH DIFFERENCE TWO YEARS EARLIER?  
 18 **A. YES.**  
 19 **Q.** AND WHEN YOU WERE DEPOSED, IT WAS APRIL OF 2010?  
 20 **A. YES.**  
 21 **Q.** SO EVEN MORE TIME HAD ELAPSED BY THAT POINT?  
 22 **A. TWO-AND-A-HALF YEARS.**  
 23 **Q.** ARE YOU CONFIDENT THAT YOU WERE HONEST AND  
 24 STRAIGHTFORWARD WITH WHAT YOUR CURRENT THINKING WAS AT  
 25 THE UTAH P&T?

1 **A. YES, IN THE SENSE THAT I WANTED TO MAKE SURE**  
 2 **THAT PIOGLITAZONE WAS ON THE FORMULARY, BUT THE QUESTION**  
 3 **BEFORE US WAS WHETHER OR NOT TO DELETE OR KEEP**  
 4 **ROSIGLITAZONE. MY THOUGHT WAS GIVEN THE POTENTIAL THAT**  
 5 **ROSIGLITAZONE MIGHT BE USEFUL IN CASE -- IN PATIENTS WHO**  
 6 **COULD NOT TOLERATE PIOGLITAZONE, IT WOULD BE PREFERABLE**  
 7 **TO HAVE IT KEPT ON THE FORMULARY AS AN ALTERNATIVE BASED**  
 8 **ON OTHER BENEFITS OF THIS CLASS OF DRUGS SO THAT WE**  
 9 **WOULD NOT EXCLUDE THOSE PATIENTS FROM THAT CLASS.**  
 10 **Q.** IT WAS A RISK BENEFIT ANALYSIS IN THE CLINICAL  
 11 SETTING?  
 12 **A. YES.**  
 13 **Q.** ARE YOU CONFIDENT THAT THE OPINIONS THAT YOU ARE  
 14 EXPRESSING HERE ARE TRUTHFUL AND HONEST AND BASED UPON  
 15 YOUR BEST REVIEW OF ALL OF THE EVIDENCE AVAILABLE TO  
 16 YOU?  
 17 **A. YES. A MORE THOROUGH AND COMPLETE AND**  
 18 **COMPREHENSIVE REVIEW THAN I WAS ABLE TO DO AT THE TIME**  
 19 **IN OCTOBER OF 2007.**  
 20 **Q.** DID YOU KNOW IN MID 2007 THAT AVANDIA INCREASED  
 21 LP-PLA2?  
 22 **A. NO.**  
 23 **Q.** DID YOU KNOW IN 2007 THAT THE COMPANY KNEW THAT  
 24 AS EARLY AS 2000 AND REFUSED TO PUBLISH IT?  
 25 **A. NO.**

1 Q. DID YOU KNOW AND WERE YOU AWARE THAT THE COMPANY  
 2 WHEN THEY PUBLISHED ALL OF THE OTHER DATA FROM THAT  
 3 STUDY DID NOT PUBLISH THE LP-PLA2 DATA?  
 4 A. NO.  
 5 Q. DID YOU KNOW THAT THE LABEL DID NOT ADEQUATELY  
 6 REFLECT THE IMPACT UPON INDIVIDUAL PATIENTS IN THE  
 7 PATIENT POPULATION?  
 8 A. NO.  
 9 Q. DID YOU KNOW 74 PERCENT OF THE PATIENTS HAD AN  
 10 INCREASE IN LDL CHOLESTEROL?  
 11 A. NO.  
 12 Q. WAS THERE ANY INFORMATION IN THE LABEL ABOUT  
 13 APO-B?  
 14 A. NONE.  
 15 Q. DID YOU KNOW THAT 24 PERCENT OF THE PATIENTS HAD  
 16 A DECREASE IN GOOD CHOLESTEROL?  
 17 A. NO.  
 18 Q. DID YOU KNOW THAT THEY -- THAT THE COMPANY KNEW  
 19 THE DIFFERENCES IN THE LIPID PROFILES BETWEEN ACTOS AND  
 20 AVANDIA AS EARLY AS 2000?  
 21 A. NO.  
 22 Q. DID YOU KNOW, DR. BRINTON, THAT IN 2000, THE  
 23 COMPANY MADE A CONSCIOUS DECISION PER SENIOR MANAGEMENT  
 24 REQUESTS --  
 25 HONORABLE CYNTHIA M. RUFÉ: EXCUSE ME, I

1 DON'T WHAT THIS HAS TO DO WITH HIS OPINION.  
 2 MR. ZONIES: MS. BENNES HAS PUT AN  
 3 IMPLICATION IN THAT DR. BRINTON SOMEHOW HAS MODIFIED HIS  
 4 OPINION BASED UPON NO NEW KNOWLEDGE. THIS IS ALL NEW  
 5 KNOWLEDGE THAT INFORMED HIS OPINION.  
 6 HONORABLE CYNTHIA M. RUFÉ: I DON'T THINK  
 7 THAT IS WHAT HE IS CHANGING HIS POSITION ON. HE HAS  
 8 TESTIFIED THAT HE CHANGED IT BECAUSE HE STARTED TO STUDY  
 9 IT AND NOT BECAUSE ANYONE TOLD HIM OR DIDN'T TELL HIM.  
 10 THIS IS INAPPROPRIATE.  
 11 MR. ZONIES: YOUR HONOR, I DON'T MEAN TO  
 12 BE INAPPROPRIATE.  
 13 HONORABLE CYNTHIA M. RUFÉ: NO, I MEAN,  
 14 IT COMES THROUGH THE BRIEFING, TOO. IT JUST IS NOT PART  
 15 OF YOUR OWN EXPERTS' BASIS FOR THEIR STATED OPINIONS.  
 16 THAT IS WHAT I'M READING. SO I DON'T THINK REDIRECT IS  
 17 APPROPRIATE RIGHT NOW.  
 18 MR. ZONIES: THANK YOU, YOUR HONOR.  
 19 THANK YOU, DR. BRINTON.  
 20 HONORABLE CYNTHIA M. RUFÉ: ALL RIGHT.  
 21 THAT'S IT. WE WILL TAKE A BREAK.  
 22 (BREAK TAKEN.)  
 23 THE CLERK: ALL RISE.  
 24 HONORABLE CYNTHIA M. RUFÉ: GOOD  
 25 AFTERNOON. PLEASE BE SEATED.

1 HONORABLE SANDRA MAZER MOSS: I JUST  
 2 WANTED YOU TO KNOW THAT I'M GOING TO BE LEAVING EARLY  
 3 AND YOU SHOULD NOT TAKE IT AS AN INSULT. I HAVE A PRIOR  
 4 COMMITMENT. I WILL PROBABLY SNEAK OUT ABOUT 4:30 BUT  
 5 THE NOTES OF TESTIMONY ARE HERE AND EVENTUALLY I WILL BE  
 6 ABLE TO CATCH UP WITH THEM.  
 7 HONORABLE CYNTHIA M. RUFÉ: I GET TO  
 8 STAY.  
 9 NEXT.  
 10 MR. CARTMELL: WE CALL DR. SNIDERMAN TO  
 11 THE STAND, PLEASE.  
 12 I HAVE BEEN TOLD THAT YOU HAVE MATERIALS  
 13 FOR DR. SNIDERMAN. YOU HAVE HIS REPORTS AND HIS  
 14 BIBLIOGRAPHY.  
 15 THE CLERK: STATE AND SPELL YOUR FULL  
 16 NAME FOR THE RECORD, PLEASE.  
 17 ALLAN DAVID SNIDERMAN, S-N-I-D-E-R-M-A-N.  
 18 DIRECT EXAMINATION  
 19 BY MR. CARTMELL:  
 20 Q. DR. SNIDERMAN, GOOD AFTERNOON.  
 21 A. GOOD AFTERNOON.  
 22 Q. ARE YOU A MEDICAL DOCTOR?  
 23 A. YES, I AM.  
 24 Q. WHAT TYPE OF MEDICAL DOCTOR ARE YOU?  
 25 A. CARDIOLOGIST.

1 Q. YOU RESIDE IN CANADA, IS THAT RIGHT?  
 2 A. YES, I DO.  
 3 Q. WHERE DO YOU PRACTICE MEDICINE?  
 4 A. IN MONTREAL, CANADA.  
 5 Q. WHAT IS YOUR EXPERTISE WITHIN CARDIOVASCULAR  
 6 MEDICINE?  
 7 A. I AM A CLINICAL CARDIOLOGIST AND I PRACTICE  
 8 CLINICAL CARDIOLOGY. I HAVE ALSO DONE RESEARCH IN A  
 9 NUMBER OF AREAS OF CARDIOVASCULAR MEDICINE INCLUDING  
 10 LIPID METABOLISM, METABOLISM OF FAT TISSUE AND  
 11 METABOLISM OF THE LIVER AND THE EFFECTS OF DRUGS ON  
 12 PEOPLE.  
 13 Q. WE ARE VERY CONSCIOUS OF THE TIME. SO WE ARE  
 14 GOING TO HAVE TO -- WE ARE GOING TO GO THROUGH THIS  
 15 FAST. OKAY? I'M GOING TO GIVE YOU A COPY OF YOUR  
 16 REPORTS AND ALSO YOUR BIBLIOGRAPHY SO FEEL FREE TO LOOK  
 17 AT THOSE IF YOU NEED TO. AND THEN I HAVE PUT UP ON THE  
 18 SCREEN EXHIBIT K. IT'S TITLED EXAMPLES OF  
 19 METHODOLOGICAL ERRORS OF PLAINTIFFS' EXPERT ALLAN  
 20 SNIDERMAN.  
 21 MR. CARTMELL: AND THIS IS -- YOUR  
 22 HONORS, THIS IS ACTUALLY WHAT GSK HAS IN THEIR BOOKLETS  
 23 FOR YOU OF THEIR CHALLENGES TO DR. SNIDERMAN. SO I'M  
 24 GOING TO USE THIS AS AN OUTLINE TO GO THROUGH. AND  
 25 AGAIN, AS ALWAYS, YOUR HONORS, IF YOU HAVE ANY QUESTIONS

1 SPECIFICALLY, THEN YOU CAN JUMP IN AT ANY TIME.  
 2 BY MR. CARTMELL:  
 3 Q. LET'S TALK A LITTLE BIT MORE ABOUT YOUR  
 4 QUALIFICATIONS, BUT I WANT TO MAKE SURE THAT THEY ARE  
 5 CONFINED TO THE TYPES OF THINGS THAT YOU DO IN YOUR  
 6 PRACTICE THAT ALLOW YOU TO BECOME AN EXPERT IN THIS CASE  
 7 AND THAT RELATE TO YOUR EXPERTISE.  
 8 HAVE YOU BEEN INVOLVED IN CLINICAL TRIALS  
 9 THROUGHOUT YOUR CAREER?  
 10 A. **ONE CLINICAL TRIAL.**  
 11 Q. HAVE YOU ACTUALLY WORKED WITH EPIDEMIOLOGY IN  
 12 THE PAST?  
 13 A. **YES.**  
 14 Q. YOU SAID YOU DO RESEARCH. WHY DON'T YOU TELL US  
 15 WHAT TYPE OF RESEARCH YOU HAVE BEEN DOING FOR THE LAST  
 16 30 YEARS OR SO?  
 17 A. **AT LEAST, YES.**  
 18 **I DO RESEARCH ON HUMAN BEINGS. I HAVE**  
 19 **CONDUCTED RESEARCH STUDIES ON A VARIETY OF ANIMAL**  
 20 **SPECIES. THE MAJOR AREAS HAVE BEEN THE BLOOD FATS, THE**  
 21 **CHOLESTEROL AND WHAT MAKES THEM GO UP AND WHAT MAKES**  
 22 **THEM GO DOWN. I HAVE ALSO STUDIED MANY OTHER QUESTIONS.**  
 23 Q. HAVE YOU DONE RESEARCH STUDIES THAT HAVE  
 24 INVOLVED CARDIOVASCULAR ENDPOINTS?  
 25 A. **YES.**

1 Q. HAVE YOU -- AS YOU SAID YOU HAVE DONE LOTS OF  
 2 RESEARCH INVOLVING LIPIDS AND WHAT IS CALLED APO-B, IS  
 3 THAT CORRECT?  
 4 A. **THAT'S CORRECT.**  
 5 Q. WHY DON'T YOU TELL US WHAT APO-B IS. WE HAVE  
 6 HEARD A LOT ABOUT THAT.  
 7 A. **THE CHOLESTEROL, WHICH IS WHAT MOST PEOPLE FOCUS**  
 8 **ON, IS AN OIL, AND OIL AND WATER DON'T MIX. SO IN ORDER**  
 9 **TO CARRY THE CHOLESTEROL IN THE BLOOD, THERE WAS A**  
 10 **PACKAGE CREATED. THAT PACKAGE HAS A COAT ON THE OUTSIDE**  
 11 **WHICH IS A CERTAIN KIND OF FAT, BUT IT'S ALSO GOT A**  
 12 **PROTEIN. THAT PROTEIN IS THE OUTSIDE THAT GIVES IT ITS**  
 13 **STRUCTURE. IT ALSO IS THE SIGNAL THAT ALLOWS IT TO**  
 14 **ATTACH TO SOMETHING ON THE LIVER THAT TAKES IT OUT OF**  
 15 **THE CIRCULATION. THAT PROTEIN IS CALLED APO-B.**  
 16 **EVERY LIPOPROTEIN PARTICLE THAT COULD**  
 17 **HURT YOU BY GETTING INTO THE ARTERIES HAS ONE MOLECULE**  
 18 **OF APO-B SO IF YOU WANT TO COUNT THE NUMBER OF BAD**  
 19 **PARTICLES, YOU MEASURE THE APO-B. SO APO-B IS A MEASURE**  
 20 **OF THE NUMBER OF BAD CHOLESTEROL PARTICLES.**  
 21 Q. THANK YOU VERY MUCH. AND MR. ZONIES YESTERDAY  
 22 USED AN EXAMPLE ABOUT DUMP TRUCKS OR BRINGING IN LDL AND  
 23 APO-B, THAT SORT OF THING. TELL US JUST BRIEFLY WHAT  
 24 THAT MEANS.  
 25 A. **IF A DUMP TRUCK IS A PARTICLE. THE DUMP TRUCK**

1 **IS CONTAINING CHOLESTEROL AND THERE IS NO QUESTION THAT**  
 2 **THE CHOLESTEROL IF IT STICKS IN THE ARTERY IS BAD FOR**  
 3 **THE INSIDE OF THE ARTERY. IT SETS OFF A WHOLE SERIES OF**  
 4 **EVENTS WHICH LEAD TO THE PATHOLOGY THAT THEN RESULTS IN**  
 5 **A DEATH OR A HEART ATTACK. BUT THAT CHOLESTEROL GETS IN**  
 6 **AS PART OF THE TRUCK. AND THE TRICK IN THIS CASE, THE**  
 7 **THING THAT YOU HAVE TO ADJUST YOUR THINKING TO, IS THAT**  
 8 **THE SIZE OF THE TRUCK, YOU'D NORMALLY THINK THE BIGGER**  
 9 **THE TRUCK, THE WORSE THE PROBLEM. IN THIS CASE, THAT**  
 10 **DOES NOT WORK. BECAUSE THE LDL, WHICH EVERYONE**  
 11 **ACKNOWLEDGES, LOW DENSITY LIPOPROTEINS, EVERYONE**  
 12 **ACKNOWLEDGES THAT THEY ARE THE MAJOR ACTORS, THE BAD**  
 13 **ACTORS IN CAUSING DISEASE IN THE ARTERY. AND THEY ARE**  
 14 **PARTICLES. THE PARTICLES ARE BALLS, THEY'RE SPHERES.**  
 15 **AND YOU CAN HAVE A BIG BALL OR A LITTLE BALL. AND**  
 16 **CONTRARY TO COMMON SENSE, CONTRARY TO INTUITION, THE**  
 17 **LITTLE ONES ARE JUST AS DANGEROUS AS THE BIG ONES. AND**  
 18 **THERE IS GOOD REASONS WHY THAT IS SO, BECAUSE THE LITTLE**  
 19 **ONES CAN GET INTO THE ARTERY A LITTLE BIT MORE EASILY,**  
 20 **THEY STICK A LITTLE BIT MORE EASILY. SO AT THE END OF**  
 21 **THE DAY, THE LITTLE ONES TURN OUT TO BE JUST AS RISKY**  
 22 **AND JUST AS IMPORTANT TO REDUCE AS THE BIG ONES. AND**  
 23 **THAT IS WHY COUNTING THE NUMBER OF THESE PARTICLES IS SO**  
 24 **KEY TO IDENTIFYING WHO IS AT RISK AND TREATING THEM**  
 25 **ADEQUATELY TO MAKE SURE THAT THEY WON'T DEVELOP DISEASE**

1 **IN THEIR ARTERIES, AND THEY WON'T HAVE A HEART ATTACK**  
 2 **AND DIE.**  
 3 Q. THANK YOU. NOW YOUR CURRICULUM VITAE STATES  
 4 THAT YOU HAVE BEEN PUBLISHED IN OVER 280 PEER REVIEWED  
 5 PUBLICATIONS INCLUDING LANCET, JAMA, CARDIOVASCULAR  
 6 MEDICINE JOURNALS AND EPIDEMIOLOGY JOURNALS, IS THAT  
 7 RIGHT?  
 8 A. **THAT'S CORRECT.**  
 9 Q. YOUR RESEARCH THAT YOU HAVE DONE ON APO-B HAS  
 10 ACTUALLY ALLOWED YOU TO BE ASKED TO BE ADMITTED TO THE  
 11 ROYAL SOCIETY OF CANADA, IS THAT RIGHT?  
 12 A. **THAT'S CORRECT.**  
 13 Q. AND YOU'RE MODEST, BUT I DID A LITTLE GOOGLE  
 14 SEARCH ON THAT. IS THAT THE HIGHEST HONOR FOR A  
 15 SCIENTIST IN CANADA?  
 16 A. **THAT'S CORRECT.**  
 17 Q. NOW, LET'S TALK ABOUT YOUR WORK IN THIS CASE.  
 18 YOU HAVE YOUR BIBLIOGRAPHY IN FRONT OF YOU. IT'S, I  
 19 THINK, OVER 25 PAGES LONG.  
 20 MR. CARTMELL: THERE ARE SEVERAL AGAIN,  
 21 YOUR HONORS, OF THOSE SUPPLEMENTALS.  
 22 BY MR. CARTMELL:  
 23 Q. AND THAT INCLUDES THE TOTALITY OF THE EVIDENCE  
 24 YOU REVIEWED, IS THAT CORRECT?  
 25 A. **THAT'S CORRECT.**

1 Q. IT INCLUDES PUBLISHED PEER REVIEW ARTICLES, IS  
 2 THAT RIGHT?  
 3 A. **THAT'S CORRECT.**  
 4 Q. STUDIES OF AVANDIA AND THE CARDIOVASCULAR RISK,  
 5 I THINK, OVER 150 OF THOSE TYPES OF ARTICLES, IS THAT  
 6 CORRECT?  
 7 A. **THAT'S CORRECT.**  
 8 Q. ALSO INCLUDES DOCUMENTS INTERNALLY THAT WE HAVE  
 9 RECEIVED FROM GSK, CORRECT?  
 10 A. **THAT'S CORRECT.**  
 11 Q. AND YOU HAVE LOTS AND LOTS OF FDA MATERIALS,  
 12 TRANSCRIPTS, THAT SORT OF THING?  
 13 A. **YES.**  
 14 Q. SO YOU HAVE REVIEWED ALL OF THOSE IN THE  
 15 FORMULATION OF YOUR OPINIONS, IS THAT CORRECT?  
 16 A. **THAT'S CORRECT.**  
 17 Q. OKAY.  
 18 MR. CARTMELL: IF WE CAN GO BACK TO K.  
 19 IT'S UP, K.  
 20 BY MR. CARTMELL:  
 21 Q. THE FIRST CRITICISM THAT GSK HAS OF YOU, YOU  
 22 UNDERSTAND YOU ARE HERE TODAY BECAUSE GSK IS CRITICIZING  
 23 THE METHODOLOGY THAT YOU USED IN THIS CASE WHEN YOU WERE  
 24 DOING YOUR CAUSATION ANALYSIS, RIGHT?  
 25 A. **YES.**

1 Q. OKAY. AND JUST SO IT'S CLEAR, IF WE GO TO --  
 2 ACTUALLY I THINK WE SHOULD DO THIS FIRST. IF WE GO TO  
 3 YOUR REPORT WHICH IS D, AT THE VERY FIRST PAGE.  
 4 MR. CARTMELL: AND PULL UP -- I'M SORRY,  
 5 THE SECOND PAGE -- THAT'S WRONG. IT'S PAGE THREE, I'M  
 6 SORRY, OF THE REPORT ACTUALLY. IT'S THE FIRST FULL  
 7 PARAGRAPH UNDER THE HEADING ROSIGLITAZONE AND MYOCARDIAL  
 8 ISCHEMIC EVENTS.  
 9 BY MR. CARTMELL:  
 10 Q. YOU GIVE SORT OF AN OUTLINE THERE AND A SUMMARY.  
 11 YOU SAY, BASED ON MY REVIEW, IN THE SECOND SENTENCE, I  
 12 HAVE ALSO CONCLUDED THAT THE EVIDENCE ESTABLISHES TO A  
 13 VERY HIGH DEGREE OF PROBABILITY THAT ROSIGLITAZONE  
 14 CAUSES SIGNIFICANT INCREASE IN MYOCARDIAL ISCHEMIC  
 15 EVENTS INCLUDING MYOCARDIAL INFARCTION. DO YOU SEE  
 16 THAT?  
 17 A. **YES, I DO.**  
 18 MR. CARTMELL: IF WE CAN GO BACK TO K.  
 19 BY MR. CARTMELL:  
 20 Q. NOW, THE FIRST CRITICISM THAT YOU WILL SEE FROM  
 21 THIS EXHIBIT --  
 22 MR. CARTMELL: IF WE CAN DO THE FIRST  
 23 BULLET POINT, PLEASE.  
 24 BY MR. CARTMELL:  
 25 Q. -- STATES THAT YOU REACHED YOUR CONCLUSIONS

1 ABOUT HEART ATTACK BASED ON DATA REGARDING MYOCARDIAL  
 2 ISCHEMIC EVENTS. THE ISSUE FOR ME IS NOT ISOLATING  
 3 MYOCARDIAL INFARCTION OUT OF THE PANOPLY OF SEVERE  
 4 ADVERSE CARDIOVASCULAR EVENTS. THAT IS WHY I'VE NEVER  
 5 CONSIDERED THE QUESTION IN THAT WAY.  
 6 NOW THAT IS A QUOTE FROM YOU, ISN'T IT?  
 7 A. **THAT'S CORRECT.**  
 8 Q. AND THAT WAS DURING YOUR EIGHT-HOUR DEPOSITION,  
 9 IS THAT RIGHT?  
 10 A. **THAT'S CORRECT.**  
 11 Q. TELL US WHAT YOU MEANT BY THAT WHEN YOU SAID  
 12 THAT DURING YOUR DEPOSITION IN RESPONSE TO A QUESTION.  
 13 A. **AS A CARDIOLOGIST, THERE ARE CLASSICAL**  
 14 **MYOCARDIAL ISCHEMIC EVENTS THAT WE RECOGNIZE. WE**  
 15 **RECOGNIZE SUDDEN DEATH AS A CLASSICAL UNFORTUNATELY**  
 16 **TRAGICALLY A MANIFESTATION OF AN ACUTE HEART ATTACK. WE**  
 17 **RECOGNIZE A CLASSICAL, WHAT A LAYPERSON WOULD CALL A**  
 18 **HEART ATTACK. WE ALSO RECOGNIZE THAT A PATIENT MAY**  
 19 **SUFFER PROLONGED CHEST PAIN AND NOT MEET THE DIAGNOSTIC**  
 20 **CRITERIA FOR A HEART ATTACK, BUT THERE CAN BE CLEAR**  
 21 **EVIDENCE THAT THE PAIN IS DUE TO AN ACUTE DISRUPTION**  
 22 **WITHIN ONE OF THE CORONARY ARTERIES. SO ALL OF THOSE**  
 23 **THINGS WE INCLUDE AS MYOCARDIAL ISCHEMIC EVENTS DUE TO A**  
 24 **CATASTROPHIC DISRUPTION WITHIN THE INTEGRITY OF THE**  
 25 **CORONARY ARTERY, THAT THE ENDOTHELIUM HAS SPLIT, THAT**

1 **THE INTERIOR OF THE ARTERY WHERE THE CHOLESTEROL IS IS**  
 2 **EXPOSED TO THE BLOOD AND IT'S ACUTELY -- CAUSES A BLOOD**  
 3 **CLOT AND THAT CAN EITHER KILL THE PATIENT, CAUSE A HEART**  
 4 **ATTACK OR OFTEN THE BLOOD CLOT DISSOLVES VERY QUICKLY**  
 5 **AND THE PATIENT FORTUNATELY SURVIVES, BUT THE EVENT**  
 6 **STILL OCCURRED. SO ALL OF THOSE ARE CONSEQUENCES OF THE**  
 7 **SAME CORE SIGNAL EVENT. SO THAT IN MANY -- IN MOST**  
 8 **CARDIOVASCULAR CLINICAL TRIALS YOU HAVE THESE COMPOSITE**  
 9 **CLINICAL ENDPOINTS WHICH REGROUP THESE SERIES OF EVENTS**  
 10 **AS THE COMPOSITE ENDPOINT.**  
 11 **MYOCARDIAL INFARCTION IS ALWAYS ONE OF**  
 12 **THESE MAJOR CARDIOVASCULAR EVENTS. AND AS A**  
 13 **CARDIOLOGIST WHEN YOU HAVE THE SAME CORE EVENT OCCURRING**  
 14 **YOU EXPECT A CONSISTENCY OF OUTCOMES. YOU EXPECT**  
 15 **MYOCARDIAL INFARCTION. IF IT IS INCREASED YOU EXPECT**  
 16 **ALSO TO SEE AN INCREASE IN THE TOTAL NUMBER OF**  
 17 **MYOCARDIAL ISCHEMIC EVENTS. IT WOULD BE UNUSUAL AND**  
 18 **INCONSISTENT IN THE STRENGTH OF THE EVIDENCE IF YOU**  
 19 **DIDN'T SEE THAT.**  
 20 **SO WHAT I ATTEMPTED TO SAY WAS THAT I**  
 21 **LOOKED AT COMPONENTS OF THE COMPOSITE ENDPOINTS SUCH AS**  
 22 **MYOCARDIAL INFARCTION AND INDEED THERE IS CLEAR,**  
 23 **DEFINITE EVIDENCE IN A NUMBER OF STUDIES THAT THAT**  
 24 **SPECIFIC ENDPOINT WAS SIGNIFICANTLY INCREASED IN**  
 25 **SUBJECTS WHO WERE TAKING ROSIGLITAZONE. BUT IN**

1 **ADDITION, THE COMPOSITE, THAT WAS ALSO INCREASED. SO**  
 2 **THE COMPOSITE INCLUDES THE HEART ATTACKS. THAT IS WHAT**  
 3 **I WAS TRYING TO SAY.**  
 4 Q. AND YOU LAY OUT IN YOUR 40 PAGE FIRST EXPERT  
 5 REPORT, YOU HAVE ACTUALLY DONE TWO SUPPLEMENTAL EXPERT  
 6 REPORTS, IS THAT CORRECT?  
 7 A. **YES.**  
 8 Q. OKAY. YOU LAY OUT IN DETAIL THAT THE EVIDENCE  
 9 THAT YOU LOOK AT -- THIS STEP -- THE STUDIES WITH  
 10 MYOCARDIAL INFARCTION ENDPOINTS THAT YOU RELIED ON FOR  
 11 YOUR OPINION, CORRECT?  
 12 A. **THAT'S CORRECT.**  
 13 Q. AND THEN SEPARATE AND APART FROM THAT YOU ALSO  
 14 LOOKED AT EVIDENCE, LIKE THE ICT 42 FOR INSTANCE, THAT  
 15 DEALS WITH MYOCARDIAL ISCHEMIA ENDPOINTS, CORRECT?  
 16 A. **THAT'S CORRECT.**  
 17 Q. IS IT FAIR TO SAY THAT YOU RELIED ON MYOCARDIAL  
 18 ISCHEMIC EVIDENCE FOR YOUR MYOCARDIAL INFARCTION OPINION  
 19 ENTIRELY?  
 20 A. **NO. THEY ARE TWO SEPARATE QUESTIONS. AND WHEN**  
 21 **BOTH WERE POSITIVE, I SAW A CONSISTENCY IN THE EVIDENCE.**  
 22 Q. NOW, YOU I THINK ALSO LAY OUT IN -- YOU DO IN  
 23 YOUR REPORT THE METHODOLOGY YOU USED AND ONE THING YOU  
 24 DID WAS LOOK AT ALL OF THE RANDOMIZED CONTROLLED TRIALS,  
 25 IS THAT CORRECT?

1 A. **THAT'S CORRECT.**  
 2 Q. YOU LOOKED AT THE LARGE RANDOMIZED CONTROLLED  
 3 TRIALS LIKE RECORD AND ADOPT AND DREAM, IS THAT RIGHT?  
 4 A. **THAT'S CORRECT.**  
 5 Q. YOU ALSO HAVE A SECTION IN YOUR REPORT THAT  
 6 REFERS SPECIFICALLY TO OTHER TRIALS, LIKE -- YOU ADDRESS  
 7 THE APPROACH TRIAL WHICH IS A RANDOMIZED CONTROLLED  
 8 TRIAL, CORRECT?  
 9 A. **THAT'S CORRECT.**  
 10 Q. YOU LOOKED AT THE SMALLER RANDOMIZED CONTROLLED  
 11 TRIALS THAT WERE IN GSK'S CLINICAL TRIAL PROGRAM AS  
 12 WELL, CORRECT?  
 13 A. **I DEFINITELY DID.**  
 14 Q. AND YOU ACTUALLY LOOKED AT PATIENT LEVEL DATA IN  
 15 SEVERAL OF THOSE TRIALS, IS THAT CORRECT?  
 16 A. **YES, I DID.**  
 17 Q. NOW -- AND YOU ALSO LAY OUT IN A SECTION IN YOUR  
 18 REPORT THAT YOU LOOKED AT THE META-ANALYSIS, THE VARIOUS  
 19 META-ANALYSIS THAT ARE ON YOUR BIBLIOGRAPHY WHEN YOU  
 20 WERE DEVELOPING YOUR OPINIONS, IS THAT RIGHT?  
 21 A. **YES.**  
 22 Q. AND DID YOU FIND AN ASSOCIATION BETWEEN AVANDIA  
 23 AND MYOCARDIAL INFARCTION FROM THE META-ANALYSES?  
 24 A. **YES, I DID.**  
 25 Q. YOU LOOKED AT THE ICT 42 META-ANALYSIS THAT HAD

1 A STATISTICALLY SIGNIFICANT INCREASED RISK OF MYOCARDIAL  
 2 ISCHEMIC EVENTS, CORRECT?  
 3 A. **CORRECT.**  
 4 Q. THE FDA ANALYSIS AS WELL, CORRECT?  
 5 A. **CORRECT.**  
 6 Q. THE 2010 META-ANALYSIS FROM THE FDA THAT HAD A  
 7 1.8 OR AN 80 PERCENT INCREASED RISK IN MYOCARDIAL  
 8 INFARCTION THAT WAS STATISTICALLY SIGNIFICANT?  
 9 A. **YES.**  
 10 Q. YOU ALSO LOOKED AT GSK'S ICT 52 STUDY THAT HAD  
 11 ENDPOINTS ON MYOCARDIAL ISCHEMIA AND THE MACE ENDPOINT,  
 12 DIDN'T YOU?  
 13 A. **YES, I DID.**  
 14 Q. YOU ALSO LOOKED AT MULTIPLE OBSERVATIONAL  
 15 STUDIES. I THINK SOME 20 OR CLOSE TO 20 ARE ON YOUR  
 16 BIBLIOGRAPHY, AND YOU LISTED SEVERAL OF THEM IN YOUR  
 17 REPORT, IS THAT CORRECT?  
 18 A. **THAT'S CORRECT.**  
 19 Q. DID YOU LIST IN YOUR REPORT THE ANALYSES THAT  
 20 YOU WENT THROUGH IN REVIEWING THE STUDIES AND DATA FOR  
 21 THOSE STUDIES?  
 22 A. **I INDICATED IN MY REPORT HOW I EVALUATED THE**  
 23 **RELATIVE STRENGTHS OF THE DIFFERENT CLASSES OF STUDIES.**  
 24 **AND THEN IN THIS PARTICULAR INSTANCE, I FOCUSED MOST ON**  
 25 **THE RECORD STUDY SINCE IT WAS -- EVERYONE HAS**

1 **ACKNOWLEDGED IT TO BE THE MOST -- IT HAS GOTTEN THE MOST**  
 2 **ATTENTION AND THAT IS THE ONE THAT I PAID THE MOST**  
 3 **ATTENTION TO. AND IN MY REPORT I INDICATED -- I**  
 4 **INDICATE HOW I EVALUATED EACH OF THE PIECES OF EVIDENCE**  
 5 **THAT I INCLUDED AND WHY. I TRIED TO GIVE A REASON FOR**  
 6 **WHY I WOUND UP SAYING THAT A PARTICULAR STUDY WAS A WELL**  
 7 **DONE STUDY OR NOT A WELL DONE STUDY.**  
 8 Q. I NOTICED THAT IN YOUR REPORT YOU INCLUDED  
 9 OBSERVATIONAL STUDIES THAT SHOWED THAT AVANDIA IS  
 10 ASSOCIATED WITH INCREASED RISK AND HAVE STATISTICALLY  
 11 SIGNIFICANT FINDINGS. YOU ALSO IN THERE FOR FAIR  
 12 BALANCE HAVE OBSERVATIONAL DATA AND STUDIES THAT YOU  
 13 LOOKED AT THAT DON'T SHOW THAT, IS THAT CORRECT?  
 14 A. **THAT'S CORRECT.**  
 15 Q. WHY DID YOU DO THAT?  
 16 A. **BECAUSE YOU HAVE TO INCLUDE ALL OF THE EVIDENCE.**  
 17 MR. CARTMELL: NOW, WE CAN GO TO THE NEXT  
 18 BULLET POINT. ACTUALLY I'M SORRY -- THIS IS IT.  
 19 BY MR. CARTMELL:  
 20 Q. RELIED ON NONSTATISTICALLY SIGNIFICANT DATA  
 21 SUBSTITUTING CLINICAL SIGNIFICANCE FOR STATISTICAL  
 22 SIGNIFICANCE.  
 23 I WANT TO JUST ASK YOU, DID YOU RELY  
 24 SOLELY ON NONSTATISTICALLY SIGNIFICANT DATA?  
 25 A. **NO.**

1 Q. DID YOU RELY ON LOTS OF STATISTICALLY  
 2 SIGNIFICANT DATA?  
 3 A. I DIDN'T UNDERSTAND WHAT YOU SAID.  
 4 Q. DID YOU RELY ON A LOT OF STATISTICALLY  
 5 SIGNIFICANT DATA?  
 6 A. YES.  
 7 Q. AND IS THAT OUTLINED IN YOUR REPORTS?  
 8 A. YES.  
 9 Q. AND DURING YOUR DEPOSITION TESTIMONY FOR EIGHT  
 10 HOURS?  
 11 A. YEAH, I BELIEVE IT IS.  
 12 Q. THE NEXT CRITICISM BY GSK STATES THAT YOU DID  
 13 NOT EVEN ATTEMPT TO RULE OUT BIAS AND CONFOUNDING. IS  
 14 THAT TRUE?  
 15 A. THAT IS NOT TRUE.  
 16 Q. TELL US WHAT YOU DID DURING YOUR METHODOLOGY,  
 17 YOUR SCIENTIFIC REVIEW HERE TO ATTEMPT TO RULE OUT BIAS  
 18 AND CONFOUNDING.  
 19 A. IF I CAN GIVE A SPECIFIC EXAMPLE. IN THE RECORD  
 20 TRIAL WHICH I PAID A LOT OF ATTENTION TO, I LOOKED AT  
 21 THE USE OF STATINS IN THE PATIENTS WHO WERE TREATED WITH  
 22 ROSIGLITAZONE VERSUS THE PATIENTS WHO WERE NOT TREATED  
 23 WITH ROSIGLITAZONE. IT IS AN ESTABLISHED CARDIOVASCULAR  
 24 FACT THAT STATINS REDUCE THE FREQUENCY OF HEART ATTACKS  
 25 AND THEY REDUCE THE FREQUENCY OF CARDIAC DEATH. I DON'T

1 BELIEVE ANYBODY DISPUTES THAT. IT'S AN ESTABLISHED  
 2 CARDIOVASCULAR FACT THAT THE STRENGTH OF THAT EFFECT  
 3 RELATES TO THE DOSE OF THE STATIN, HOW MUCH OF THE  
 4 STATIN YOU USED, AND HOW POWERFUL THE PARTICULAR DRUG,  
 5 THE PARTICULAR STATIN YOU USED. THERE ARE FIVE OR SIX  
 6 DIFFERENT STATINS. SO SOME ARE MORE POWERFUL THAN  
 7 OTHERS. THERE IS CLEAR EVIDENCE FROM THE SCIENTIFIC  
 8 LITERATURE THAT THE MORE POWERFUL ONES WILL PRODUCE  
 9 GREATER CLINICAL BENEFIT.  
 10 SO I LOOKED AT THE RECORD STUDY TO  
 11 DETERMINE WHETHER OR NOT THERE WAS SOMETHING THAT  
 12 TECHNICALLY IS CALLED PERFORMANCE BIAS. THE STRENGTH OF  
 13 A RANDOMIZED CLINICAL TRIAL, THE REASON IT'S HELD UP IN  
 14 SUCH HIGH REGARD, IS THAT ONCE THE PATIENTS ARE RANDOMLY  
 15 BY CHANCE ALLOCATED INTO ONE OF THE TWO GROUPS, THE ONLY  
 16 THING THAT CAN BE DIFFERENT ABOUT THOSE TWO GROUPS IS  
 17 WHETHER OR NOT THEY GET THE TREATMENT THAT IS BEING  
 18 STUDIED. IF THEY WERE TO GET ANOTHER TREATMENT THAT IS  
 19 ACKNOWLEDGED TO BE LIFE SAVING, AND IF MORE OF ONE GROUP  
 20 THAN THE OTHER WERE TO RECEIVE THAT TREATMENT, THEN  
 21 CLEARLY THAT WOULD NOT BE A RANDOMIZED CONTROLLED TRIAL.  
 22 IT WOULD BE, IN THE LANGUAGE I USE IN MY REPORT, IS A  
 23 RANDOMIZED UNCONTROLLED TRIAL.  
 24 I DO NOT HAVE THE FULL DATA AVAILABLE TO  
 25 ME OF THE USE OF STATINS IN THE RECORD TRIAL, BUT I HAVE

1 CLEAR EVIDENCE THAT THE USE WAS UNBALANCED AND IT IS A  
 2 SERIOUS POTENTIAL LIMITATION IN THE VALIDITY OF THE  
 3 FINDINGS OF RECORD. SO THAT IS AN EXAMPLE OF SEARCHING  
 4 FOR BIAS, WHICH I DID. I ALSO BY THE WAY SOUGHT FOR  
 5 BIAS THAT WOULD FAVOR THE DRUG. I DID NOT SIMPLY GO IN  
 6 AS A SEARCH AND DESTROY MISSION TO LOOK FOR ANYTHING  
 7 THAT WOULD BE AGAINST THE DRUG. I LOOKED FOR ANYTHING  
 8 THAT I COULD IDENTIFY THAT WOULD BE UNFAIRLY ACTING  
 9 AGAINST THE DRUG. I DID NOT IDENTIFY ANY SUCH FACTORS,  
 10 BUT I SOUGHT THEM OUT.  
 11 MR. CARTMELL: CAN WE GO TO D, PAGE 24,  
 12 PLEASE. IF YOU WOULD HIGHLIGHT THAT LAST METHODOLOGICAL  
 13 LIMITATION SECTION.  
 14 BY MR. CARTMELL:  
 15 Q. THIS IS PAGE 24 OF YOUR REPORT. YOU TALK ABOUT  
 16 SOME METHODOLOGICAL LIMITATIONS HERE. SPECIFICALLY YOU  
 17 ARE TALKING ABOUT SOME OF THE LACK OF ADJUDICATION. WE  
 18 HEARD A LOT ABOUT THAT IN THE LAST DAY AND-A-HALF ABOUT  
 19 A LOT OF THESE STUDIES DID NOT HAVE ADJUDICATION, IS  
 20 THAT CORRECT?  
 21 A. THAT'S CORRECT.  
 22 Q. IS THAT A BIAS THAT WOULD TEND TO PUSH THE BIAS  
 23 TOWARDS THE NULL? THE RISK TOWARD THE NULL?  
 24 A. YES. BECAUSE IT'S, AS DR. JEWELL EXPLAINED  
 25 EARLIER TODAY, IT INCREASES THE NOISE. ANYTHING THAT

1 INCREASES THE NOISE TENDS TO FAVOR THE NULL, WHICH WOULD  
 2 BE THAT THE DRUG WOULD NOT BE SHOWN TO HAVE A  
 3 SIGNIFICANT INCREASED RISK OF ADVERSE EVENTS.  
 4 Q. ON THE NEXT PAGE, PAGE 25, THE FIRST FULL  
 5 PARAGRAPH, THE FIRST SENTENCE STATES: THE SECOND FACTOR  
 6 LIMITING THE SENSITIVITY OF THESE STUDIES TO IDENTIFY  
 7 EXCESS ADVERSE EVENTS IS THAT ALMOST ALL OF THE ROSI  
 8 STUDIES WERE CONDUCTED IN RELATIVELY LOW RISK  
 9 CARDIOVASCULAR POPULATIONS. DO YOU SEE THAT?  
 10 A. YES, I DO.  
 11 Q. IS THAT ANOTHER LIMITATION OR BIAS THAT WOULD  
 12 TEND TO PUSH THE RISK OF AVANDIA TOWARDS THE NULL?  
 13 A. THAT'S CORRECT. ALSO IF I CAN JUST INTERJECT  
 14 WITH IT, THAT IN THE ICT 42 IT WAS NOTED BY THE FDA  
 15 ANALYSIS THAT THE RISK WAS CLEAREST IN THE PATIENTS WHO  
 16 WERE TAKING INSULIN. NOW THAT IS A GROUP THAT YOU WOULD  
 17 EXPECT TO BE A HIGHER RISK BECAUSE THEY WOULD HAVE  
 18 LIKELY HAD THE DIABETES FOR A LONGER PERIOD OF TIME  
 19 AND MORE CORONARY DISEASE. AND THAT IS CONSISTENT WITH  
 20 YOUR BEING ABLE TO SEE ADVERSE EVENTS MORE CLEARLY IN  
 21 HIGHER RISK PEOPLE. THE SAME OBSERVATION WAS MADE ABOUT  
 22 NITROGLYCERINE, A DRUG THAT IS USED TO TREAT PEOPLE WITH  
 23 HEART DISEASE. SO THAT LOOKING AT BOTH THE LOW RISK END  
 24 OF IT AND THE HIGH RISK END OF IT, IT PAINTED A VERY  
 25 CONSISTENT PICTURE FOR ME.

1 Q. NOW, ONCE YOU FOUND AN ASSOCIATION FROM THE DATA  
2 BETWEEN AVANDIA AND MYOCARDIAL ISCHEMIC EVENTS INCLUDING  
3 MYOCARDIAL INFARCTIONS, AND YOU LOOKED AT BIAS AND  
4 CONFOUNDING AND RULED THAT OUT, DID YOU APPLY THE  
5 BRADFORD-HILL CRITERIA, SOME OF THE FACTORS OF THE  
6 BRADFORD-HILL CRITERIA?

7 A. **YES, I DID.**

8 Q. IS THAT SPECIFICALLY, NOT THE WORDS  
9 BRADFORD-HILL, BUT SEVERAL OF THE CRITERIA DISCUSSED AT  
10 LENGTH IN YOUR REPORT?

11 A. **YES.**

12 MR. CARTMELL: IF WE CAN GO BACK TO K,  
13 THE FOURTH BULLET POINT DOWN.

14 BY MR. CARTMELL:

15 Q. GSK STATES THAT YOU DID NOT APPLY THE  
16 BRADFORD-HILL CRITERIA. INSTEAD YOU EQUATED ASSOCIATION  
17 WITH CAUSATION. DO YOU SEE THAT?

18 A. **YES, I DO.**

19 Q. IS THAT TRUE?

20 A. **THAT IS NOT TRUE.**

21 Q. AND JUST SO WE CAN BE QUICK, I WENT THROUGH YOUR  
22 REPORT -- YOU CAN, IF YOU WANT TO GO THROUGH WITH ME,  
23 BUT YOU TALK ABOUT REPLICATION IN YOUR REPORT, IS THAT  
24 CORRECT?

25 A. **THAT'S CORRECT.**

1 Q. YOU TALK ABOUT REPLICATION IN THE FIRST FULL  
2 PARAGRAPH OF PAGE 26 OF YOUR REPORT. THAT IS ONE OF THE  
3 BRADFORD-HILL CRITERIA?

4 A. **YES, IT IS.**

5 Q. ON PAGE 27 IN THE LAST PARAGRAPH, YOU TALK ABOUT  
6 CONSISTENCY AND REPLICATION RELATED TO THE SINGH  
7 META-ANALYSIS, IS THAT RIGHT?

8 A. **YES, THAT'S CORRECT.**

9 Q. THAT IS A META-ANALYSIS THAT HAD A STATISTICALLY  
10 SIGNIFICANT INCREASED RISK FOR MYOCARDIAL INFARCTION --

11 A. **THAT'S CORRECT.**

12 Q. -- WITH AVANDIA.

13 YOU TALK ABOUT REPLICATION ON PAGE 29 --

14 MR. CARTMELL: IF YOU HIGHLIGHT THE TOP

15 PARAGRAPH THERE.

16 BY MR. CARTMELL:

17 Q. YOU ARE TALKING ABOUT STUDIES. YOU SAY: IN MY  
18 OPINION THERE IS TOO MUCH UNCERTAINTY ABOUT THE MATERIAL  
19 AND METHODS OF THE MANNUCCI STUDY FOR IT TO OFFSET THE  
20 REPEATED FINDINGS. THAT IS REPLICATION, ISN'T IT?

21 A. **THAT'S CORRECT.**

22 Q. YOU TALK ABOUT A BIOLOGICAL PLAUSIBLE MECHANISM  
23 IN MULTIPLE PLACES AND EXTENSIVELY IN YOUR REPORT.

24 A. **IN TERMS OF REPLICATION I ALSO TALK ABOUT THE  
25 MONOTONOUS REGULARITY OF THE OUTCOME.**

1 Q. THAT'S RIGHT, THOSE ARE YOUR WORDS.

2 A. **MONOTONOUS REGULARITY. SOMEWHERE IN THAT  
3 REPORT.**

4 Q. OKAY, OKAY.

5 I WANT TO GET TO BIOLOGICAL PLAUSIBILITY  
6 BECAUSE THAT IS A BIG PART OF YOUR REPORT AND WE TALKED  
7 A LITTLE BIT ABOUT APO-B. WHY DON'T YOU TELL US WHAT  
8 YOUR OPINION IS WITH RESPECT TO WHAT THE BIOLOGICALLY  
9 PLAUSIBLE MECHANISM OF ACTION YOU BELIEVE IS FOR WHAT  
10 YOU ARE SEEING IN THE STUDIES AS FAR AS AVANDIA  
11 INCREASING THE RISK OF HEART ATTACKS.

12 A. **I BELIEVE THAT THE EVIDENCE TAKEN IN ITS  
13 TOTALITY INDICATES THAT AN INCREASE IN LDL, WHETHER IT'S  
14 QUANTITATED BY LDL CHOLESTEROL OR BY APO-B, THEY ARE  
15 COMPLEMENTARY, ACCOUNTS FOR A VERY SUBSTANTIAL PORTION  
16 OF THE RISK. I THINK IT'S CRITICAL TO MY  
17 INTERPRETATION, THIS UNDERSTANDING, BECAUSE IT ALLOWS  
18 ONE TO UNDERSTAND WHY A STUDY DONE UNDER ONE  
19 CIRCUMSTANCE WILL DEMONSTRATE A STATISTICALLY  
20 SIGNIFICANT DIFFERENCE IN CLINICAL EVENTS AND WHY  
21 ANOTHER STUDY DONE DID NOT FIND A CLINICALLY SIGNIFICANT  
22 DIFFERENCE IN EVENTS.**

23 **AND LDL IS A POISON. STATINS ARE THE  
24 ANTIDOTE TO THAT POISON. IF YOU GIVE THE ANTIDOTE ALONG  
25 WITH THE POISON, YOU WILL NOT DEMONSTRATE IN THE SIZE OF**

1 **THE STUDIES THAT WERE DONE ANY SIGNIFICANTLY INCREASED  
2 RISK WITH ROSIGLITAZONE. IF, HOWEVER, AS WAS THE CASE  
3 IN THE STUDIES USED IN THE EARLIER META-ANALYSIS, MUCH  
4 LESS OF THE ANTIDOTE IS GIVEN, THAT'S WHEN YOU WILL SEE  
5 THE RESULT MORE STRONGLY.  
6 SO THAT I'M TRYING TO NOT SAY I WANT THIS  
7 STUDY BECAUSE IT SUPPORTS THIS PARTICULAR POINT OF VIEW  
8 OR THAT STUDY BECAUSE IT DOESN'T. I'M TRYING TO REGROUP  
9 BIOLOGICALLY, A BIOLOGICAL META-ANALYSIS, AS IT WERE.  
10 IF YOU PUT IT ALL TOGETHER, IS THERE A DEEP CONSISTENCY  
11 IN THE FINDINGS? I BELIEVE IF YOU USE THAT AS AN  
12 INTERPRETATIVE FRAMEWORK -- THE NUMBERS THEMSELVES SPEAK  
13 FOR THEMSELVES, YOU DON'T -- I DON'T IMPUTE ANYTHING  
14 ABOUT CAUSALITY FROM THE LDL RELATIONSHIPS, BUT THEY  
15 GIVE YOU A DEEP UNDERSTANDING OF THE FACTORS AT PLAY AND  
16 ALLOW ALL OF THE INFORMATION TO BE INTEGRATED IN A  
17 COHERENT AND CONSISTENT WAY.**

18 HONORABLE SANDRA MAZER MOSS: HOLD ON.  
19 SHE HAS TO LET ME OUT.

20 MR. CARTMELL: OKAY. THANK YOU.

21 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.

22 PLEASE BE SEATED AND LET'S CONTINUE.

23 BY MR. CARTMELL:

24 Q. NOW CONTINUING ON, WE ARE TALKING ABOUT THE  
25 BIOLOGICALLY PLAUSIBLE MECHANISM. I WANT TO MAKE SURE

1 -- YOU JUST SAID SOMETHING. I WANT MAKE SURE THAT'S  
 2 CLEAR. YOU SAID I DON'T IMPUTE ANY CAUSALITY FROM THE  
 3 LDL. AND I JUST WANT TO MAKE IT CLEAR, YOU ARE TALKING  
 4 ABOUT -- YOU ARE NOT USING THE BIOLOGICALLY PLAUSIBLE  
 5 MECHANISM TO JUMP TO CAUSATION AS FAR AS MYOCARDIAL  
 6 INFARCTION?  
 7 **A. NO. ZERO. NIENIE. NOT AT ALL.**  
 8 **Q.** BUT YOU DO BELIEVE THAT LDL -- AN INCREASE IN  
 9 LDL SIGNIFICANTLY LIKE AVANDIA DOES, RIGHT?  
 10 **A. THAT'S CORRECT.**  
 11 **Q.** THAT THAT CAUSES ATHEROSCLEROSIS AND THEREBY AN  
 12 INCREASED RISK OF MYOCARDIAL INFARCTION?  
 13 **A. AS A CARDIOVASCULAR SCIENTIST, IT'S A SCIENTIFIC**  
 14 **FACT THAT I KNOW.**  
 15 **Q.** IS THE SAME TRUE WITH APO-B, THAT IF YOU  
 16 ACTUALLY INCREASE APO-B LIKE AVANDIA DOES, THERE IS  
 17 SCIENCE THAT SUPPORTS THAT THAT CAUSES INCREASED  
 18 ATHEROSCLEROSIS AND ACTUALLY INCREASE OF MYOCARDIAL  
 19 EVENTS?  
 20 **A. YES, SIR.**  
 21 **Q.** IS THAT ACTUALLY SUPPORTED BY DECADES -- LET'S  
 22 GO TO LDL FIRST. IS LDL SUPPORTED BY DECADES OF  
 23 RANDOMIZED CONTROLLED TRIALS SHOWING THAT?  
 24 **A. LDL CHOLESTEROL?**  
 25 **Q.** RIGHT.

1 **A. YES, ABSOLUTELY.**  
 2 **Q.** WITH APO-B HAVE THERE NOW BEEN RANDOMIZED  
 3 CONTROLLED TRIALS THAT HAVE SHOWN THAT TO BE TRUE, THAT  
 4 CAUSAL CONNECTION?  
 5 **A. ABSOLUTELY.**  
 6 MR. CARTMELL: IF WE CAN LOOK AT H  
 7 PLEASE. IF WE CAN HIGHLIGHT THE SECOND FULL PARAGRAPH  
 8 DOWN UNDER -- THE NEXT ONE. THANKS. THIS ONE.  
 9 BY MR. CARTMELL:  
 10 **Q.** THIS IS ACTUALLY A GSK DOCUMENT THAT WAS  
 11 PROVIDED TO US IN THIS LITIGATION. I WILL GIVE THE  
 12 AVMDL NUMBER JUST WE'RE IT'S CLEAR ON THE RECORD. IT'S  
 13 AVMDL 07283129.  
 14 THIS STATES: AS REVIEWED IN SNIDERMAN  
 15 2003, FOUR LARGE PROSPECTIVE EPIDEMIOLOGICAL STUDIES  
 16 HAVE DIRECTLY COMPARED APO-B WITH LDL-C AND ALL HAVE  
 17 SHOWN APO-B TO BE THE SUPERIOR PREDICTOR OF VASCULAR  
 18 RISK.  
 19 YOU HAVE SEEN THIS DOCUMENT, IS THAT  
 20 CORRECT?  
 21 **A. THAT'S CORRECT.**  
 22 **Q.** THIS GSK DOCUMENT THAT WAS PREPARED BY A GSK  
 23 INDIVIDUAL ACTUALLY REFERENCES YOU -- YOU ARE DR.  
 24 SNIDERMAN?  
 25 **A. THAT'S CORRECT.**

1 **Q.** -- FOR THE PROPOSITION THAT YOU ARE HOLDING IN  
 2 THIS LAWSUIT, IS THAT CORRECT?  
 3 **A. THAT'S CORRECT.**  
 4 **Q.** NOW, I WANT TO GO BACK TO K IF WE CAN AND LOOK  
 5 AT THE LAST --  
 6 HONORABLE CYNTHIA M. RUFÉ: COULD I ASK  
 7 YOU TO CLARIFY, MR. CARTMELL.  
 8 MR. CARTMELL: SURE.  
 9 HONORABLE CYNTHIA M. RUFÉ: A SUPERIOR  
 10 PREDICTOR OF VASCULAR RISK, THAT DOES NOT IN MY MIND  
 11 EQUATE TO THE PRESENCE OF APO-B IS THE CAUSE OF  
 12 MYOCARDIAL INFARCTION. SO CAN YOU TELL ME WHERE THAT  
 13 FITS IN YOUR SCHEME.  
 14 MR. CARTMELL: LET'S GO BACK TO H. LET'S  
 15 HIGHLIGHT THAT AGAIN.  
 16 BY MR. CARTMELL:  
 17 **Q.** ACTUALLY WE SHOULD READ THE NEXT SENTENCE, I  
 18 BELIEVE: FURTHERMORE A NUMBER OF STATIN INTERVENTION  
 19 STUDIES HAVE DETERMINED THE RESIDUAL RISK IN PATIENTS  
 20 TREATED WITH STATIN THERAPY AND RELATED IT TO ON  
 21 TREATMENT LEVELS OF CHOLESTEROL OR APOLIPOPROTEIN B. IN  
 22 MOST OF THESE STUDIES THE RELATION TO RESIDUAL RISK WAS  
 23 SIGNIFICANTLY STRONGER TO APOLIPOPROTEIN B THAN TO LDL  
 24 C.  
 25 THE QUESTION I WANT TO ASK YOU --

1 MR. CARTMELL: DO YOU WANT ME TO RESPOND  
 2 OR DO YOU WANT ME TO ASK HIM A QUESTION?  
 3 HONORABLE CYNTHIA M. RUFÉ: I WANT YOU TO  
 4 GET IT FROM YOUR WITNESS.  
 5 MR. CARTMELL: OKAY. THAT'S WHAT I  
 6 SHOULD DO.  
 7 BY MR. CARTMELL:  
 8 **Q.** I WANT TO ASK YOU -- SO THIS IS REFERRING TO  
 9 STUDIES THAT HAVE ACTUALLY BEEN DONE RANDOMIZED, I THINK  
 10 THEY CALLED THEM STATIN TRIALS. TELL US WHY IT IS THAT  
 11 YOU CAN SAY, YOU KNOW, THAT THIS IS A CAUSAL CONNECTION  
 12 AND HOW THAT FITS INTO YOUR MECHANISM.  
 13 **A. WE HAVE DIFFERENT LEVELS OF EVIDENCE TO PUT**  
 14 **FORWARD. THE TWO MOST CRITICAL ARE THE EVIDENCE FROM**  
 15 **PROSPECTIVE EPIDEMIOLOGICAL STUDIES, JUST LIKE**  
 16 **FRAMINGHAM, THAT LOOK AT PEOPLE OVER A LONG PERIOD OF**  
 17 **TIME AND DETERMINE WHETHER THEIR RISK, THE LIKELIHOOD**  
 18 **THAT THEY WOULD HAVE A HEART ATTACK, RELATED TO THEIR**  
 19 **INITIAL LDL CHOLESTEROL LEVEL AND THEIR APO-B LEVEL. IT**  
 20 **TURNS OUT THAT IN MOST OF THOSE STUDIES THEY SHOW THAT**  
 21 **BOTH PREDICT RISK, BUT ACTUALLY APO-B DOES A SUPERIOR**  
 22 **JOB. IT DOES A SUPERIOR JOB BECAUSE IT'S A BETTER**  
 23 **MEASURE OF THE NUMBER OF PARTICLES. THE CHOLESTEROL IS**  
 24 **THE AMOUNT OF OIL AND IT'S DIVIDED AMONGST THE DIFFERENT**  
 25 **LITTLE TRUCKS. AND MEASURING THE NUMBER OF TRUCKS TURNS**

1 **OUT TO BE A MORE EFFECTIVE CLINICAL TECHNIQUE.**  
 2 **THE SECOND CRITICAL PIECE OF EVIDENCE IS**  
 3 **THAT LOWERING THE APO-B IS ASSOCIATED WITH A REDUCTION**  
 4 **OF EVENTS. THE MORE YOU LOWER IT, THE MORE YOU REDUCE**  
 5 **EVENTS. SO IF THE LIKELIHOOD OF DEATH OR A HEART ATTACK**  
 6 **GOES UP WHEN THE LEVEL GOES UP AND THE LIKELIHOOD GOES**  
 7 **DOWN WHEN THE LEVEL GOES DOWN, THAT ESTABLISHES A -- AND**  
 8 **YOU TAKE ALL OF THE OTHER EVIDENCE INTO ACCOUNT, THAT**  
 9 **ESTABLISHES A CAUSAL RELATIONSHIP.**

10 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.

11 BY MR. CARTMELL:

12 Q. AND THE CRITICAL POINT OF THAT IS THAT THIS DATA  
 13 THAT YOU ARE CITING IS FROM RANDOMIZED CONTROLLED  
 14 TRIALS?

15 A. **THAT'S CORRECT.**

16 Q. IN OTHER WORDS, THESE ARE TRIALS WHERE THEY ARE  
 17 ACTUALLY TAKING PATIENTS AND LOOKING AT THEIR LEVELS OF  
 18 LDL AND APO-B AND TRACKING THOSE AND CORRELATING THEM  
 19 WITH MYOCARDIAL INFARCTIONS. THEY'RE RANDOMIZED, THEY  
 20 ARE THE HIGHEST LEVEL OF EVIDENCE.

21 A. **ABSOLUTELY. THESE ARE THE TRIALS THAT**  
 22 **ESTABLISHED STATINS TO BE THE LIFE SAVING DRUGS THAT WE**  
 23 **KNOW THEY ARE.**

24 Q. OKAY.

25 LET'S GO -- DID THAT ANSWER YOUR

1 **I CAN USE THE EXAMPLE OF THE APPROACH STUDY. THIS WAS A**  
 2 **STUDY THAT WAS DESIGNED BY A SCIENTIST FUNDED BY GSK TO**  
 3 **DETERMINE WITH THE SPECIFIC STATED OBJECTIVE, TO**  
 4 **DETERMINE WHETHER ALL OF THESE OTHER GUYS --**  
 5 Q. WHEN YOU SAY OTHER GUYS ARE YOU TALKING ABOUT  
 6 CRP?  
 7 A. CRP.  
 8 Q. THE OTHER BIOMARKERS.  
 9 A. **THE OTHER BIOMARKERS. IT'S SPECIFICALLY STATED**  
 10 **IN THE STUDY. THE OBJECTIVE OF THE STUDY WAS TO**  
 11 **DETERMINE WHETHER OR NOT THESE OTHER PLAYERS WOULD --**  
 12 **WHICH WERE FAVORABLY INFLUENCED BY ROSIGLITAZONE WHEN**  
 13 **YOU MEASURE THEIR QUANTITY IN THE BLOOD, WOULD THAT BE**  
 14 **ASSOCIATED WITH AN IMPROVEMENT IN ATHEROSCLEROSIS AS**  
 15 **MEASURED BY ULTRASOUND IN THE CORONARY ARTERY. THE**  
 16 **STUDY FAILED TO SHOW ANY BENEFIT. NOW THESE WERE PEOPLE**  
 17 **IN WHOM THE CHOLESTEROL WAS NOT ALLOWED TO RISE BECAUSE**  
 18 **THEY WERE TREATED WITH STATINS. SO THE LDL IS OFF THE**  
 19 **TABLE. THE BAD GUY IS TAKEN OFF THE TABLE. WHAT THEY**  
 20 **HAD AND WHAT THEY WANTED TO TEST, WHAT THEY DESIGNED THE**  
 21 **STUDY TO TEST WAS WHETHER THE PUTATIVE GOOD GUYS WOULD**  
 22 **DO ANYTHING THAT MATTERED IF THEY WERE GIVEN A CHANCE,**  
 23 **AND THE DATA FROM THE STUDY SHOW THAT THERE WAS NO**  
 24 **BENEFIT FROM THE ROSIGLITAZONE. THAT IS THE EVIDENCE,**  
 25 **THE TRIAL -- THE EXPERIMENTAL EVIDENCE THAT I USED TO**

1 QUESTION?

2 HONORABLE CYNTHIA M. RUFÉ: YES.

3 MR. CARTMELL: LET'S GO BACK TO K, PLEASE

4 AND THE LAST BULLET POINT HERE.

5 BY MR. CARTMELL:

6 Q. SO GSK SAYS, OKAY, WELL, YOU TALK ABOUT APO-B  
 7 AND LDL BEING INCREASED AND THEY DO. YOU ACTUALLY  
 8 LOOKED AT THE LDL AND APO-B LEVELS AT THE PATIENT DATA  
 9 LEVEL, CORRECT?

10 A. **YES.**

11 Q. I'M NOT GOING TO GO THROUGH IT AGAIN, BUT YOU  
 12 ALSO FOUND THAT THE LEVELS WERE MUCH GREATER THAN  
 13 18 PERCENT IF YOU LOOK AT THE PATIENT LEVEL DATA,  
 14 CORRECT?

15 A. **THAT'S CORRECT.**

16 Q. AND THEY SAY, OKAY, SO BUT YOU DON'T TAKE INTO  
 17 CONSIDERATION OTHER CARDIOVASCULAR RISK FACTORS LIKE HDL  
 18 OR CRP, MMP OR PAI 1, AND SOME OTHER OF THESE OTHER RISK  
 19 FACTORS. DID YOU TAKE THOSE INTO CONSIDERATION?

20 A. **YES, I DID AND I DEMONSTRATE -- I HOPE TO**  
 21 **DEMONSTRATE IN MY REPORT EXACTLY HOW I TOOK THEM INTO**  
 22 **CONSIDERATION. THIS DRUG CAUSES MANY CHANGES IN MANY**  
 23 **DIFFERENT CONSTITUENTS THAT CAN BE MEASURED. SOME OF**  
 24 **THESE CONSTITUENTS ARE ASSOCIATED WITH INCREASED RISK.**  
 25 **SOME OF THEM ARE ASSOCIATED WITH DECREASED RISK. AND IF**

1 **REACH MY BIOLOGICAL CONCLUSION, THAT THESE OTHER FACTORS**  
 2 **ARE INTERESTING, SOME OF THEM MAY TURN OUT TO BE**  
 3 **IMPORTANT, BUT THEY ARE NOT MATERIAL IN THIS PRESENT**  
 4 **CASE.**  
 5 Q. OKAY. AND IN ALL OF THOSE OTHER BIOMARKERS THAT  
 6 YOU TALK ABOUT, CRP, AND MMP, PAI 1, THERE ARE SEVERAL  
 7 THAT WERE ACTUALLY DISCUSSED IN THE OPENING. DO ANY OF  
 8 THOSE BIOMARKERS RISE TO THE LEVEL LIKE LDL OR APO-B AS  
 9 BEING CAUSATIVE OF INCREASED MYOCARDIAL EVENTS LIKE MI?  
 10 A. **NO. MY OPINION IS NOT DIFFERENT THAN THE**  
 11 **OPINION I READ FROM COLLEAGUES WHO ARE TESTIFYING ON**  
 12 **BEHALF OF GSK.**  
 13 Q. AND A KEY PART OF THAT, ISN'T IT, IS THAT LDL  
 14 AND APO-B HAVE BEEN IN RANDOMIZED CONTROLLED TRIAL AFTER  
 15 RANDOMIZED CONTROLLED TRIAL, WHERE THEY ARE SHOWING  
 16 THIS, THESE OTHER SURROGATE BIOMARKERS, THEY DON'T HAVE  
 17 THAT EVIDENCE TO SUPPORT THAT THEY CAUSE INCREASED RISK,  
 18 CORRECT?  
 19 A. **THAT IS CORRECT.**  
 20 Q. NOW, YOU DID -- IN YOUR REPORT THOUGH YOU TALKED  
 21 ABOUT HDL, YOU TALKED ABOUT CRP, YOU CONSIDERED ALL OF  
 22 THESE OTHER BIOMARKERS, DID YOU NOT?  
 23 A. **THAT'S CORRECT, I WOULD BE PREPARED TO GO**  
 24 **THROUGH EACH ONE.**  
 25 Q. UNFORTUNATELY WE DON'T HAVE THE TIME.

1 **A. THAT'S RIGHT. BUT I DID CONSIDER THEM.**  
 2 **Q.** THAT IS THE KEY. ALL RIGHT. SO I JUST WANT TO  
 3 WRAP UP. I WANT TO MAKE SURE IT IS CLEAR. YOU ARE NOT  
 4 SAYING THAT AVANDIA INCREASES THE RISK OR CAUSES MI'S  
 5 BECAUSE OF THE BIOLOGICAL PLAUSIBLE MECHANISM. YOU ARE  
 6 SAYING THAT IS THE PLAUSIBLE MECHANISM, CORRECT?  
 7 **A. THAT'S CORRECT, AND IT'S ONE OF THE ELEMENTS**  
 8 **WITHIN THE BRADFORD-HILL THAT YOU ARE SUPPOSED TO**  
 9 **CONSIDER.**  
 10 **Q.** YOU ARE SAYING -- YOUR CAUSATION OPINION THAT  
 11 YOU HAVE MADE AFTER LOOKING AT THE BRADFORD-HILL AND  
 12 DOING AN ANALYSIS OF BIAS AND CONFOUNDING IS BASED ON  
 13 THE DATA FROM THE RANDOMIZED CONTROLLED TRIALS, THE  
 14 META-ANALYSIS AND THE OBSERVATIONAL STUDIES, IS THAT  
 15 CORRECT?  
 16 **A. YES, THAT'S CORRECT.**  
 17 MR. CARTMELL: THANKS. I DON'T HAVE  
 18 ANYTHING FURTHER.  
 19 HONORABLE CYNTHIA M. RUFÉ: YOU SAVED A  
 20 FEW MINUTES.  
 21 MR. CARTMELL: ALL RIGHT.  
 22 HONORABLE CYNTHIA M. RUFÉ: THANK YOU,  
 23 MR. CARTMELL.  
 24 MS. GUSSACK: BOB GLANVILLE WILL BE  
 25 CONDUCTING THE CROSS EXAMINATION OF DR. SNIDERMAN.

1 HONORABLE CYNTHIA M. RUFÉ: WOULD YOU  
 2 PLEASE SPELL YOUR LAST NAME FOR ME.  
 3 MR. GLANVILLE: G-L-A-N-V-I-L-L-E.  
 4 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.  
 5 CROSS EXAMINATION  
 6 BY MR. GLANVILLE:  
 7 **Q.** GOOD AFTERNOON, DOCTOR.  
 8 **A. GOOD AFTERNOON.**  
 9 **Q.** HAPPILY FOR BOTH OF US, I THINK THIS ENCOUNTER  
 10 WILL BE A LOT SHORTER THAN THE LAST ONE.  
 11 **A. I HOPE SO.**  
 12 **Q.** ARE WE READY?  
 13 DOCTOR, BEFORE YOU WERE RETAINED AS  
 14 PLAINTIFFS' EXPERT IN THIS LITIGATION, YOU HAD NO  
 15 OPINION ON THE QUESTION OF WHETHER AVANDIA CAUSES HEART  
 16 ATTACKS, IS THAT CORRECT?  
 17 **A. THAT'S CORRECT.**  
 18 **Q.** WOULD IT BE FAIR TO SAY THEN THAT THE OPINIONS  
 19 YOU HAVE EXPRESSED IN YOUR EXPERT REPORT AND HERE IN THE  
 20 COURT TODAY WERE FORMED SOLELY FOR PURPOSES OF  
 21 LITIGATION?  
 22 **A. IT WAS FORMED FOR THE PROCESS, YES.**  
 23 **Q.** YOU DON'T HAVE A DEGREE IN EPIDEMIOLOGY OR  
 24 BIOSTATISTICS, DO YOU?  
 25 **A. I DO NOT.**

1 **Q.** YOU DON'T HOLD YOURSELF OUT AS AN EPIDEMIOLOGIST  
 2 OR A BIOSTATISTICIAN, DO YOU?  
 3 **A. I DO NOT.**  
 4 **Q.** YOU HAVE HAD NO FORMAL TRAINING IN EITHER  
 5 BIOSTATISTICS OR EPIDEMIOLOGY BEYOND WHAT ANYBODY WHO  
 6 ATTENDS MEDICAL SCHOOL GETS, RIGHT?  
 7 **A. FORMAL TRAINING, NO.**  
 8 **Q.** AND IN FACT, YOU HAVE TOLD YOUR COLLEAGUES THAT  
 9 YOU ARE ALSO NOT A LIPIDOLOGIST, BUT RATHER YOU'RE ONLY  
 10 A CARDIOLOGIST WHO HAS DONE SOME RESEARCH ON LOW DENSITY  
 11 LIPOPROTEIN METABOLISM. DO YOU RECALL MAKING THAT  
 12 STATEMENT?  
 13 **A. YES. I PROBABLY SAID SOMETHING LIKE THAT. THE**  
 14 **BIGGEST THING IN MY LIFE IS BEING A CARDIOLOGIST.**  
 15 **Q.** WELL, IS IT AN ACCURATE STATEMENT THAT YOU ARE  
 16 NOT A LIPIDOLOGIST?  
 17 **A. WELL, I HAVE THAT CERTIFICATE FROM THE AMERICAN**  
 18 **BOARD OF CLINICAL LIPIDOLOGY. I SEE PATIENTS WITH LIPID**  
 19 **DISORDERS, BUT I DESCRIBE MYSELF AS A CARDIOLOGIST.**  
 20 **THAT IS ACCURATE.**  
 21 **Q.** DOCTOR, YOU HAVE WRITTEN THAT TOTAL PERSONAL  
 22 RISK RELATES TO THE TOTAL PROFILE OF THE MAJOR RISK  
 23 FACTORS IN AN INDIVIDUAL, NOT SIMPLY TO THE LEVEL OF  
 24 PROATHEROGENIC OR ANTI-ATHEROGENIC CLINICAL PROTEINS,  
 25 HAVEN'T YOU?

1 **A. THAT'S CORRECT.**  
 2 **Q.** WHAT WE ARE TALKING ABOUT THERE IS APO-B AND LDL  
 3 ON THE ONE HAND AND HDL ON THE OTHER, RIGHT,  
 4 PRINCIPALLY?  
 5 **A. FOR THE LIPOPROTEIN PART OF IT.**  
 6 **Q.** YEAH.  
 7 **A. YES.**  
 8 **Q.** SO WHAT YOU ARE SAYING THERE IS THAT YOU CAN'T  
 9 ASSESS TOTAL PERSONAL RISK BY LOOKING IN ISOLATION AT  
 10 FACTORS LIKE LDL OR APO-B. YOU HAVE TO LOOK AT THE  
 11 ENTIRE RISK PROFILE OF THE PATIENT, CORRECT?  
 12 **A. THE EVIDENCE, YES.**  
 13 **Q.** WOULD IT BE FAIR TO SAY, DOCTOR, THAT THE CORE  
 14 OF YOUR OPINION IN THIS MATTER IS THAT YOU BELIEVE THAT  
 15 AVANDIA CAUSES ISCHEMIC HEART DISEASE INCLUDING HEART  
 16 ATTACKS BECAUSE OF ITS ALLEGED EFFECT IN RAISING APO-B  
 17 AND LDL-C IN SOME PATIENTS?  
 18 **A. NO.**  
 19 **Q.** TURN TO PAGE THREE OF YOUR EXPERT REPORT.  
 20 MR. GLANVILLE: THIS IS 1402, PAGE THREE.  
 21 EXHIBIT 1402. I'M SORRY.  
 22 BY MR. GLANVILLE:  
 23 **Q.** DOCTOR, YOU TELL US THERE THAT THE ADVERSE  
 24 EFFECTS OF ROSIGLITAZONE ON APO-B LIPOPROTEIN ARE THE  
 25 PATHOPHYSIOLOGICAL MECHANISM RESPONSIBLE FOR INCREASED

1 CLINICAL EVENTS, DON'T YOU?  
 2 **A. THAT'S CORRECT.**  
 3 **Q.** YOU DON'T -- YOU ARTICULATE THAT AS AN  
 4 ESTABLISHED FACT, NOT EVEN AN HYPOTHESIS, CORRECT?  
 5 **A. THAT IS THE SENTENCE, YES.**  
 6 **Q.** DOCTOR, IS THERE ANYBODY IN THE ENTIRE WORLDWIDE  
 7 PEER REVIEWED SCIENTIFIC LITERATURE WHO HAS PUBLISHED AN  
 8 ASSERTION THAT YOU KNOW OF THAT AVANDIA'S EFFECTS ON  
 9 APO-B CAUSE HEART ATTACKS?  
 10 **A. WELL, WHAT I WAS, IF I CAN --**  
 11 **Q.** WELL, WHAT I WOULD LIKE YOU TO DO IS ANSWER THE  
 12 QUESTION, IF YOU COULD.  
 13 **A. MY CONCLUSION ABOUT AVANDIA AND HEART ATTACKS IS**  
 14 **BASED ON THE RELATIONSHIP BETWEEN AVANDIA AND THE**  
 15 **FREQUENCY OF HEART ATTACKS. THIS SENTENCE SPECIFICALLY**  
 16 **IS TO BIOLOGICAL PLAUSIBILITY. IT'S TO MECHANISM.**  
 17 HONORABLE CYNTHIA M. RUFÉ: THE QUESTION  
 18 WAS WHO ELSE IF ANYONE HAS PUBLISHED SUCH AN ASSERTION?  
 19 BY MR. GLANVILLE:  
 20 **Q.** HAS ANYONE AND YOU HAVE NOT, RIGHT?  
 21 **A. THAT'S CORRECT.**  
 22 **Q.** HAS ANYONE ELSE TO YOUR KNOWLEDGE PUBLISHED SUCH  
 23 AN ASSERTION?  
 24 **A. NO.**  
 25 **Q.** AND WHAT YOU ARE SAYING HERE, IS THAT YOU

1 BELIEVE --  
 2 **A. CAN I JUST -- PEOPLE HAVE -- OKAY. I APOLOGIZE.**  
 3 **Q.** PEOPLE HAVE SPECULATED ABOUT POSSIBLE  
 4 MECHANISMS, RIGHT, DOCTOR?  
 5 **A. YES.**  
 6 **Q.** YOU ARE NOT SAYING THIS IS A HYPOTHETICAL  
 7 MECHANISM. YOU ARE SAYING IT'S AN ESTABLISHED FACT,  
 8 AREN'T YOU?  
 9 **A. I'M SAYING IN TERMS OF MY ANALYSIS THAT THE**  
 10 **PATHOPHYSIOLOGICAL MECHANISM I PROPOSE IS A STRONG ONE,**  
 11 **YES. THAT IS -- I'M SAYING THE PATHOPHYSIOLOGICAL**  
 12 **MECHANISM UNDER BRADFORD-HILL THAT I SOUGHT FOR IS A**  
 13 **COHERENT AND CONSISTENT AND COMPELLING ONE.**  
 14 **Q.** YOU SAT THROUGH DR. BRINTON'S TESTIMONY, DIDN'T  
 15 YOU?  
 16 **A. I'M SORRY.**  
 17 **Q.** YOU SAT THROUGH DR. BRINTON'S TESTIMONY HERE,  
 18 DIDN'T YOU?  
 19 **A. YES, I DID.**  
 20 **Q.** YOU HEARD HIM REAFFIRM WHAT HE SAID AT HIS  
 21 DEPOSITION, THAT JUST BECAUSE SOMETHING INCREASES LDL  
 22 DOES NOT MEAN IT INCREASES CARDIOVASCULAR RISK. YOU  
 23 HEARD THAT TESTIMONY, DIDN'T YOU?  
 24 **A. YES, I DID.**  
 25 **Q.** DO YOU DISPUTE THAT?

1 **A. NO.**  
 2 **Q.** SO IF DR. BRINTON IS RIGHT AND YOU SEEM TO AGREE  
 3 THAT HE IS, IT WOULD BE WRONG TO IMPOSE A PRESUMPTION  
 4 THAT JUST BECAUSE SOMETHING INCREASES LDL, IT INCREASES  
 5 CARDIOVASCULAR RISK, WOULDN'T IT?  
 6 **A. BUT THAT IS THE SPECIFIC WORD THAT I USED WAS**  
 7 **PRESUMPTION. FOR ME A PRESUMPTION AS I KNOW THE WORD IS**  
 8 **THAT YOU SUPPOSE SOMETHING TO BE THE CASE BASED ON THE**  
 9 **LIKELIHOOD THAT IT IS. A PRESUMPTION IS NOT A**  
 10 **CONCLUSION. I WAS NOT STATING A CONCLUSION WHEN I USED**  
 11 **THE WORD I PRESUMED IT TO BE TRUE. WHAT I WAS SAYING**  
 12 **WAS THERE IS A VERY HIGH PROBABILITY THAT IT'S TRUE,**  
 13 **JUST THE WAY DO YOU A PRESUMPTION OF EVIDENCE. YOU**  
 14 **DON'T SAY THAT EVERYBODY WHO COMES INTO THE COURTROOM IS**  
 15 **ABSOLUTELY INNOCENT. YOU SAY THEY ARE PRESUMED TO BE**  
 16 **INNOCENT. THAT IS THE -- I THINK THE CORRECT USE OF THE**  
 17 **WORD.**  
 18 **Q.** SO DOCTOR, YOU ARE NOT SAYING THAT YOU KNOW OR  
 19 THAT ANYBODY ELSE KNOWS THAT AVANDIA'S EFFECTS ON LDL-C  
 20 CAUSES HEART ATTACKS?  
 21 **A. NO, I AM NOT.**  
 22 **Q.** ONE WAY TO TEST THAT HYPOTHESIS OR PRESUMPTION,  
 23 AS YOU CALLED IT, WOULD BE TO EXAMINE PATIENT LEVEL DATA  
 24 TO TRY TO DISCERN WHETHER THE PATIENTS WITH THE HIGHEST  
 25 LDL OR APO-B LEVELS ON AVANDIA ARE THE ONES THAT ARE

1 HAVING THE HEART ATTACKS, RIGHT?  
 2 **A. THE GREATEST CHANGE, YES, IT WOULD BE.**  
 3 **Q.** OKAY, DOCTOR. YOU HAVE NOT DONE SUCH AN  
 4 EXAMINATION, HAVE YOU?  
 5 **A. NO, I HAVE NOT.**  
 6 **Q.** YOU UNDERSTAND THAT AT THE 2007 ADCOM IN JUNE OF  
 7 2007 GSK PRESENTED WHAT IT CALLED A TERTILE ANALYSIS  
 8 THAT ATTEMPTED TO SEE WHETHER THERE WAS ANY RELATIONSHIP  
 9 BETWEEN AVANDIA ASSOCIATED LDL LEVELS ON THE ONE HAND  
 10 AND HEART ATTACK ON THE OTHER, DON'T YOU?  
 11 **A. YES, I DO.**  
 12 **Q.** THEY FOUND NO SUCH RELATIONSHIP, DID THEY?  
 13 **A. DO YOU HAVE THAT TABLE?**  
 14 **Q.** YEAH, WE CAN PUT THAT UP.  
 15 **A. COULD WE LOOK AT THAT TABLE, PLEASE.**  
 16 MR. GLANVILLE: IT'S EXHIBIT 1431 AT THE  
 17 BOTTOM OF THE PAGE, PAGE 79. FIRST WE WILL LOOK AT THE  
 18 TEXTUAL DISCUSSION.  
 19 BY MR. GLANVILLE:  
 20 **Q.** DOCTOR, I'M NOT ASKING IF YOU AGREE WITH THAT  
 21 ANALYSIS. I'M ASKING YOU WHETHER --  
 22 MR. GLANVILLE: LET'S HIGHLIGHT AND BLOW  
 23 UP IF YOU WOULD THE PRECEDING PAGE, THE LAST PARAGRAPH.  
 24 BY MR. GLANVILLE:  
 25 **Q.** DOCTOR, DON'T THE AUTHORS OF THAT ANALYSIS

1 CONCLUDE THAT IT IS UNLIKELY THAT EARLY CHANGES IN LDL-C  
 2 IS ASSOCIATED WITH MYOCARDIAL INFARCTION?  
 3 **A. THE AUTHORS DO.**  
 4 **Q.** YOU DON'T ACCEPT THAT, RIGHT?  
 5 **A. NO, I DO NOT.**  
 6 **Q.** BUT YOU HAVEN'T DONE AN ANALYSIS OF ANY AVANDIA  
 7 RELATED LDL OR APO-B DATA THAT EVEN EXAMINES THAT  
 8 QUESTION, HAVE YOU?  
 9 **A. NO. BUT ON THE BASIS OF THEIR DATA, I REJECT**  
 10 **THEIR ASSERTION.**  
 11 **Q.** BUT YOU DON'T HAVE ANY AFFIRMATIVE DATA TO  
 12 SUPPORT YOUR POSITION?  
 13 **A. THAT IS CORRECT.**  
 14 **Q.** IN FACT YOU KNOW THAT LAST JULY AT THE 2010  
 15 ADCOM THERE WAS ANOTHER ANALYSIS OF THAT SAME ISSUE  
 16 PRESENTED, DON'T YOU?  
 17 **A. I DON'T RECALL THE DETAILS OF THAT AT THIS**  
 18 **MOMENT.**  
 19 MR. GLANVILLE: LET'S TURN TO PAGE 280  
 20 LINES 7 THROUGH 281 LINE FOUR OF THE ADCOM TRANSCRIPT,  
 21 FIRST DAY, THE 13TH.  
 22 BY MR. GLANVILLE:  
 23 **Q.** DO YOU RECALL A PRESENTATION BY DR. HOBERMAN?  
 24 **A. NO, I DON'T. I MEAN, I KNOW THERE WAS A**  
 25 **PRESENTATION BY HOBERMAN, BUT I DON'T RECALL IT.**

1 MR. GLANVILLE: IT BEGINS WITH LINE  
 2 SEVEN, GOES THROUGH 281 LINE FOUR.  
 3 BY MR. GLANVILLE:  
 4 **Q.** HE SAYS THAT OBVIOUSLY IT HAS PLENTY OF CAVEATS  
 5 BUT THE STRIKING THING --  
 6 MR. GLANVILLE: WILL YOU ILLUMINATE  
 7 BEGINNING LINE 12.  
 8 BY MR. GLANVILLE:  
 9 **Q.** BUT THE STRIKING THING ABOUT THE SLIDE IS THAT  
 10 THOSE WHO DID HAVE EVENTS HAD VIRTUALLY THE SAME LDLS  
 11 OVER TIME AS THOSE WHO DID NOT HAVE EVENTS AND IN SOME  
 12 CASES, EVEN LOWER. DOES THAT REFRESH YOUR RECOLLECTION  
 13 ABOUT THE ANALYSIS THAT DR. HOBERMAN OF THE FDA DID AND  
 14 PRESENTED?  
 15 **A. WELL, I'M NOT FAMILIAR WITH THE TOTAL ANALYSIS,**  
 16 **BUT THAT SENTENCE IS NOT A MEANINGFUL SCIENTIFIC**  
 17 **SENTENCE TO ME. THE ISSUE IS RISK, THE LIKELIHOOD THAT**  
 18 **AN EVENT WILL OCCUR AT ANY PARTICULAR LEVEL. NO --**  
 19 MR. GLANVILLE: YOUR HONOR, WITH ALL DUE  
 20 RESPECT, I ASKED HIM A SIMPLE QUESTION AND IF I'M  
 21 LOOKING FOR AN EXPLANATION, I WILL ASK HIM FOR THAT.  
 22 HONORABLE CYNTHIA M. RUFÉ: ALL RIGHT. I  
 23 THINK YOU ARE IN CONTROL THERE.  
 24 BY MR. GLANVILLE:  
 25 **Q.** DOESN'T DR. HOBERMAN CONCLUDE THERE THAT THERE

1 IS LITTLE EVIDENCE OF AN ASSOCIATION OF LDL WITH EVENTS?  
 2 **A. HE DOES SAY PLENTY OF CAVEATS, BUT IT'S HIS**  
 3 **CONCLUSION.**  
 4 **Q.** YOU ARE NOT AWARE OF ANY ANALYSIS DONE BY  
 5 ANYBODY PUBLISHED ANYWHERE OR PRESENTED ANYWHERE THAT IS  
 6 CONTRARY TO THE ANALYSES PRESENTED BY GSK IN 2007 AND  
 7 FDA SCIENTISTS THEMSELVES IN 2010, ARE YOU?  
 8 **A. I'M NOT AWARE OF ANY FULL ANALYSES OF THE ISSUE**  
 9 **ANYWHERE.**  
 10 **Q.** SO IS IT FAIR TO SAY THAT TO THE EXTENT THAT  
 11 YOUR PRESUMPTION HAS BEEN EXAMINED TWICE, ONCE BY GSK  
 12 AND ONCE BY FDA, IT'S BEEN FOUND THAT THERE IS NO  
 13 EVIDENCE TO SUPPORT IT?  
 14 **A. NO, SIR, THAT IS NOT FAIR.**  
 15 **Q.** DOCTOR, DO YOU RECALL WRITING BACK IN 2001,  
 16 2 YEARS AFTER AVANDIA WAS LICENSED FOR SALE IN THE U.S.,  
 17 THAT THE IDEA THAT DYSLIPIDEMIAS ACCOUNT FOR A MAJOR  
 18 PORTION OF MACROVASCULAR DISEASE IN DIABETICS IS ONLY A  
 19 HYPOTHESIS, ALBEIT ONE WITH CONSIDERABLE SUPPORT?  
 20 **A. I RECALL WRITING THAT SENTENCE. I DON'T RECALL**  
 21 **WHERE OR IN WHAT CONTEXT, BUT I DID WRITE IT.**  
 22 **Q.** YOU TOLD ME AT YOUR DEPOSITION THAT YOU BELIEVE  
 23 THAT REPRESENTED AN ACCURATE STATEMENT OF THE SCIENTIFIC  
 24 CONSENSUS AT THE TIME, DIDN'T YOU?  
 25 **A. YES, SIR.**

1 **Q.** AND DOCTOR, IS IT STILL THE CASE THAT TODAY IT  
 2 IS STILL ONLY A HYPOTHESIS THAT DYSLIPIDEMIAS ACCOUNT  
 3 FOR A MAJOR PORTION OF MACROVASCULAR DISEASE IN  
 4 DIABETICS, ALBEIT ONE WITH CONSIDERABLE SUPPORT?  
 5 **A. ALBEIT? ABSOLUTELY NOT.**  
 6 **Q.** AND WHEN DO YOU CLAIM IT SHIFTED FROM HYPOTHESIS  
 7 TO WHAT IS IT, A SCIENTIFIC CERTAINTY IN YOUR JUDGEMENT  
 8 NOW?  
 9 **A. YES.**  
 10 **Q.** WHEN DID THAT SHIFT OCCUR?  
 11 **A. I CAN'T PRECISE THE MOMENT THAT THAT OCCURRED**  
 12 **BECAUSE THE COHERENCE OF THE STATIN TRIALS, THE MULTIPLE**  
 13 **REPORTS OF THE STATIN TRIALS ABOUT THE BENEFITS OF**  
 14 **STATINS WHICH ACT BY LOWERING LDL IN DIABETICS BECAME SO**  
 15 **POWERFUL OVER THE LAST MULTIPLE YEARS. I HAD ALWAYS**  
 16 **THOUGHT IT WAS THE CASE, BUT I DIDN'T WANT TO**  
 17 **OVER-STRETCH MY CONVICTIONS WHEN I WAS WRITING TO**  
 18 **COLLEAGUES. SO I DON'T RECALL THE MOMENT THAT IT BECAME**  
 19 **A GENERAL VIEW, BUT IT'S WITH THE ACCUMULATION OF**  
 20 **KNOWLEDGE.**  
 21 **Q.** OKAY. AND IN THAT SAME PUBLICATION YOU SAID, WE  
 22 STILL KNOW MUCH MORE ABOUT ASSOCIATION THAN ABOUT  
 23 CAUSATION, AND YOU WERE TALKING WITH RESPECT TO  
 24 CARDIOVASCULAR DISEASE, WEREN'T YOU?  
 25 **A. YES, THAT IS TRUE.**

- 1 Q. IS THAT A TRUE STATEMENT TODAY OR IS THAT --
- 2 A. **THAT IS TRUE.**
- 3 Q. OKAY.
- 4 AND IN THAT SAME ARTICLE YOU TELL US THAT
- 5 LOW HDL AND ELEVATED LDL FROM AN EPIDEMIOLOGIC
- 6 PERSPECTIVE ARE IMPORTANT RISK FACTORS FOR PREMATURE
- 7 VASCULAR DISEASE, RIGHT?
- 8 A. **THAT'S CORRECT.**
- 9 Q. WHEN YOU TALK ABOUT EPIDEMIOLOGIC PERSPECTIVE,
- 10 WHAT YOU ARE TALKING ABOUT IS STUDIES THAT LOOK AT
- 11 CHANGES IN ONE OF THOSE PARAMETERS IN ISOLATION,
- 12 CORRECT?
- 13 A. **OR THE EFFECT OVER THE LONG TERM OF AN INITIAL**
- 14 **VALUE OF ONE OF THOSE LEVELS. MOST OF THE**
- 15 **EPIDEMIOLOGICAL PROSPECTIVE STUDIES ARE NOT ABOUT**
- 16 **CHANGES.**
- 17 Q. RIGHT. AND THEY CAN'T TELL YOU ANYTHING ABOUT
- 18 THE OVERALL EFFECTS OF A MULTIPLICITY OF CHANGES THAT
- 19 OCCUR SIMULTANEOUSLY, CAN THEY?
- 20 A. **THAT SINGLE ELEMENT OF EVIDENCE, NO.**
- 21 Q. RIGHT. YOU ARE AWARE OF THE -- IN FACT, DURING
- 22 DR. BRINTON'S TESTIMONY I THINK THE GOLDBERG STUDY WAS
- 23 DISCUSSED. YOU ARE FAMILIAR WITH THAT PAPER, AREN'T
- 24 YOU?
- 25 A. **YES, I AM.**

- 1 Q. AND THAT COMPARED LIPID EFFECTS WITH PIO TO
- 2 LIPID EFFECTS WITH AVANDIA, CORRECT?
- 3 A. **THAT'S CORRECT.**
- 4 Q. IT WAS SPONSORED BY THE MANUFACTURER OF PIO,
- 5 TAKEDA, RIGHT?
- 6 A. **YES.**
- 7 Q. SO YOU WILL AGREE WITH ME THAT THOSE SCIENTISTS
- 8 DID NOT HAVE ANY REASON TO BE ESPECIALLY KIND TO
- 9 AVANDIA?
- 10 A. **I WOULD THINK ANY SCIENTIST REPORTS WHAT THEY**
- 11 **FIND, YES.**
- 12 Q. WHAT THEY CONCLUDED WAS THAT ALTHOUGH THERE WAS
- 13 A DIFFERENCE IN THE LIPID PROFILE OF AVANDIA VERSUS PIO,
- 14 THEY SAID THAT CLINICAL IMPLICATIONS OF THOSE
- 15 DIFFERENCES IN TERMS OF IMPACT ON LDL, APO-B AND HDL
- 16 WERE UNCLEAR AND REMAINED TO BE DEFINED BY FURTHER
- 17 RESEARCH, RIGHT?
- 18 A. **YES, THEY DID.**
- 19 Q. TO THE EXTENT THAT THEY LOOKED AT THE
- 20 RELATIONSHIP BETWEEN THOSE LIPID CHANGES AND HEART
- 21 ATTACKS AND OTHER CARDIOVASCULAR RISKS BETWEEN PATIENTS
- 22 TAKING PIO AND THOSE TAKING AVANDIA, THEY DID NOT FIND
- 23 ANY SIGNIFICANT DIFFERENCE, DID THEY?
- 24 A. **I'M NOT AWARE THAT THEY LOOKED IN THAT STUDY.**
- 25 **IN GOLDBERG, DID THEY LOOK FOR CLINICAL INPUT? I CAN'T**

- 1 **REMEMBER, BUT I DON'T THINK THEY DID.**
- 2 Q. THAT SAME GROUP PUBLISHED ANOTHER PAPER BY DEEG,
- 3 FIRST AUTHOR, DIDN'T THEY?
- 4 A. **YES.**
- 5 Q. AND IS IT YOUR CLAIM THAT NEITHER ONE OF THOSE
- 6 PAPERS EXAMINED CLINICAL ENDPOINTS?
- 7 A. **MY CLAIM IS CERTAINLY I DON'T REMEMBER AND IT**
- 8 **WOULD -- I WOULD LOOK AT THE PAPERS, BUT IT WAS NOT IN**
- 9 **MY MEMORY THAT THEY DID. THEY FOCUSED ON THE ACUTE**
- 10 **CHANGES. I THOUGHT THEY WERE SHORT TERM, RELATIVELY**
- 11 **SHORT TERM STUDIES, NOT OVER YEARS AND WERE NOT DESIGNED**
- 12 **TO LOOK AT CLINICAL EVENTS. THAT'S MY MEMORY.**
- 13 Q. YOU KNOW THAT JUST LAST YEAR, THE AMERICAN
- 14 DIABETES ASSOCIATION ISSUED A STATEMENT CONCERNING
- 15 THE -- AMONG OTHER THINGS, THE LIPID DIFFERENCES BETWEEN
- 16 AVANDIA AND ACTOS, DON'T YOU?
- 17 A. **YES.**
- 18 Q. AND WHAT THEY CONCLUDED WAS THAT WHEREAS ACTOS
- 19 HAD A FAVORABLE LIPID PROFILE, AVANDIA'S LIPID PROFILE
- 20 WAS NEUTRAL, CORRECT?
- 21 A. **YES, I BELIEVE THAT'S CORRECT.**
- 22 Q. AND THAT IS A POSITION YOU REJECT, CORRECT?
- 23 A. **THAT IS NOT MY POSITION, THAT'S CORRECT.**
- 24 Q. NOW, DOCTOR, IN YOUR EXPERT REPORT YOU TELL US
- 25 THAT THE EXAMPLE OF TORCETRAPIB ESTABLISHES

- 1 UNEQUIVOCALLY THAT THE CLINICAL SIGNIFICANCE OF
- 2 MEDICATION INDUCED HDL CHOLESTEROL IS NOT NECESSARILY
- 3 THE SAME AS THE IDENTICAL LEVEL OF HDL CHOLESTEROL THAT
- 4 IS THE RESULT OF NATURAL METABOLISM, CORRECT?
- 5 A. **YES, THAT'S CORRECT.**
- 6 Q. IT ESTABLISHES THAT WITH RESPECT TO TORCETRAPIB,
- 7 BUT IT DOES NOT ESTABLISH IT WITH RESPECT TO ANY OTHER
- 8 DRUG, DOES IT, DOCTOR?
- 9 A. **THAT'S CORRECT, I THINK THAT IS TRUE.**
- 10 Q. OKAY. SO IN ORDER TO KNOW WHAT THE CONSEQUENCES
- 11 ARE OF LIPID CHANGES INDUCED BY A DIFFERENT DRUG, YOU
- 12 HAVE TO DO THE CLINICAL OUTCOME STUDIES, DON'T YOU?
- 13 A. **IN ORDER TO KNOW THE CONSEQUENCES OF THE DRUG ON**
- 14 **CLINICAL EVENTS, YOU HAVE TO DO THE STUDIES LOOKING AT**
- 15 **THE RELATIONSHIP OF THE DRUG TO CLINICAL EVENTS. THOSE**
- 16 **ARE THE ONES THAT I RELIED ON TO REACH MY JUDGMENT AS TO**
- 17 **THE ASSOCIATION OF THE DRUG WITH CLINICAL EVENTS. LDL**
- 18 **IS ONE MECHANISM OF ADVERSE EFFECTS.**
- 19 Q. DOCTOR, THAT IS WAY BEYOND WHAT I THINK IS AN
- 20 APPROPRIATE RESPONSE TO THE QUESTION. YOU AGREE THAT
- 21 YOU HAVE TO DO THE STUDIES TO KNOW WHAT THE CLINICAL
- 22 IMPACT ON ENDPOINTS IS, RIGHT?
- 23 A. **YOUR QUESTION AGAIN, PLEASE.**
- 24 Q. IN ORDER TO KNOW WHAT THE CLINICAL IMPACT IS ON
- 25 OUTCOMES, SUCH AS MYOCARDIAL INFARCTION, DUE TO CHANGES

1 IN LIPIDS INDUCED BY MEDICATION, YOU HAVE TO DO THE  
 2 NECESSARY CLINICAL TRIALS?  
 3 **A. YES.**  
 4 **Q.** AND DO YOU AGREE WITH DR. BRINTON THAT THERE ARE  
 5 A NUMBER OF MEDICATIONS THAT REDUCE LDL -- RATHER THAT  
 6 INCREASE LDL AND YET REDUCE CARDIOVASCULAR RISK?  
 7 **A. WHICH MEDICATIONS, I'M NOT SURE.**  
 8 **Q.** WELL, THE EXAMPLE HE GAVE AS THE MOST  
 9 SIGNIFICANT IN HIS VIEW WAS OMEGA 3 FATTY ACIDS AND HE  
 10 SPECIFICALLY REFERENCED LOVAZA?  
 11 **A. I DON'T AGREE WITH THAT VIEW.**  
 12 **Q.** NOW, DOCTOR, I THINK WE NEED TO CLARIFY YOUR  
 13 METHODOLOGY WITH RESPECT TO THE ENDPOINTS YOU EXAMINED  
 14 IN REACHING YOUR OPINION THAT AVANDIA CAUSES MYOCARDIAL  
 15 ISCHEMIC EVENTS, INCLUDING HEART ATTACKS. YOU HAVE READ  
 16 DR. AUSTIN'S REPORT, RIGHT?  
 17 **A. DR. AUSTIN?**  
 18 **Q.** YEAH, THE PLAINTIFFS' EPIDEMIOLOGIST, THEIR ONLY  
 19 EPIDEMIOLOGIST.  
 20 **A. OH, YES, YES.**  
 21 **Q.** AND YOU ARE AWARE ALSO -- DID YOU READ HIS  
 22 DEPOSITION TRANSCRIPT AS WELL?  
 23 **A. NO.**  
 24 **Q.** I WILL REPRESENT TO YOU, AND I THINK IT'S BEEN  
 25 SHOWN ON THE SCREEN, THAT HE TESTIFIED AT HIS DEPOSITION

1 THAT IF MY ANALYSIS IS ON MI, THE MYOCARDIAL ISCHEMIC  
 2 EVENTS REALLY DON'T PROVIDE MUCH INFORMATION FOR THAT.  
 3 YOU READ THAT TESTIMONY?  
 4 **A. I THINK I HEARD SOMETHING LIKE THAT TODAY, YEAH.**  
 5 **Q.** DO YOU AGREE WITH DR. AUSTIN OR NOT?  
 6 **A. NO. I THINK THAT MYOCARDIAL ISCHEMIC EVENTS**  
 7 **PROVIDE INFORMATION.**  
 8 **Q.** HE IS NOT SAYING THEY DON'T PROVIDE INFORMATION,  
 9 WHAT HE IS SAYING IS IF I'M INTERESTED IN FINDING OUT  
 10 WHETHER AVANDIA CAUSES HEART ATTACKS, THE BEST  
 11 INFORMATION THAT SHEDS LIGHT ON THAT IS DATA RELATING TO  
 12 AVANDIA AND HEART ATTACKS, NOT DATA RELATING TO  
 13 MYOCARDIAL ISCHEMIC EVENTS?  
 14 **A. SURE, THAT IS A TAUTOLOGY, I AGREE.**  
 15 **Q.** ON DIRECT EXAMINATION I THINK YOU SAID TO MR.  
 16 CARTMELL THAT YOU MADE AN INDEPENDENT, SEPARATE  
 17 EXAMINATION OF THE DATA OF AVANDIA RELATING TO  
 18 MYOCARDIAL INFARCTION, HEART ATTACKS, IS THAT CORRECT?  
 19 **A. EVALUATION, YES.**  
 20 **Q.** THAT IS NOT WHAT YOU TOLD ME AT YOUR DEPOSITION,  
 21 IS IT?  
 22 **A. I'M SORRY. I DON'T REMEMBER THE EXACT PHRASE I**  
 23 **USED IN MY -- BUT IN MY REPORTS, INCLUDING MY INITIAL**  
 24 **REPORT, IT SPECIFICALLY STATES THAT I FOLLOWED A**  
 25 **RELATIONSHIP BETWEEN AVANDIA AND HEART ATTACKS. THAT IS**

1 **IN MY INITIAL REPORT.**  
 2 **Q.** DOCTOR, WITH ALL DUE RESPECT, WHAT YOUR REPORT  
 3 SAYS IS AVANDIA AND MYOCARDIAL ISCHEMIC EVENTS INCLUDING  
 4 HEART ATTACK. DO YOU RECALL I SPECIFICALLY ASKED YOU AT  
 5 YOUR DEPOSITION, DID YOU LOOK SEPARATELY AT DATA  
 6 RELATING TO MYOCARDIAL INFARCTION? DO YOU REMEMBER  
 7 THAT?  
 8 **A. NO, I DON'T.**  
 9 **Q.** THAT WOULD BE AS 20.  
 10 (VIDEO PLAYED.)  
 11 QUESTION: THE WHOLE PURPOSE OF THIS IS  
 12 FOR ME TO KNOW AND FOR US TO LEARN WHAT YOUR VIEW OF THE  
 13 EVIDENCE IS, AND SINCE THE FUNDAMENTAL CLAIM HERE IS,  
 14 AND THE CLAIM ADVANCED IN YOUR REPORT IS THAT AVANDIA  
 15 CAUSES HEART ATTACKS I'D LIKE TO KNOW IF YOU BELIEVE  
 16 THAT THE WEIGHT OF THE EVIDENCE WITH RESPECT TO THE  
 17 RELATIONSHIP BETWEEN AVANDIA AND HEART ATTACKS  
 18 ESTABLISHES A STATISTICALLY SIGNIFICANT INCREASED RISK.  
 19 ANSWER: YES, WELL FIRST OF ALL, I  
 20 REITERATE, BECAUSE I WROTE THE REPORT, THAT MY OPINION  
 21 IS BASED UPON THE TOTALITY OF THE EVIDENCE, WHICH  
 22 INCLUDES A BALANCING OF RISK VERSUS ADVERSE EFFECT. AND  
 23 ONE OF THE STRIKING THINGS FOR ME IN REVIEWING THE DATA  
 24 ON AVANDIA IS THAT I DO NOT SEE EVIDENCE OF CLINICAL  
 25 BENEFIT. I SEE NO TRIAL THAT DEMONSTRATED A CLINICAL

1 ADVANTAGE TO THE PATIENT BY TAKING AVANDIA. THE -- WITH  
 2 REGARD TO THE COMPLICATIONS, THE CARDIOVASCULAR  
 3 COMPLICATIONS, FOR ME THE CRITICAL ISSUE IS THE TOTALITY  
 4 OF THE ADVERSE CARDIOVASCULAR COMPLICATIONS. MY MEMORY  
 5 IS THAT MYOCARDIAL INFARCTIONS WERE STATISTICALLY  
 6 SIGNIFICANT INCREASED IN SOME OF THOSE STUDIES, BUT I  
 7 WOULD HAVE TO REVIEW THE MATERIAL TO BE ABLE TO  
 8 IMMEDIATELY DOCUMENT THAT. THE ISSUE FOR ME IS NOT  
 9 ISOLATING MYOCARDIAL INFARCTION OUT OF A PANOPLY OF  
 10 SEVERE ADVERSE CARDIOVASCULAR EVENTS. THAT'S WHY I'VE  
 11 NEVER CONSIDERED THE QUESTION IN THAT WAY.  
 12 (VIDEO ENDED.)  
 13 BY MR. GLANVILLE:  
 14 **Q.** NOW DOCTOR, DO YOU RECALL THAT TESTIMONY?  
 15 **A. YES, I DO.**  
 16 **Q.** AS I INTERPRETED IT, YOU DID NOT MAKE A SEPARATE  
 17 INDEPENDENT ANALYSIS OF WHETHER AVANDIA CAUSES HEART  
 18 ATTACKS. YOU LOOKED AT THE LARGER CATEGORY OF  
 19 MYOCARDIAL ISCHEMIC EVENTS THAT INCLUDED HEART ATTACKS  
 20 AND YOU REACHED THE CONCLUSION THAT AVANDIA CAUSES THAT  
 21 WHOLE RANGE OF EVENTS, RIGHT?  
 22 **A. I APOLOGIZE IF I DIDN'T COMMUNICATE WELL, BUT**  
 23 **THAT IS NOT WHAT I CONCLUDED.**  
 24 **I AGREE A NUMBER OF TIMES IN MY**  
 25 **DEPOSITION YOU SAID I WAS NOT RESPONSIVE, AND I**

1 **CERTAINLY WAS NOT VERY GOOD ON THAT QUESTION, I AGREE**  
 2 **WITH THAT ENTIRELY, BUT IN MY REPORTS RIGHT FROM THE**  
 3 **VERY BEGINNING, I HAVE BEEN AS CLEAR AS I CAN POSSIBLY**  
 4 **BE, THAT -- SO WITH REGARD TO MYOCARDIAL ISCHEMIC**  
 5 **EVENTS, AVANDIA INCREASES MYOCARDIAL ISCHEMIC EVENTS.**  
 6 **WITH REGARD TO MYOCARDIAL INFARCTION, AVANDIA INCREASES**  
 7 **THE LIKELIHOOD OF MYOCARDIAL INFARCTION.**

8 **I APOLOGIZE FOR THAT POOR PERFORMANCE.**

9 Q. AND IS IT YOUR ASSERTION THAT SOMEWHERE IN YOUR  
 10 REPORT THERE IS A STATEMENT THAT SAYS SPECIFICALLY THAT  
 11 AVANDIA CAUSES HEART ATTACKS OR INCREASES THE RISK OF  
 12 HEART ATTACKS, MYOCARDIAL INFARCTION, AS DISTINGUISHED  
 13 FROM THIS BROAD CATEGORY OF MYOCARDIAL ISCHEMIC EVENTS?

14 A. **IT IS IN MY INITIAL REPORT, IT'S IN MY THIRD**  
 15 **SUPPLEMENTAL AT THE BEGINNING AND AT THE END. IT'S IN**  
 16 **MY CONCLUDING STATEMENTS.**

17 Q. SEPARATE ANALYSIS RELATED TO MYOCARDIAL  
 18 INFARCTION?

19 A. **THAT I DID A SEPARATE ANALYSIS?**

20 Q. RIGHT.

21 A. **NO, I DREW A CONCLUSION THAT'S BASED ON A**  
 22 **SEPARATE ANALYSIS. THAT IS HOW I GOT TO THE CONCLUSION.**

23 Q. AND YOUR CONCLUSION IS THAT AVANDIA INCREASES  
 24 MYOCARDIAL ISCHEMIC EVENTS, INCLUDING MI, CORRECT?

25 A. **NO. MY CONCLUSION THAT IS AVANDIA INCREASES**

1 **MYOCARDIAL ISCHEMIC EVENTS, MYOCARDIAL INFARCTION IS A**  
 2 **MYOCARDIAL ISCHEMIC EVENT. AVANDIA INCREASES MYOCARDIAL**  
 3 **INFARCTION.**

4 Q. YOUR STATEMENT IS SOMEWHERE THAT ASSERTION  
 5 APPEARS IN YOUR REPORT?

6 A. **BEGINNING AND IN THE MIDDLE.**

7 Q. DOCTOR, YOU AGREE THAT NOBODY KNOWS WHAT CAUSES  
 8 A PLAQUE TO DESTABILIZE AND RUPTURE, RIGHT?

9 A. **YES.**

10 Q. AND YOU HAVE NOT IDENTIFIED ANY ACTION THAT  
 11 AVANDIA HAS ON ATHEROSCLEROTIC PLAQUES THAT CONTRIBUTES  
 12 TO THEIR RUPTURE PRODUCING A HEART ATTACK, HAVE YOU?

13 A. **OTHER THAN INCREASING LDL, NO.**

14 Q. AS LONG AS WE ARE TALKING ABOUT ATHEROSCLEROSIS,  
 15 YOU HAVE REVIEWED THE STUDIES LOOKING AT THE  
 16 RELATIONSHIP BETWEEN AVANDIA USE AND ATHEROSCLEROSIS,  
 17 HAVEN'T YOU?

18 A. **BY ATHEROSCLEROSIS YOU MEAN THE NON-INVASIVE**  
 19 **MEASURES OF ATHEROSCLEROSIS?**

20 Q. RIGHT.

21 A. **OKAY, YES, YES, I HAVE.**

22 Q. AND YOU KNOW THAT THERE ARE AT LEAST FIVE  
 23 RANDOMIZED CONTROLLED TRIALS EXAMINING THE RELATIONSHIP  
 24 BETWEEN AVANDIA AND THE PROGRESSION OF ATHEROSCLEROSIS,  
 25 DON'T YOU?

1 A. **THAT'S CORRECT.**

2 Q. AND NOT ONE OF THEM FINDS AN INCREASE IN THE  
 3 PROGRESSION OF ATHEROSCLEROSIS DURING AVANDIA THERAPY,  
 4 CORRECT?

5 A. **THAT'S CORRECT.**

6 Q. AND, IN FACT, SOME OF THEM FIND ON AT LEAST  
 7 SECONDARY ENDPOINTS A REDUCTION IN THE PROGRESSION OF  
 8 ATHEROSCLEROSIS, CORRECT?

9 A. **THAT'S CORRECT.**

10 Q. ARE YOU AWARE OF ANY STUDY PUBLISHED BY ANYBODY  
 11 WHO SHOWS THAT AVANDIA PROGRESSES ATHEROSCLEROSIS?

12 A. **NO.**

13 Q. YOU PARTICIPATED AS A CO-AUTHOR IN THE 2009  
 14 CANADIAN CARDIOVASCULAR GUIDELINES, DIDN'T YOU?

15 A. **I DID.**

16 Q. AMONG OTHER THINGS, THOSE GUIDELINES SAY MANY  
 17 BIOMARKERS INCLUDING LEVELS OF SERUM LIPID LEVELS,  
 18 LIPOPROTEINS, APO-LIPOPROTEINS AND VARIOUS DERIVED  
 19 RATIOS PREDICT CVD RISK. HOWEVER, IT IS IMPORTANT TO  
 20 KEEP IN MIND THAT NONE OF THE TRADITIONAL CVD RISK  
 21 FACTORS OR BIOMARKERS REFLECT THE ACTUAL PRESENCE OR  
 22 ABSENCE OF ATHEROSCLEROSIS. THAT IS PART OF THE  
 23 STATEMENT, ISN'T IT?

24 A. **THAT'S CORRECT.**

25 Q. AND YOU TOLD ME AT YOUR DEPOSITION THAT YOU

1 AGREED WITH THAT?

2 A. **ABSOLUTELY.**

3 Q. OKAY. SO WHAT THAT MEANS IS THAT SIMPLY BECAUSE  
 4 YOU HAVE AN INCREASE IN APO-B OR LDL, IT DOES NOT MEAN  
 5 YOU WILL HAVE A PROGRESSION OF ATHEROSCLEROSIS, CORRECT?

6 A. **THAT'S CORRECT.**

7 Q. OKAY.

8 YOU ARE FAMILIAR WITH THE APPROACH TRIAL,  
 9 RIGHT?

10 A. **YES.**

11 Q. AND THE PUBLICATION ASSOCIATED WITH THAT BY  
 12 GERSTEIN, ET AL?

13 A. **YES.**

14 Q. AND THEY TELL US IN THAT PUBLICATION THAT  
 15 THIAZOLIDINEDIONES HAVE EFFECTS ON CARDIOVASCULAR RISK  
 16 FACTORS INCLUDING INSULIN SENSITIVITY, INFLAMMATORY  
 17 BIOMARKERS, ENDOTHELIAL FUNCTION, COAGULABILITY, PLAQUE  
 18 INSTABILITY AND BLOOD PRESSURE THAT MAY SLOW THE  
 19 PROGRESSION OF CORONARY ATHEROSCLEROSIS, DON'T THEY?

20 A. **YES, THEY DO.**

21 Q. YOU DON'T AGREE WITH THAT, DO YOU?

22 A. **NO. I AGREE WITH THE STATEMENT THAT YOU READ.**

23 Q. OKAY.

24 AND DOCTOR, THOSE ATHEROSCLEROSIS

25 PROGRESSION STUDIES, YOU HAVE NOT DONE ANY ANALYSIS THAT

1 DEMONSTRATES EITHER THAT THERE WAS A STATISTICALLY  
 2 SIGNIFICANT DIFFERENTIAL USE OF STATINS IN THOSE RCT'S  
 3 OR THAT ANY DIFFERENTIAL USE HAD A MATERIAL EFFECT ON  
 4 THE OUTCOMES, HAVE YOU?  
 5 **A. WHICH STUDIES ARE YOU REFERRING TO?**  
 6 **Q.** YOU ACKNOWLEDGED A FEW MINUTES AGO THAT YOU WERE  
 7 AWARE OF FIVE --  
 8 **A. THE NON-INVASIVE, THAT'S CORRECT.**  
 9 **Q.** DOCTOR, YOU ALSO AGREED THAT NONE OF THE  
 10 META-ANALYSES ON WHICH YOU RELIED TO SUPPORT YOUR  
 11 CONCLUSION THAT AVANDIA CAUSES MYOCARDIAL ISCHEMIC  
 12 EVENTS EXPLICITLY STATED THAT THEY EXAMINED THOSE  
 13 META-ANALYSES FOR BIAS OR CONFOUNDING; DO YOU RECALL  
 14 THAT EXCHANGE?  
 15 **A. NO, I DON'T. I'M NOT EVEN CLEAR ON YOUR**  
 16 **QUESTION RIGHT NOW.**  
 17 **Q.** MY QUESTION IS: YOU'VE RELIED ON VARIOUS  
 18 META-ANALYSES TO SUPPORT YOUR POSITION HERE, CORRECT?  
 19 **A. I RELIED ON ALL OF THE EVIDENCE THAT I COULD**  
 20 **FIND, YES.**  
 21 **Q.** AND NONE OF THE META-ANALYSES FINDING  
 22 STATISTICALLY SIGNIFICANT INCREASED RISK OF MI WITH  
 23 AVANDIA SPECIFICALLY STATE THAT THEY HAVE EXAMINED THE  
 24 DATA FOR BIAS OR CONFOUNDING OR THEY MADE ANY  
 25 ADJUSTMENTS TO DEAL WITH ISSUES OF BIAS ON CONFOUNDING,

1 CORRECT?  
 2 **A. I THINK THAT IS CORRECT.**  
 3 **Q.** YOU DID NOT MAKE ANY INDEPENDENT EXAMINATION OF  
 4 THOSE META-ANALYSES FOR BIAS OR CONFOUNDING, DID YOU?  
 5 **A. OH, I DID. AT LEAST WITH REGARD TO ONE OF THE**  
 6 **STUDIES THAT WAS INCLUDED IN MANY OF THE META-ANALYSES,**  
 7 **I WAS -- THE LEBOVITZ STUDY WAS INCLUDED IN MANY OF**  
 8 **THOSE ANALYSES AND FROM THE MATERIALS I EXAMINED, THERE**  
 9 **WAS A SEVERE DISCORDANCE BETWEEN THE LEBOVITZ STUDY**  
 10 **WHICH WAS USED IN --**  
 11 **MR. GLANVILLE: YOUR HONOR, I HAVE**  
 12 **LIMITED TIME AND I ASKED HIM WHETHER HE MADE AN ANALYSIS**  
 13 **OF BIAS AND CONFOUNDING OF THE META-ANALYSES. HE IS**  
 14 **TELLING ME ABOUT ONE STUDY OF 40 SOME --**  
 15 HONORABLE CYNTHIA M. RUFÉ: AT THIS TIME  
 16 I WOULD LIKE TO GIVE HIM THE CHANCE TO EXPLAIN. IS THE  
 17 LEBOVITZ STUDY PART OF THE META-ANALYSIS, IF YOU DID  
 18 ANY?  
 19 THE WITNESS: YES.  
 20 HONORABLE CYNTHIA M. RUFÉ: THEN  
 21 CONTINUE.  
 22 THE WITNESS: IT'S PART OF MANY OF THE  
 23 META-ANALYSES THAT WERE DONE AND THE PUBLISHED REPORTS  
 24 SAY THAT THERE WAS NO HEART ATTACKS AMONGST THE PATIENTS  
 25 IN THAT STUDY.

1 THE FINAL CLINICAL REPORT, STUDY REPORT  
 2 SUBMITTED TO THE FDA NOTES THAT THERE WERE SIX HEART  
 3 ATTACKS, FIVE IN THE ROSIGLITAZONE GROUP, IF MEMORY IS  
 4 CORRECT, ONE IN THE NON-ROSIGLITAZONE GROUP. THOSE SIX  
 5 HEART ATTACKS WOULD NOT BE INCLUDED IN THE TOTAL  
 6 ANALYSIS.  
 7 I'M NOT CLAIMING THAT THOSE SIX HEART  
 8 ATTACKS BY THEMSELVES WOULD CHANGE THE FINAL RESULT, BUT  
 9 I EXAMINED HIS RESPONSE TO HIS QUESTION ABOUT BIAS. A  
 10 STUDY IS VALID ONLY IF THE NUMBERS THAT GO INTO IT ARE  
 11 VALID. AND I UNFORTUNATELY DISCOVERED THAT IN AT LEAST  
 12 ONE INSTANCE THERE WAS A SEVERE DISCREPANCY, A TOTAL  
 13 DISCREPANCY BETWEEN DIFFERENT REPORTS OF THE STUDY. AND  
 14 THAT MEANS THAT THE -- THIS WOULD UNDERESTIMATE THE RISK  
 15 ATTRIBUTED TO ROSIGLITAZONE. THAT IS WHY I USED THE  
 16 EXAMPLE.  
 17 BY MR. GLANVILLE:  
 18 **Q.** DOCTOR, JUST TO REITERATE, YOU DID NOT MAKE ANY  
 19 DETERMINATION THAT ANY ERRORS IN THE COUNTING OF EVENTS  
 20 IN THE LEBOVITZ STUDY MATERIALLY AFFECTED THE RESULTS IN  
 21 THE META-ANALYSIS, DID YOU?  
 22 **A. NO, I DID NOT.**  
 23 **Q.** DO YOU RECALL WE HAD A DISCUSSION AT YOUR  
 24 DEPOSITION ABOUT ODDS RATIOS THAT ARE NUMERICALLY BUT  
 25 NOT STATISTICALLY SIGNIFICANTLY DIFFERENT AND YOU TOLD

1 ME THAT NUMBERS THAT ARE NUMERICALLY DIFFERENT, EVEN IF  
 2 THEY ARE 50 PERCENT APART, BUT NOT STATISTICALLY  
 3 SIGNIFICANTLY DIFFERENT, ARE NO DIFFERENT IN SCIENCE, DO  
 4 YOU RECALL THAT DISCUSSION?  
 5 **A. NOT COHERENTLY, NOT AT THE MOMENT, BUT IT HAS A**  
 6 **RING TO IT.**  
 7 **Q.** THAT IS YOUR VIEW, ISN'T IT, THAT IF THERE ARE  
 8 ELEVATED ODDS RATIOS, EVEN 30, 50 PERCENT, THAT ARE NOT  
 9 STATISTICALLY SIGNIFICANTLY DIFFERENT, THEN IN SCIENCE  
 10 THEY ARE NOT DIFFERENT. THAT IS WHAT YOU TOLD ME IN  
 11 MARCH AND THAT IS STILL YOUR VIEW, ISN'T IT?  
 12 **A. YES, TAKEN AS AN INDIVIDUAL STUDY, THAT IS MY**  
 13 **VIEW. ON ITS OWN.**  
 14 **Q.** AND IF WE LOOK AT INDIVIDUAL STUDIES INVOLVING  
 15 AVANDIA AND HEART ATTACKS, YOU AGREE THAT THERE IS NOT A  
 16 SINGLE RANDOMIZED PLACEBO CONTROLLED TRIAL THAT YOU KNOW  
 17 OF THAT FINDS A STATISTICALLY SIGNIFICANT INCREASED RATE  
 18 OF EITHER HEART ATTACK OR MYOCARDIAL ISCHEMIC EVENTS ON  
 19 AVANDIA COMPARED TO WHATEVER THE COMPARATOR WAS?  
 20 **A. YES, BUT AS DR. JEWELL EXPLAINED THIS MORNING --**  
 21 **MR. GLANVILLE: YOUR HONOR, HE IS DOING**  
 22 **IT AGAIN.**  
 23 THE COURT: ALL RIGHT. I DON'T THINK YOU  
 24 NEED TO GO FURTHER.  
 25 THE WITNESS: THANK YOU.

1 BY MR. GLANVILLE:  
 2 **Q.** AND DOCTOR, THERE ARE VARIOUS META-ANALYSES THAT  
 3 YOU HAVE CITED IN YOUR REPORT IN SUPPORT OF YOUR  
 4 POSITION, CORRECT?  
 5 **A.** **CORRECT.**  
 6 **Q.** AND YOU KNOW THAT FOR EVERY META-ANALYSIS THAT  
 7 FINDS A STATISTICALLY SIGNIFICANT INCREASED RISK OF MI  
 8 THERE IS AT LEAST ONE THAT DOES NOT FIND A STATISTICALLY  
 9 SIGNIFICANT INCREASED RISK OF MI, DON'T YOU?  
 10 **A.** **THERE ARE DIFFERENT RESULTS, YES.**  
 11 **Q.** YOU HAVE ALSO LOOKED AT THE OBSERVATIONAL DATA,  
 12 HAVEN'T YOU?  
 13 **A.** **YES, I HAVE.**  
 14 **Q.** YOU KNOW THAT FOR EVERY OBSERVATIONAL TRIAL THAT  
 15 FINDS A SIGNIFICANT INCREASED RISK OF MYOCARDIAL  
 16 INFARCTION WITH AVANDIA, THERE ARE TWO THAT DON'T FIND A  
 17 SIGNIFICANTLY INCREASED RISK, DON'T YOU?  
 18 **A.** **I DON'T KNOW THAT PROPORTION.**  
 19 **Q.** WELL, HAVEN'T YOU EXAMINED THE TOTALITY OF THAT  
 20 EVIDENCE?  
 21 **A.** **YES, BUT I'M SAYING AT THIS MOMENT I DON'T KNOW**  
 22 **THE PROPORTION. I KNOW THAT THERE ARE MANY THAT DON'T.**  
 23 **I DON'T KNOW THE EXACT BREAKDOWN.**  
 24 **Q.** YOU DON'T KNOW IF IT'S MORE?  
 25 **A.** **YEAH, THERE CERTAINLY BOTH SIDES. THERE IS NO**

1 **QUESTION ABOUT THAT.**  
 2 **Q.** AND YOU AGREE THAT IN THE HIERARCHY OF EVIDENCE  
 3 RCT'S ARE THE BEST, RIGHT?  
 4 **A.** **YES.**  
 5 **Q.** AND META-ANALYSES AND OBSERVATIONAL STUDIES ARE  
 6 SECOND TIER DATA IF YOU ARE TRYING TO FIND ASSOCIATIONS  
 7 THAT YOU WANT TO CONCLUDE ARE CAUSAL, CORRECT?  
 8 **A.** **THAT'S CORRECT.**  
 9 **Q.** OKAY. SO YOU HAVE RELIED ON WHAT YOU  
 10 CHARACTERIZED AS "NOT TO THE HIGHEST STANDARD DATA" IN  
 11 MAKING YOUR ANALYSIS, HAVEN'T YOU?  
 12 **A.** **YOU ARE CHARACTERIZING, YES.**  
 13 **Q.** WELL, THAT WAS YOUR TESTIMONY.  
 14 **A.** **OKAY.**  
 15 **Q.** NOW, YOU HAVE HAD SOME CRITICISMS -- WELL, AS A  
 16 MATTER OF FACT, IF YOU READ THE TRANSCRIPT OF THE ADCOM  
 17 PROCEEDINGS FROM JULY, YOU KNOW THAT DR. ELLIS UNGER,  
 18 THE DEPUTY DIRECTOR OF FDA'S OFFICE OF DRUG EVALUATION,  
 19 WAS HIGHLY CRITICAL OF THE META-ANALYSIS, DON'T YOU?  
 20 **A.** **I DON'T RECALL HIS TESTIMONY.**  
 21 **Q.** DO YOU RECALL HIM CHARACTERIZING THEM AS GARBAGE  
 22 IN, GARBAGE OUT?  
 23 **A.** **NO, I DO NOT.**  
 24 **Q.** DO YOU RECALL HIM PARTICULARLY TALKING ABOUT  
 25 META-ANALYSES THAT DID NOT EXAMINE PATIENT LEVEL DATA AS

1 IN THE FOLLOWING TERMS -- AND JAMIE, MAYBE WE CAN BRING  
 2 THIS UP IT'S FROM THE TRANSCRIPT, PAGE 203 LINES 11  
 3 THROUGH 16.  
 4 CAN YOU SEE THAT, DOCTOR? HE SAYS, IF AN  
 5 AUTHOR OR AUTHORS GO THROUGH THE BACK TABLES IN A  
 6 PUBLICATION AND THEY THINK THEY ARE LOOKING AT ACUTE MI  
 7 OR HEART FAILURE OR NEW CANCERS AND THEY HAVE NOT LOOKED  
 8 AT THE PATIENT LEVEL DATA, THEN THEY REALLY DON'T HAVE A  
 9 CLUE WHAT THEY ARE ACTUALLY COUNTING.  
 10 DO YOU REMEMBER THAT TESTIMONY?  
 11 **A.** **NO, I DON'T REMEMBER IT, BUT I CAN READ IT.**  
 12 **Q.** YOU AGREE WITH IT, DON'T YOU?  
 13 **A.** **NO, I DO NOT. NO, I DON'T THINK SO.**  
 14 **Q.** OKAY. IF THAT CRITICISM OF DR. UNGER IS VALID,  
 15 IT APPLIES TO BOTH NISSAN META-ANALYSES, DOESN'T IT?  
 16 **A.** **YES, IT DOES.**  
 17 **Q.** IT APPLIES TO THE SINGH META-ANALYSIS?  
 18 **A.** **YES, IT DOES.**  
 19 **Q.** IT APPLIES TO VIRTUALLY EVERY OTHER  
 20 META-ANALYSIS YOU RELIED ON EXCEPT THE FDA  
 21 META-ANALYSIS, CORRECT?  
 22 **A.** **YES, I BELIEVE THAT IS CORRECT.**  
 23 **Q.** AND YOU WERE CRITICAL OF DIFFERENTIAL STATIN USE  
 24 IN THE RECORD TRIAL, WEREN'T YOU?  
 25 **A.** **YES.**

1 **Q.** AND YOU KNOW THE AUTHORS OF THE RECORD TRIAL  
 2 EVALUATED THAT AND CONCLUDED THAT IT MADE NO SIGNIFICANT  
 3 DIFFERENCE IN THE OUTCOME, DON'T YOU?  
 4 **A.** **THAT IS THEIR CONCLUSION.**  
 5 **Q.** RIGHT, FDA INDEPENDENTLY EVALUATED THAT SAME  
 6 ISSUE AND REPORTED THAT IT MADE NO SIGNIFICANT  
 7 DIFFERENCE IN THE OUTCOME, DIDN'T THEY?  
 8 **A.** **I'M AWARE OF THAT.**  
 9 **Q.** AND YOU CRITICIZED META-ANALYSIS AS SUPERFICIAL,  
 10 DIDN'T YOU, OR SIMPLISTIC?  
 11 **A.** **YES, THAT'S CORRECT.**  
 12 **Q.** YOU HAVE NOT SUBMITTED AN EXPERT REPORT  
 13 CONTAINING ANY ALTERNATIVE ANALYSIS OF THAT DATA  
 14 DEMONSTRATING THAT IT MADE A SIGNIFICANT DIFFERENCE,  
 15 HAVE YOU?  
 16 **A.** **NO, BUT I DID --**  
 17 **Q.** DOCTOR, NO IS GOOD ENOUGH.  
 18 THE COURT: YOU WILL HAVE A CHANCE ON  
 19 REDIRECT, IF THERE IS TIME.  
 20 BY MR. GLANVILLE:  
 21 **Q.** AND YOU KNOW THAT FDA EVALUATED THE QUESTION OF  
 22 WHETHER THERE WAS MORE POTENT STATINS OR HIGHER DOSES OF  
 23 STATINS GIVEN TO AVANDIA PATIENTS, DON'T YOU?  
 24 **A.** **YES, I DO.**  
 25 **Q.** AND THEY CONCLUDED THERE WASN'T ANY SUPPORT FOR

1 THAT, DIDN'T THEY?

2 **A. NO, THAT IS NOT WHAT THEY DEMONSTRATED.**

3 **Q.** THEY CONCLUDED AND THEY REPORTED AT THE ADCOM

4 THAT THERE WAS -- OVERALL IT APPEARS THAT THE

5 INVESTIGATORS WERE NOT PREFERENTIALLY CHOOSING THE MOST

6 POTENT STATINS FOR ROSIGLITAZONE PATIENTS. THAT IS WHAT

7 DR. MAHONEY PRESENTED, WASN'T IT?

8 **A. I'M AWARE OF OTHER MATERIAL THAT WAS PRESENTED.**

9 **I'M NOT AWARE OF THAT SENTENCE. I FOCUSED ON WHAT I**

10 **THOUGHT WERE VERY IMPORTANT REPORTS OF STATIN USE IN**

11 **THAT PRESENTATION, BUT IT WAS NOT THAT SENTENCE I**

12 **FOCUSED ON.**

13 **Q.** YOU DON'T CLAIM THAT ANYBODY FROM FDA PRESENTED

14 DATA SHOWING THAT ANY DIFFERENTIAL USE OF STATINS IN

15 THAT TRIAL MATERIALLY AFFECTED THE OUTCOME, DO YOU,

16 DOCTOR?

17 **A. NO, I DO NOT CLAIM THAT.**

18 **Q.** OKAY.

19 **A. I DO CLAIM THAT THEY DEMONSTRATED -- THEY**

20 **PRESENTED MATERIAL THAT THERE WAS DIFFERENTIAL USE.**

21 **THAT THEY DID PRESENT THAT I'M AWARE OF.**

22 **Q.** THAT HAS NEVER BEEN AN ISSUE. THE AUTHORS

23 THEMSELVES RECOGNIZED THAT, BUT THEY DID AN ANALYSIS

24 THAT SHOWED IT MADE NO SIGNIFICANT DIFFERENCE IN THE

25 OUTCOME, DIDN'T THEY, DOCTOR?

1 **A. WITH RESPECT, THEY LOOKED AT THE PERCENTAGE OF**

2 **PEOPLE TAKING STATINS IN THE PUBLISHED PAPER. THE**

3 **EFFECT OF THE STATIN DEPENDS ON THE DOSE AND THE TYPE SO**

4 **THE ANALYSIS PRESENTED IN THE PAPER --**

5 **MR. GLANVILLE: YOUR HONOR?**

6 HONORABLE CYNTHIA M. RUFÉ: YEAH, I DON'T

7 THINK THAT IS THE QUESTION THAT IS BEFORE YOU, SIR.

8 THE WITNESS: OKAY.

9 BY MR. GLANVILLE:

10 **Q.** AND YOU HAVE EMBRACED DR. MARCINIAK'S CRITICISM

11 OF THE RECORD TRIAL, HAVEN'T YOU?

12 **A. I HAVE NOTED IT.**

13 **Q.** IN FACT, YOU HAVE CITED IT IN YOUR REPORT AND

14 YOU CITED IT UNDERMINED YOUR CONFIDENCE IN THE RESULT OF

15 RECORD, DIDN'T YOU?

16 **A. THAT'S CORRECT.**

17 **Q.** YOU KNOW THAT MARCINIAK'S CRITIQUE WAS ITSELF

18 HEAVILY CRITICIZED BY HIS COLLEAGUES AND HIS SUPERIORS

19 AT FDA, DON'T YOU?

20 **A. I KNOW THERE WERE CRITICISMS, YES.**

21 **Q.** IN FACT, DR. UNGER REPORTED TO THE ADCOM THAT

22 HIS DIVISION DID NOT AGREE WITH DR. MARCINIAK'S METHODS,

23 DIDN'T HE?

24 **A. I BELIEVE SOME STATEMENTS WERE MADE, YES.**

25 **Q.** ONE OF THE THINGS HE CRITICIZED WAS THAT DR.

1 MARCINIAK DID AN UNBLINDED READJUDICATION OF EVENTS IN

2 THE RECORD TRIAL AND THEN MADE HIS OWN RECALCULATIONS OF

3 RISK, DIDN'T HE?

4 **A. I DON'T REMEMBER THIS WHOLE DISCUSSION IN THAT**

5 **DETAIL.**

6 **Q.** ONE FINAL POINT, DOCTOR. AT YOUR DEPOSITION, I

7 ASKED YOU ABOUT WHETHER YOU THOUGHT THAT LP-PLA2

8 CONSTITUTES A PLAUSIBLE BIOLOGICAL MECHANISM BY WHICH

9 AVANDIA CAN CAUSE HEART ATTACKS. DO YOU RECALL THAT

10 DISCUSSION?

11 **A. I REMEMBER IT GENERALLY, I THINK, YES.**

12 **Q.** YOUR TESTIMONY WAS THAT THE PROPOSITION IS A

13 WEAK ONE. DO YOU REMEMBER THAT?

14 **A. I THINK SO.**

15 **Q.** IT WAS WEAK THEN, AND IT'S JUST AS WEAK NOW,

16 ISN'T IT, DOCTOR?

17 **A. IN MY PERSONAL VIEW THAT IS TRUE.**

18 MR. GLANVILLE: THANK YOU.

19 MR. CARTMELL: JUST A SHORT REDIRECT.

20 HONORABLE CYNTHIA M. RUFÉ: VERY BRIEF.

21 REDIRECT EXAMINATION

22 BY MR. CARTMELL:

23 **Q.** IF YOU CAN PULL UP J, PLEASE.

24 HAVE YOU EVER TESTIFIED LIKE THIS IN A

25 COURTROOM?

1 **A. NO, DEAR HEAVEN.**

2 **Q.** YOU ARE ALMOST DONE, I PROMISE YOU. I HAVE JUST

3 GOT A VERY FEW QUESTIONS.

4 MR. GLANVILLE JUST ASKED YOU ABOUT AN

5 ANALYSIS THAT GSK DID IN 2007 AT THE FDA REGARDING

6 WHETHER OR NOT LDL INCREASES AND WHAT IT DOES TO MI'S,

7 DO YOU RECALL THAT?

8 **A. I DO.**

9 **Q.** YOUR RESPONSE WAS DO YOU HAVE THAT CHART AND YOU

10 ASKED HIM AND HE DIDN'T SHOW YOU THAT CHART, DID HE?

11 **A. THAT'S CORRECT.**

12 **Q.** NOW, THIS IS THE CHART. THIS IS GSK'S ANALYSIS

13 THAT THEY CLAIM THEY DID THAT JUSTIFIES THAT AS LDL

14 INCREASES, THE NUMBER OF MI'S DON'T INCREASE, BUT YOU

15 CAN SEE ON THE RIGHT-HAND SIDE THERE IS RSG. THAT IS

16 ROSIGLITAZONE AND THEN YOU HAVE BELOW THAT, THE N -- I

17 WISH I HAD A POINTER. YOU HAVE AN N THERE. THE N IS

18 WHAT, IS THAT THE NUMBER OF PATIENTS?

19 **A. YES.**

20 **Q.** AND THEN YOU HAVE TOTAL WITH MI EQUALS 45. THIS

21 IS THE ICT ANALYSIS THEY DID. SO THE 42 TRIALS WHAT

22 THEY DID WAS THEY LOOKED FOR ALL OF MI'S THAT THEY HAD

23 AND THEN THEY SET THEM OUT BY THE TERTILE OF LDL, RIGHT?

24 AND THIS ONE SAYS NEGATIVE 136, WHAT DOES THAT MEAN? IS

25 THAT MILLIGRAMS PER DECILITER; WHAT IS THAT?

- 1 **A. I'M NOT TOTALLY SURE.**
- 2 **Q.** HOW FAR IT GOES DOWN?
- 3 **A. YEAH.**
- 4 **Q.** SO LDL GOES DOWN IN SOME PATIENTS UP TO 136 AND
- 5 THEN LESS THAN 1 AND THEN THERE IS A SECOND TERTILE 1.
- 6 PEOPLE WHO HAVE 1 MILLIGRAM PER DECILITER UP TO 23 AND
- 7 THEN 23 UP TO AN INCREASE IN LDL OF 315. DO YOU SEE
- 8 THAT?
- 9 **A. YES.**
- 10 **Q.** 315 MILLIGRAMS PER DECILITER, SOMEBODY HAD AN
- 11 INCREASE THAT LARGE.
- 12 THEN YOU LOOK AT THE NUMBER OF MI'S. IN
- 13 THIS FIRST TERTILE THERE WAS 6, IN THE SECOND TERTILE
- 14 THERE WAS 7, AND THE THIRD TERTILE THERE WAS 9, RIGHT?
- 15 **A. THAT'S CORRECT.**
- 16 **Q.** THEY ARE INCREASING, PER -- LDL GOES UP, THEY
- 17 INCREASE. THIS IS A SMALL STUDY SO IT'S NOT
- 18 STATISTICALLY SIGNIFICANT, RIGHT?
- 19 **A. THAT'S CORRECT.**
- 20 **Q.** IF YOU EXTRAPOLATE THAT OVER MILLIONS OF PEOPLE,
- 21 THAT COULD BECOME STATISTICALLY SIGNIFICANT?
- 22 **A. IT MIGHT, IT MIGHT NOT. DEPENDS.**
- 23 **Q.** NOW, RIGHT HERE WITH RESPECT TO THE MI'S, IT
- 24 SAYS 45 MI'S RIGHT HERE?
- 25 **A. THAT'S CORRECT.**

- 1 **Q.** BUT WHEN YOU COUNT UP THE NUMBER OF MI'S THEY
- 2 HAVE IN THEIR ANALYSIS, 6 PLUS 7 IS 13 PLUS 9 IS 22?
- 3 **A. THAT'S CORRECT.**
- 4 **Q.** BUT THERE IS A STAR NUMBER TO THE MI'S AND YOU
- 5 GO TO SIDE THAT SAYS 23. MORE THAN HALF OF THE MI'S, 23
- 6 OUT OF 3,184 ROSI AND 7 OUT OF 2,209 HAD AN MI AND ARE
- 7 MISSING AN LDL VALUE OR THE MI OCCURRED PRIOR TO WEEK 8.
- 8 DO YOU SEE THAT?
- 9 **A. YES, I DO.**
- 10 **Q.** SO IN THEIR ANALYSIS THAT THEY DID TO TRY TO
- 11 SAY, LOOK, LDL GOES UP BUT WE DON'T HAVE MI'S, THEY ARE
- 12 MISSING -- WE DON'T GET TO SEE MORE THAN HALF OF THE
- 13 MI'S THAT OCCURRED, RIGHT?
- 14 **A. RIGHT.**
- 15 **Q.** WE DON'T KNOW IF THOSE MI'S WERE UP HERE IN THE
- 16 HIGH LDL OR IN THE SECOND ONE OR THE FIRST ONE, DO WE?
- 17 **A. THAT'S WHY AT MY DEPOSITION WHEN I WAS PRESENTED**
- 18 **THIS MATERIAL I REJECTED IT AS SCIENTIFICALLY**
- 19 **MEANINGLESS.**
- 20 **Q.** RIGHT. OKAY, SO WE DON'T KNOW, THIS IS THE ONLY
- 21 ANALYSIS. GSK HAS THE DATA, CORRECT, THEY ARE THE ONES
- 22 THAT HAVE THE DATA?
- 23 **A. YES.**
- 24 **Q.** THIS IS THE ONLY ANALYSIS YOU HAVE EVER SEEN
- 25 FROM GSK, CORRECT?

- 1 **A. THAT'S CORRECT.**
- 2 **Q.** DO YOU THINK THIS IS A VALID ANALYSIS OF THAT?
- 3 **A. IT IS NOT A VALID ANALYSIS BECAUSE ALMOST HALF**
- 4 **OF THE SUBJECTS IN THE ANALYSIS ARE NOT ACCOUNTED FOR.**
- 5 **Q.** CAN WE LOOK REAL QUICKLY, YOUR HONOR, AT PAGE 3
- 6 OF D. THIS IS A SUBTLE POINT, BUT I THINK IT'S VERY
- 7 IMPORTANT FOR PURPOSES OF THIS AND IF WE PULL UP WHAT HE
- 8 -- MR. GLANVILLE HAD TALKED ABOUT, NEAR THE END OF THAT
- 9 SECOND PARAGRAPH. YES, DO THE REST OF THE PARAGRAPH, IF
- 10 YOU CAN HIGHLIGHT THAT.
- 11 OKAY, NOW MR. GLANVILLE HIGHLIGHTED A
- 12 PORTION OF THIS AND HE STARTED WITH SPECIFICALLY -- HE
- 13 STARTED AT SPECIFICALLY, THAT THE ADVERSE EFFECTS OF
- 14 ROSI ON APO-B LIPOPROTEINS ARE THE PATHOPHYSIOLOGICAL
- 15 MECHANISM RESPONSIBLE FOR THE INCREASE CLINICAL -- HE
- 16 ASKED YOU ABOUT THAT, RIGHT, AND THAT IS WHAT HE
- 17 HIGHLIGHTED?
- 18 **A. THAT'S CORRECT.**
- 19 **Q.** HE DID NOT HIGHLIGHT WHAT'S RIGHT ABOVE IT WHERE
- 20 YOU SAY, I BELIEVE IT REASONABLE TO CONCLUDE THAT THE
- 21 TWO ARE CONNECTED.
- 22 **A. THAT'S CORRECT.**
- 23 **Q.** YOU ARE SAYING THAT IS YOUR REASONABLE
- 24 CONCLUSION IN THIS CASE, CORRECT?
- 25 **A. THAT'S CORRECT.**

- 1 **Q.** BASED ON ALL OF THE EVIDENCE YOU HAVE REVIEWED?
- 2 **A. YES, THAT'S CORRECT.**
- 3 **Q.** NOW, YOU WERE ASKED TO DETERMINE FROM ALL THE
- 4 STUDIES WHETHER OR NOT AVANDIA CAUSES MI'S AND
- 5 MYOCARDIAL ISCHEMIC EVENTS, FROM THE STUDIES?
- 6 **A. THAT'S CORRECT.**
- 7 **Q.** SEPARATE AND APART FROM THAT, ONE OF THE
- 8 ELEMENTS OF THE BRADFORD-HILL IS DO YOU BELIEVE WITHIN A
- 9 REASONABLE DEGREE OF MEDICAL CERTAINTY THAT THERE IS A
- 10 BIOLOGICALLY PLAUSIBLE MECHANISM, CORRECT?
- 11 **A. THAT'S CORRECT.**
- 12 **Q.** EVEN IF THAT IS NOT THE MECHANISM, AS YOU SAY,
- 13 THAT LDL AND APO-B GOES UP, YOU STILL BELIEVE THAT
- 14 AVANDIA CAUSES MYOCARDIAL INFARCTIONS, CORRECT?
- 15 **A. ABSOLUTELY.**
- 16 **Q.** YOUR OPINION IS BASED ON THE STUDIES FOR THAT,
- 17 CORRECT?
- 18 **A. THAT'S CORRECT.**
- 19 **Q.** AND THEN YOU WENT TO THE BRADFORD-HILL AND YOU
- 20 SAID, IS THERE A MECHANISM THAT COULD BE CAUSING THIS,
- 21 CORRECT?
- 22 **A. THAT'S CORRECT.**
- 23 **Q.** IS TONY GOTTO, WHO IS THE DEAN OF CORNELL,
- 24 BECAUSE ONE OF THE ISSUES HERE IS WHETHER OR NOT YOUR
- 25 OPINIONS ARE WELL ACCEPTED IN THE SCIENTIFIC COMMUNITY.

1 IS TONY GOTTO ONE OF THE EXPERTS IN THE LIPID COMMUNITY  
 2 INTERNATIONALLY?  
 3 **A. YES, HE IS.**  
 4 **Q.** HE IS AN EXPERT FOR GSK IN THIS CASE?  
 5 **A. THAT'S CORRECT.**  
 6 **Q.** AND WE ASKED HIM SPECIFICALLY -- LET'S HEAR WHAT  
 7 HE SAYS, WHETHER OR NOT LDL AND APO-B CAUSE INCREASED  
 8 RISK OF CARDIOVASCULAR EVENTS.  
 9 (VIDEO PLAYED.)  
 10 QUESTION: DO YOU AGREE THAT APO-B AND  
 11 THE APO-B TO A-1 RATIO SHOULD BE MEASURED IN CERTAIN  
 12 PATIENT POPULATIONS?  
 13 ANSWER: YES.  
 14 QUESTION: AND THAT THOSE ARE VALID  
 15 PREDICTORS OF CARDIOVASCULAR RISK?  
 16 ANSWER: THEY PREDICT RISKS.  
 17 QUESTION: THE AMERICAN COLLEGE OF  
 18 CARDIOLOGY NOW RECOMMENDS MEASURING APO-B AND HAS FOUND  
 19 THAT APO-B IS A SUPERIOR PREDICTOR OF CARDIOVASCULAR  
 20 RISK?  
 21 ANSWER: I DON'T DISAGREE WITH THAT.  
 22 QUESTION: OKAY. LDL APO-B HAS BEEN  
 23 SUGGESTED AS A MORE SENSITIVE RISK MARKER THAN TOTAL  
 24 CHOLESTEROL OR LDL-C BECAUSE IT MORE ACCURATELY REFLECTS  
 25 THE PRESENCE OF ALL ATHEROGENIC LIPOPROTEINS. DO YOU

1 AGREE WITH THAT?  
 2 ANSWER: YOU ARE READING THAT FROM WHERE?  
 3 QUESTION: THIS IS PAGE 57 OF YOUR BOOK.  
 4 ANSWER: YES, I AGREE WITH THAT.  
 5 (VIDEO ENDED.)  
 6 BY MR. CARTMELL:  
 7 **Q.** ACTUALLY THAT WAS NOT THE CLIP THAT I THOUGHT IT  
 8 WAS. BUT YOU'VE READ DR. KEANEY'S REPORT WHO'S SITTING  
 9 IN HERE TODAY, I WILL USE THAT BECAUSE I DON'T HAVE THE  
 10 CLIP OF THE DEPOSITION OF DR. GOTTO. HE SAYS IN HIS  
 11 REPORT, LDL CAUSES, IS CAUSAL OF ATHEROSCLEROSIS AND  
 12 INCREASED MI'S, IS THAT CORRECT?  
 13 **A. THAT'S CORRECT.**  
 14 **Q.** THAT IS YOUR BELIEF. AND IT'S BASED ON  
 15 RANDOMIZED CONTROLLED TRIALS OVER DECADES THAT HAVE  
 16 SHOWN IT, RIGHT?  
 17 **A. THAT'S CORRECT.**  
 18 **Q.** YOU COULD NOT GET TO CAUSE ON THAT UNLESS YOU  
 19 HAD RANDOMIZED CONTROLLED TRIALS, RIGHT?  
 20 **A. THAT'S CORRECT.**  
 21 **Q.** BUT INDEPENDENT OF THAT, YOU LOOKED AT ALL THE  
 22 EVIDENCE IN THE STUDIES TO INFORM YOUR OPINION AND TO  
 23 DEVELOP YOUR OPINION IN THIS CASE?  
 24 **A. THAT'S CORRECT.**  
 25 **MR. CARTMELL: ALL RIGHT. I DON'T HAVE**

1 **ANYTHING ELSE.**  
 2 HONORABLE CYNTHIA M. RUFÉ: NOTHING?  
 3 MR. GLANVILLE: NO.  
 4 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.  
 5 DOCTOR, YOU MAY STEP DOWN. THANK YOU  
 6 VERY MUCH.  
 7 (WITNESS EXCUSED.)  
 8 HONORABLE CYNTHIA M. RUFÉ: THAT WILL  
 9 CONCLUDE THE PRESENTATION OF THE PLAINTIFF'S SELECTED  
 10 EXPERTS. NOW WE NEED TO ADDRESS WHO, IF ANY, THE  
 11 DEFENSE WOULD LIKE TO PRESENT TOMORROW.  
 12 MS. GUSSACK: YOUR HONOR, COULD YOU GIVE  
 13 US SOME GREATER CLARITY ABOUT YOUR SCHEDULE TOMORROW  
 14 BECAUSE I THINK THAT WILL AFFECT OUR DECISION MAKING  
 15 ABOUT WHO WE CALL.  
 16 HONORABLE CYNTHIA M. RUFÉ: I DID WANT TO  
 17 START AT 9:30 AND HEAR WHATEVER EVIDENCE. I THINK OUR  
 18 MDL CONFERENCE FOLLOWS WHATEVER WE DO HERE. I DON'T  
 19 THINK THAT WILL BE VERY LONG AND I DON'T SUPPOSE IN ANY  
 20 EVENT IT COULD TAKE PLACE BEFORE 2 O'CLOCK IN THE  
 21 AFTERNOON. SO IT WAS MY DESIRE AND INTENT TO HAVE THIS  
 22 RUN ALL MORNING.  
 23 MS. GUSSACK: YOUR HONOR, IF WE COULD  
 24 TAKE A LITTLE TIME TO REFLECT ON WHAT WE HAVE HEARD  
 25 TODAY TO DETERMINE WHO OF OUR AVAILABLE WITNESSES WILL

1 TESTIFY, WE WILL BE GLAD TO NOTIFY THE PSC AND BE  
 2 PREPARED TO START AT 9:30. WE TOLD YOUR HONOR YESTERDAY  
 3 THAT THE THREE POSSIBLE WITNESSES THAT WE WOULD CALL,  
 4 DR. GAVIN, DR. KEANEY AND DR. HENNEKENS ARE LIKELY OR  
 5 UNDER CONSIDERATION, LET ME SAY THAT.  
 6 SINCE THERE IS NO CHALLENGE TO OUR  
 7 EXPERTS, IT'S OBVIOUSLY IN OUR JUDGMENT WHAT, IF  
 8 ANYTHING, IS NECESSARY HERE.  
 9 HONORABLE CYNTHIA M. RUFÉ: AND I'M NOT  
 10 REQUIRING ANYTHING OF THE PARTIES IN THAT REGARD BECAUSE  
 11 YOU DON'T HAVE THE BURDEN HERE. YOU ARE NOT BEING  
 12 CHALLENGED, THAT IS.  
 13 MS. GUSSACK: EXACTLY.  
 14 HONORABLE CYNTHIA M. RUFÉ: THAT WOULD  
 15 COME AT ANOTHER TIME. I THINK THERE ARE MOTIONS, BUT WE  
 16 HAVE NOT ADDRESSED THOSE.  
 17 MR. CARTMELL: NOT SPECIFICALLY THOUGH ON  
 18 THEIR EXPERTS. AND ALL WE WOULD ASK FOR IF THEY ARE  
 19 GOING TO BRING SOME, THAT WE HAVE A LITTLE NOTICE SO WE  
 20 CAN PREPARE, BUT WE ARE FINE IF THEY DON'T WANT TO.  
 21 HONORABLE CYNTHIA M. RUFÉ: THAT IS FAIR.  
 22 THAT IS VERY FAIR.  
 23 MS. GUSSACK: IS IT YOUR PREFERENCE THAT  
 24 THERE BE AN OPPORTUNITY IF WE CAN ARRANGE IT TO HAVE ANY  
 25 CLOSING COMMENTS BY COUNSEL?

1 HONORABLE CYNTHIA M. RUFÉ: I WOULD LOVE  
 2 CLOSING ARGUMENT. I DON'T KNOW WHERE IN THE SCHEDULE  
 3 THAT FALLS. I KNOW WE WILL HAVE NOTES OF TESTIMONY HERE  
 4 TO REFLECT UPON AND ALL OF THE EXHIBITS AND REPORTS AND  
 5 THAT IS ALL I NEED. I DON'T THINK I NEED MORE ARGUMENT.  
 6 AS WELL PREPARED AS EACH SIDE HAS BEEN, I REALLY DON'T  
 7 THINK I NEED IT.

8 MS. GUSSACK: THANK YOU, YOUR HONOR.  
 9 THAT RAISES ONE LAST HOUSEKEEPING ISSUE WHICH IS WOULD  
 10 IT BE YOUR HONOR'S PREFERENCE THAT THE PARTIES SUBMIT  
 11 FINDINGS OF FACTS AND CONCLUSIONS OF LAW WITHIN ABOUT  
 12 30 DAYS OR WE COULD DISCUSS THOSE SCHEDULES?

13 THE COURT: WE WILL DISCUSS THE SCHEDULE  
 14 AND YES, IT WOULD BE MOST APPROPRIATE. I DON'T THINK  
 15 THE NOTES OF TESTIMONY WILL TAKE TOO LONG. THEY ARE  
 16 ALREADY WORKING ON THEM. IT'S NOT REALTIME, BUT IT'S  
 17 PRETTY QUICK.

18 MS. GUSSACK: WE HAVE BEEN VERY LUCKY TO  
 19 HAVE THEM.

20 HONORABLE CYNTHIA M. RUFÉ: YES, WE ARE  
 21 LUCKY AND WE DON'T WANT TO TAKE ADVANTAGE OF GOOD  
 22 FINGERS FOR TOO MUCH LONGER TODAY. SO WE CAN ADDRESS  
 23 THE SCHEDULE. I DON'T KNOW IF 30 DAYS FITS IN THAT TIME  
 24 FRAME. THAT MAY BE TOO LONG.

25 MS. GUSSACK: THANK YOU, YOUR HONOR.

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1 SO WE WILL BE READY TO PROCEED AT 9:30.  
 2 WE WILL GIVE THE PSC A HEADS UP WITHIN AN HOUR OR SO SO  
 3 THEY KNOW WHAT TO EXPECT. AND WE'LL PLAN THE SCHEDULE  
 4 ACCORDINGLY.

5 HONORABLE CYNTHIA M. RUFÉ: WE WILL BE  
 6 READY IN ANY EVENT, BUT IF THERE IS TO BE NO TESTIMONY  
 7 TOMORROW MORNING, BECAUSE GSK CHOOSES NOT TO, I THINK WE  
 8 NEED TO TELL JUDGE MOSS SO SHE DOES NOT COME OVER HERE  
 9 FROM CITY HALL, BECAUSE THAT IS THE ONLY REASON SHE  
 10 WOULD BE COMING.

11 MS. GUSSACK: UNDERSTOOD.

12 HONORABLE CYNTHIA M. RUFÉ: THANK YOU.

13 ALL COUNSEL: THANK YOU.

14 HONORABLE CYNTHIA M. RUFÉ: WE ARE

15 ADJOURNED.

16 (COURT ADJOURNED AT 5:30.)

17  
18  
19 I CERTIFY THAT THE FOREGOING IS A CORRECT  
 20 TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE  
 21 ABOVE-ENTITLED MATTER.

22  
23  
24 DATE SUZANNE R. WHITE

25 OFFICIAL COURT REPORTER

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