SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 14 HON. TERRY A. GREEN, JUDGE

APRIL CHRISTINE CABANA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. BC465313
	)	
STRYKER BIOTECH LLC, ET AL.,	)	
	)	
DEFENDANT.	)	
	)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS

MONDAY, SEPTEMBER 9, 2013

APPEARANCES:

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KAREN ALGORRI, CSR NO. 8319
OFFICIAL REPORTER

CASE NUMBER:	BC465313
CASE NAME:	APRIL CHRISTINE CABANA VS. STRYKER BIOTECH LLC, ET AL.
LOS ANGELES, CALIFORNIA	MONDAY, SEPTEMBER 9, 2013
DEPARTMENT NO. 14	HON. TERRY A. GREEN, JUDGE
REPORTER:	KAREN ALGORRI, CSR NO. 8319
TIME:	A.M. SESSION

APPEARANCES:

PLAINTIFF APRIL CHRISTINE CABANA, REPRESENTED BY COUNSEL BIJAN ESFANDIARI, ATTORNEY AT LAW; DEFENDANT STRYKER BIOTECH LLC, REPRESENTED BY COUNSEL JAMES L. NELSON, ATTORNEY AT LAW; DEFENDANT MEDTRONIC REPRESENTED BY COUNSEL MICHAEL K. BROWN, ATTORNEY AT LAW; DEFENDANT ALI MESIWALA REPRESENTED BY COUNSEL DANIELLE SUNDBERG BLAUVELT, ATTORNEY AT LAW

THE COURT: THE COURT: CABANA CASES.

MR. ESFANDIARI: GOOD MORNING, YOUR HONOR. BIJAN ESFANDIARI ON BEHALF OF THE PLAINTIFF, APRIL CHRISTINE CABANA.

MS. BLAUVELT: GOOD MORNING, YOUR HONOR. DANIELLE BLAUVELT ON BEHALF OF DEFENDANT, ALI MESIWALA.

MR. NELSON: GOOD MORNING, YOUR HONOR. JIM NELSON ON BEHALF OF THE STRYKER DEFENDANTS.

MR. CONNOLLY: YOUR HONOR, I'M BOB CONNOLLY HERE FROM KENTUCKY ON BEHALF OF THE STRYKER DEFENDANTS. THANK YOU FOR ALLOWING ME TO APPEAR HERE.

MR. BROWN: MICHAEL BROWN FOR MEDTRONIC DEFENDANTS, YOUR HONOR.

THE COURT: AND DR. MESIWALA?

MS. BLAUVELT: I HAVE DR. MESIWALA, YOUR HONOR.

THE COURT: HAVE A SEAT. WE'LL TAKE STRYKER FIRST. IT'S UP ON TOP HERE.

FIRST OF ALL, MY CONGRATULATIONS TO ALL OF YOU FOR REALLY SOME PROVOCATIVE WELL-WRITTEN MOTIONS. I ALWAYS THOUGHT MARCO POLO DID GO TO CHINA, BUT IS THERE SOME DEBATE ABOUT THAT NOW, OR WE DON'T KNOW?

MR. ESFANDIARI: IF WE HAVE ONE DISPUTED FACT, THEN I GUESS THAT WILL BE IT, YOUR HONOR.

THE COURT: DIDN'T MARCO POLO GO TO CHINA AND JUST NOT NOTICE THE GREAT WALL OF CHINA?

IT WAS INTERESTING READING. SOME OF THESE DOCUMENTS THAT ARE FILED UNDER SEAL ARE HARD TO GET TO BECAUSE YOU HAVE TO UNDO THE COURT FILE, THEN UNDO THE PACKAGES, BUT I COULDN'T GET TO ALL THE ONES THAT WERE UNDER SEAL BECAUSE THEY ARE HARD TO GET TO IT.

MR. ESFANDIARI: YOUR HONOR, WE SUBMITTED COURTESY COPIES IN A BINDER CONTAINING ALL THE DOCUMENTS FOR YOUR HONOR.

THE COURT: IN A BINDER?

MR. ESFANDIARI: CORRECT. WE CREATED A WHOLE BINDER FOR YOU AS A COURTESY COPY FOR DEPARTMENT 14,

HIGHLIGHTED AND --

THE COURT: I GOT SOME THAT WERE HIGHLIGHTED. I GOT A LOT OF EXHIBITS THAT WERE HIGHLIGHTED.

MR. ESFANDIARI: RIGHT. YOUR HONOR'S COPY WOULD HAVE HAD EVERYTHING, EVEN THE ONES THAT WERE UNDER SEAL BECAUSE IT WAS --

THE COURT: I DIDN'T SEE THAT.

AT ANY RATE, I FEEL I HAVE A FUND OF KNOWLEDGE THAT I THINK IS GOOD ENOUGH. WE'LL HAVE TO WAIT AND SEE WHETHER YOU THINK IT IS GOOD ENOUGH.

BUT IT WAS WELL DONE. VERY INTERESTING CASE.

AS TO STRYKER. STRYKER, FIRST OF ALL, YOU HAD OBJECTIONS IN THE MESIWALA MSJ. I TOOK THOSE OFF CALENDAR. I READ THAT COLUMBUS LINE CASE. I DON'T THINK A CODEFENDANT HAS STANDING TO BRING OBJECTIONS AGAINST ANOTHER DEFENDANT UNLESS THERE IS AN ADVERSE PLEADING RELATIONSHIP.

IN COLUMBUS LINE THERE WAS AN ADVERSE PLEADING RELATIONSHIP AT ONE POINT DURING THAT LITIGATION, SO I'VE NEVER SEEN A CODEFENDANT BRING OBJECTIONS TO ANOTHER CODEFENDANT'S MSJ.

BUT THAT WAS MY RULING ON IT, SO AT ANY RATE, AS TO THE MERITS OF THE STRYKER MOTION ITSELF, FIRST OF ALL, WE HAVE A REQUEST FOR JUDICIAL NOTICE TO BE GRANTED. I LOOKED THROUGH THAT.

IT'S GRANTED IN SO MUCH AS IT SAYS WHAT IT SAYS, BUT THERE WAS A LOT OF SCIENTIFIC CONCLUSIONS IN

THERE, AND I'M NOT GOING TO ACCEPT THAT FOR THE TRUTH OF THE FACTS. I'M NOT PREPARED TO SAY THAT THOSE FACTS ARE TRUE FACTS BECAUSE I DON'T KNOW ENOUGH ABOUT SCIENCE. I DON'T KNOW ENOUGH ABOUT THESE PROCEDURES TO SAY THAT THOSE ARE TRUE FACTS, BUT THEY ARE WHAT THEY ARE. THEY ARE OFF THESE WEBSITES, AND IT SAYS WHAT IT SAYS, SO I WILL TAKE JUDICIAL NOTICE TO THAT EXTENT.

WE HAVE THE PREEMPTION ARGUMENT THAT HAS BEEN RAISED, AND IT'S AN INTERESTING AND SERIOUS PREEMPTION ARGUMENT, SO LET'S TALK ABOUT IT.

AS TO THE STRYKER, THE OP-1, IT WAS APPROVED ACCORDING TO WHAT I READ. IT WAS A HUMANITARIAN EXCEPTION TO THE RIGOROUS PREMARKET APPROVAL. THIS IS, AS MY NOTES SAY, CLASS 3 MEDICAL DEVICE MDA. ALL RIGHT? SO THERE IS A HUMANITARIAN EXCEPTION ALLOWING THIS, AND THERE ARE CONDITIONS AND WHATEVER, THE HUMANITARIAN EXCEPTION CAN BE USED, AND THE CALSTRUX WAS ENTERED UNDER A 510(K). SO NOW I KNOW ALL ABOUT THIS.

NOW, THE QUESTION IS, ARE THESE PRE-EMPTED JUST GENERICALLY? AND THE PLAINTIFF SAYS SUITS INVOLVING THE HUMANITARIAN EXCEPTION, THERE ARE NO SUITS ALLOWING THIS PREEMPTION AND AS TO THE GRANDFATHERED IN, THERE ARE NO CASES ALLOWING THIS PREEMPTION.

BUT MOVING ON IT'S THE THEORY OF THE PLAINTIFFS FOR WHICH THERE IS SOME EVIDENCE THAT WHATEVER APPROVAL TOOK PLACE FROM THE FDA DID NOT INCLUDE A COMBINED USE OF OP-1 AND CALSTRUX.

AND SO THAT WOULD BE A USE IN VIOLATION OF THE FDA RULES, AND AS ONE CASE SAID, IT WOULD BE AN ANOMALOUS RESULT, IF THAT WAS THE PHRASE THEY USED, BIZARRE RESULT OR SOMETHING LIKE THAT, FEDERAL LAW PREEMPTING STATE LAW CAUSES OF ACTION FOR CASES WHERE FEDERAL LAW WAS BROKEN.

SO I THINK THAT THERE PROBABLY -- THERE IS NO PREEMPTION IN THAT CASE FOR ANY NUMBER OF REASONS. FIRST THE 510(K) AND HUMANITARIAN DRUGS, THERE ARE NO CASES ALLOWING PREEMPTION. BEYOND THAT, THIS IS A CASE WHERE THE THEORY IS A VIOLATION OF FDA RULES, AND I THINK IT WOULD BE AN ANOMALOUS RESULT IF THE FEDERAL COURT SAID THE STATE COURTS WERE PREEMPTED FROM HAVING STATE COURT CAUSES OF ACTION THERE.

IT'S NOT A CASE OF FRAUD AGAINST THE FDA. THERE WAS A CASE THAT WAS CITED WHERE PEOPLE LIED TO THE FDA, OR SOMEBODY WITHHELD EVIDENCE. THIS IS NOT THAT CASE. I LOOKED AT THE OTHER CASES. I DIDN'T SEE WHERE ANY OF THEM FIT.

I KNOW THIS IS AN IMPORTANT ISSUE BECAUSE IT'S BEEN RAISED. I READ LINFIELD'S OPINION. I THINK IT WAS THE MEDTRONIC CASE. I THOUGHT IT WAS VERY WELL REASONED. WE'LL GET TO THAT IN THE MEDTRONIC CASE.

BUT THIS HAS BEEN DISCUSSED, AND IT IS CERTAINLY A SERIOUS ARGUMENT RAISED BY THE DEFENDANTS, BUT I TEND TO AGREE WITH JUDGE LINFIELD THAT IT IS NOT PREEMPTED, AND IN THE STRYKER MOTION, THESE INDIVIDUAL DRUGS, I DON'T THINK THAT THE STATE LAW CAUSES OF ACTION

ARE PREEMPTED OR SHOULD BE PREEMPTED BECAUSE THE ALLEGATIONS ARE VIOLATIONS OF THE FDA RULES.

AT ANY RATE, THIS IS SORT OF A DISTURBING CASE. THE ONLY INTRODUCTION I GET TO CASES ARE THROUGH THE PLEADINGS AND WHAT I READ IN THE EVIDENCE ATTACHED. THIS IS A SUMMARY JUDGMENT MOTION, SO, AGAIN, WE'RE JUST LOOKING FOR QUESTIONS OF FACT. THIS IS NOT A TRIAL.

BUT MY QUESTIONS FOR STRYKER ARE THE FOLLOWING: THE ALLEGATIONS RAISED IN THE PLAINTIFF'S MOTION ARE DISTURBING AND SERIOUS. THEY SAY -- AND THERE IS SOME EVIDENCE TO SUPPORT -- THAT FDA APPROVAL WAS SOUGHT FOR OP-1, AND IT WAS REJECTED.

THEY SAY -- AND THEY HAVE DECLARATIONS OF KESSLER. I REMEMBER HIS NAME BECAUSE SC'S STARTING QUARTERBACK WAS NAMED KESSLER. I HOPE THIS DOCTOR HAS A BETTER GAME.

BUT KENNEDY, AMONG OTHER DECLARATIONS THAT I READ WITH INTEREST -- WEINER, WHINER (PHONETIC), DECLARATION, ANOTHER ONE I READ WITH INTEREST -- BUT THEY SAY THAT THERE WAS AN ATTEMPT TO GET FDA APPROVAL OF THIS, AND THAT WAS TURNED DOWN.

IN EITHER CASE, WHATEVER APPROVALS CAME FROM THE FDA FOR CALSTRUX AND OP-1 CAME WITH A STIPULATION NOT TO BE USED IN COMBINATION WITH OTHER PRODUCTS.

YET DESPITE THIS, THERE WAS AN ACT OF MARKETING OF THE COMBINED USE OF THESE PRODUCTS, AND, AGAIN, THERE IS SOME EVIDENCE OF THIS.

AT THE SAME TIME THERE WAS THIS MARKETING, AND THESE THINGS WERE BEING SOLD IN COMBINATION. THERE WAS AN INTERNAL DEBATE AT STRYKER ABOUT WHETHER THIS USE IN COMBINATION WAS SAFE. I MEAN, THEY HAD THE HOLY GRAIL, I GUESS, WITH OP-1, BUT IT WAS HARD AND DIFFICULT TO WORK WITH, AND SO THEY MIXED IT WITH CALSTRUX, AS I UNDERSTAND.

I MEAN, I HAVE NO BACKGROUND OF -- BIOMEDICAL BACKGROUND BY ANY MEANS, BUT -- AND THIS SUPPOSEDLY WAS A REAL CASH COW, BUT THERE'S THIS INTERNAL DEBATE ABOUT WHETHER IT WAS SAFE AND WHETHER THERE WAS BONE MIGRATION AND WHATEVER, AND THERE WERE SOME CORRESPONDENCE BETWEEN THE SALESPEOPLE AND THE SCIENCE PEOPLE ABOUT WHAT YOU SHOULD INCLUDE IN DOCTORS -- DEAR DOCTOR LETTERS AND WHATEVER, AND IT'S DISTURBING THAT -- I MEAN, I THINK, AS I RECALL, MR. WHALEN * CAME OUT AND PERSONALLY MIXED THE STUFF FOR DR. MESIWALA.

I DON'T KNOW WHAT HE KNEW, BUT THERE WAS -- ASIDE FROM THE PRINTED LABELS THAT MIGHT HAVE CONTAINED WARNINGS, THERE WAS NOTHING THAT WAS CONFERRED DIRECTLY, OH, BY THE WAY, WE EXPECT THESE PROBLEMS, AND IT BECAME SUFFICIENTLY SERIOUS THAT -- I GATHER THAT THEY WERE -- THAT THEY CEASED MAKING IT.

RATHER THAN PULL IT OFF THE SHELVES, THEY JUST LEFT THE EXISTING INVENTORY WEAR DOWN UNTIL THEY WERE GONE, AND THAT WAS THE TIME PERIOD WHERE MS. CABANA HAD HER OPERATION.

I THINK THE DOCTOR TESTIFIED -- MESIWALA TESTIFIED THAT HAD HE KNOWN ALL THIS THAT LATER CAME OUT, HE NEVER WOULD HAVE USED THE PRODUCT.

THEN THERE WAS -- AND BY THEN IT WAS TOO LATE. SHE HAD ISSUES.

THE QUESTION I HAD FOR COUNSEL FROM STRYKER, DO YOU BASICALLY DISPUTE THOSE FACTS? IS THERE A DISPUTE THAT THAT -- THAT WHAT I JUST SAID ACTUALLY HAPPENED? YOU HAD THIS INTERNAL DEBATE. THERE WERE THESE CORRESPONDENCE. SOME OTHER COMPANY FELT THAT THIS WAS UNSAFE.

ASIDE FROM THE LABELS THAT WENT OUT, THE WARNING LABELS -- AND I READ ONE WARNING LABEL. MY EYES ARE NOT GOOD ENOUGH. I COULDN'T MAKE OUT WHAT IT SAID, BUT I DON'T KNOW IF THAT WAS THIS OR THE INFUSE, BUT DO YOU BASICALLY DISPUTE THIS?

IS THIS -- IS THERE EVIDENCE IN THE RECORD TO SUPPORT WHAT I JUST SAID, MY UNDERSTANDING OF THE CASE?

WHO WANTS TO SPEAK FROM STRYKER?

MR. CONNOLLY: YOUR HONOR, YES, THERE ARE ASPECTS OF WHAT YOU SAID THAT ARE TRUE, AND THERE ARE ASPECTS THAT WE DISPUTE.

THE COURT: ALL RIGHT.

MR. CONNOLLY: FIRST OF ALL, THE DEBATE THAT OCCURRED, THE SO-CALLED DEBATE, WASN'T TRULY A DEBATE INVOLVING THE SALES REPRESENTATIVE. MANAGEMENT OF THE COMPANY, THE REGULATORY PEOPLE, THE SCIENTIFIC PEOPLE,

THE PRESIDENT OF THE COMPANY, THE OFFICERS OF THE COMPANY, THOSE WERE THE FOLKS WHO WERE DEBATING WHAT SHOULD GO IN THE WARNING.

THE SALES REPRESENTATIVES WERE SAYING -- OR THE NATIONAL SALES DIRECTOR -- AND THOSE WERE THE E-MAILS THAT YOU WERE SHOWN -- WAS SAYING, I DON'T WANT THIS KIND OF A WARNING TO GO TO THE HOSPITALS THAT ARE USING IT. IT WILL KILL OUR SALES.

EVERYONE HAS TESTIFIED HIS INPUT MEANT NOTHING TO THEM. HE DID NOT HAVE A VOTE AT THE TABLE, AND THE FOLKS THAT DECIDED IT, DECIDED IT AND ASKED THE FDA, ARE THE WARNINGS THAT WE'RE GIVING APPROPRIATE, AND THE FDA SAID YES.

THAT'S EXHIBIT 15 TO BERNADETTE ALFRED'S DEPOSITION. THE FDA SAID FINE, THE WAY YOU ARE WARNING.

FURTHERMORE, IN THE DEPOSITION TESTIMONY OF THE SURGEON, I SHOWED HIM -- HE'S ASKED BY COUNSEL FOR PLAINTIFF, AND COUNSEL FOR PLAINTIFF HAS CITED THIS -- "IF YOU HAD ONLY SEEN THESE WARNINGS, WOULD YOU HAVE COMBINED OP-1 AND CALSTRUX?"

HE SAID, "NO, I NEVER WOULD HAVE."

OKAY. WE CONTEND THAT'S SPECULATIVE, BUT IT'S NOT THE WHOLE STORY BECAUSE I SHOWED --

THE COURT: BUT HE HAS TO SAY THAT. I DON'T MEAN IT'S NOT TRUE. I'M JUST SAYING THAT FOR A FRAUD CAUSE OF ACTION, FOR EXAMPLE, THEY HAVE TO SHOW THAT IF YOU HAD KNOWN THE TRUE FACTS, WOULD YOU HAVE DONE THIS? THAT'S AN ELEMENT OF PROVING FRAUD. OKAY. SO I CAN'T

SAY -- I DIDN'T SUSTAIN THE OBJECTION TO THAT.

MR. CONNOLLY: BUT SO I SHOWED HIM -- HE HAD NEVER READ -- HE HAD NEVER BOTHERED TO READ THE WARNINGS THAT WE ACTUALLY DID PROVIDE. SO I SHOWED HIM THOSE WARNINGS AND HAD HIM READ THEM, AND IT SAYS CALSTRUX BONE VOID FILLER SHOULD NOT BE USED IN COMBINATION WITH OTHER PRODUCTS. THAT'S ON OUR WARNING LABEL.

THE COURT: HERE IS THE QUESTION I HAVE FOR YOU. I APPRECIATE STRYKER HAS A POINT OF VIEW IN THIS CASE. TRUST ME, I DO.

MR. CONNOLLY: ANYWAY, MY POINT -- EXCUSE ME. MY POINT IS SIMPLY, WHEN I SHOWED THAT TO HIM, I SAID, "IF YOU HAD BOTHERED TO READ THIS WARNING LABEL WHICH WAS IN EFFECT AT THE TIME OF THIS SURGERY, WHAT WOULD YOU HAVE DONE?"

HE SAID, "I WOULD HAVE USED INFUSE."

SO MY POINT IS, YOUR HONOR, A, HE DIDN'T SEE OUR WARNINGS, AND, B, IF HE HAD SEEN OUR WARNINGS, HE SAID THEY WOULD HAVE CHANGED HIS COURSE OF CONDUCT.

THE COURT: HERE IS THE QUESTION I HAVE FOR YOU. THIS IS WHAT I WAS STRUGGLING WITH IN READING THIS. OKAY.

IF THERE IS THIS DEBATE WITHIN THE COMPANY -- AND THERE IS SOME EVIDENCE OF THAT. THERE IS SOME EVIDENCE THAT SOMEONE IN THE COMPANY THOUGHT THERE WAS BONE MIGRATION. SOMEONE IN THE COMPANY THOUGHT THIS WAS DANGEROUS. SOMEONE IN THE COMPANY DIDN'T THINK IT WAS EFFECTIVE AND WOULD CAUSE HARM. THERE'S SOME

THOUGHT.

WHAT KEPT COMING TO MIND WAS THE O-RING IN THIS PATIENT. THEY FOUND SOME MEMO YEARS EARLIER THAT DON'T USE AN O-RING FOR THE FORD PINTO. THEY FOUND SOME MEMO YEARS EARLIER THAT SAID A $20.00 PART COULD DO THIS. THAT'S WHAT CAME TO MIND.

WHAT OBLIGATION DO COMPANIES LIKE STRYKER HAVE TOWARDS THE PUBLIC WHEN YOU HAVE A WARNING LABEL -- AND I KNOW THE WARNING LABEL SAID THAT -- BUT THAT, YOU KNOW, YOU KNOW THINGS THAT -- YOU KNOW DOCTORS, IN THIS CASE, DOCTORS -- YOU KNOW THEY ARE GOING FORWARD WITH THIS PROCEDURE. YOU KNOW THEY ARE BECAUSE YOU ARE THERE MIXING THE STUFF FOR THEM. YOU KNOW THEY ARE, AND YOU KNOW THERE ARE PROBLEMS.

WHAT OBLIGATION DO PEOPLE IN STRYKER OR THE COMPANIES IN STRYKER'S POSITION HAVE TO TELL SOMEBODY THAT YOU HAVE THESE SUSPICIONS OF THESE PROBLEMS?

MR. CONNOLLY: I DON'T KNOW THAT THERE'S A HARD-AND-FAST RULE TO THAT, YOUR HONOR, BUT WHAT HAPPENED HERE WAS THEY BEGAN GETTING REPORTS OF MIGRATION, AND THEIR FIRST REACTION WAS LET'S SEND OUT A "DEAR DOCTOR" LETTER ABOUT IT.

THEN AS THEY MET AND DEBATED WHAT IT SHOULD CONTAIN, THEY SAID, "WE DON'T KNOW WHAT'S GOING ON HERE." SO INSTEAD OF JUST THROWING OUT A WARNING, LET'S TRY TO FIGURE OUT WHAT'S HAPPENING.

SO THEY BEGAN TO STUDY IT, AND THEN THEY CAME UP WITH THE WARNINGS THAT THEY EVENTUALLY SENT OUT

IN AUGUST OF 2006, TWO YEARS BEFORE HER SURGERY.

SO TWO YEARS BEFORE HER SURGERY INVOLVING OP-1, THE CALSTRUX LABEL HAD IN IT, "WARNING, DON'T USE IT IN COMBINATION WITH OTHER PRODUCTS.

THE COURT: DON'T YOU THINK THERE'S A QUESTION OF FACT AS TO WHETHER THAT IS A SUFFICIENT WARNING, GIVEN THE FACT THAT THERE WAS ACTUAL KNOWLEDGE ON BEHALF OF THE COMPANY REPS THAT DOCTORS WERE USING THESE IN COMBINATION?

IN FACT, MESIWALA SAID IN HIS DEPOSITION OR HIS DECLARATION -- IT'S UNCLEAR WHAT HIS FOUNDATION WAS FOR THIS -- BUT HE SAID LOTS OF DOCTORS USE THESE IN COMBINATION. I DON'T KNOW HOW HE KNEW THAT, BUT DOCTORS ALWAYS USE THIS STUFF IN COMBINATION.

THAT COULD BE TRUE, BUT WE DO KNOW THAT IN THIS CASE IT WAS BEING USED. I MEAN, AFFIRMATIVELY ISN'T THERE A QUESTION OF FACT THAT WHEN YOU POSSESS THESE DOUBTS -- AND THIS IS PRETTY CATASTROPHIC STUFF. APPARENTLY MS. CABANA IS IN HER EARLY THIRTIES, 31 OR 32 SOMETHING.

APPARENTLY FROM WHAT I READ, IT'S DIFFICULT, IF NOT IMPOSSIBLE, TO CORRECT THIS SITUATION. SHE LIVES IN CHRONIC PAIN. THIS IS SERIOUS STUFF. THIS IS A LIFE SENTENCE, AS IT WERE.

IN LIGHT OF THAT, ISN'T THERE A FACTUAL QUESTION ABOUT THAT WHEN YOU HAVE ACTUAL KNOWLEDGE ABOUT THE DEBATE, THAT YOU SHOULD GO BEYOND WHAT'S IN THE PRINTED LABEL AND TELL SOMEBODY AS YOU ARE MIXING IT,

"OH, BY THE WAY, WE'VE HAD ISSUES OF THIS"?

ISN'T THERE A QUESTION OF FACT, AT LEAST, THAT THIS SHOULD BE A FAILURE TO WARN, AND A JURY SHOULD DECIDE WHETHER THAT'S SUFFICIENT?

MR. CONNOLLY: I WOULD LOVE TO BE ABLE TO ANSWER YOU WITH A SIMPLE "YES" OR "NO."

THE COURT: IT'S A HARD CASE. I KNOW.

MR. CONNOLLY: IT IS A COMPLEX SERIES OF LAWS HERE THAT APPLY. THE FIRST THING I WOULD SAY IS WHERE A PHYSICIAN WHO KNOWS HE HAS A RESPONSIBILITY TO READ THESE LABELS OR INSTRUCTIONS FOR USE, AND DOES NOT, THE CASE LAW IN CALIFORNIA IS PRETTY CLEAR THAT WE'VE SUBMITTED -- WE CANNOT -- THAT THERE'S NO CAUSATION HERE IF -- THERE'S NO ISSUE FOR THE JURY TO DECIDE.

IT'S A QUESTION OF LAW. IF HE DIDN'T READ THE WARNINGS, WHATEVER WE WOULD HAVE SAID IN THE WARNINGS HAS NO APPLICATION.

NOW, THE SECOND LEVEL OF WHAT YOU ARE ASKING IS, SHOULDN'T THE SALES REP HAVE SAID SOMETHING?

THE COURT: OR SOMEBODY, RIGHT. WHALEN OR SOMEBODY.

MR. CONNOLLY: BRIAN WHALEN WAS THE SALES REPRESENTATIVE. THERE IS NO OBLIGATION UNDER THE FDA REGULATIONS FOR SALESMEN TO SIT AND READ THE IFU TO A PHYSICIAN. THAT'S WHY THEY ARE WRITTEN THE WAY THEY ARE. THEY ARE WRITTEN FOR SOPHISTICATED USERS, LIKE DOCTORS, TO READ THEM AND UNDERSTAND THEM.

SECOND, TO THE EXTENT THAT THIS COURT WOULD

LIKE TO IMPOSE SUCH AN OBLIGATION, WE'VE ALSO CITED THE CASES THAT SAY THAT WOULD BE A VIOLATION OF THE BUCKMAN DECISION, THE SUPREME COURT DECISION, THAT SAYS THAT THAT'S -- THERE'S NO PRIVATE RIGHT OF ACTION TO ENFORCE LABELING REQUIREMENTS UNDER THE FDA.

THE COURT: I DON'T SEE THIS AS A BUCKMAN ISSUE. THAT'S NOT THE CAUSE OF ACTION. WHAT THEY ARE SAYING IS THAT THIS WAS IN THE LABEL, AND EVEN IF THEY SAY THE LABEL WAS SUFFICIENT, THEY ARE SAYING THAT -- OR SUFFICIENT WARNING, THAT IT WAS APPARENT, AT LEAST A FACTUAL QUESTION, THAT PEOPLE WERE PROCEEDING ANYWAY, AND ALONG A PATH THAT -- THEIR POINT IS -- KESSLER'S POINT WAS IN HIS DECLARATION.

AND I DID NOT ACCEPT IT AS A LEGAL CONCLUSION WHAT HE SAID, BUT IT WAS VERY INTERESTING, GIVEN HIS BACKGROUND, AS TO WHAT THE REQUIREMENTS ARE, AND OF AFFIRMATIVELY -- IF YOU HAVE CONCERNS AFFIRMATIVELY SHARING THOSE CONCERNS, MAKING SURE EVERYBODY KNOWS, AT LEAST THERE'S A FACTUAL QUESTION.

MY FIRST INCLINATION WAS TO AGREE WITH YOU ON THIS ONE AND GRANT YOUR MOTION AS TO THIS ISSUE, BUT THE MORE I THOUGHT ABOUT IT, THE MORE I READ THESE DECLARATIONS, THE MORE I THOUGHT, THERE COULD BE A FACTUAL QUESTION HERE.

I DIDN'T SEE A CASE -- I DIDN'T SEE A CASE LIKE THIS. I DIDN'T SEE A CASE LIKE THIS WHERE THERE WAS ACTUAL KNOWLEDGE ON BEHALF OF THE DEFENDANT.

WE HAVE FACTS. I MEAN, WE CAN DEBATE

WHETHER THERE WAS -- HOW BIG IT WAS, BUT NOW WE'RE JUST LOOKING AT A FACTUAL QUESTION WHERE THERE IS EVIDENCE OF ACTUAL KNOWLEDGE OF PEOPLE AND DOCTORS USING THIS FAIRLY WIDESPREAD, ACCORDING TO MESIWALA -- THERE'S ANOTHER FACT I CAN TAKE INTO CONSIDERATION -- DESPITE WHAT'S ON THE WARNING LABEL.

AND THE QUESTION OF FACTS AS TO WHETHER NOW YOU HAVE TO SAY, "NO, WAIT, HERE IS A 'DEAR DOCTOR' LETTER. WE'RE GOING TO SEND THIS OUT. WE'RE GOING TO SEND OUT A BULLETIN. WE'RE GOING TO NOTIFY THE HOSPITALS. YOU GUYS OUGHT TO PROCEED WITH CAUTION. IT'S YELLOW LIGHT TIME."

THAT'S WHY I KIND OF FLIPPED ON THIS ONE.

MR. CONNOLLY: IF YOU TAKE A LOOK -- AND THERE ARE MANY CASES HERE TO READ, I KNOW, AND THEY ARE ALL FAIRLY LONG, COMPLICATED CASES. BELIEVE ME, I KNOW WHAT YOU WERE DOING YESTERDAY BECAUSE I WAS DOING THE SAME THING.

THE PEREZ CASE, WHICH IS A NINTH CIRCUIT OPINION, ADDRESSES WHETHER OR NOT STATES CAN CREATE THIS SO-CALLED ADDITIONAL REMEDY UNDER THE FDA REGULATIONS, AND IT REJECTED THAT CONCEPT.

THESE LABELS, THESE INSTRUCTIONS FOR USE, ARE SUBMITTED TO THE FDA FOR THEIR REVIEW PURSUANT TO A CERTAIN REGULATORY SCHEME, AND THE FDA DETERMINES WHETHER OR NOT THEY ARE APPROPRIATE OR NOT.

AND THAT GETS BACK TO OUR PREEMPTION ARGUMENT THAT I KNOW YOU HAVE FEELINGS ABOUT. IF I GET AN OPPORTUNITY --

THE COURT: YOU WILL.

MR. CONNOLLY: -- I'D LIKE TO TAKE ANOTHER WHACK AT THAT.

SO TO SAY THERE'S A CAUSE OF ACTION FOR A SALES REPRESENTATIVE NOT SAYING, "HEY, DOC" --

THE COURT: FORGET WHALEN. FOR SOMEBODY IN THE COMPANY TO SEND A LETTER OUT TO SAY SOMETHING.

MR. CONNOLLY: WELL, THE COMPANY DID SEND A LETTER OUT IN AUGUST OF 2006. BECAUSE DR. MESIWALA, THE SURGEON HERE, WAS NOT AN ACTIVE USER OF CALSTRUX AT THAT TIME, HE DID NOT RECEIVE THE LETTER. IT ONLY WENT TO DOCTORS WHO HAD ACTUALLY PHYSICALLY USED CALSTRUX.

BUT FROM THEN ON, WHEN THEY PURCHASED CALSTRUX, EVERY DOCTOR WHO PURCHASED IT GOT THE NEW LABEL THAT SAID, "DON'T MIX IT WITH OTHER PRODUCTS."

THE COURT: AND WHY WOULD THEY PROMOTE IT TO BE MIXED? WHY WERE YOU DOING IT? WHY WAS THE COMPANY THEN TURNING AROUND AND MIXING? WHY DID WHALEN TURN OUT THERE IN '08 OR '09, WHENEVER IT WAS, AND SIT THERE AND MIX IT FOR THEM? WHY DID HE DO THAT FOR THEM IF THE LABEL SAID DON'T DO IT?

MR. CONNOLLY: ACCORDING TO BRIAN WHALEN'S TESTIMONY AND ACCORDING TO DR. MESIWALA'S TESTIMONY, THERE WAS ONE MEETING BETWEEN THEM IN 2006 WHERE MIXING WAS DISCUSSED.

THE COURT: THEY SAID 12 TIMES.

MR. CONNOLLY: AND THEN THERE WERE 12 SURGERIES AFTER THAT. DR. MESIWALA'S TESTIMONY WAS THAT BRIAN

WHALEN OR SOMEONE FROM THE COMPANY WAS IN THE O.R. EACH OF THOSE 12 TIMES MIXING. BRIAN WHALEN DENIES THAT.

THE COURT: FACTUAL QUESTION.

MR. CONNOLLY: YES, BUT AT BOTTOM IS THE ISSUE THAT THE COURT IS ASKING. THE LEGAL QUESTION IS, IS THERE A DUTY FOR BRIAN WHALEN TO SAY SOMETHING OR WHOEVER IS IN THE O.R. TO SAY SOMETHING BEYOND WHAT'S IN THE INSTRUCTIONS FOR USE?

THE COURT: EVEN BEYOND THAT. IS THERE A DUTY NOT TO ENGAGE IN BEHAVIOR THAT THE LABEL SAYS IS DANGEROUS? THAT'S THE BIGGER ISSUE. IT'S WHAT YOU DO. NOT WHAT YOU SAY.

MR. CONNOLLY: THAT REALLY GETS TO THIS WHOLE ISSUE OF OFF-LABEL USE, WHICH IS PERMITTED IN OUR COUNTRY. PHYSICIANS CAN ENGAGE IN OFF-LABEL USE. EVERY PROCEDURE HAS RISKS AND BENEFITS. EVERY DECISION THAT'S MADE BY A SURGEON HAS RISKS AND BENEFITS.

A SURGEON IS FREE TO SAY, YEAH, I WANT THESE PRODUCTS MIXED, OR HE'S FREE TO SAY, I DON'T WANT THEM MIXED. WHICHEVER. THAT'S THE SURGEON'S CALL.

THE COURT: SEE, I THINK THERE IS GOING TO BE A FACTUAL ISSUE ON THIS. I THINK THE LABEL IS YOUR STRONG ARGUMENT, THAT YOU HAVE OTHER STRONG ARGUMENTS, BUT THE FACT THAT THE COMPANY WAS SENDING REPS OUT TO DO EXACTLY WHAT THE RED LABEL SAID NOT TO DO TENDS TO DIMINISH THE EFFECT OF THE LABEL.

THIS IS NOT JUST A FAILURE TO WARN, BUT THIS ALSO SPILLS OVER INTO THE NEGLIGENCE CAUSE OF

ACTION AND THE EXPRESS -- THE BREACH OF EXPRESS WARRANTY, BECAUSE THERE IS TESTIMONY THAT MESIWALA WAS TOLD HOW SUPERIOR THIS WAS, BETTER THAN INFUSE, AND WHATEVER. THERE ARE CASES THAT SAY THAT THAT IS SAFE TO USE AND WHATEVER. THE CASES THAT SAY IT, THAT IS AN EXPRESS WARRANTY.

IT'S KIND OF A CORE ISSUE WHAT WAS GOING ON AT THE COMPANY AT THE TIME, WHAT THEY WERE SAYING IN THEIR LABEL, WHAT THEY WERE DOING IN TERMS OF PROMOTING THE OFF-LABEL USE.

AND IN YOUR PAPERS YOU SAY THAT PLAINTIFF IS TAKING THIS FAILURE TO WARN OR WHATEVER AND TURNING IT INTO AN ENTIRE CASE, AND FROM THAT SPAWNS NEGLIGENCE, FRAUD OR WHATEVER. THAT'S TRUE. THAT'S TRUE. AND FOR THE PURPOSES OF SUMMARY ADJUDICATION, I DON'T KNOW THAT THAT IS NECESSARILY WRONG.

AS A MATTER OF LAW, I CAN'T -- AS A MATTER OF LAW UNDER THESE FACTS, I CAN'T SAY THAT THE LABEL WAS SUFFICIENT IN LIGHT OF EVERYTHING ELSE.

UNDER THE FACTS OF THIS CASE, I CAN'T SAY THAT A COMPANY KNOWING THAT -- AND YOU HAVE TO LOOK AT IT FROM THEIR POINT OF VIEW FOR SUMMARY JUDGMENT; OKAY? -- THAT KNOWING THERE'S A PROBLEM AND SITTING ON THE INFORMATION WHILE THEIR PEOPLE ARE GOING OUT THERE AND ENGAGING IN CONDUCT THAT IS PROHIBITED UNDER THEIR LABEL, AND TELLING EVERYBODY THAT THIS IS A GREAT PRODUCT, BETTER THAN THE COMPETITION, AND IT'S SAFE WHEN THERE IS KNOWLEDGE TO THE CONTRARY, IT DOES SORT OF

CARRY THROUGH ALL THE CAUSES OF ACTION.

MR. CONNOLLY: WELL, WHAT THE PLAINTIFF HAS SUCCESSFULLY DONE HERE UNFORTUNATELY, IT'S A LITTLE BIT OF A SLIGHT OF HAND. BECAUSE SOMEONE OVER HERE WAS ENGAGED IN AN OFF-LABEL PROMOTION, BECAUSE SOMEONE OVER HERE MAY HAVE BEEN ENGAGED IN AN OFF-LABEL PROMOTION, THE PLAINTIFF HAS CONVINCED YOU THAT BRIAN WHALEN WAS ENGAGED IN AN OFF-LABEL PROMOTION.

THE COURT: BUT THERE'S A FACTUAL QUESTION. MAYBE YOU ARE GOING TO WIN THIS CASE. YOU ARE NOT WITHOUT ARGUMENT, AND YOU COULD VERY WELL IMPANEL A JURY AND PREVAIL. THAT'S NOT WHY WE'RE HERE. YOU KNOW THAT.

I'M LOOKING AT THIS PUTTING ON MY PLAINTIFF'S HAT, BECAUSE I HAVE TO GO THROUGH AND LINE UP BREAD CRUMB FACTS AND ASSUME THAT THEY ARE TRUE IF THEY ARE IN THE EVIDENCE AND OTHERWISE NOT OBJECTIONABLE, AND IF THEY CAN SURVIVE THAT TRAIL OF BREAD CRUMBS, THEY ARE GOING TO SURVIVE THE MOTION. THAT'S WHERE I AM.

SO THE SAME THING IS ALSO TRUE ON THE FRAUD CAUSES OF ACTION. IT'S ALL -- THESE ARE ALL THE SAME MILIEU OF FACT.

NOW, YOU WANT TO BE HEARD ON THE PREEMPTION. THIS IS A SERIOUS ISSUE. I HAD A COUPLE POINTS ON THIS.

NUMBER ONE, THEY POINTED OUT -- AND I COULDN'T CONTRADICT IT -- THAT THE HUMANITARIAN AND THE 510(K), THERE WERE NO CASES THAT SAID THOSE ARE SUBJECT

TO PREEMPTION. THERE ARE REASONS FOR THAT, BECAUSE THE GRANDFATHER ONE DOESN'T HAVE INDIVIDUALIZED TESTING, AND THE HUMANITARIAN ONE IS SUPPOSED TO BE, LIKE, FOR HUMANITARIAN REASONS. YOU FLY OFF TO SOME COUNTRY WITH NO MEDICINE, AND YOU ARE WHEREVER; SOMEBODY COMES IN AND YOU HAVE TO HELP THEM OUT.

I UNDERSTAND THAT. I UNDERSTAND THE FRUSTRATION THAT DOCTORS AND COMPANIES HAVE WITH THE FDA. WE'VE HAD CASES HERE INVOLVING STEM CELLS AND NONABORTED FETUSES' STEM CELLS, UMBILICAL CORD STEM CELLS, AND STILL THE FDA HAS REQUIREMENTS THAT OTHER COUNTRIES DON'T HAVE. I UNDERSTAND THERE'S THE FRUSTRATION HERE.

PEOPLE GO TO THE BAHAMAS OR WHEREVER FOR STEM CELL ORTHOPEDIC WORK, OR THEY GO TO EUROPE OR WHEREVER. I UNDERSTAND THERE'S A REAL FRUSTRATION WITH THEM, BUT STILL, THAT IS THE GAME WE PLAY WITH.

SO I THINK THE BREACH OF -- THE FDA DID PUT RESTRICTIONS ON HOW TO USE CALSTRUX AND OP-1, BUT GETTING BACK TO THE PREEMPTION ARGUMENT, SO WE HAVE NO CASES SAYING PREEMPTION FOR THAT.

YOU ALSO HAVE THAT ONE QUOTE ABOUT IT BEING AN ANOMALOUS RESULT OF FEDERAL LAW WHERE -- WHAT IT WAS ACTUALLY, AN ANOMALOUS RESULT OF FEDERAL LAW -- OF FEDERAL LAW ALLOWED PREEMPTION OR DEMANDED PREEMPTION FOR STATE LAW CAUSES OF ACTION CASES WHERE FEDERAL LAW -- FEDERAL PROCEDURE WAS VIOLATED. I TEND TO AGREE WITH THAT.

SO FOR ALL THOSE REASONS, I DON'T THINK THIS IS A FRAUD ON THE FDA. I DON'T THINK THEY ARE SAYING THAT SOMEBODY IN FRONT OF THE FDA FORGED THE DATA OR SOMETHING. THEY ARE NOT SAYING THAT.

THEY ARE NOT MOVING TO ENFORCE FEDERAL RULES. THESE ARE JUST VERY MUCH STANDARD PLAINTIFF STATE LAW CAUSES OF ACTION: FAILURE TO WARN, NEGLIGENCE, BREACH OF EXPRESS WARRANTY, FRAUD. THESE ARE PLAIN VANILLA STATE LAW CAUSES OF ACTION.

THEY MAY INVOLVE SOME OF THOSE FACTS, BUT I DON'T THINK THOSE ARE FEDERAL PREEMPTION ISSUES. THEY ARE ISSUES, BUT I DON'T THINK THAT CARRIES THE DAY. I THINK WINFIELD'S OPINION WAS VERY GOOD ON THE MEDTRONIC CASE AS FAR AS COVERING THE CASE LAW, BUT YOU HAVE A DIFFERENT POINT OF VIEW.

MR. CONNOLLY: MAY I COMMENT ON THE PREEMPTION?

THE COURT: YES, PLEASE.

MR. CONNOLLY: THANK YOU, YOUR HONOR.

SO THE WAY THE FEDERAL SCHEME WORKED, THERE'S 510(K) OVER HERE. WE'RE NOT ARGUING THAT 510(K) IS PREEMPTED. THERE IS THE PMA, PREMARKET APPROVAL PROCESS, AND THEN UNDERNEATH THAT, THERE'S THE IDE, THE INVESTIGATIONAL DEVICE EXEMPTION, AND THERE'S THE HUMANITARIAN DEVICE EXEMPTION.

SO THE DIFFERENCE BETWEEN THE HDE, WHICH IS HOW OP-1 WAS APPROVED, AND THE PMA, THE FULL APPROVAL, THE ONLY DIFFERENCE IS EFFECTIVENESS.

IT'S A TWO-STEP APPROVAL PROCESS. THE

FIRST STEP IS THAT THE FDA DETERMINES THAT THE PRODUCT IS SAFE AND THAT THE PROBABLE BENEFIT OUTWEIGHS THE RISK.

NOW, WHAT'S IMPORTANT THERE IS, THAT'S THE LIABILITY CONSTRUCT THAT THE SUPREME COURT USED IN THE RIEGEL CASE TO DETERMINE WHETHER OR NOT THERE COULD BE STATE LAW CAUSES OF ACTION THAT ARE NOT PREEMPTED. I'LL COME BACK TO THAT IN A MINUTE.

THE SECOND PRONG OF THAT EFFECTIVENESS, THAT IS, IS THE PRODUCT MORE EFFECTIVE THAN WHAT IS OTHERWISE AVAILABLE, OR AT LEAST EQUALLY EFFECTIVE?

IN OP-1'S CASE, THEY DID NOT SATISFY THAT PRONG, AND THAT'S WHY THE LEVEL OF APPROVAL WAS NOT THE FULL PMA APPROVAL, BUT SOLELY THE HDE APPROVAL.

NOW, ANALYTICALLY THERE IS NO DIFFERENCE FOR PURPOSES OF THE SUPREME COURT'S DETERMINATION IN RIEGEL THAT WHEN THE FDA HAS SPENT ALL THIS TIME DETERMINING PROBABILITY AND SAFETY, OR THE PROBABLE SAFETY OF A PRODUCT, AND THAT IT OUTWEIGHS THE RISK OF THE PRODUCT.

UNDER THOSE CIRCUMSTANCES, THE RIEGEL COURT SAID WE'RE NOT GOING TO LET STATE LAW JURIES OR STATE JURIES MAKE DECISIONS THAT WILL ABEND THE REGULATORY SCHEME. WE WANT THE FEDERAL FDA SYSTEM DOING THIS, NOT IMPACTED BY THE SYMPATHY FOR AN INDIVIDUAL PLAINTIFF.

AND SO RIEGEL SAID YOU HAVE TO FIND A CAUSE OF ACTION THAT IS PREMISED ON A VIOLATION OF FEDERAL REGULATION, AND HERE WE BELIEVE THAT THEY HAVE BEEN

UNABLE TO DO SO.

THE COURT: WHAT IS THE RECOURSE FOR MS. CABANA? WHAT IS -- AS A RESULT OF ALL THIS, IS THERE A RECOURSE AGAINST STRYKER FOR WHAT HAPPENED TO HER?

MR. CONNOLLY: WE BELIEVE THERE SHOULD NOT BE.

THE COURT: ANYWHERE, IN ANY FORM, ANYWHERE?

MR. CONNOLLY: ANY FORM.

THE COURT: THAT'S A CANDID ANSWER.

SEE, I THINK THAT WOULD BE KIND OF A DRACONIAN RESULT. I'VE BEEN READING THROUGH THIS. THEY HAVE AN ARGUMENT. THEY HAVE AN ARGUMENT THAT I'VE OUTLINED THAT IF A JURY WERE TO BELIEVE IT, MESIWALA IS GOING TO TESTIFY, "I WOULDN'T HAVE DONE THIS HAD I KNOWN THE FDA SAID NOT TO BE USED IN COMBINATION."

THESE WERE USED IN COMBINATION. THAT THE COMPANIES SPEAK WITH FORK TONGUE, AS IT WERE, THEY SAY "DON'T USE IT WITH COMBINATION." YET, THEY WERE SELLING IT THAT WAY, AND HERE I AM EARLY THIRTIES, AND THE REST OF MY LIFE I'M GOING TO BE IN THIS TERRIBLE AGONY THAT ISN'T CURABLE, AND I HAVE NO RECOURSE. THAT'S TOUGH. THAT'S PRETTY TOUGH.

MR. CONNOLLY: WELL, OUR PREEMPTION ARGUMENT, YOU WERE TOLD BY SOMEBODY THERE WERE NO CASES. TO SOME EXTENT THAT IS TRUE, BUT THERE IS THE CALIFORNIA CASE -- I THINK IT WAS THE ROBINSON DECISION -- THAT LOOKED AT THE SAME SITUATION WITH THE IDE, THE INVESTIGATIONAL DEVICE EXEMPTION, AND, AGAIN, APPLIED THE RIEGEL ANALYSIS AND SAID THERE IS NO CAUSE OF ACTION HERE.

SO SIMILARLY THE HDE, WHICH FALLS UNDER THE PMA, THERE SHOULD BE NO CAUSE OF ACTION HERE.

THE COURT: WELL, I KEEP GOING BACK TO THE FDA APPROVED THESE DEVICES NOT TO BE USED IN COMBINATION WITH OTHER DEVICES, AND THEY WERE BEING USED IN COMBINATION WITH OTHER DEVICES OR OTHER THINGS. THAT APPARENTLY LED TO THE PROBLEMS IN THIS CASE.

MR. CONNOLLY: WELL, BUT THAT'S ASSUMING THERE'S A CAUSE OF ACTION FOR OFF-LABEL PROMOTION. WE HAVE SUGGESTED THAT THERE IS NOT. WE'VE CITED SEVERAL CASES ON THAT, AND PERHAPS THE MOST SIGNIFICANT IS ACTUALLY A CRIMINAL CASE CALLED THE CARONIA DECISION OUT OF SECOND CIRCUIT, AND THAT GOES THROUGH A VERY SOPHISTICATED FIRST AMENDMENT ANALYSIS.

NOW, I'M NOT A FIRST AMENDMENT LAWYER, YOUR HONOR, BUT IT SAYS THAT WHEN YOU LOOK AT THESE CLAIMS OF OFF-LABEL PROMOTION, YOU HAVE TO SUBJECT THEM TO THE HIGHEST LEVEL OF SCRUTINY, AND DOES THE FDA TRULY BAN OFF-LABEL PROMOTION? IS THERE ANY KIND OF A REMEDY FOR THAT? AT LEAST IN THE CRIMINAL CONTEXT, IT CONCLUDES THAT THERE ARE NOT.

WE HAVE ALSO CITED THE COURT TO A NUMBER OF CIVIL STATE LAW CASES WHICH HAVE SAID THERE'S NO CAUSE OF ACTION FOR THIS SO-CALLED OFF-LABEL PROMOTION FOR IT BECAUSE THE SIMPLE FACT IS, DOCTORS ARE PERMITTED TO USE PRODUCTS OFF-LABEL.

THE COURT: SURE. THAT'S ALL TRUE.

MR. CONNOLLY: AND SO WHAT THEY'RE -- THEY KEEP

THROWING SORT OF KITCHEN SINK FACTUALLY AND LEGALLY HERE, BUT AT THE END OF THE DAY, THERE ARE NO CAUSES OF ACTION FOR VIOLATION OF THE FDA THAT CAN BE PURSUED BY A STATE LAW PLAINTIFF. THAT'S OUR POSITION.

THE COURT: I CERTAINLY RESPECT THAT POSITION, AND IT'S NOT WITHOUT AUTHORITY. CERTAINLY NOT WITHOUT -- YOU HAVE YOUR LEGAL AND FACTUAL ARGUMENTS. I JUST, FROM READING THE SAME CASES, CAME TO THE CAME CONCLUSION LINFIELD DID, AND THAT IS, IT DOESN'T FOLLOW FROM THE CASES.

THAT WOULD BE AWFULLY HARSH, ESPECIALLY GIVEN THE FACT THAT THEN FEDERAL LAW WOULD SAY STATE LAW CAUSES OF ACTION ARE PREEMPTED WHEN THE ALLEGATIONS IN THOSE CASES ARE THAT THE FEDERAL PROCEDURES WERE VIOLATED. THAT WOULD BE AN ANOMALUS -- IT WOULD IMMUNIZE FOR VIOLATING THE FEDERAL PROCEDURES AND SAY THAT FEDERAL LAW DEMANDS THAT.

MR. CONNOLLY: NO, IT WOULDN'T IMMUNIZE THEM BECAUSE THE FEDERAL GOVERNMENT STILL HAS CAUSES OF ACTION AGAINST ANY MANUFACTURER WHO VIOLATES THE --

THE COURT: BUT CABANA IS OUT ON THE STREET, AS IT WERE. I RESPECT YOUR POSITION. IT WAS CERTAINLY WELL ARTICULATED, AND I WENT BACK AND FORTH.

NOW, ON A COUPLE OF ISSUES THEY WERE NOT PUSHING BACK ON THE DESIGN DEFECTS AND -- BUT THE MANUFACTURING DEFECTS AND DESIGN DEFECTS.

MR. CONNOLLY: WHAT ABOUT THE FACTS, YOUR HONOR, THAT THE STRICT LIABILITY FAILURE TO WARN UNDER

KENTUCKY -- I'M SORRY -- UNDER CALIFORNIA LAW; EXCUSE ME -- IT FOCUSES ON THE LABEL AND NOT THE MANUFACTURER'S CONDUCT, AND HERE THE LABEL SAID DON'T MIX.

THE COURT: MY FIRST -- IN FACT, I CROSSED IT OFF MY NOTES HERE -- GRANT BECAUSE MESIWALA CANNOT RECALL SEEING THE INSTRUCTIONS, AND THE LABEL HAD SAID WHAT IT SAID. THEREFORE, CANNOT SHOW CAUSAL CONNECTION BETWEEN REPRESENTATION/OMISSION AND INJURY.

THAT WAS MY FIRST REACTION. THEN I JUST WAS THINKING ABOUT IT. I WAS THINKING ABOUT YOU ARE LOOKING FOR A QUESTION OF FACT HERE, AND FOR ALL THE REASONS I SAID, YOU HAVE THIS AFFIRMATIVE KNOWLEDGE ON THE PART OF THE COMPANY, AND YOU HAD CONDUCT ON THE PART OF THE COMPANY INCONSISTENT WITH THE LABEL.

THEY SAID THE LABEL SAYS "DON'T DO X," AND THE COMPANY WAS PROMOTING AND ACTIVELY ENGAGED IN DOING X.

SO I THOUGHT IT WOULD BE A QUESTION OF FACT. WHO'S TO SAY? WHO'S TO SAY WHAT THE JURY INSTRUCTIONS ARE GOING TO REQUIRE?

MR. CONNOLLY: YOUR HONOR, I DO HAVE COMMENTS ON SOME OF OUR OTHER ARGUMENTS, BUT I'M GOING TO DO WHAT YOU TELL ME TO DO.

THE COURT: I'M TELLING YOU TO -- I'M SAYING I'M GOING TO ACCEPT THE DESIGN DEFECTS AND MANUFACTURING DEFECT. I AM GOING TO DENY THE SUMMARY ADJUDICATION.

MR. CONNOLLY: I DO HAVE AN IMPORTANT ARGUMENT IF I COULD ON --

THE COURT: PLEASE.

MR. CONNOLLY: -- OVERALL CAUSATION IN THIS CASE, YOUR HONOR.

WE HAVE SUBMITTED -- WELL, FIRST, LET ME BACK UP AND JUST EXPLAIN A LITTLE BIT MORE ABOUT THIS, IF YOU WILL BEAR WITH ME, TO EXPLAIN A LITTLE BIT MORE ABOUT WHAT WAS HAPPENING HERE.

THEY WERE DISCOVERING THAT WHEN THESE PRODUCTS WERE USED IN COMBINATION, THERE WAS A RISK OF MIGRATION, AND THE COMPANY BELIEVED THAT WAS DUE TO ONE OF TWO THINGS: EITHER THE AREA WHERE THE PRODUCT WAS BEING USED WAS BEING OVERPACKED AND SO IT WAS ESSENTIALLY UNDER PRESSURE, AND THIS PRODUCT WOULD GRAVITATE OUT.

THE COURT: RIGHT.

MR. CONNOLLY: THE OTHER REASON WAS IN CLOSING, THE SURGEON MAY NOT HAVE TIGHTLY CLOSED AN AREA, WHICH WOULD PERMIT IT TO FLOW BACK UP OUT INTO THE BODY LIQUIDS.

IN THIS PARTICULAR CASE, WHAT WE BELIEVE HAPPENED WAS DURING THE AXIAL LIFT PROCEDURE, THE DRILL THAT GOES IN THROUGH THE TAILBONE OR THE SACRUM AT THE BOTTOM OF THE SPINE WAS OFF AT A SLIGHT ANGLE AND PIERCED THE DISK, AND IN PIERCING THE DISK, THAT MATERIAL THEN SQUISHED OUT.

THERE'S A FIBROTIC COVERING AROUND THE DISK CALLED THE ANNULUS, AND AS PART OF THE PROCEDURE, THIS MATERIAL WAS PUSHED INTO THAT AREA, BUT IT WASN'T

CONTAINED, AND IT WENT OUT THROUGH THIS HOLE.

WHAT HAPPENED WAS THAT THERE WAS BONY HETEROTOPIC GROWTH, WHICH IS SOMETHING THAT WE'VE BEEN WARNING OF FROM THE VERY BEGINNING, THAT THERE WAS THE POTENTIAL FOR HETEROTOPIC BONE GROWTH.

IN ADDITION TO THAT, THERE WAS A LACK OF UNION OF THE L5 VERTEBRA WITH S1, THE SACRUM, AND THAT BECAUSE OF THAT LACK OF UNION, SHE HAS EXPERIENCED THESE PROBLEMS AND COMPLICATIONS.

WE WARNED OF THE LACK OF NONUNION FROM THE BEGINNING AS WELL, SO THESE WERE THINGS THAT WERE IN OUR WARNINGS, AND THE CAUSATION HERE ISN'T SOME MYSTERIOUS MIGRATION. IT'S A SIMPLE HOLE IN THE WALL OF THE ANNULUS THAT DR. COUFAL IDENTIFIED, AND NO ONE HAS REALLY CRITIQUED THAT OR COME UP WITH A DIFFERENT THEORY AS TO WHY THIS UNFORTUNATE WOMAN IS EXPERIENCING THESE PROBLEMS.

SO AT THE HEART OF IT, WE BELIEVE THAT WE HAVE A VERY STRONG ARGUMENT ON CAUSATION.

THE COURT: THERE'S LOTS OF ARROWS THAT YOU HAVE THAT YOU CAN FIRE YET, BUT THEY ARE FACTUAL ARROWS. THEY ARE ARROWS TO FIRE AT TRIAL.

MR. CONNOLLY: WELL, EXCEPT AT THIS POINT NONE OF THE EXPERTS HAVE REALLY COME UP WITH A DIFFERENT THEORY OF WHAT HAPPENED TO HER, AND THAT'S WHY WE THINK WE SHOULD WIN NOW ON CAUSATION.

THE COURT: WELL, I THINK ALSO KENNEDY SAYS OTHERWISE. HIS PARAGRAPHS 44, 45, 46, RIGHT AROUND

THERE, HE DID SAY -- AND IT WAS FAIRLY CONCLUSORY, AND HE WAS LUMPING A LOT OF THINGS TOGETHER, BUT HE DID LUMP THIS AS A CAUSAL INJURY, SO THAT IS A FACT.

MR. CONNOLLY: WELL, BUT HE DOESN'T EXPLAIN HOW. HE JUST SAYS THE USE OF THE OP-1 AND CALSTRUX CAUSED HER INJURY. THAT'S A CONCLUSION, BUT IT DOESN'T EXPLAIN HOW IT DID.

THE COURT: IT JUST CLEARLY RAISES A FACTUAL QUESTION. WHETHER HE HAS A GOOD REASON FOR THAT OR NOT WOULD BE A FACTUAL QUESTION FOR THE JURY TO DECIDE WHETHER'S IT'S A GOOD REASON OR A BAD REASON.

I DID HEAR -- I DID READ YOUR ARGUMENT ON CAUSATION, AND I WENT BACK AND RE-READ THOSE PARAGRAPHS, AND, YES, IT'S A CONCLUSORY STATEMENT, BUT HIS DECLARATION OTHERWISE IS FAIRLY PERSUASIVE. HE'S IMPRESSIVE.

WHENEVER YOU GET INTO THE MEDICAL FIELD ON BOTH SIDES, EVERYBODY WHO TESTIFIES HAS CREDENTIALS THAT ARE WORLD-BEATER CREDENTIALS. THAT IS WHAT HE SAID. THAT CERTAINLY WOULD BE -- I THINK IF I WERE TO GRANT YOUR MOTION ON CAUSATION -- I THINK IT'S PARAGRAPH 44, 45 OR 46, ONE OF THOSE -- WITH THAT CONCLUSION FROM A DOCTOR, DR. KENNEDY, THAT IT WOULD BE -- I'D GET REVERSED IN A HEARTBEAT.

CLEARLY IT PRESENTS A FACTUAL ISSUE. YOU MAY WIN ON THAT FACTUAL ISSUE, BUT WE'VE GOT TO MOVE ON. LOOK, I REALLY APPRECIATE YOUR ARGUMENTS. THEY WERE WELL PRESENTED AND SERIOUS ONES, BUT I AM GOING TO

ACCEPT WHERE I SAID I AM GOING TO GRANT AS TO THE DESIGN DEFECT, MANUFACTURE DEFECT AND OTHERWISE OVERRULE.

THAT INCLUDES PUNITIVE DAMAGES, BECAUSE I THINK THAT IF THE JURY BELIEVES THE PLAINTIFF'S CASE, THAT YOU HAD ALL THIS INFORMATION THAT YOU FAKED LEFT AND RAN RIGHT AS IT WERE.

MR. CONNOLLY: WELL, EVEN IF YOU ACCEPT THAT ARGUMENT, YOUR HONOR, I THINK PUNITIVE DAMAGES IS A DIFFERENT ANIMAL, BECAUSE HERE YOU HAVE THE FDA SAYING YOUR WARNINGS ARE APPROPRIATE. YOU HAVE THE HEIGHTENED STANDARD OF CLEAR AND CONVINCING, AND YOU HAVE WARNINGS THAT ACTUALLY WARNED HER OF THE CONSEQUENCES THAT SHE EXPERIENCED, AND SO UNDER THOSE CIRCUMSTANCES, PUNITIVE DAMAGES WOULD BE SIMPLY INAPPROPRIATE.

THE COURT: NO, BUT IT MAY BE INAPPROPRIATE AT TRIAL, BUT FOR THIS PURPOSE, YOU ALSO THEN HAD CONDUCT ON BEHALF OF THE COMPANY REPRESENTATIVE THAT WAS INCONSISTENT WITH THE WARNING LABEL.

WE'VE BEEN THROUGH THIS. THAT IS THE PLAINTIFF'S BEST ARGUMENT RIGHT THERE. YES, THERE WERE THESE WARNINGS, BUT THE COMPANY ITSELF WOULDN'T HAVE BEEN PROMOTING THIS COMBINED USE AND ENCOURAGING IT BY GOING OUT AND MIXING IT.

ANYWAY, I HAVE TO MOVE ON. THANK YOU SO MUCH.

LET'S DO MESIWALA NEXT. OKAY. I OVERRULED HIS OBJECTIONS. THE OBJECTIONS THAT I RULED ON, I GAVE THEM TO MR. CLERK. THEY WILL BE SCANNED, AND YOU CAN

TAKE A LOOK AT THEM.

THIS IS A STATUTE OF LIMITATIONS ISSUE AND A MED MAL ISSUE. SO SHE HAD THESE OPERATIONS, THINGS DID NOT GO WELL. THEN SHE HAD A SECOND OPERATION, AND THINGS DID NOT GO WELL.

SO THEN IN -- SO SHE IS WONDERING WHY THE '09 OPERATION DID NOT GO WELL. SHE STILL HAS PAIN, SO SHE DOES WHAT EVERY PATIENT DOES AND LOOKS ON THE INTERNET WEB M.D. I CAN TELL YOU WHAT THE SITES ARE. YOU ALL GO THERE, AND YOU START LOOKING THIS UP, AND THIS WAS ABOUT FEBRUARY OF 2010.

MR. ESFANDIARI: OCTOBER.

THE COURT: THAT'S WHEN SHE GOOGLED IT, BUT SHE STARTS HAVING THESE -- SHE ORDERED HER RECORDS AROUND FEBRUARY OR MARCH. THEN IT WAS ON HALLOWEEN SHE GOOGLES OP-1, AND THEN SHE GETS -- THEN SHE SEES ALL THESE CRIMINAL INDICTMENTS AND WHATEVER, AND THAT'S HALLOWEEN.

THEN IN JULY '11 THE CASE WAS FILED, SO IT WAS UNDER A YEAR.

SO WE HAVE THE SUBJECTIVE AND OBJECTIVE DISCOVERY TESTS. SUBJECTIVE, THE ACTUAL SUSPICION BY THE PLAINTIFF THAT HER INJURIES WERE CAUSED BY WRONGDOING.

THE OBJECTIVE ONE, THAT A REASONABLE PERSON PRESENTED WITH THIS EVIDENCE WOULD CONCLUDE THAT THE INJURIES WERE CAUSED BY WRONGDOING. DEFENSE ARGUES THAT, WELL, THEY HAD -- SHE SHOULD HAVE KNOWN SOMETHING WAS WRONG. SHE HAD TWO OPERATIONS AFTER '09. THINGS

WEREN'T GOING WELL. SHE GETS HER -- ORDERS HER RECORDS OBVIOUSLY. SHE'S SUSPICIOUS OF SOMETHING.

SHE COMES BACK AND SAYS, YES, I CONSULTED VARIOUS DOCTORS. NOW, ONE OF THE MEMBERS SAID MY PROBLEMS WERE A RESULT OF MALPRACTICE. HOW DO I KNOW? I'M NOT A DOCTOR.

PERHAPS HER BACKGROUND OF THE BIOLOGICAL SCIENCES MIRRORS MINE. I HAD A BIOLOGY CLASS IN TENTH GRADE AT JOHN MUIR HIGH SCHOOL IN 1962. THAT IS MY BACKGROUND IN BIOLOGY/PHYSIOLOGY.

AND SHE SAYS, HOW DO I KNOW THAT THIS IS CAUSED BY WRONGDOING BY PHYSICIANS WHO HAVE THESE FABULOUS CREDENTIALS WHO HAVE BEEN IN SCHOOL LONGER THAN I'VE BEEN ALIVE?

THAT'S A PERSUASIVE ARGUMENT. HOW IN THE WORLD IS SHE GOING TO KNOW THAT THIS IS CAUSED BY WRONGDOING?

PUTTING YOURSELF IN A PATIENT'S POSITION, IT'S NICE TO THINK THAT OPERATIONS ALL END UP IN THE MIDDLE OF THE BELL CURVE, AND YOU DON'T HAVE COMPLICATIONS. THE FACT OF THE MATTER IS EVERYTHING HAS COMPLICATIONS. EVERY COMPLICATION HAS ITS OWN BELL CURVE, AND YOU ARE TOLD THAT GOING IN.

EVERYBODY KNOWS THAT EVEN IF YOU AREN'T TOLD THAT A NATURAL CONSEQUENCE OF THIS -- OF ANY SURGERY IS GOING TO BE A MINORITY OF THE PEOPLE RIGHT OFF THE BELL CURVE ARE GOING TO SUFFER THEIR OWN OTHER PROBLEMS, AND EACH PROBLEM HAS A BELL CURVE, AND SO YOU

TEND TO NOT BE SHOCKED AND DISMAYED WHEN YOU DON'T GO OUT THE NEXT WEEK AND RUN A MARATHON OR SOMETHING.

IT'S PART OF -- IT'S PART OF HAVING SURGERY. PART OF BEING IN A HOSPITAL. PART OF HAVING MEDICAL PROBLEMS. SO THE FACT THAT SHE HAD PROBLEMS DOESN'T NECESSARILY MEAN THERE'S MALPRACTICE. IT'S NOT THE FIRST THING THAT WOULD POP INTO, I THINK, A REASONABLE PERSON'S MIND. I HAVE NO EVIDENCE THAT IT WOULD POP INTO HER MIND UNTIL HALLOWEEN, OR THEREABOUTS.

SO I THINK THAT THE STATUTE OF LIMITATIONS IS NOT A GREAT DEFENSE ARGUMENT.

TO SHOW YOU HOW HARD IT IS TO WIN A SUMMARY JUDGMENT ON STATUTE OF LIMITATIONS, I HAD A CASE, A HUGE BUSINESS CASE THAT INVOLVED A SALE OF A COUPLE OF MALLS, AND I GRANTED SUMMARY JUDGMENT, AND THE COURT OF APPEALS AFFIRMED ME, EXCEPT FOR ONE LITTLE PORTION OF THE CASE WHERE I, FOR ONE DEFENDANT, HAD GRANTED SUMMARY ADJUDICATION OR SUMMARY JUDGMENT BASED ON STATUTE OF LIMITATIONS.

AND THE FACTS WERE THE SOPHISTICATED BUSINESSMEN WERE IN A SOPHISTICATED BUSINESS TRANSACTION, AND SUSPECTED THAT THERE WAS WRONGDOING ON THE PART OF THE PEOPLE WHO ENDED UP BEING THE DEFENDANT. THEY HIRED LAWYERS WHO THREATENED LAWSUITS. THEY JUST DIDN'T PULL THE TRIGGER IN TIME.

SO I SAID, LOOK, YOU ARE SOPHISTICATED PEOPLE. YOU UNDERSTAND THESE TRANSACTIONS. YOU HIRE LAWYERS. THEY ARE GOOD. THEY THREATEN TO SUE. THEY

JUST DIDN'T PULL THE TRIGGER. YOU ARE OUT OF COURT. REVERSED COURT OF APPEAL.

THAT'S HOW HARD IT IS TO WIN A SUMMARY JUDGMENT ARGUMENT ON STATUTE OF LIMITATIONS.

ON THE STANDARD OF CARE ISSUE, I THINK MESIWALA CAN TESTIFY ON HIS OWN BEHALF. HE'S A DOCTOR. HE HAS GOOD CREDENTIALS. HE CAN DO THAT. IT WAS SOMEWHAT CONCLUSORY. HE SAID THE VAST MAJORITY OF DOCTORS USE THESE DRUGS OFF-LABEL. I WASN'T QUITE SURE WHERE HE CAME UP WITH THAT. OKAY. ALL RIGHT. THAT'S HIS POINT OF VIEW.

KENNEDY HAS HIS POINT OF VIEW IN PARAGRAPHS 37 THROUGH 47. THERE'S A FACTUAL DISPUTE ABOUT WHETHER MS. CABANA WAS AN APPROPRIATE CANDIDATE FOR THIS, WHETHER THERE WERE APPROPRIATE WAIVERS OR INFORMED CONSENT. THEY ARE JUST FACTUAL QUESTIONS. THIS IS A STANDARD MED MAL CASE.

NICE TRY, THOUGH.

MS. BLAUVELT: YOUR HONOR, MAY I BE HEARD ON THE STATUTE OF LIMITATIONS ISSUE? WE WILL CONCEDE AFTER THE STANDARD OF CARE ISSUE --

THE REPORTER: CAN YOU SLOW DOWN, PLEASE.

MS. BLAUVELT: I'M SORRY.

WE UNDERSTAND THERE'S TRIABLE ISSUES OF FACT AS TO STANDARD OF CARE, BUT ON THE STATUTE OF LIMITATIONS ARGUMENT, JUST RETURNING TO THAT FEBRUARY 2010 DATE WHERE MS. CABANA REQUESTED AND RECEIVED HER MEDICAL RECORDS FROM POMONA VALLEY HOSPITAL MEDICAL

CENTER, SHE TESTIFIED IN HER OWN DEPOSITION THAT SHE REQUESTED THE RECORDS TO SEE WHAT WAS GOING ON. THAT INDICATES THAT SHE SUSPECTED SOMETHING WAS GOING ON AND THAT SHE HAD SUSPICION OF SOMETHING GOING ON.

FURTHERMORE, BOTH THE SANCHEZ VS. SOUTH HOOVER HOSPITAL CASE AND ARTEL VS. ALLEN CASES HOLD THAT THE ONE-YEAR STATUTE OF LIMITATIONS TRIGGER POINT IS DISJUNCTIVE. IT'S EITHER THE PLAINTIFF HAVING REASONABLE NOTICE --

THE COURT: SURE.

MS. BLAUVELT: -- OR HAVE THE OPPORTUNITY TO OBTAIN KNOWLEDGE FROM SOURCES AVAILABLE AND OPEN TO HER INVESTIGATION.

IN THIS CASE, AS OF FEBRUARY 2010, SHE HAD THOSE POMONA VALLEY HOSPITAL RECORDS. THOSE ARE THE SAME RECORDS THAT SHE LOOKED AT IN OCTOBER 2010 THAT LET HER START GOOGLING OP-1 AND LEARN ABOUT THE CRIMINAL ASPECTS OF THE PRODUCT AND MIXING ISSUES AND WHATNOT.

SO AS OF FEBRUARY 2010, SHE HAD THAT VERY SAME OPPORTUNITY THAT SHE ACTUALLY EXERCISED IN OCTOBER 2010.

THE COURT: LET'S ASSUME SHE READS THESE RECORDS. WHAT DO THE RECORDS TELL HER? IT'S LIKE I HAVE READ THE MEDICAL RECORDS. I'VE HAD CASES INVOLVING MED MAL OR WHATEVER, AND I READ THE RECORDS.

IT'S NOT LIKE -- NOT EVEN LIKE THE BUSINESS TRANSACTION OF SELLING THE MALL I TOLD YOU ABOUT. A LOT OF THIS STUFF IS JUST COMPLEX MULTIPLE LAYERS TO THE

ONION, LOTS OF MOVING PARTS, EVERYTHING IN MEDICINE.

I THINK PART OF BEING A DOCTOR AND WHY THEY'VE INSULATED THEIR PROFESSION SO WELL, IS EVERY NAME OF EVERY DRUG OR CELL OR PORTION OF THE BODY IS SO LONG YOU CAN'T PRONOUNCE IT; RIGHT? AFTER THE FIRST FOUR OR FIVE SYLLABLES, YOU GIVE UP.

IT'S SORT OF LIKE PALEOANTHROPOLOGY. WHY CAN'T THEY LABEL ANCIENT LIFE FORMS JOE, SAM, BILL? IT'S TO BE AUSTRALOPITHECUS AFRICANUS -- OR SOMETHING. IT'S GOT TO BE SOMETHING YOU CAN'T PRONOUNCE OR REMEMBER.

MS. BLAUVELT: YOU PRONOUNCED IT VERY WELL.

THE COURT: THAT'S BECAUSE I LIKE PALEONTOLOGY. BAD EXAMPLE. BUT I DON'T KNOW ENOUGH ABOUT BIOLOGY TO DO IT FOR BIOLOGY.

MS. BLAUVELT: AGREED, YOUR HONOR, BUT MS. CABANA TESTIFIED THAT WHEN SHE LOOKED AT THE RECORDS, SHE SAW THAT TERM OP-1, DIDN'T KNOW WHAT IT WAS, AND DECIDED TO PROCEED WITH GOOGLING IT, AND THAT'S WHEN SHE DISCOVERED THE INFORMATION.

THE COURT: IN OCTOBER.

MS. BLAUVELT: IN OCTOBER, BUT THAT INFORMATION WAS CONTAINED IN THE POMONA VALLEY RECORDS THAT SHE OBTAINED IN FEBRUARY. SO HAD SHE ACTUALLY TAKEN IT UPON HERSELF TO LOOK AT THE RECORDS SHE REQUESTED, SHE WOULD HAVE STILL SEEN THAT OP-1 TERM REFERENCED, AND THEN COULD HAVE STILL TAKEN IT UPON HERSELF TO GOOGLE IT WHEN SHE DIDN'T KNOW WHAT IT WAS, AND LAUNCH HER

INVESTIGATION.

SO THE POINT IS THAT SHE HAD THE OPPORTUNITY TO INVESTIGATE IT, BUT SHE CHOSE TO SIT ON THESE RECORDS FOR EIGHT MONTHS, NOT LOOKING AT THEM. THE CASE LAW HOLDS THAT HER FAILURE TO EXERCISE DILIGENCE IN CONDUCTING HER INVESTIGATION DOES NOT DELAY ACCRUAL OF THE STATUTE OF LIMITATIONS.

THE COURT: IT'S A TOUGH ARGUMENT ESPECIALLY SOMETHING AS COMPLEX AS MEDICINE IS. NICE TRY.

MS. BLAUVELT: THANK YOU, YOUR HONOR.

THE COURT: NICE TRY, BUT I'LL DENY SUMMARY ADJUDICATION ON THAT.

MEDTRONIC. OKAY. YOUR REQUEST FOR JUDICIAL NOTICE IS GRANTED. AGAIN, I READ THROUGH LINFIELD'S OPINION. IT WAS WELL DONE. I SHOULDN'T BE SURPRISED. HE'S A VERY BRIGHT GUY.

COUNTER-INTUITIVE, THAT'S WHAT THE CASE SAID. IT WASN'T BIZARRE RESULT OR ANOMALOUS. IT WAS COUNTER-INTUITIVE.

HERE WAS THE QUOTE: THAT YOU CANNOT HAVE A PREEMPTION CLAIMS WHEN IT VIOLATES FEDERAL LAW IF THE RESULT WHERE OTHERWISE IT WOULD BE COUNTER-INTUITIVE. THAT WAS THE BUZZ WORD.

AT ANY RATE, FOR ALL THE REASONS I STATED, FOR WHY I BELIEVE THAT THESE CAUSES OF ACTION ARE NOT PREEMPTED BY FEDERAL LAW WOULD APPLY HERE TO INFUSE, SO OBVIOUSLY THERE ARE SOME DIFFERENT ISSUES. YOU DON'T HAVE THE HUMANITARIAN ISSUE AND ALL THAT, BUT THE

ISSUE IS GOING TO BE -- LINFIELD ALREADY HAD THIS DISCUSSION, WROTE A VERY DETAILED, WELL-REASONED OPINION.

YOUR CONTENTION AT MEDTRONIC IS THAT DR. MESIWALA TESTIFIED AND GAVE NEW EVIDENCE THAT SHOULD SPARK A RE-EXAMINATION OF THE ISSUE OF PREEMPTION.

I LOOKED THROUGH THAT, AND I DON'T NECESSARILY AGREE THAT THIS WAS NEW EVIDENCE. I DON'T AGREE THAT DR. MESIWALA TESTIFIED THAT MEDTRONIC DID NOT PROMOTE INFUSE OR FOR USE IN THE POSTERIOR SURGERIES.

THERE IS A LOT OF EVIDENCE THAT I READ ABOUT THE CORONADO CONVENTION -- NOT CONVENTION -- CORONADO SEMINAR. HIS EXPENSES WERE PAID BY MEDTRONIC WHERE THEY HAD SUPPOSEDLY -- I MEAN, THIS IS WHAT THE EVIDENCE WAS -- THE USE OF INFUSE IN A MANNER THAT HAD NOT BEEN APPROVED TO POSTERIOR AS OPPOSED TO ANTERIOR.

NOW, APPARENTLY THERE IS A GOOD REASON FOR THAT ABOUT WHERE HE PUT SCREWS OR SOMETHING. I DIDN'T GET INTO THAT LEVEL OF DETAIL, BUT IT WAS -- THERE WAS -- THERE WERE ARTICLES THAT WERE DISSEMINATED, SO I DO NOT NECESSARILY THINK THAT WHAT DR. MESIWALA TESTIFIED TO WAS NEW.

I DON'T AGREE WITH YOU OF THE CHARACTERIZATION OF HIS TESTIMONY, AND I DO AGREE -- I THINK LINFIELD'S ANALYSIS WAS EXCELLENT, WELL-REASONED, WELL PRESENTED, AND I AGREE WITH IT.

SO I WILL HEAR FROM YOU, OF COURSE, BUT I WOULD DENY SUMMARY JUDGMENT BASED ON PREEMPTION.

AGAIN, THIS IS A -- THIS PRESENTS SOME TOUGH ISSUES. I WAS PRETTY SHORT STRIPPED WITH THE PLAINTIFF IN THE DISCOVERY MOTION ABOUT WANTING TO GET THE RECORDS PERTAINING TO THE KEY OPINION LEADERS.

I STILL DON'T WANT TO TURN THIS INTO A TRIAL OF THE KEY OPINION LEADERS. I DON'T WANT TO TURN THIS INTO A TRIAL ABOUT WHO WROTE WHAT, WHO EDITED WHAT, BECAUSE I THINK THAT IF YOU WERE TO MARCH DOWN THAT ROAD, IT WOULD BE A REALLY SLIPPERY SLOPE. IT WOULD REALLY EXPAND THIS TRIAL, AND I DON'T KNOW THAT IT WOULD ADD ANYTHING TO THE DEBATE FOR THIS PLAINTIFF, AND IT WOULD CERTAINLY BE PREJUDICIAL.

I HAVE GREAT RESPECT FOR BIOMEDICAL FIRMS. I THINK WHAT BIOMEDICAL FIRMS DO IN DEVELOPING DRUGS AND NEW DEVICES IS A GREAT PUBLIC SERVICE, AND THEY SAVE LIVES. SO I AM NOT ONE WHO HAS PARANOIA. I DON'T KNOW IF I SHOULD SAY PARANOIA. I DON'T HAVE THE ERIN BROCKOVICH MENTALITY OF ASSUMING THAT PEOPLE DO THINGS NEFARIOUSLY TO MAKE MONEY AT THE EXPENSE OF THE HEALTH AND WELFARE OF OTHERS.

I DON'T BELIEVE THAT OF THE BIOMEDICAL FIELD CERTAINLY, BUT THERE ARE ALLEGATIONS HERE AGAIN THAT ARE DISTURBING ABOUT MISUSE OF ARTICLES THAT WENT OUT TO DOCTORS, WHERE THINGS WERE WRITTEN THAT, ACCORDING TO DR. WEINER, AMONG OTHERS -- I THINK IT WAS WEINER -- THAT WERE VERY MISLEADING AND CAME ACTUALLY IN A "SPINE JOURNAL."

I'VE NEVER READ "SPINE JOURNAL." THAT'S A

MAGAZINE, BUT APPARENTLY IT'S A TRADE MAGAZINE WHERE ORTHOPEDISTS DEVOTED A WHOLE ISSUE ON THE INFUSE ISSUE, AND WAS VERY CRITICAL OF THE ARTICLES THAT HAD BEEN WRITTEN AND DISSEMINATED AS BEING VERY MISLEADING TO THE MEDICAL PROFESSION.

ON THE ONE HAND, THEY HAD THESE WARRANTIES OR CLAIMS THAT THIS WAS, AT LEAST WITH THE POSTERIOR PROCEDURE, WAS SAFE AND ADVERTISED, AND PEOPLE GAVE SPEECHES ABOUT HOW GOOD IT IS, AND DOCTORS LIKE MESIWALA WENT THERE AND LISTENED ON THE DIME OF MEDTRONIC, AND WALKED AWAY FEELING THAT THEY COULD SAFELY USE THIS PRODUCT IN THIS MANNER, AND THEN LATER FIND OUT THAT A LOT OF WHAT THEY'VE BEEN RELYING UPON, AT LEAST AS THE PLAINTIFF'S CONTENTION, DR. WEINER'S CONTENTION, THAT THAT WAS NOT ACCURATE.

THAT'S DISTURBING. IT'S DISTURBING TO READ. I'M SURE MEDTRONIC, WHOM I HAVE GREAT RESPECT FOR, HAS THEIR OPINION ON THIS, BUT AT A SUMMARY ADJUDICATION STAGE, OBVIOUSLY WE'RE JUST LOOKING AT A FACTUAL TRAIL OF BREAD CRUMBS THAT THE PLAINTIFF HAS STRUNG TOGETHER FOR THESE CAUSES OF ACTION.

SO ON THE BREACH OF EXPRESS WARRANTY, YOU HAVE THE SEMINARS AND THE ARTICLES THAT TOUT INFUSE, AND YET YOU HAVE FOR THIS POSTERIOR USE, AND THAT YOU HAVE THE PROBLEMS THAT CAME UP WITH IT.

AGAIN, MEDTRONIC CITES THE LABEL. I LOOKED AT THE LABEL. I DON'T KNOW IF SOMEBODY PUT THAT LABEL IN A SHRINKING XEROX AND MADE IT EXTRA SMALL SO I

COULDN'T READ IT, BUT I DON'T KNOW IF THAT WAS THE ACTUAL SIZE, BUT IT WAS VERY, VERY TOUGH TO READ, AT LEAST FOR MY EYES. I HAD A VERY DIFFICULT TIME MAKING OUT WHAT IT SAID.

BUT AGAIN, THESE ARE FACTUAL QUESTIONS. FOR THE EXPRESS WARRANTY, WE HAVE THE CONSUMER EXPECTATION. IT'S NOT, I THINK, WHAT MS. CABANA THOUGHT. IT'S WHAT THE DOCTORS THOUGHT. THEY ARE THE ONES THAT DEAL WITH IT.

THE DOCTOR TESTIFIED THAT MEDTRONIC MADE CERTAIN REPRESENTATIONS TO HIM IN SAN DIEGO. HE READ ARTICLES. TURNED OUT THAT THE ARTICLES HAD ISSUES. KENNEDY SAYS THAT, JUST LIKE HE DID WITH STRYKER, THAT THE USE OF INFUSE CAUSED THE INJURY. I HAVE IT HERE. PARAGRAPHS 44, 45 AND 46.

SO I THINK FOR SUMMARY JUDGMENT PURPOSES THAT'S SUFFICIENT FOR BREACH OF EXPRESS WARRANTY AND NEGLIGENCE, WHICH IS ISSUES 1 THROUGH 3 AND 5. YOU INTERPOSED A BLURB, INTERMEDIARY DEFENSE, BUT YOU HAVE WARNINGS ISSUES. YOU HAVE THE WARNING ISSUES AND WHETHER THEY WERE ADEQUATE.

AND IN LIGHT OF WHAT MEDTRONIC KNEW OR THE PLAINTIFF CLAIMED MEDTRONIC KNEW, AND YOU HAVE THE DOCTOR SAYING THAT HAD HE KNOWN WHAT WAS IN THE "SPINE JOURNAL," HE WOULD NOT HAVE -- OR DISCLOSED BY THE "SPINE JOURNAL" ARTICLE, HE WOULD NOT HAVE PERFORMED THE OPERATION THE WAY HE DID.

I UNDERSTAND ALSO IN SCIENCE YOU HAVE NEW

DISCOVERIES, AND JUST BECAUSE YOU WERE USING SOMETHING ON DAY ONE, WHICH THOUGHT IT WAS GOOD, AND LATER YOU LEARN ON DAY TEN THAT IT HAD PROBLEMS.

WE HAD THE SAME WE LEARNED IN ASBESTOS CASES. THEY SAY DURING THE WAR THEY THOUGHT ASBESTOS WAS THE NAME OF THE GAME. LATER THEY FOUND OUT THAT THERE WAS A PROBLEM WITH IT AS A DEFENSE VIEWPOINT, BUT HERE, AT LEAST FOR A FACTUAL QUESTION, I THINK YOU HAVE -- I THINK THEY'VE MADE OUT A NEGLIGENCE CAUSE OF ACTION. NEGLIGENCE PER SE, BOTH STRYKER AND MEDTRONIC HAVE THAT CAUSE OF ACTION AGAINST THEM.

I ALWAYS THOUGHT THAT WAS A RULE OF EVIDENCE. I DIDN'T THINK THAT WAS A CAUSE OF ACTION, BUT THERE'S A CASE THAT THEY CITED SAYING OTHERWISE, THE FAA CASE, THE BEECHCRAFT CASE. BEECH AIRCRAFT, BUT IT WAS BEECHCRAFT. THEY CITE THAT CASE, SO FOR SUMMARY ADJUDICATION PURPOSES, THEY GET PAST THAT HURDLE.

FRAUD CAUSE OF ACTION, AGAIN, IT'S THE SAME ANALYSIS I HAD WITH STRYKER. THE ALLEGATIONS ARE THAT THEY MADE REPRESENTATIONS AT CONFERENCES AND ARTICLES THAT THEY SHOULD HAVE KNOWN WERE NOT TRUE, NOT ACCURATE, OR NOT COMPLETE, SO YOU HAD BOTH THE AFFIRMATIVE MISREPRESENTATION AND THE CONCEALMENT. THOSE ARE THE BREAD CRUMBS. THERE'S EVIDENCE TO SUPPORT THOSE BREAD CRUMBS.

SO I WOULD SAY FOR THE FRAUD CAUSE OF ACTION THEY SURVIVE THAT.

AND AS PUNITIVE DAMAGES, AGAIN, SAME

ANALYSIS. I DON'T MEAN TO BE DRAMATIC BY SAYING IT'S AN O-RING ISSUE OR A FORD PINTO GAS TANK ISSUE, BUT I THINK THEY ARE GOING TO SAY THAT, AND THEN THERE IS SOME EVIDENCE OF KNOWING THAT THE PRODUCT HAD PROBLEMS WHEN USED IN A CERTAIN MANNER, AND YET NOT DISCLOSING THAT. INDEED, ADVERTISING IT IN THE CONTRARY.

AGAIN, IT'S A TOUGH MOTION. THIS IS A TOUGH CASE FROM BOTH SIDES, BUT THOSE ARE MY THOUGHTS.

MR. BROWN: THANK YOU, YOUR HONOR. MICHAEL BROWN ON BEHALF OF THE MEDTRONIC DEFENDANTS.

AS THE COURT KNOWS, WE BROUGHT THIS MOTION BOTH ON STATE LAW GROUNDS AND PREEMPTION. I'D LIKE TO ADDRESS THE STATE LAW GROUNDS FIRST, AND THEN MOVE TO PREEMPTION, AND DURING THAT PART OF THE DISCUSSION, I'D BE HAPPY TO TALK ABOUT JUDGE LINFIELD'S PRIOR ORDER.

AT THE LAST SUMMARY JUDGMENT HEARING, THE CAUSES OF ACTION GOT REDUCED BECAUSE THERE ARE NO STRICT LIABILITY CLAIMS AT ALL, INCLUDING FAILURE TO WARN. THERE ARE NO MANUFACTURING OR DESIGN CLAIMS, SO ESSENTIALLY WE HAVE EXPRESS WARRANTY, NEGLIGENT FAILURE TO WARN, AND FRAUD.

IF I COULD GO TO --

THE COURT: AND NEGLIGENCE PER SE.

MR. BROWN: AND NEGLIGENCE PER SE WITHOUT THE IDENTIFICATION OF ANY ALLEGED STATUTE THAT'S BEEN VIOLATED, BUT I WILL GET TO THAT.

ON EXPRESS WARRANTY, YOUR HONOR, CALIFORNIA CASE LAW IS CLEAR THAT IT REQUIRES AN AFFIRMATION OF

FACT BY MEDTRONIC, AND THAT ISN'T PRESENT IN THE RECORD.

ONE THING THAT THE COURT, IN DEALING WITH THE OTHER MOTIONS, HAS TALKED A LOT ABOUT ALLEGATIONS THAT HAVE BEEN MADE, BUT NOW WE'RE INTO WHAT EVIDENCE IS, AND HERE FOR EXPRESS WARRANTY, ARTICLES WRITTEN BY DOCTORS, AND, AGAIN, THERE'S NO ADMISSIBLE EVIDENCE THAT MEDTRONIC WROTE ANY OF THOSE ARTICLES, BUT IF YOU GO BACK TO WHAT AFFIRMATION OF FACT WAS A WARRANTY THAT MEDTRONIC MADE TO DR. MESIWALA.

I ASKED HIM, AND DR. MESIWALA SAID THAT MEDTRONIC MADE NO REPRESENTATION TO HIM, MADE NO GUARANTEE TO HIM, AND THAT THEY DIDN'T CONCEAL ANYTHING FROM HIM.

I ASKED MS. CABANA THE SAME THING. SHE HAD NEVER HEARD OF MEDTRONIC UNTIL THIS LAWSUIT. THERE WERE NO COMMUNICATIONS. SO AT A VERY FUNDAMENTAL LEVEL, THERE IS NO AFFIRMATION OF FACT THAT CAN BE THE BASIS OF AN EXPRESS WARRANTY CLAIM, YOUR HONOR. I THINK UNDER CASES LIKE THE WEINSTAT CASE, THAT SIMPLY NOT SUFFICIENT.

NOW, PLAINTIFF HAS SUGGESTED -- AND ALSO THE LABEL THAT WAS APPROVED AND MANDATED BY THE FDA HAS EXPRESS DISCLAIMERS OF ANY WARRANTY, AND UNDER THE CALIFORNIA COURT OF APPEALS DECISION IN TEMPLE VS. VELCRO, THAT'S DETERMINATIVE. THERE CAN'T BE A WARRANTY IF, IN FACT, THERE'S A WRITTEN DISCLAIMER.

PLAINTIFF'S RESPONSE TO THAT IS IT WAS TOO SMALL IN FONT SIZE. UNFORTUNATELY, THE FEDERAL

REGULATIONS DON'T GIVE THEM ANY RELIEF THERE EITHER BECAUSE 21 CODE OF FEDERAL REGULATION, 801.15 SUBPARAGRAPH A, SUBPARAGRAPH 6, TALKS ABOUT FONT SIZE. THE FDA DICTATES ALL OF THOSE THINGS.

SO WHAT WE HAVE HERE IS NO AFFIRMATION OF FACT, WRITTEN DISCLAIMERS. DR. MESIWALA, THE PERSON WHO WOULD HAVE BEEN THE RECIPIENT OF ANY WARRANTY, EXPRESSLY SAYS NO. THEY DID NOT WARRANT ANYTHING, AND HE DIDN'T WARRANT ANYTHING TO MS. CABANA.

SO I THINK WHEN WE'RE TALKING ABOUT EVIDENCE AND WHAT THE RECORD ACTUALLY SAYS, THE EXPRESS WARRANTY CLAIM CAN'T SURVIVE. WE HAVE A LOT OF ARGUMENT OF COUNSEL IN THE BRIEFS, BUT NOT EVIDENCE. WE KNOW UNDER HAYNES VS. HUNT CITED IN THE SIXTIES ARGUMENT OF COUNSEL CAN'T CREATE A TRIABLE ISSUE OF FACT.

ON NEGLIGENT FAILURE TO WARN, YOUR HONOR, IN 1988 THE CALIFORNIA SUPREME COURT DEFINED THE SCOPE OF THE MANUFACTURER'S DUTY AS A PRESCRIPTION DRUG OR DEVICE. ESSENTIALLY TO WARN OF KNOWN AND SCIENTIFICALLY KNOWABLE RISK. THE BROWN VS. SUPERIOR COURT CASE FOLLOWED A COUPLE YEARS LATER.

HERE, WE ONLY HAVE A NEGLIGENT FAILURE TO WARN, SO THAT MEANS THAT THE LABEL, THE WARNINGS, JUST NEEDED TO BE REASONABLE. NEEDED TO BE WHAT A REASONABLE MEDICAL DEVICE MANUFACTURER WOULD HAVE BEEN.

WELL, HERE WE HAVE A SITUATION WHERE NOT ONLY WERE THEY REASONABLE. THEY WERE, IN FACT, MANDATED BY THE FDA. IN OTHER WORDS, THE WARNINGS THAT WE ISSUED

TO DR. MESIWALA AND EVERY OTHER DOCTOR WHEN WE SOLD THE PRODUCT IS EXACTLY WHAT HAD TO BE ON IT. WE CAN'T WARN OF ANYTHING ELSE.

THE COURT: BUT WAIT A MINUTE. WE HAVE THE SAME PROBLEM WE HAD WITH STRYKER. WE HAVE CONDUCT INCONSISTENT. YOU HAVE THE CORONADO CONFERENCE THAT WAS PAID FOR -- EXPENSES WERE PAID FOR BY MEDTRONIC TO GO AND LISTEN TO THE POSTERIOR USE OF INFUSE.

MR. BROWN: YOUR HONOR, WE TOOK THE DEPOSITION -- THAT'S WHAT PLAINTIFFS HAVE BEEN SAYING.

THE COURT: THOSE ARE THE FACTS, AREN'T THEY?

MR. BROWN: NO, THEY ARE NOT. WE TOOK THE DEPOSITION OF THE DOCTOR WHO PRESENTED AT THAT CONFERENCE TEN YEARS AGO. WE TOOK THAT DEPOSITION ON THURSDAY. WE SUBMITTED THAT TO THE COURT ON FRIDAY JUST BECAUSE WE GOT THE TRANSCRIPT THURSDAY NIGHT.

THE COURT: I HAVEN'T SEEN IT.

MR. BROWN: CAN I GIVE YOU A COPY OF THAT?

THE COURT: NO.

MR. BROWN: IT'S IMPORTANT, BECAUSE WE HAVE ALLEGATIONS, BUT NOT SUPPORTED BY EVIDENCE. DR. LANMAN, THE PRESENTER AT THE CONFERENCE, SAID THERE WAS NO PROMOTION OF INFUSE FOR OFF-LABEL USE. NEVER HAS DONE, THAT. THE CONFERENCE BROCHURE SAYS NOTHING ABOUT INFUSE.

WHAT DR. MESIWALA SAID WAS THAT IT WAS AT A DINNER MEETING AS PART OF THE CONFERENCE, HE HEARD DR. LANMAN TALK ABOUT SOMETHING CALLED HYDROSORB, WHICH

IS A CERVICAL CAGE, AND USING INFUSE WITH THAT. WE ESTABLISHED IN DR. LANMAN'S DEPOSITION THAT WAS AN FDA-SPONSORED PIVOTAL STUDY FOR CERVICAL USE OF INFUSE.

SO THE FACT THAT HE WAS DOING A STUDY, THAT'S NOT PROMOTION, SO -- AND IT HAS NOTHING TO DO WITH THIS CASE BECAUSE MS. CABANA HAD A LUMBAR SURGERY, NOT A CERVICAL SURGERY, SO THIS IDEA THAT SOMEHOW THAT INFLUENCED HIM, DR. MESIWALA SAID HE WAS NOT INFLUENCED IN TERMS OF ANY DECISION HE MADE HERE.

ONE OTHER POINT, YOUR HONOR, THIS IS -- IT DEALS LESS WITH THE SPECIFIC ISSUES THAT I THINK WOULD -- MAY BE COLORING THE COURT A LITTLE BIT, AND THAT IS THE SUPPOSED TRAGIC CIRCUMSTANCES THAT ARE INVOLVED HERE.

THE FACT OF THE MATTER IS, IS THAT MS. CABANA, YES, SHE'S A YOUNG WOMAN, HAD THREE VERY SERIOUS AUTO ACCIDENTS, AND BEFORE SHE EVER HAD EVEN THE STRYKER SURGERY, SHE WAS TOTALLY DISABLED, HAD PAIN THAT WAS TEN OUT OF TEN, AND TESTIFIED IN HER DEPOSITION THAT SHE FELT LIKE SHE WAS BEING ELECTROCUTED FROM THE INSIDE. THIS IS ALL BEFORE THE LUMBAR SURGERIES. OKAY?

SO I THINK THAT'S JUST SORT OF CONTEXTUAL. IT DOESN'T REALLY DEAL WITH THOSE PARTICULAR THINGS, BUT WE THEN HAVE A SITUATION WHERE -- AND I THINK IT'S IMPORTANT BEFORE THE COURT ISSUES A FINAL RULING -- NOW, THE SCHEDULING WAS NOT MINE. PLAINTIFFS TOOK THE DEPOSITION OF DR. LANMAN. I SUBMITTED EXCERPTS. THE PLAINTIFF DIDN'T. I THINK THE REASON BEING BECAUSE HE

DIDN'T THINK THE TESTIMONY HELPED HIM.

SO WE HAVE A SITUATION WHERE --

MR. ESFANDIARI: BECAUSE I HADN'T RECEIVED IT YET.

MR. BROWN: YOU GOT THE ROUGH TRANSCRIPT THE SAME TIME I DID.

THE COURT: I'M STILL HERE.

MR. BROWN: SORRY, YOUR HONOR. THE SITUATION IS HE DIDN'T PROMOTE FOR THAT. THEN YOU GET INTO THE NEXT LAYER, WELL, WHAT IF HE DID?

DR. MESIWALA LEARNED ABOUT INFUSE IN HIS RESIDENCY AT THE UNIVERSITY OF WASHINGTON. THE ATTENDING DOCTORS THERE WERE USING INFUSE IN THE POSTERIOR SPINE THEN. HE HAD BEEN USING INFUSE IN THE POSTERIOR SPINE FOR FIVE YEARS BEFORE HE OPERATED ON MS. CABANA.

SO THIS IDEA THAT SOMETHING SOMEBODY TOLD HIM AT A DINNER CONVERSATION TEN YEARS AGO HAD ANY INFLUENCE WHEN I ASKED HIM WHETHER THAT HAD ANY INFLUENCE, AND HE SAID NO.

NOW, THE COURT SAID IN ITS TENTATIVE OR PRELIMINARY THOUGHTS THAT DR. MESIWALA TESTIFIED THAT HE WOULDN'T HAVE USED INFUSE HAD HE KNOWN THE TRUE STORY.

THE COURT: THAT WAS THE "SPINE JOURNAL."

MR. BROWN: THAT IS NOT TRUE. DR. MESIWALA DID NOT SAY THAT. NOWHERE IN DR. MESIWALA'S TRANSCRIPT DID HE SAY THAT HE WOULD NOT HAVE USED INFUSE. IN FACT --

THE COURT: WAIT A MINUTE.

MR. BROWN: -- BECAUSE SHE'S A SMOKER, AND FAILED

TO FUSE, THAT'S WHY HE USED IT AGAIN.

THE COURT: MY NOTES HERE -- WHERE DID I GET THE FACT THAT HAD HE KNOWN ABOUT THE PROBLEMS OF INFUSE THAT CAME OUT IN THE "SPINE JOURNAL," HE WOULD NOT HAVE DONE THE OPERATION?

MR. BROWN: NO, YOUR HONOR. I WOULD ASK THAT THE COURT PROVIDE A CITE, BECAUSE I DON'T THINK HE EVER SAID THAT.

HE STILL USES INFUSE. DR. MESIWALA DOES.

THE COURT: IN POSTERIOR USE?

MR. BROWN: YES. YES, YOUR HONOR. BY THE WAY, IT'S ALSO IN DR. MESIWALA'S DEPOSITION. HE USED IT FOR FIVE YEARS. NOT ONCE DID HE HAVE A COMPLICATION. YOU KNOW WHAT? HE DIDN'T HAVE A COMPLICATION HERE EITHER BECAUSE, YES, AFTER THE STRYKER SURGERY, MS. CABANA GOT WHAT THEY CALL BONY OVERGROWTH.

IT'S BEEN REFERRED TO HERE AS ECTOPIC BONE GROWTH. HETEROTOPIC BONE GROWTH. ALL ESSENTIALLY THE SAME THING. THAT DID NOT HAPPEN AFTER THE INFUSE SURGERY. THAT HAPPENED IN THE 2008 SURGERY. AND SO, BUT IF WE GET TO WHAT SHOULD WE HAVE WARNED OF, AND THE CLAIM IS THAT WHAT MS. CABANA HAS IS PAIN, NONUNION OR FAILED FUSION, AND ECTOPIC BONE GROWTH.

THE ONLY EVIDENCE IN THE RECORD IS THAT SHE DOES NOT HAVE ECTOPIC BONE GROWTH FROM INFUSE. SO THAT'S POINT NUMBER ONE.

POINT NUMBER TWO, PAIN AND -- ONE, ECTOPIC BONE GROWTH -- PAIN AND FAILED UNION IS SOMETHING WE

WARNED OF. SO THERE'S THIS BIG CRUSADE AGAINST MEDTRONIC ON OFF-LABEL USE AND PROMOTION. ALL OF THAT WOULD BE, WELL, IF FOR A DIFFERENT USE, YOU SHOULD HAVE WARNED ABOUT SOME UNIQUE RISK THAT OCCURS ONLY WHEN YOU USE IT IN THE POSTERIOR SPINE.

THE COURT: I HAVE A QUESTION HERE.

MR. BROWN: YES.

THE COURT: FIRST OF ALL, AS FAR AS SUMMARY JUDGMENT GOES, AND YOU ARE SAYING THAT -- WHAT YOU ARE SORT OF SAYING THAT INFUSE CAUSED NO HARM. KENNEDY SAYS OTHERWISE.

MR. BROWN: NO. YOUR HONOR --

THE COURT: WELL, WASN'T THAT THAT IN 45, 47?

MR. BROWN: ABSOLUTELY NOT, YOUR HONOR. IN FACT, THOSE PARAGRAPHS ALL -- THE OPINION IN THOSE PARAGRAPHS IS THAT DR. MESIWALA BREACHED THE STANDARD OF CARE. HE DOES NOT OPINE THAT INFUSE CAUSED ANYTHING.

THE COURT: HE LISTED INFUSE ALONG WITH THE -- HE LISTED IT; RIGHT?

MR. BROWN: THAT IT WAS USED.

THE COURT: WELL --

MR. BROWN: ESSENTIALLY HE'S SAYING IT WAS A SUBSTANDARD PROCEDURE.

THE COURT: I THINK WHAT HE SAID WAS HE LISTED ALL THE THINGS THAT HE THOUGHT CAUSED THE HARM, AND THAT WAS ONE OF THE THINGS THAT CAUSED THE HARM.

MR. BROWN: YOUR HONOR, THE JULY 13, 2009 SURGERY IS DEALT WITH IN PARAGRAPHS 43 THROUGH 46.

THE COURT: RIGHT.

MR. BROWN: THEY ARE ALL ABOUT DR. MESIWALA BREACHING THE STANDARD OF CARE. THEN HE SAYS PARAGRAPH 44, "IN LIGHT OF THE FACT THAT INFUSE BMP HAS A KNOWN RISK OF ECTOPIC BONE GROWTH" --

THE COURT: YOU HAVE TO SLOW DOWN A LITTLE BIT. THAT'S A LITTLE FAST. ONLY I CAN SPEAK FAST.

MR. BROWN: MY APOLOGY TO YOU AND THE COURT REPORTER.

IT SAYS, "IN LIGHT OF THE FACT THAT INFUSE BMP HAS A KNOWN RISK OF ECTOPIC BONE GROWTH, IT WAS A SUBSTANDARD DECISION TO IMPLANT THE PRODUCT IN A PATIENT WHO HAD PREVIOUSLY SUFFERED ECTOPIC BONY OVERGROWTH WITH ANOTHER BMP."

THE COURT: GO TO 45. FIRST LINE.

MR. BROWN: THAT MESIWALA'S FAILURE TO OBTAIN AN INFORMED CONSENT TOGETHER WITH HIS DECISION TO IMPLANT INFUSE WERE ALL SUBSTANTIAL CONTRIBUTING FACTORS TO --

THE COURT: MINE SAYS, "IT IS MY MEDICAL OPINION STATED TO A REASONABLE DEGREE OF MEDICAL PROBABILITY THAT DR. MESIWALA'S DECISION TO IMPLANT INFUSE MIXED WITH OSTEOCELE WERE ALL SUBSTANTIAL CONTRIBUTING FACTORS TO MS. CABANA'S INJURIES AND DAMAGES."

MR. BROWN: THE WAY I READ THAT, THAT'S AN OPINION THAT DR. MESIWALA BREACHED THE STANDARD OF CARE BY DECIDING TO DO IT. HE'S NOT SAYING THAT INFUSE CAUSED ANYTHING. IN FACT, YOUR HONOR, THIS IS REALLY IMPORTANT BECAUSE ON THE CAUSATION FRONT, DR. MESIWALA TOOK CARE

OF MS. CABANA FOR ABOUT NINE OR TEN MONTHS AFTER THE JULY SURGERY.

I ASKED HIM, DURING THAT PERIOD OF TIME, DID INFUSE CAUSE ANY INJURY OR EVEN A SYMPTOM. HE SAID NO. THERE IS NO DOCTOR THAT HAS SAID THAT INFUSE CAUSED ANY SYMPTOM.

WHAT WE HAVE HERE -- MS. CABANA SUBMITTED A SUPPLEMENTAL DECLARATION. WHAT SHE SAYS IS THE JULY SURGERY WAS THAT SHE FAILED TO GET BETTER. SHE DIDN'T FUSE. OKAY. THAT'S NOT AN INJURY. THE FACT IS SHE HAD ECTOPIC BONE GROWTH AFTER THE 2008 SURGERY.

DR. MESIWALA DECIDED TO GO IN, DECOMPRESS THE NERVE, BUT SHE STILL WASN'T FUSED. SO HE DECIDED TO USE INFUSE THERE, BUT NOWHERE DOES ANYONE SAY THAT INFUSE CAUSED ANY NEW DIFFERENT PROBLEM.

YES, SHE SAYS I STILL HAVE THE BACK PAIN I HAD BEFORE, BUT THAT'S NOT AN INJURY. THE FACT OF THE MATTER IS, IS THAT WE WARNED OF THE EXACT THINGS THAT SHE'S COMPLAINING OF.

THE COURT: WHAT WAS FDA'S PROBLEM WITH THE POSTERIOR USE OF INFUSE?

MR. BROWN: JUST -- THEY DIDN'T HAVE A PROBLEM PER SE, YOUR HONOR. JUST THAT IT WAS APPROVED WITH AN INDICATION FOR ANTERIOR USE.

THE COURT: ANTERIOR.

MR. BROWN: RIGHT. THE IMPORTANT POINT SORT OF GOES TO PREEMPTION. FDA DOESN'T APPROVE USES. THEY APPROVE LABELS AND WHAT CAN BE SAID ON THEM. THEY

APPROVE DEVICES. THE POINT IS, MOST OF THE TIME IT IS USED OFF-LABEL IN POSTERIOR SPINE. MR. CONNELLY SAID THAT'S CERTAINLY THE PURVIEW OF DOCTORS. THEY CAN DO WHATEVER THEY WANT. THE CODE OF FEDERAL REGULATION, SECTION 396, SAID OFF-LABEL USE IS PERMISSIBLE.

THE U.S. SUPREME COURT SAYS IT'S AN IMPORTANT COROLLARY TO THE PRACTICE OF MEDICINE.

THE COURT: WHAT IS YOUR TAKE ON THE ARTICLE? WHAT HAPPENED HERE? WHY IS IT THAT WE HAVE THESE ARTICLES ABOUT INFUSE AND USE POSTERIORLY, THAT MESIWALA -- I JUST THINK HE SAW WHERE -- HE SAID HE HAD READ THESE ARTICLES, BUT, OKAY, HE SAID HE WENT TO THE CORONADO CONFERENCE; THEY DISCUSSED THIS USE; HE READ ARTICLES, AND THE ARTICLES REALLY -- DR. WEINER REALLY READ A FAIRLY DAMNING DECLARATION, AND APPARENTLY THE "SPINE JOURNAL" WAS VERY CRITICAL.

WHERE DO THESE ARTICLES COME FROM? WHAT WAS MEDTRONIC'S CONNECTION WITH THEM? WAS THERE JUST A BAD GUARDIAN ANGEL OUT THERE WHO WAS WRITING THESE THAT HAPPENED TO BENEFIT MEDTRONIC? WHAT WAS THE ROLE MEDTRONIC HAD IN THESE ARTICLES?

MR. BROWN: YOUR HONOR, SOME OF THE LEADING SPINE SURGEONS WROTE THESE ARTICLES. MANY OF THEM WERE CONSULTANTS FOR MEDTRONIC. NOW, IT'S UP TO THOSE INDIVIDUALS AND THE JOURNAL IN WHICH THEY PUBLISH ARTICLES TO DISCLOSE WHATEVER CONNECTIONS THEY MAY HAVE. THAT STANDARD HAS EVOLVED, BY THE WAY, OVER THE LAST 13 YEARS, SO IN 2000 OR 2002 WHEN INFUSE WAS IMPROVED.

THE THRUST OF IT WAS THAT THESE ARTICLES SUGGESTED THAT THERE WERE NO ADVERSE EVENTS WITH INFUSE.

YOU CAN'T READ -- IF YOU REALLY BELIEVE THAT BECAUSE IN LOOKING -- WE CITED IN OUR REPLY BRIEF FOOTNOTE AN ARTICLE THAT TALKS ABOUT THESE THINGS, BUT THE POINT IS HERE: IF THERE WAS SOME RISK OR COMPLICATION THAT WAS EMERGING OUT OF OFF-LABEL USE OF INFUSE THAT WAS DIFFERENT THAN AN ON-LABEL RISK, MAYBE THERE WOULD BE SOMETHING TO TALK ABOUT.

BUT HERE, ECTOPIC BONE GROWTH, PAIN AND FAILED UNION ARE RISKS, WHETHER YOU USE IT ON-LABEL OR OFF-LABEL. SO THEN YOU GET TO -- IF YOU LOOK AT THE CAUSES OF ACTION, SO RATHER THAN JUST YOU GUYS ARE BAD GUYS KIND OF THEORY THAT PLAINTIFF LIKES TO HAVE, AND YOU SAY I HAVE A NEGLIGENT FAILURE TO WARN CAUSE OF ACTION, YOU THEN HAVE A SITUATION OF, IF THAT'S GOING TO BE SUBMITTED TO THE JURY, SOMEBODY IS GOING TO HAVE TO SAY, YOU SHOULD HAVE WARNED OF X.

THE COURT: RIGHT.

MR. BROWN: OKAY. HERE WHAT THEY ARE SAYING IS SHE HAD ECTOPIC BONE GROWTH, WHICH THERE'S NO EVIDENCE OF, TO PAIN AND NONUNION. WE WARNED OF ALL THOSE THINGS. IT'S IN THE FDA-MANDATED LABEL. SO HOW DO I GO TO A JURY AND HAVE A QUESTION SUBMITTED ON FAILURE TO WARN, WHEN, ONE, THAT'S THE ONLY WARNING I COULD GIVE BECAUSE THE FDA MANDATES IT, AND, TWO, IT'S THE EXACT THINGS THAT SHE SUFFERED.

THE COURT: I'M NOT SAYING TO THE STRYKER

DEFENDANTS -- ACTUALLY MESIWALA DEFENDANT -- I'M NOT SAYING YOU DON'T HAVE POWERFUL ARROWS TO FIRE. I'M JUST SAYING THAT THESE ARE QUESTIONS OF FACT FOR A JURY.

I READ WEINER'S DECLARATION A LITTLE DIFFERENTLY. HE WAS VERY DAMNING ACTUALLY. IT WAS SERIOUS -- WELL, YOU KNOW, I THINK THERE ARE MANY WAYS TO READ THAT. I AM NOT ONE WHO HOPEFULLY RUNS AROUND WITH A TINFOIL HAT. I DON'T SEE CONSPIRACIES AND NEFARIOUS CONDUCT, WHATEVER.

BUT STILL IT WAS DISTURBING, AND I DON'T KNOW IF THIS IS TRUE OR FALSE. I DON'T KNOW IF KENNEDY IS RIGHT WHEN HE SAID THE USE OF INFUSE IN THIS MANNER CONTRIBUTED TO THE HARM. I DON'T KNOW THAT. MAYBE THE FDA IS ALL WET WHEN THEY HAVE A PROBLEM WITH POSTERIOR USE. MAYBE THEY ARE ALL WET. MAYBE YOU DID EVERYTHING YOU COULD DO, BUT THAT'S A FACTUAL ISSUE OF TRIAL. THOSE ARE TRIAL ISSUES.

MR. BROWN: YOUR HONOR, WE'RE TALKING ABOUT WHETHER THERE'S A TRIABLE ISSUE BASED ON ADMISSIBLE EVIDENCE. FIRST OF ALL, DR. WEINER'S DECLARATION IS SUGGESTING MEDTRONIC INVOLVEMENT IN ARTICLES BASED ON NO FOUNDATION OR PERSONAL USE.

THE COURT: YOU SAID THAT THESE WERE DISCLOSURES IN THE ARTICLES. THESE WERE DISCLOSURES ABOUT CONSULTANTS.

MR. BROWN: AND THERE ARE LOT OF DISCLOSURES ABOUT MEDTRONIC BEING A CONSULTANT. AGAIN, YOUR HONOR, THIS WOULD BE THE EQUIVALENT. SO THERE WAS SOMEONE -- AND

DR. CARRAGEE IS THE GUY FROM THE "SPINE JOURNAL," AND THEN AFTER HIS MOST RECENT DIATRIBE, SOMEBODY FROM ORTHOPEDIC WEEK CAME OUT AND SAID DR. CARRAGEE SHOULD RESIGN HIS POSITION BECAUSE OF THE -- IT'S NOT SCIENCE -- THAT DOESN'T REALLY HAVE A PLACE IN THIS MOTION EITHER.

THE COURT: I DIDN'T WANT TO GO THERE FOR THAT REASON. I DIDN'T WANT TO MARCH DOWN THAT FIELD, BUT STILL AFTER I READ THIS, I THOUGHT I MIGHT HAVE BEEN A LITTLE TOO PRECIPITOUS WITH PLAINTIFF AND DENY DISCOVERY ON THIS. I STILL DON'T WANT TO GO THERE IF I DON'T HAVE TO GO THERE.

MR. BROWN: YOUR HONOR, LET ME, IF I COULD, BECAUSE ON THE FAILURE TO WARN -- AND I THINK THIS IS IMPORTANT. TO SUSTAIN IT, TO DEFEAT SUMMARY JUDGMENT, THERE'S GOT TO BE A CAUSATION ELEMENT ON FAILURE TO WARN. IN OTHER WORDS, BUT FOR -- IF YOU WARNED -- TO CAUSE THE INJURY IN SOME WAY.

HERE, CALIFORNIA LAW IS PERFECTLY CLEAR THAT IF THE RISKS THAT WE'RE TALKING ABOUT THAT SUPPOSEDLY WEREN'T WARNED OF ARE KNOWN IN THE MEDICAL COMMUNITY GENERALLY, THERE CANNOT BE PROXIMATE CAUSE FOR FAILURE TO WARN.

THE CALIFORNIA SUPREME COURT DECISION CARLIN SAYS THAT. THE MOTUS VS. PFIZER CASE AND THE PLENGER VS. ALZA CASE.

THE COURT: IF THIS WAS SO WIDESPREAD, WHY WAS IT IN 2010 OR 2011 THAT THE "SPINE JOURNAL" HAD AN ENTIRE

ISSUE EXPOSE ON THIS? THE DANGERS COULD NOT HAVE BEEN THAT WIDELY KNOWN BECAUSE IF IT HAD BEEN THAT WIDELY KNOWN, NOBODY WOULD HAVE BOUGHT THE "SPINE JOURNAL" ISSUE OF THAT 2011 ISSUE.

THIS WAS AN EXPOSE. THIS WAS SOMETHING WHERE, WAIT, WE HAVE ALL THESE PROBLEMS. THEY COULDN'T HAVE BEEN THAT WELL KNOWN.

MR. BROWN: THEY WEREN'T ABOUT PAIN, AND IT WASN'T ABOUT FAILED FUSION, AND IT HAD SOMETHING TO DO WHETHER OR NOT THERE MIGHT BE A CANCER RISK, BUT THE FACT IS, IF IT WAS SO WELL KNOWN, WHY WOULDN'T THE FDA REQUIRE MEDTRONIC TO PUT IT ON ITS LABEL? THEY DID. IT WAS ON THE LABEL.

NUMBER ONE, IT'S KNOWN IN THE MEDICAL COMMUNITY. I ASKED DR. MESIWALA. I SAID, DID YOU KNOW THAT AT THE TIME OF YOUR RESIDENCY THAT ECTOPIC BONE GROWTH WAS A RISK WITH ANY BMP LIKE AN INFUSE? YES. HE KNEW THAT. HE KNEW THAT IN HIS RESIDENCY.

I ASKED, WELL, DID YOU KNOWN THAT PAIN COULD BE A POTENTIAL COMPLICATION OF SPINAL SURGERY? YES. THE SAME WITH A FAILED FUSION OR NONUNION.

SO THE ONLY EVIDENCE WE HAVE THAT RELATES TO APRIL CABANA AS OPPOSED TO THE WORLD AT LARGE IS THAT THE RISKS WERE KNOWN BY THE DOCTOR WHO OPERATED. THAT TAKES -- THERE IS NO PROXIMATE CAUSE FOR FAILURE TO WARN THERE, AND SO THE CASES ARE CLEAR, AND SO, AGAIN, IF YOU LET THAT CLAIM GO TO THE JURY, THEN WHAT?

SO THEN IT WOULD BE I SHOULD HAVE WARNED OF

SOMETHING. IF I DO THIS -- AND THIS SNEAKS OVER INTO PREEMPTION -- I'D BE IN VIOLATION OF FEDERAL LAW BECAUSE THE LABEL HAS TO SAY WHAT THE FDA SAYS IT DOES.

HERE, WE DON'T EVEN NEED TO GO THERE BECAUSE WE WARNED OF THE ACTUAL THINGS THAT SHE HAD.

THE COURT: COUNSEL MAKES SOME GOOD POINTS. JUST ON THE MEDTRONIC MOTION, RESPOND TO THAT.

MR. ESFANDIARI: CERTAINLY, YOUR HONOR.

THE COURT: THESE ARE STRONG ARGUMENTS. THEN I UNDERSTAND THAT I'M FOLLOWING BREAD CRUMBS HERE, AND THE FACT THAT SOMEBODY HAS A STRONG ARGUMENT AND LOTS OF POWERFUL ARROWS TO SHOOT AT TRIAL BELONG TO BE SHOT AT TRIAL, WHAT ABOUT WHAT COUNSEL SAYS?

MR. ESFANDIARI: MR. BROWN IS GIVING A MYOPIC VIEW OF THE RECORD, YOUR HONOR. WHAT DR. MESIWALA TESTIFIED AND WHAT HE PUT FORTH IN VERIFIED DISCOVERY RESPONSES WAS, WE ASKED HIM, "HOW DID YOU LEARN ABOUT INFUSE AND USING INFUSE FOR POSTERIOR USES WHEN IT HADN'T BEEN APPROVED BY THE FDA?" HE IDENTIFIED THE SEMINAR HE ATTENDED IN SAN DIEGO.

THE COURT: AND ARTICLES.

MR. ESFANDIARI: RIGHT. INITIALLY HE IDENTIFIED THE SEMINAR IN SAN DIEGO AND SAID, "DR. LANMAN CAME AND TALKED ABOUT POSTERIOR USES, AND I WAS INVITED TO THIS SEMINAR AND MEDTRONIC PAID FOR" --

THE COURT: AND HE SAID THAT SOME REPRESENTATIVE CAME BY AND SAW HIM. YOU ASKED HIM, WAS IT SO AND SO. HAD SAID, NO, IT WASN'T HIM. IT WAS SOMEBODY ELSE, BUT

YEAH.

MR. ESFANDIARI: RIGHT, BUT HE IDENTIFIED CERTAINLY THAT MEDTRONIC SEMINAR THAT HE WAS PAID -- THAT MEDTRONIC PAID HIM TO ATTEND. THAT'S THE SOURCE WHERE HE OBTAINED INFORMATION REGARDING POSTERIOR USES.

HE FURTHER THEN TESTIFIED THAT AFTER THESE DISCOVERY RESPONSES CAME OUT IS WHEN THE SENATE INVESTIGATION CAME OUT REGARDING THOSE ARTICLES BEING WRITTEN BY MEDTRONIC KEY OPINION LEADERS AND NOT DISCLOSING THE TRUTH AND UNDERESTIMATING THE SAFETY AND EFFICACY.

I WENT THROUGH THOSE ARTICLES WITH DR. MESIWALA. THERE'S ABOUT A DOZEN ARTICLES. HE TESTIFIED I THINK THERE WAS AT LEAST NINE OR TEN OF THOSE ARTICLES, INCLUDING ARTICLES DISCUSSING POSTERIOR USES, THAT HE RECALLS READING AND RELYING UPON.

IN FACT, IN SUBSEQUENT DISCOVERY RESPONSES I SAID -- I ASKED, "CAN YOU IDENTIFY WHAT YOU RELIED ON IN DETERMINING THAT INFUSE IS GOING TO BE SAFE AND EFFECTIVE?"

THE COURT: BUT, SEE, COUNSEL IS BEING A LITTLE MORE SPECIFIC. HE'S SAYING WHAT ABOUT IT? HOW DO YOU SHOW A CAUSATION BETWEEN WHAT WENT WRONG WITH -- IF ANYTHING, WITH MS. CABANA, AND WHAT WAS IN THOSE ARTICLES, AND WHAT SHOULD BE IN THE LABEL? THAT'S WHAT HE'S SAYING.

MR. ESFANDIARI: HERE IS WHAT HAPPENED. THE REPRESENTATION THAT MEDTRONIC MADE IN THE JOURNAL

ARTICLES -- AND THIS IS THE EXPOSE THAT THE "SPINE JOURNAL" REVEALED -- IN THOSE ARTICLES THEY TOUTED AND OVERPROMOTED INFUSE FOR USES THAT WERE NOT APPROVED BY THE FDA.

THEY DID NOT REPORT THE ADVERSE EVENTS THAT --

THE COURT: TIE IN WITH WHAT CABANA --

MR. ESFANDIARI: SURE. AND DR. MESIWALA RELIED ON THAT AND USED INFUSE IN CABANA'S SURGERY. I ASKED DR. MESIWALA -- I SAID, "WELL, NOW, NOW THAT THE EXPOSE AND THE 'SPINE JOURNAL' HAS COME OUT SAYING THAT THOSE ARTICLES THAT MEDTRONIC WROTE BACK IN 2002/2003 THAT YOU RELIED UPON, HOW IS YOUR PRACTICING HABITS VIS-À-VIS INFUSE CHANGED?"

HE SAID, "WE DON'T USE INFUSE AS MUCH ANYMORE" --

THE REPORTER: I NEED YOU TO SLOW DOWN A LITTLE BIT.

MR. ESFANDIARI: I APOLOGIZE, MADAM COURT REPORTER.

HE SAID AS THE RESULT OF THESE PUBLICATIONS, AND HE SAID ALSO THESE PUBLICATIONS ARE NOW BEING DISCUSSED IN SEMINARS THAT HE ATTENDS, THAT HE HAS MORE DETAILED DISCUSSIONS WITH HIS PATIENTS REGARDING --

THE COURT: THAT'S RIGHT.

MR. ESFANDIARI: HE SAID NOW HE SPECIFICALLY TELLS THEM, "HEY, I'M GOING TO BE USING THIS OFF-LABEL. THERE

ARE THESE NEW RISKS THAT HAVE COME OUT REGARDING THESE -- BASED ON THESE JOURNALS. DO YOU STILL WANT TO PROCEED?"

THE COURT: WHAT HAPPENED TO MS. CABANA AS A RESULT OF --

MR. ESFANDIARI: MS. CABANA, YOUR HONOR, ONCE THE HARM OCCURRED AS A RESULT OF THE STRYKER PRODUCT, AND SHE DIDN'T FUSE AND SHE HAD THE MIGRATED BONE, SHE HAD ESSENTIALLY ONE CHANCE WHERE THE DOCTOR COULD GO IN, REMOVE THE MIGRATED BONE, AND ACHIEVE FUSION. YOU CAN'T KEEP HAVING SURGERY OVER AND OVER AGAIN.

SO DR. MESIWALA RELIED THE THOUGHT THAT MAYBE THIS INFUSE IS GOING TO BE THE MIRACLE CURE. IT'S GOING TO FUSE HER SPINE, BASED UPON EVERYTHING THAT HE HAD BEEN TOLD BY DR. LANMAN, BY THE MEDICAL JOURNAL ARTICLES, AND HE USED INFUSE IN AN OFF-LABEL MANNER WHICH MEDTRONIC HAD PROMOTED.

SHE NEVER ACHIEVED FUSION. HER SPINE HAS BEEN DESTABILIZED, AND AS A RESULT OF THIS INEFFECTIVE SURGERY, YOUR HONOR, ALL HOPE HAS BEEN LOST.

THE COURT: IS IT YOUR POSITION -- BECAUSE SOME OF THE ARTICLES DID SAY THAT THE ADVERSE REPORTS WERE THAT IT WAS INEFFECTIVE -- IS IT YOUR POSITION THAT THE USE OF THIS -- THAT IT WAS PROMOTED AS BEING -- WELL, YOU'VE ALSO SEEN THE HOLY GRAIL. WE CAN'T USE THAT ANALOGY -- WAS PROMOTED AS BEING THE BE-ALL-END-ALL FOR THIS? WHAT THEY SUPPRESSED WERE THE ADVERSE REPORTS SHOWING IT WAS INEFFECTIVE, SO DR. MESIWALA CHOSE THIS BASED ON THE

ARTICLES HE READ, NOT KNOWING IT WOULD BE INEFFECTIVE, AND THAT WAS MS. CABANA'S ONE SHOT, HER GOLDEN BULLET, AND IT WAS SPENT USING SOMETHING THAT WAS INEFFECTIVE, AND THAT HAD THE DOCTOR KNOWN THE TRUE FACTS ABOUT HOW THERE WERE ISSUES ABOUT IT BEING INEFFECTIVE, HE WOULD NOT HAVE USED IT? HE WOULD HAVE USED ANOTHER GOLDEN BULLET?

MR. ESFANDIARI: AND ALSO HE WOULD HAVE --

THE COURT: "YES" OR "NO," IS THAT IT?

MR. ESFANDIARI: YES, AND ALSO MORE TO THE POINT, HE WOULD HAVE GIVEN MORE OPTIONS, WHICH HE TESTIFIED HE DOES NOW. HE DISCUSSES THESE RISKS WITH HIS PATIENTS, AND MS. CABANA WOULD HAVE BEEN ARMED WITH GREATER INFORMATION.

THE COURT: THIS WAS HER SHOT, AND HE USED AN INEFFECTIVE PRODUCT BECAUSE HE WAS MISLEAD BY ARTICLES. IS THAT YOUR THEORY?

MR. ESFANDIARI: EXACTLY, BECAUSE THE GOLD STANDARD IN THIS TYPE OF SPINE SURGERY, YOUR HONOR, IS TAKING PLUG BONE FROM THE ILIAC CREST AND USING IT, AND THAT COULD HAVE BEEN DONE IN THIS SURGERY. THAT'S WHAT SHOULD HAVE BEEN DONE, BUT FOR MEDTRONIC CLAIMING THAT INFUSE IS FAR SUPERIOR THAN ILIAC CREST AND HAS LESS ADVERSE EFFECTS.

THE COURT: THE ONLY THING I SAW FOR CAUSATION WAS KENNEDY'S DECLARATION. NOW, WAS THERE SOMETHING ELSE THERE THAT SAID THAT? YOU JUST TOLD ME.

YOU CAN CIRCUMSTANTIALLY INFER THAT BECAUSE

THE ADVERSE REPORTS OF INEFFECTIVENESS WERE NOT ADEQUATELY CONVEYED TO THE MEDICAL PROFESSION, THAT THE EFFECTIVENESS WAS OVEREMPHASIZED; THEREFORE, THAT THIS DOCTOR CHOSE IT BECAUSE HE HAD READ IT AND DIDN'T KNOW THAT IT WAS INEFFECTIVE, AND THAT HE USED THIS INEFFECTIVE PRODUCT FOR THE ONE LAST BEST SHOT, WHEN HAD HE KNOWN THE TRUTH, HE WOULD NOT HAVE.

YOU CAN DRAW THOSE CONCLUSIONS CIRCUMSTANTIALLY. I CAN READ THIS AND FOLLOW THOSE BREAD CRUMBS.

MY QUESTION, IS THERE SOMEBODY HERE WHO SAID THAT BESIDES KENNEDY?

MR. ESFANDIARI: DR. MESIWALA TESTIFIED THAT HE USED INFUSE AS A RESULT --

THE COURT: THAT'S NOT WHAT I'M SAYING. I'M SAYING IS THERE SOMEBODY ELSE THAT SAYS THAT THERE'S SOME OTHER PROBLEM WITH INFUSE, OR THAT THIS WAS HER ONE SHOT AT HAVING THIS PROBLEM FIXED, AND HE JUST BASICALLY USED -- HE WAS MISLED INTO USING THE WRONG DRUG. IS THERE SOMEBODY ELSE WHO IS SAYS THAT?

MR. ESFANDIARI: WE HAVE DR. KENNEDY.

THE COURT: OKAY, KENNEDY.

MR. ESFANDIARI: WE HAVE DR. MESIWALA SAYING HE NO LONGER USES INFUSE AS FREQUENTLY AS HE USED TO AS A RESULT OF THESE NEW REVELATIONS.

THE COURT: OKAY.

MR. ESFANDIARI: AND HE SAYS HE HAS GREATER DETAILED INFORMED CONSENT DISCUSSIONS WITH HIS PATIENTS

NOW AFTER THE "SPINE JOURNAL" ARTICLES BECAME RELEASED. MS. CABANA TESTIFIED IN HER AFFIDAVIT THAT HAD SHE BEEN INFORMED OF THESE RISKS THAT DR. MESIWALA NOW WARNS ABOUT AND GOES OVER WITH HIS PATIENTS, SHE WOULDN'T HAVE CONSENTED TO THIS SURGERY.

THINK ABOUT IT. YOUR HONOR, PUT YOURSELF IN MS. CABANA'S POSITION. SHE JUST HAD A SURGERY. THE DOCTOR COMES IN AND SAYS YOU HAVE BONE OF UNKNOWN ORIGIN IN YOUR SPINE.

THEN IF HE HAD TOLD HER WHAT HE TELLS PATIENTS NOW, THAT NOW I AM GOING TO USE INFUSE, WHICH BY THE WAY, ALSO LEADS TO UNWARRANTED BONE GROWTH AFTER YOU HAVE ALREADY HAD BONE GROWING IN YOUR SPINE --

THE COURT: DID IT HERE?

MR. ESFANDIARI: I'M SORRY?

THE COURT: DID IT HERE?

MR. ESFANDIARI: HERE IT WAS INEFFECTIVE, YOUR HONOR, SO BASICALLY IT WAS THE MAGIC BULLET THAT YOUR HONOR REFERRED TO.

AS A RESULT -- NOW, MR. BROWN CAN DOWNPLAY THAT AS MUCH AS HE WANTS, BUT THAT IS A HARM, YOUR HONOR. TO PUT SOMEONE -- SHE PAID -- $80,000 SURGERY. ALL THE RISKS THAT ARE ATTENUATED TO THAT SURGERY, HER ONE CHANCE AT RECOVERY AND TO USE A PRODUCT THAT IS INEFFECTIVE, THAT IS HARM.

THE COURT: WHAT ABOUT THAT?

MR. ESFANDIARI: AND 12 PEOPLE CAN AGREE WITH THAT.

MR. BROWN: YOUR HONOR, IT'S NOT CONSISTENT WITH THE RECORD. THERE'S NO TESTIMONY THAT THIS WAS HER ONE SHOT AT THE MAGIC BULLET. IT'S AN INTERESTING CONSTRUCT YOU MADE, BUT IT'S NOT CONSISTENT WITH WHAT THE RECORD IS.

THE FACT OF THE MATTER IS --

THE COURT: I THINK I DID READ THAT. I THINK I DID READ THAT SHE'S NOW NO LONGER A CANDIDATE FOR SURGERY. I DID READ THAT.

MR. BROWN: SOMEBODY SAID SHE'S NO LONGER A CANDIDATE FOR SURGERY, BUT THEY DIDN'T SAY IT WAS BECAUSE OF INFUSE.

THE COURT: NO. I THINK I DID READ WHERE SHE HAD CERTAINLY A LIMITED NUMBER OF OPTIONS, A LIMITED NUMBER OF POSSIBLE SURGERIES, IF NOT THIS ONE ONLY, AND THAT THIS PRODUCT WAS INEFFECTIVE, AND THIS WAS THE ONE THAT WAS CHOSEN. I DID READ THAT SOMEPLACE.

MR. BROWN: NOWHERE DID DR. MESIWALA SAY THAT THE PRODUCT WAS INEFFECTIVE.

THE COURT: NO. THAT'S ANOTHER BREAD CRUMB.

MR. BROWN: IN FACT, HE'S USED IT EFFECTIVELY FOR FIVE YEARS BEFORE MS. CABANA. NOT ONE COMPLAINT. SO ALL OF THOSE WERE SUCCESSFUL SURGERIES, SO THIS IDEA THAT THE RECORD SUGGESTS IT WAS INEFFECTIVE IS JUST NOT TRUE.

THE FACT THAT SHE DIDN'T FUSE AGAIN, SHE'S A SMOKER. SHE HAD A PREVIOUS FAILED SURGERY. NO ONE HAS OPINED THAT INFUSE WAS THE REASON SHE DIDN'T FUSE.

FRANKLY, YOUR HONOR, I'D ASK YOU TO GO BACK TO DR. KENNEDY'S DECLARATION. HE DOES NOT OFFER A CRITICISM OF INFUSE BY SAYING IT WAS DEFECTIVE, OR IT LED TO ANY INJURY.

THE FACT THAT --

THE COURT: I JUST READ IT IN PARAGRAPH 45.

MR. BROWN: HE TALKS ABOUT THAT WAS A DECISION MADE BY MESIWALA THAT WAS A SUBSTANDARD DECISION. HE DOESN'T SAY THAT INFUSE CAUSED HER ANY PARTICULAR HARM.

THE COURT: WAIT A MINUTE. I'M LOOKING AT KENNEDY'S DECLARATION. I THINK THAT'S THE WHOLE IDEA OF THE DECLARATION. IT WASN'T THAT -- JUST DAMNING DR. MESIWALA. HE WAS SAYING THIS PRODUCT USED IN CONJUNCTION WITH SOMETHING ELSE IN THIS MANNER WAS THE SUBSTANTIAL CAUSE OF THE HARM. THAT'S WHAT HE SAID.

MR. BROWN: YOUR HONOR, WITH ALL DUE RESPECT, PARAGRAPH 45 DOESN'T SAY THAT.

ANOTHER THING, WHAT IS IT THAT WE SHOULD HAVE WARNED ABOUT, IS WHAT I'M TRYING TO THINK? EVEN DR. WEINER IN PARAGRAPHS 11 AND 24 OF HIS DECLARATION SAYS ECTOPIC BONE GROWTH WAS A COMMONLY KNOWN RISK IN 2002.

SO, AGAIN, THE PROXIMATE CAUSE -- AND, YOUR HONOR, WE HAVE ANOTHER PROXIMATE CAUSE ISSUE HERE ON TOP OF THE ONE THAT -- EACH OF THE RISKS THAT MS. CABANA ULTIMATELY IS COMPLAINING ABOUT WERE WELL KNOWN IN THE MEDICAL COMMUNITY, AND ALSO THAT WE WARNED OF THOSE THINGS.

DR. MESIWALA TESTIFIED HE DIDN'T READ THE INSTRUCTIONS FOR USE ON IT. YOU CAN'T HAVE PROXIMATE CAUSE ON FAILURE TO WARN IF THE DOCTOR DOESN'T READ IT AS IT RELATES TO THIS. HE READ THE LABEL ONCE IN 2004, WAS HIS TESTIMONY.

THE COURT: WELL, AGAIN, I GO BACK TO THE SAME ANALYSIS I HAD BEFORE ABOUT THERE WAS A LOT OF MISLEADING INFORMATION BEING DISSEMINATED, AND THERE'S SOME EVIDENCE OF MEDTRONIC'S FINGERPRINTS ON THOSE.

SO I JUST THINK FOR PURPOSES OF SUMMARY JUDGMENT, I'D HAVE TO DISAGREE.

YOU WANTED TO BE HEARD ON THE PREEMPTION.

MR. BROWN: CAN I JUST DO A QUICK THING? ON FRAUD SIMILAR TO THE EXPRESS WARRANTY?

THE COURT: RIGHT.

MR. BROWN: DR. MESIWALA TESTIFIED NO MISREPRESENTATIONS. NO CONCEALMENT. THERE IS NO EVIDENCE TO SUPPORT A FRAUD CLAIM AS IT RELATES TO THIS PLAINTIFF, THIS DOCTOR. THERE IS NO FRAUD IN THE MARKET IN CALIFORNIA.

THERE HAS TO BE A REPRESENTATION THAT DR. MESIWALA -- I ASKED HIM SPECIFICALLY BECAUSE I KNEW WHAT THE REMAINING CAUSES OF ACTION WERE AT THE TIME WE TOOK HIS DEPOSITION. HE SAID, "I WAS NOT MISREPRESENTED TO." THE TWO SALES REPS -- HE SAID CHRIS BANAS ABSOLUTELY DIDN'T, AND THEN HE SAID, "I DON'T EVEN KNOW THE NAME OF THE OTHER GUY. NEVER SAW THEM BECAUSE WE STOCKED IT ON THE SHELF."

SO THERE'S NOTHING IN THE RECORD. RICK BROOMS (PHONETIC) -- AND WE SUBMITTED THEIR TESTIMONY AS WELL -- SAYING THEY DIDN'T PROMOTE IT TO HIM. DR. MESIWALA HAS NOWHERE IN THE RECORD SAYING THAT THE SALES REPRESENTATIVES PROMOTED INFUSE IN THE OFF-LABEL MANNER.

THE COURT: I THINK HE DOES.

THE COURT: READING THIS IT SAYS, "JUST SO IT'S CLEAR, WERE YOU DURING AND PRIOR TO 2009 HAD YOU BEEN DETAILED BY MEDTRONIC SALES REPS FOR INFUSE?

"ON SEVERAL OCCASIONS THEY CAME BY MY OFFICE."

QUESTION: "I BELIEVE IN YOUR DISCOVERY RESPONSE YOU IDENTIFIED AN INDIVIDUAL CHRIS BAYLIS."

ANSWER: "CHRIS BAYLIS WAS A MEDTRONIC REP FOR THE INSTRUMENTATION.

MR. BROWN: WHICH IS NOT INFUSE. INSTRUMENTATION IS SCREWS AND RODS.

THE COURT: THEN THEY SAID, "WAS HE THE ONE WHO SAID THIS?

"NO."

THEN IT WAS, "AND WAS THE POSTERIOR" -- PAGE 150, LINES 19 THROUGH 23 -- "AND WAS THE POSTERIOR USE OF INFUSE SOMETHING THAT WAS DISCUSSED AT THE MEDTRONIC SEMINAR WHERE YOU ATTENDED IN SAN DIEGO WHEN YOU WERE IN RESIDENCY?"

ANSWER: "YES."

MR. BROWN: YOUR HONOR, THOSE ARE TWO DIFFERENT

THINGS.

THE COURT: I KNOW. I KNOW.

MR. BROWN: SO ON PAGE 151, LINE 5, TO 152, LINE 17, DR. MESIWALA SAYS THAT CHRIS BANAS DID NOT PROMOTE INFUSE TO HIM. THE IDEA THAT THEY WENT TO HIS OFFICE AND DETAILED INFUSE, BUT IT DOESN'T SAY OFF-LABEL. NOWHERE DOES HE SAY THAT SALES REPRESENTATIVES PROMOTED OFF-LABEL.

MR. ESFANDIARI: YOUR HONOR, MAY I RESPOND?

THE COURT: OKAY. BUT I HAVE TO --

MR. ESFANDIARI: CERTAINLY, YOUR HONOR.

BUT DR. MESIWALA DID TESTIFY THAT MEDTRONIC SENT HIM TO A FANCY RESORT IN SAN DIEGO.

THE COURT: CORONADO.

MR. ESFANDIARI: CORONADO, AND WHERE DR. LANMAN, A MEDTRONIC KEY OPINION LEADER, DISCUSSED OFF-LABEL USE, AND THAT WAS ONE OF THE SOURCES THAT HE RELIED UPON.

DR. MESIWALA ALSO TESTIFIED THAT NINE OUT OF THE 12 JOURNAL ARTICLES THAT MEDTRONIC WROTE REGARDING THE EFFICACY OF INFUSE FOR OFF-LABEL USES, HE RELIED UPON INCLUDING THE VERY ONE DISCUSSING THE POSTERIOR USE OF INFUSE, WHEREIN MEDTRONIC AND ITS KEY OPINION LEADERS STATED THAT THE USE OF INFUSE FOR POSTERIOR USES IS SAFE AND EFFECTIVE AND HAD NO ADVERSE EVENTS.

AND THOSE ARE THE --

THE COURT: WAIT. WAIT.

MR. ESFANDIARI: -- ALLEGATIONS --

THE COURT: I'VE GOT TO MAKE A COMMANDO DECISION HERE. I THINK MEDTRONIC HAS SOME EXCELLENT ARGUMENTS, BUT FOR SUMMARY JUDGMENT, I STILL THINK THAT THE PLAINTIFF SHOULD PREVAIL ON THESE ISSUES. MEDTRONIC HAS SOME EXCELLENT ARGUMENTS, AND THEY ARE SERIOUS ARGUMENTS, AND THEY ARE ARGUMENTS THAT -- TO BE HEARD AT TRIAL, BUT FOR THE REASONS I STATED, I THINK THAT THERE'S ENOUGH OF A BREAD CRUMB TRAIL HERE IN THE EVIDENCE AND IN THE RECORD TO OVERCOME.

YOU WANT TO BE HEARD ON THE --

MR. BROWN: I DID, YOUR HONOR. SPECIFICALLY WHAT'S NEW AS IT RELATES TO PREEMPTION, AND I'D LIKE TO TALK ABOUT JUDGE LINFIELD'S ORDER TOO.

NUMBER ONE, WITH ALL DUE RESPECT TO JUDGE LINFIELD, I THINK HE GOT IT WRONG IN A FEW AREAS. NUMBER ONE, HE IDENTIFIED THAT IT WAS MEDTRONIC'S BURDEN ON THE PARALLEL CLAIM ISSUE.

THE SECOND DISTRICT COURT OF APPEAL IN JESSEN, J-E-S-S-E-N, VS. MENTOR MAKES IT CLEAR THAT ONCE WE ESTABLISH WE HAVE PMA APPROVAL, AND, TWO, THERE WOULD BE STATE REQUIREMENTS PRIMA FACIALLY, WE ARE ENTITLED TO PREEMPTION.

THE NARROW EXCEPTION IS THE PARALLEL CLAIM PREMISED ON FEDERAL VIOLATION. THAT IS THE PLAINTIFF'S BURDEN.

YOUR HONOR, I THINK IMPORTANTLY ABOUT -- YOU ASKED MR. CONNOLLY ABOUT RECOURSE FOR APRIL CABANA. THE FACT OF THE MATTER IS, MEDTRONIC PRODUCT DID GO

THROUGH THE RIGOROUS PMA PROCESS. ONLY ONE PERCENT OF ALL THE APPROVAL THAT ARE OUT THERE GO THROUGH THIS PROCESS. 99 PERCENT GO THROUGH A MUCH LESS RIGOROUS PROCESS.

IN EXCHANGE FOR THAT, HOWEVER, CONGRESS PUT IN AN EXPRESS PREEMPTION PROVISION.

THE COURT: FOR ANTERIOR USE. THEY WOULDN'T APPROVE FOR THE POSTERIOR USE.

MR. BROWN: BUT HOW IT'S USED IS THE DOCTOR'S DECISION.

THE COURT: THEN WHY DID THE FDA DRAW A DISTINCTION?

MR. BROWN: BECAUSE THAT'S WHAT THE STUDY WAS BASED ON. THEY MAKE A DISTINCTION BASED ON THE EVIDENCE THAT'S PRESENTED AND WHAT THE LABELING SHOULD BE FOR THAT.

BUT A COUPLE OTHER THINGS ABOUT JUDGE LINFIELD'S ORDER AND WHAT'S NEW, BECAUSE ONE OF THE THINGS THAT'S NEW IS, THERE HAVE BEEN FIVE OR SIX NEW FEDERAL DECISIONS CONCERNING THE INFUSE DEVICE ON PREEMPTION. I THINK THOSE ARE REALLY WORTH READING.

FRANKLY, THE ONE CASE THAT PLAINTIFF RELIES ON HEAVILY IS A CASE CALLED RAMIREZ. UP UNTIL RAMIREZ NOT ONE FEDERAL CASE SAID THAT OFF-LABEL PROMOTION -- LET'S ASSUME IT HAPPENED. I DON'T THINK THE RECORD SUPPORTS IT -- OFF-LABEL PROMOTION TAKES THE CASE OUT OF PREEMPTION.

THE COURT SUGGESTED A COUPLE OF TIMES --

YOU WERE REFERRING TO IT; YOU DIDN'T CALL IT BY NAME, BUT IT WAS A CASE CALLED BAUSCH VS. STRYKER FROM THE SEVENTH CIRCUIT THAT SAID IT WOULD BE COUNTER-INTUITIVE AND ALL THAT.

YOUR HONOR, IN THAT CASE, ONE, IT WAS PLEADINGS CASE. TWO, THE PARTICULAR LOT THAT THE PLAINTIFF IN THAT CASE FOUND, THERE WAS A WARNING LETTER BASICALLY SAYING THE MANUFACTURING PROCEDURES HADN'T BEEN FOLLOWED.

SO THERE YOU HAVE A FEDERAL VIOLATION, AND OF COURSE FRANKLY IT MAKES SENSE.

AGAIN, STRYKER PROBABLY WILL DISAGREE WITH ME, BUT THAT'S THE SITUATION. THE PARALLEL CLAIM IDEA WAS INTENDED TO BE VERY NARROW. YOU HAVE SEEN THE PHRASE "NARROW GAP" A LOT.

JUSTICE BREYER IDENTIFIED WHAT IT WAS REALLY FOR. HE DID THIS IN A SUPREME COURT CASE, MEDTRONIC VS. LOHR. HE SAID IF THE FDA MANDATES THAT YOU MAKE THE DEVICE WITH A TWO-INCH WIRE AND YOU CAN MAKE IT WITH A ONE-INCH WIRE, YOU DON'T GET PREEMPTION BECAUSE YOU DIDN'T FOLLOW THE FEDERAL REQUIREMENTS.

HERE, PLAINTIFF'S VIEW WOULD EVISCERATE PREEMPTION AS WE KNOW IT NOW UNDER 360(K) AND THE SUPREME COURT'S DECISION IN RIEGEL AND IN BUCKMAN.

NOW, ANOTHER DISAGREEMENT JUDGE LINFIELD. THAT IS, IN HIS ORDER, AGAIN, IN TERMS OF ALL THE AUTHORITIES WE PROVIDED TO YOU, NONE ARE BINDING ON YOU; ALL THE INFUSE CASES AREN'T. YOU ARE BOUND BY THE TWO

U.S. SUPREME COURT DECISIONS AND ONLY POST RIEGEL CALIFORNIA STATE COURT OF APPEALS DECISION CALLED MCGUAN VS. ENDOVASCULAR.

FRANKLY, JUDGE LINFIELD MISREAD MCGUAN, AND I DON'T JUST SAY AN INTERPRETATION OF IT. HE SAID THAT MCGUAN DID NOT INVOLVE A CASE WHERE THERE WERE ALLEGED FEDERAL VIOLATIONS. HE WAS RIGHT ABOUT PLAINTIFF MCGUAN, BUT HE WAS WRONG ABOUT PLAINTIFF LILLIAN JOHNSON WHO WAS ALSO IN THAT CASE.

ON PAGE 986 OF MCGUAN, IT TALKS ABOUT A CLAIM BASED ON A VIOLATION OF FEDERAL REGULATIONS. THE COURT HELD THAT THE CLAIMS WERE IMPLIEDLY PREEMPTED UNDER BUCKMAN.

THAT CAN'T BE RECONCILED. THAT WAS JUST FRANKLY A MISREAD. I GET IT BECAUSE THERE ARE A COUPLE PLACES IN THE DECISION WHERE IT SAID NO VIOLATION OF FEDERAL REGULATIONS ALLEGED, BUT IT HAD TO DO WITH PLAINTIFF MCGUAN AND NOT PLAINTIFF LILLIAN JOHNSON.

THE COURT: DID YOU SEEK ANY SORT OF APPELLATE REVIEW OF LINFIELD'S DECISION? YOU ARE MAKING A GOOD ARGUMENT TO THE WRONG TRIBUNAL. I CAN'T OVERRULE LINFIELD.

MR. BROWN: WELL, I THINK YOU CAN, YOUR HONOR. THERE ARE CASES THAT TALK -- I THINK 437(C)(F)(2) SAYS YOU CAN BRING ANOTHER SUMMARY JUDGMENT, AND THE THING IS, WE HAVE OTHER AUTHORITY THAT I WOULD ASK THE COURT TO LOOK AT, AND I THINK THE COURT IS PERFECTLY ENTITLED TO LOOK AT MCGUAN AGAIN TO SEE WHETHER FUNDAMENTALLY

JUDGE LINFIELD SORT OF --

THE COURT: I DISAGREE WITH YOU ON THAT.

MR. BROWN: WELL, ANOTHER CASE, YOUR HONOR, THAT'S SINCE JUDGE LINFIELD'S ORDER, AND THAT IS THE NINTH CIRCUIT PEREZ DECISION. MR. CONNOLLY MENTIONED IT BRIEFLY. IT'S AN OFF-LABEL PROMOTION CASE, AND IT'S A PREEMPTION CASE. IT WAS ISSUED MARCH 25, 2013, SO AFTER JUDGE LINFIELD.

THERE, THEY SAID THAT THERE WAS A PROMOTION, AN OFF-LABEL PROMOTION, LIKE THE ALLEGATIONS ARE HERE, AND THERE WAS A FRAUD CLAIM THERE, FRAUD BY OMISSION.

THE NINTH CIRCUIT SAID -- AND BASICALLY WHAT THE PLAINTIFFS WERE SAYING IS, YOU SHOULD HAVE TOLD US, YOU SHOULD HAVE TOLD DOCTORS THE DEVICE WAS UNAPPROVED FOR THIS USE AND WAS BEING USED OFF-LABEL.

WHAT THE NINTH CIRCUIT SAID WAS, BUT TO IMPOSE A DISCLOSURE REQUIREMENT LIKE THAT, MEANING GO TELL PEOPLE IT'S OFF-LABEL, WOULD BE CREATING A REQUIREMENT THAT IS DIFFERENT FROM OR IN ADDITION TO THE FEDERAL REQUIREMENT. THUS, IT'S CLASSICALLY BARRED UNDER SECTION 360(K) AND RIEGEL.

THEN, AGAIN, AS THE COURTS ARE REQUIRED TO DO, EVEN IF IT WAS ABLE TO ESCAPE EXPRESS PREEMPTION, YOU HAVE TO LOOK TO SEE WHETHER IT MIGHT BE IMPLIED PREEMPTED. THERE, THEY SAID THE DEVICE, BY BEING PROMOTED OFF-LABEL WAS MISBRANDING AND ADULTERATED.

THE COURT SAID, LOOK, WHETHER THEY ENGAGED

IN ILLEGAL OFF-LABEL PROMOTION OR MISBRANDED OR IT WAS MISBRANDED OR ADULTERATED ARE ISSUES FOR THE FDA, AND NOT FOR THIS COURT, AND UNDER THE NO PRIVATE RIGHT OF ACTION PROVISION OF 21 UNITED STATES CODE SECTION 337(A) FOUND THAT THE CLAIMS IN PEREZ WERE BOTH EXPRESSLY AND IMPLIEDLY PREEMPTED.

IN THIS CASE, IT CAN'T BE RECONCILED THAT YOU CAN HAVE AUTHORITY LIKE PEREZ AND ALLOW AN OFF-LABEL PROMOTION CLAIM TO GO FORWARD HERE.

THERE IS, AGAIN, UP UNTIL THIS JUAN RAMIREZ CASE, THERE WAS NO FEDERAL COURT THAT SAID OFF-LABEL PROMOTION SOMEHOW TAKES YOU OUT OF IT.

ON YOUR POINT OF VIOLATING FEDERAL REGULATION, HERE IS ANOTHER EXAMPLE. IT TIES INTO A CASE FROM THE FOURTH DISTRICT COURT OF APPEAL IN CALIFORNIA. IT IS CITED IN OUR PAPERS. IT IS CALLED BLANCO VS. BAXTER.

THERE, THE ISSUE ON APPEAL WAS WHETHER OR NOT THE FACT THAT BAXTER ULTIMATELY RECALLED ITS PRODUCTS TOOK THE CASE OUT OF PREEMPTION.

ONCE AN FDA RECALL TAKES PLACE, IT'S AUTOMATICALLY DEEMED VIOLATIVE AND ADULTERATED. SO THERE YOU WOULD HAVE A FEDERAL VIOLATION, UNDER THE PLAINTIFF'S VIEW, THAT WOULD TAKE PREEMPTION AWAY.

THE FOURTH DISTRICT COURT OF APPEALS IN BLANCO SAID, NO, IT'S WHAT IS APPROVED AT THE TIME AND A RECALL, EVEN IF IT'S VIOLATIVE, DOESN'T TAKE THE CASE OUT OF PREEMPTION.

YOU CAN'T LOOK AT THOSE AUTHORITIES AND SORT OF SQUARE A DECISION THAT ON A LEGAL BASIS THE CLAIMS GET TO GO FORWARD, YOUR HONOR.

THE COURT: WHAT ABOUT PEREZ? I UNDERSTAND -- I LOOK AT THE SUPREME COURT AND THE CALIFORNIA COURT OF APPEAL DECISIONS, DISTRICT NINTH CIRCUIT DECISION, BUT WHAT ABOUT THAT INTERPRETATION?

MR. ESFANDIARI: MR. BROWN IN HIS DISSERTATION, HOWEVER, YOUR HONOR, FAILS TO MENTION THE SUPREME COURT DECISION FROM CALIFORNIA CALLED IN RE FARM RAISED SALMON --

THE COURT: THAT'S RIGHT.

MR. ESFANDIARI: -- WHERE THAT CASE INVOLVED A FOOD PRODUCT, BUT DEFENDANTS MADE THE EXACT SAME ARGUMENT THAT MR. BROWN IS MAKING SAYING, WELL, THE FDA --

THE COURT: I THINK LINFIELD CITED THAT CASE.

MR. ESFANDIARI: WE CITED TO HIM. I DON'T KNOW IF HE SPECIFICALLY CITED TO THAT CASE, BUT IN THAT CASE DEFENDANTS MADE THE SAME ARGUMENTS. THEY SAID FOR YOU TO COME IN AND SAY THAT A FOOD WAS MISBRANDED OR ADULTERATED, THAT'S THE FUNCTION OF THE FDA. YOU CAN'T DO THAT.

AND CALIFORNIA SUPREME COURT SAID, NO, WHEN A VIOLATION -- WHEN YOU VIOLATE FEDERAL LAW AND THAT LAW PARALLELS STATE LAW, WHICH WE HAVE IN THIS CASE, THEN THERE IS NO PREEMPTION. THE PLAINTIFFS ARE NOT TRYING TO BASICALLY ENFORCE FEDERAL LAW. PLAINTIFFS ARE SIMPLY

TRYING TO --

THE COURT: WHY DIDN'T YOU SEEK APPELLATE REVIEW OF THE LINFIELD ORDER?

MR. BROWN: BECAUSE, YOUR HONOR, WE KNEW THAT WE HAD ONGOING TESTIMONY FROM DR. MESIWALA. FRANKLY, THE VIEW WAS THAT SOMEHOW WE REALLY DID PROMOTE AND DR. LANMAN. WE FIGURED, ALL RIGHT, WELL, IF IT REQUIRES GETTING MORE EVIDENCE, WE'LL TAKE ANOTHER SHOT.

FRANKLY, IF THE COURT DENIES THE MOTION HERE, WE MAY SEEK INTERLOCUTORY REVIEW BECAUSE WE THINK ON THE EVIDENTIARY RECORD AS IT RELATES TO APRIL CABANA AND DR. MESIWALA, NOT THE "SPINE JOURNAL" AND THINGS LIKE THAT, THEY ARE FRANKLY -- THE CLAIMS ARE BOTH PREEMPTED, AND THERE'S NO EVIDENCE THAT, ONE, WE FAILED TO WARN OR THAT IT CAUSED ANY INJURY.

THE COURT: I RESPECT YOUR POSITION, BUT I THINK THERE ARE BREAD CRUMBS THAT I CAN FOLLOW.

MR. BROWN: YOUR HONOR, CAN I ASK -- JUST RESPOND TO THE FARM RAISED SALMON? TOTALLY INAPPOSITE. DEAL WITH FOOD LABELING LAWS THAT DON'T HAVE THE SAME KIND OF EXPRESS PREEMPTION PROVISION AS THE DEVICE REGULATIONS.

TWO, IT WAS NOT A VIOLATION OF FEDERAL LAW. IT WAS A VIOLATION OF CALIFORNIA HEALTH AND SAFE CODE. CALIFORNIA HEALTH AND SAFETY CODE PERMITS A PRIVATE RIGHT OF ACTION FOR THAT KIND OF CLAIM. TOTALLY DIFFERENT THAN HERE.

THE COURT: I AM VERY RELUCTANT TO -- I CANNOT OVERRULE ANOTHER SUPERIOR COURT JUDGE. I DON'T THINK

THERE HAS BEEN A CHANGE IN THE FACTS. I DISAGREE WITH YOU ON THAT.

I REVISIT MY OWN RULINGS, AND I'VE CHANGED THEM WHEN I'M CONVINCED THAT I MADE A MISTAKE, BUT I'M VERY UNCOMFORTABLE DOING THAT, THE RULING MADE BY ANOTHER JUDGE, WHEN THAT RULING WAS VERY WELL-REASONED AND PUT FORTH IN GREAT DETAIL.

SO I WOULD CERTAINLY -- I TELL THIS TO EVERYBODY -- IF YOU DISAGREE WITH ME, I RESPECT THAT DISAGREEMENT. I ASK YOU TO SEEK APPELLATE REVIEW. I ASK YOU TO GO GET A SECOND SET OF EYES TO LOOK AT THIS. IF THEY AGREE WITH ME, THAT'S FINE. IF THE COURT OF APPEALS AGREES, THAT'S FINE. IF THEY DON'T AGREE, THAT'S FINE, TOO. I'M NOT EMOTIONALLY READ TO THIS POSITION.

I'VE GOT TO MOVE ON.

MR. BROWN: WOULD THE COURT CONSIDER CERTIFYING IT UNDER CODE OF CIVIL PROCEDURE 166 --

THE COURT: I THOUGHT ABOUT THAT IN THE PAST. I DON'T WANT TO TELL THE COURT OF APPEALS HOW TO DO THEIR JOB. IF THEY FEEL THIS IS AN IMPORTANT ONE, THEN THEY WILL TAKE IT.

I WAS A LAWYER FOR A LONG TIME, TOO, AND I HAD A CYNICAL VIEW OF WRITS, THAT THEY HAD A MACHINE DOWN THERE ON SOUTH SPRING WHICH INTERCEPTED MY WRIT APPLICATION AND FLUNG IT BACK TO ME JUST UNDER THE SPEED OF LIGHT.

THEY TURNED IT INTO A POSTCARD AND SHOT IT

BACK JUST UNDER THE SPEED OF LIGHT.

SINCE THEN I HAVE GOTTEN TO KNOW MANY JUSTICES VERY WELL AS PERSONAL FRIENDS, AND WE HAVE LUNCH TOGETHER, AND THEY SHOW ME THEIR OPERATION. THEY TAKE WRITS VERY SERIOUSLY. THEY HAVE WRIT DAYS. THEY HAVE WRIT LAWYERS WHERE THE WRIT LAWYERS REVIEW THE WRITS, AND THEN THE JUSTICES GET TOGETHER AND DISCUSS THE WRITS.

THIS IS A BIG CASE. THIS IS A CASE WITH A LOT OF MOVING PARTS. I JUST READ TODAY THAT THERE ARE GOING TO BE 37 NEW ONES.

THEY MAY VERY WELL TAKE IT. THAT'S THEIR DECISION. THAT'S NOT MY DECISION.

MR. BROWN: YOUR HONOR, ONE THING -- AND I KNOW THE COURT IS LIKELY GOING TO ISSUE A RULING WITH CITES TO THE EVIDENCE --

THE COURT: WELL, I'M NOT GOING TO ISSUE A WRITTEN RULING. I REALLY DON'T HAVE -- MY SHOULDERS ARE SUCH WHERE I CAN'T SIT DOWN ON A TYPEWRITER ANYMORE AND TYPE. I GO THROUGH THESE DETAILED RULINGS ON THE RECORD. THAT'S THE BEST I CAN DO FOR YOU.

MR. BROWN: MAYBE THEN ONE QUESTION FOR THE COURT, OR EVEN PLAINTIFF'S COUNSEL. THIS ALL SEEMS TO HAVE PREMISED ON THAT THERE'S A VIOLATION OF FEDERAL REGULATIONS OR STATUTE.

THE COURT: IT'S PREMISED ON --

MR. BROWN: FOR THE PREEMPTION.

THE COURT: -- YEAH, FOR THE PREEMPTION, THAT THIS

WAS OFF-LABEL, THAT THE FDA HAS APPROVED THIS FOR ANTERIOR USE, AND IT WAS BEING USED FOR POSTERIOR USE.

MR. BROWN: MY QUESTION, YOUR HONOR, SINCE THERE IS NO REGULATION THAT EXPRESSLY PROHIBITS OFF-LABEL PROMOTION, I DON'T SEE THAT THERE'S A VIOLATION. IT MEETS THE FIRST PRONG.

THE COURT: THERE'S ALSO NOT ONE THAT SAYS GROW IT IN YOUR EAR. THERE IS A LOT OF THINGS IT DOESN'T SAY. IT'S APPROVED FOR ANTERIOR USE. IT'S NOT APPROVED FOR THIS USE, AND FRANKLY THERE IS AN FDA APPROVAL FOR -- PROCESS FOR A REASON -- I'M GETTING TIRED. IT'S BEEN A LONG MORNING -- AND IT HAS ISN'T BEEN APPROVED FOR THAT.

SO, I MEAN, THIS IS MY FIRST INTRODUCTION INTO THIS AREA. I SPENT A LOT OF TIME ON IT. I SPENT A GOOD MANY HOURS ON THIS TRYING TO COME UP TO SPEED. I WILL NEVER BE ABLE TO MATCH THE KNOWLEDGE OF THE COUNSEL IN THIS CASE FOR THE MINUTIA OF THE CASE.

I HAVE ENOUGH KNOWLEDGE, I THINK, TO BE COMFORTABLE WITH MY DECISION, BUT THAT MEANS SOMETHING TO ME. IT MEANS SOMETHING TO ME IN THE CONTEXT OF WHAT I'VE READ HERE THAT THE USE HERE WAS NOT DONE WITH THE APPROVAL OF THE FDA.

NOW, WE CAN DEBATE WHETHER THIS APPROVAL WAS A GOOD THING OR A BAD THING, AND IT'S TOO STRICT, NOT STRICT, WHAT IT MEANS NOT TO HAVE APPROVAL AND STILL GO AHEAD AND USE IT, BUT IF THEY APPROVE IT FOR ONE PURPOSE AND NOT ANOTHER, THAT'S A MEANINGFUL DISTINCTION FOR ME.

NOW, IS IT A MEANINGFUL DISTINCTION TO OTHERS? WILL IT BE A MEANINGFUL DISTINCTION TO THE COURT OF APPEALS? I DON'T KNOW. IT'S JUST MEANINGFUL -- I SAID IT ON THE RECORD. IT'S NOT A SECRET.

MR. BROWN: YOUR HONOR, YOU MENTIONED THAT WE HAD FILED DR. LANMAN EXCERPTS. I HAVE A COPY HERE. AS LONG AS IT'S PART OF THE RECORD, I'M FINE WITH THAT.

THE COURT: I DIDN'T SEE THEM. BY ALL MEANS, MAKE IT PART OF THE RECORD.

MR. BROWN: THANK YOU, YOUR HONOR.

THE COURT: THANK YOU. THANK ALL OF YOU FOR EXCELLENT WORK, AND I LOOK FORWARD TO CONTINUING WORK ON THIS CASE.

I THINK, PLAINTIFF, THAT YOUR COLLEAGUE MAKES SOME PRETTY GOOD ARGUMENTS. THE REASON I POINT THIS OUT IS I'M ALWAYS TRYING TO FIND A WAY TO HAVE THE PARTIES RESOLVE MATTERS. I THINK IN EVERYBODY'S INTERESTS -- I'D LOVE TO TRY THIS CASE. THAT'S ONLY BECAUSE I LOVE TRIAL, AND I LOVE SCIENCE. I'D LOVE TO LISTEN TO THIS, BUT THAT'S SELFISH ON MY PART, ISN'T IT? BECAUSE IT'S NOT IN THE BEST INTERESTS OF THE PARTIES TO ROLL DICE IN FRONT OF THE JURIES.

WHAT ARE YOU DOING BY WAY OF MEDIATION?

MR. ESFANDIARI: WE ALREADY HAD MEDIATION IN FRONT OF JUDGE BOSTROM LAST YEAR. IT WAS UNSUCCESSFUL. WE ARE TRYING TO SET UP AN MSC THROUGH THE COURT. STRYKER'S COUNSEL -- I BELIEVE WE'VE ALL AGREED ON A

DATE, SEPTEMBER 26TH.

THE COURT: HAVE YOU TALKED TO HELEN BENDIX ABOUT THIS?

MR. BROWN: YES.

MR. ESFANDIARI: WE'RE WAITING TO BE -- MR. NELSON HAS MORE INFORMATION ON THAT.

THE COURT: MAY I RECOMMEND -- ALL OF OUR MSC JUDGES ARE EXCELLENT. FOR A COMPLEX CASE, AS I GO UPSTAIRS AND I ASK FOR A FAVOR OF MY FRIEND. I DON'T KNOW IF YOU GUYS KNOW LOU, BUT HE WAS APPOINTED MAYBE SIX OR SEVEN YEARS AGO. BEFORE THEN, HE WOULD CHARGE MANY TENS OF THOUSANDS OF DOLLARS TO MEDIATE CASES LIKE THIS. NOW YOU GET IT FOR FREE.

BUT FOR COMPLEX CASES, I HIGHLY RECOMMEND LOU. IF YOU CAN GO, HE'S IN 38. IF YOU CAN GO UPSTAIRS. IF YOU ARE SO INCLINED. YOU CAN DROP MY NAME. SEE IF YOU CAN GET HIM. HE'S EXCELLENT. HE'S VERY GOOD.

I HAVE A LOT OF THINGS I HAVE TO HANDLE. THIS HAS BEEN AN INVIGORATING DISCUSSION THAT HAS WORN ME OUT IN MY OLD AGE.

MR. ESFANDIARI: THANK YOU SO MUCH FOR YOUR TIME.

THE COURT: MY PLEASURE.

MR. ESFANDIARI: THERE WAS ONE HOUSEKEEPING MATTER, YOUR HONOR. ON THE DOCUMENTS THAT WERE FILED UNDER SEAL, WE LODGED STRYKER'S DOCUMENTS UNDER SEAL. BY LAW, THEY HAD TEN DAYS TO OPPOSE. THEY DIDN'T FILE ANY OPPOSITION.

SO I WOULD ASK ALL DOCUMENTS SUBMITTED IN OPPOSITION TO STRYKER'S MSJ BE UNSEALED INCLUDING DR. KESSLER'S REPORT.

THE COURT: DO YOU WANT THOSE UNSEALED?

(A DISCUSSION WAS HELD
OFF THE RECORD.)

MR. NELSON: NO OBJECTION, YOUR HONOR.

THE COURT: YOU GIVE NOTICE, PLEASE.

MR. ESFANDIARI: OF COURSE.

MR. BROWN: YOUR HONOR, MEDTRONIC'S DOCUMENTS ARE STILL UNDER SEAL.

MR. ESFANDIARI: MEDTRONIC, YES. THERE'S FIVE OR SIX EXHIBITS THAT MEDTRONIC WANTED SEALED. THEY FILED OBJECTIONS. I HAVE NO PROBLEM TO THAT, YOUR HONOR. THEY APPEAR TO BE SUBJECT TO THE PROTECTIVE ORDER ON THE MEDTRONIC -- FEW DOCUMENTS IN OPPOSITION TO MEDTRONIC.

THE COURT: I HAVE TO GO BACK AND SEPARATE THOSE OUT THEN, BECAUSE I DID OPEN THESE ENVELOPES. I HAVE TO MAKE SURE -- IF I CAN'T, I WILL HAVE TO LET YOU KNOW. I DID OPEN THE ENVELOPES AND STARTED GOING THROUGH THEM. WAS IT A LITTLE ENVELOPE OR A BIG ENVELOPE?

MR. ESFANDIARI: I BELIEVE -- I DON'T RECALL HOW EXACTLY THEY CAME IN. MEDTRONIC DID IDENTIFY THE EXHIBITS IN THEIR NOTICE WHERE THEY SAID THEY OBJECTED TO -- THEY WANTED TO MAINTAIN THESE DOCUMENTS UNDER SEAL.

THE COURT: I WILL GO BACK.

MR. ESFANDIARI: THEY INCLUDED, FOR EXAMPLE, DR. LANMAN'S FINANCIAL INFORMATION, WHICH I THINK CERTAINLY DESERVES TO REMAIN UNDER SEAL, YOUR HONOR.

THE COURT: OKAY. ALL RIGHT.

MR. BROWN: THANK YOU, YOUR HONOR.

(THE PROCEEDINGS WERE CONCLUDED.)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 14 HON. TERRY A. GREEN, JUDGE

APRIL CHRISTINE CABANA, PLAINTIFF, VS. STRYKER BIOTECH LLC, ET AL., DEFENDANTS.	)	NO. BC465313 REPORTER'S CERTIFICATE

I, KAREN ALGORRI, OFFICIAL REPORTER OF THE SUPERIOR COURT OF THE STATE OF CALIFORNIA, FOR THE COUNTY OF LOS ANGELES, DO HEREBY CERTIFY THAT I DID CORRECTLY REPORT THE PROCEEDINGS CONTAINED HEREIN AND THAT THE FOREGOING PAGES 1 THROUGH 84, INCLUSIVE, COMPRISE A FULL, TRUE, AND CORRECT TRANSCRIPT OF THE PROCEEDINGS AND TESTIMONY TAKEN IN THE MATTER OF THE ABOVE-ENTITLED CAUSE ON MONDAY, SEPTEMBER 9, 2013.

DATED THIS 13TH DAY OF SEPTEMBER, 2013.

KAREN ALGORRI, CSR NO. 8319
OFFICIAL REPORTER