

MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 16, 2019

JS-10: 07:00

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL

NO. 16-2740

This document relates to:
Civil Action: 16-17144
Barbara Earnest
v. Sanofi S.A. et al

SECTION "H"(5)

JURY TRIAL - Day 1
Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS
LAW CLERK: SAMANTHA SCHOTT
COURT REPORTER: CATHY PEPPER/JODI SIMCOX

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID F. MICELI, KAREN MENZIES, & KYLE BACHUS, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Oath on Voir Dire is administered to prospective jurors.

Court begins at 8:40 a.m.

Case called.

Voir Dire examination by the Court.

Counsel conduct voir dire.

Jury of 8 selected, sworn and instructed.

Court recess at 1:00 p.m. – 2:00 p.m.

Opening statements presented by Counsel.

Jury out.

Plaintiffs make objections to statements made Defense counsel during openings. –
Ruling is deferred.

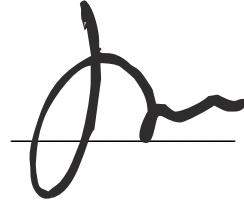
Jury in.

FRANCES POLIZZANO: Testimony by video deposition.

Jury out.

EXHIBIT: PX 192 & PX 556 offered and admitted into evidence.

Court recessed at 4:40 pm until 8:30 a.m. September 17, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 17, 2019

JS-10: 07:30

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL

NO. 2740

This document relates to:

Civil Action: **16-17144**

SECTION "H"(5)

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL - Day 2

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS

LAW CLERK: SAMANTHA SCHOTT

COURT REPORTER: CATHY PEPPER(A.M.)/JODI SIMCOX(P.M.)

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, & KYLE BACHUS, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Trial resumes at 8:35 a.m.

Objections made on the record outside jury presence.

A proposed jury instruction is tendered to the Court as Plaintiff Proffer 1.

All jurors present.

Additional jury instruction given to the jury by the court.

AMY FREEDMAN: Testimony by video deposition.

EXHIBIT: PX 175 offered and admitted into evidence.

DAVID KESSLER, M.D., J.D.: Testifies under oath in open Court. Dr. Kessler is accepted by the Court as an expert in the fields of FDA regulation, drug standards and labeling of drugs and medical devices, as well as a medical expert in the fields of epidemiology and biostatistics.

EXHIBIT: PX 200, PX 320, PX 396 offered and admitted into evidence.

Court recessed at 12:00 Noon – 1:00 p.m.

Testimony of Dr. Kessler continues.

EXHIBIT: DX-31, DX-215, DX-317 offered and admitted into evidence.

Jury out.

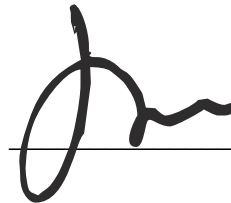
Additional testimony of Dr. Kessler is proffered along with the following exhibits:

DX-76 as Defense Proffer 1

DX-102 as Defense Proffer 2

DX-272 as Defense Proffer 3

Court recessed at 5:05 pm until 8:30 a.m. September 18, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 18, 2019

JS-10: 09:05

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)

MDL

This document relates to:

NO. 2740

Civil Action: **16-17144**

Barbara Earnest

v. Sanofi S.A. et al

SECTION "H"(5)

JURY TRIAL - Day 3

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS

LAW CLERK: SAMANTHA SCHOTT

COURT REPORTER: CATHY PEPPER(A.M.)/JODI SIMCOX(P.M.)

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, & KYLE BACHUS, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Trial resumes at 8:35 a.m.

All jurors present.

RUTH MORA AVILA: Testifies under oath in open Court.

EXHIBIT: DX 5 & DX 570 offered and admitted into evidence.

DAVID MADIGAN, Ph.D.: Testifies under oath in open Court. - Dr. Madigan is accepted by the Court as an expert in the fields of biostatistics, statistics, pharmacovigilance & safety.

EXHIBIT: PX 1231 offered and admitted into evidence.

Court recessed 11:45 a.m. – 12:50 p.m.

Testimony of Dr. Madigan continues.

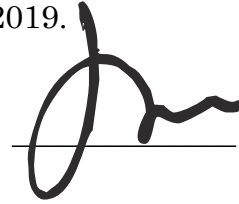
JEAN-PHILIPPE AUSSEL: Testimony by video deposition.

LAURA M. PLUNKETT, Ph.D, DABT: Testifies under oath in open Court. – Dr. Plunkett is accepted by the Court as an expert in the fields on pharmacology, toxicology, and risk assessment.

Court recess 5:30 p.m. - 5:45 p.m.

EXHIBIT: DX 388(D) offered and admitted into evidence.

Court recessed at 7:00 pm until 9:00 a.m. September 19, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 19, 2019

JS-10: 06:33

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

Civil Action: 16-17144

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL – Day 4

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS

LAW CLERK: SAMANTHA SCHOTT

COURT REPORTER: CATHY PEPPER/JODI SIMCOX

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, & KYLE BACHUS, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Trial resumes at 09:05 a.m.

EXHIBIT: PX 11, PX 131, PX 141, PX 185, & PX 526 admitted into evidence under Dr. Aussel's testimony.

All jurors present.

ANTONELLA TOSTI, M.D.: Testifies under oath in open Court. – The Court accepts Dr. Tosti as an expert in the fields of dermatology, hair, hair disorders, lack of hair regrowth, diagnoses of permanent chemotherapy induced alopecia.

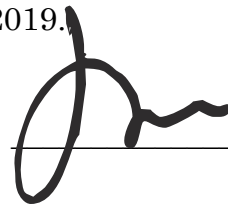
Court recessed 12:08 p.m. – 1:15 p.m.
Testimony of Dr. Tosti continues.

Court recess 3:05 p.m. – 3:20 p.m.

MICHAEL EARNEST: Testifies under oath in open Court.
EXHIBIT: DX 2034 & DX 2369 offered and admitted into evidence.

ELLEN FEIGAL, M.D.: Testifies under oath in open Court. - Dr. Feigal is accepted by the Court as an expert in the fields of clinical research, clinical study, design & interpretation & general causation.

Court recessed at 5:00 pm until 8:30 a.m. September 20, 2019.

A handwritten signature in black ink, appearing to be 'J. Feigal', written over a horizontal line.

MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 20, 2019

JS-10: 05:38

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

Civil Action: 16-17144

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL – Day 5

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS

LAW CLERK: SAMANTHA SCHOTT

COURT REPORTER: CATHY PEPPER/JODI SIMCOX

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, & KYLE BACHUS, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Trial resumes at 08:30 a.m.

All jurors present.

Testimony of expert witness, **Dr. Ellen Feigal**, continues.

Court recess 10:23 a.m. – 10:40 a.m.

LINDA BOSSERMAN, MD: Testifies under oath in open Court. – Dr. Bosserman is accepted by the Court as an expert in the fields of breast cancer diagnosis, breast cancer treatment & management of breast cancer treatment, treatment options & guidelines for breast cancer, & general care for physicians informing patients through the decision making process.

EXHIBIT: PX 1878 offered and admitted into evidence.

Court recess 11:45 a.m. – 12:45 p.m.

MICHAEL KOPRESKI, M.D.: Testifies by video deposition.

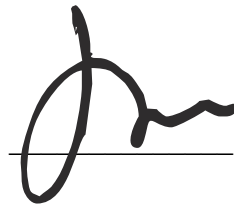
EXHIBIT: PX 205 offered and admitted into evidence.

Court recess 2:30 p.m. – 2:50 p.m.

MARIE LAGARDE, M.D.: Testifies under oath in open Court.

EXHIBIT: DX 2365 & PX 633 offered and admitted into evidence.

Court recessed at 3:45 p.m. until 8:30 a.m. on Monday, September 23, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 23, 2019

JS-10: 07:15

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

Civil Action: 16-17144

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL – Day 6

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS

LAW CLERK: SAMANTHA SCHOTT/EMMY SCHROETER

COURT REPORTER: KAREN IBOS/TONI TUSA

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, & KYLE BACHUS, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Trial resumes at 08:35 a.m.

All jurors present.

JAMES CARINDER, MD: Testifies under oath in open Court.

EXHIBIT: PX 621 offered and admitted into evidence.

Court recess 12:05 p.m. – 1:15 p.m.

Cross Examination of **Dr. Carinder** by defense counsel.

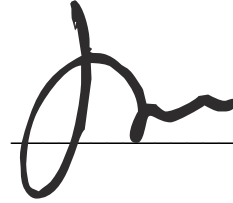
EXHIBIT: PX 28 offered and admitted into evidence.

Redirect of **Dr. Carinder** by plaintiff's counsel.

LESLIE FIERRO: Testifies by video deposition.

EXHIBIT: PX 30, PX 492, & PX 546 offered and admitted into evidence.

Court recessed at 5:00 p.m. until 8:30 a.m. on Tuesday, September 24, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 24, 2019

JS-10: 06:25

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

Civil Action: 16-17144

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL – Day 7

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS
LAW CLERK: SAMANTHA SCHOTT
COURT REPORTER: KAREN IBOS/TONI TUSA

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, KYLE BACHUS, ANDRE MURA, FOR PLAINTIFF HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, FOR DEFENDANTS

Trial resumes at 08:45 a.m.

All jurors present.

RALPH EARNEST, SR.: Testifies under oath in open Court.

EXHIBIT: PX 624 & DX 2058 offered and admitted into evidence.

MICHAEL KOPRESKI: Testifies by video deposition.

EXHIBIT: PX 32, PX 180, PX 199, PX 250 offered and admitted into evidence.

Court recess 10:12 a.m. – 10:32 a.m.

BARBARA EARNEST: Testifies under oath in open Court.

EXHIBIT: PX 649, PX 645, PX 651, PX 654, PX 655 offered and admitted into evidence.

Court recessed 12:15 p.m.

PLAINTIFF PROFFER 2: Plaintiff proffers previously excluded testimony, via sustained objections to and/or Motion in Limine rulings on Plaintiff's designated deposition testimony and all exhibits provided to the Court in labeled binders as to the following witnesses:

- 1) Frances Polizzano
- 2) Amy Freedman
- 3) Intouch Solutions (third party witness), through its corporate representative, Matthew Goyer & Sanofi employees, Leslie Fierro & Madeline Malia
- 4) Paul Chew
- 5) Nanae Hangai
- 6) Michael Kopreski
- 7) Jean-Philippe Aussel

Court in session 1:15 p.m.

Cross-examination of **Mrs. Earnest** continues.

EXHIBIT: DX 571 & DX 2434.1, offered and admitted into evidence.

Redirect of **Mrs. Earnest** by plaintiff's counsel.

Portions of Dr. Bianchini's deposition testimony is read onto the record to the jury after the parties received instruction by the Court.

Plaintiffs rest.

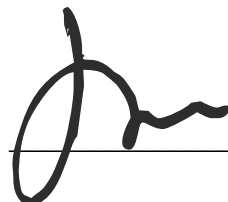
Jury Out.

Defense move for Motions for Judgment as a Matter of Law for reasons stated orally on the record.

Plaintiff counsel argues the Motions.

The Court DEFERS ruling on the Motions.

Court recessed at 4:30 p.m. until 8:30 a.m. on Wednesday, September 25, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 25, 2019

JS-10: 06:20

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

Civil Action: 16-17144

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL – Day 8

Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS
LAW CLERK: SAMANTHA SCHOTT
COURT REPORTER: KAREN IBOS/TONI TUSA

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, KYLE BACHUS, ANDRE MURA, DAN MARKOFF, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, ADRIENNE BYARD, FOR DEFENDANTS

Trial resumes at 9:00 a.m.

All jurors present.

Defense witnesses:

MICHAEL KOPRESKI: Testifies by video deposition.

Additional jury instructions given to jury by the Court:

Dr. Kopreski has not been tendered or qualified by this court as an expert.

Tamoxifen is not related to any issue in this lawsuit.

Dr. Kopreski deposition exhibits are discussed on the record outside the presence of jury.

Jury in.

JOHN GLASPY, M.D.: Testifies under oath in open Court. – Dr. Glaspy is accepted by the Court as an expert in the fields of oncology, breast cancer care & treatment, labelling, risk information for chemotherapy, clinical trials, informed consent & side effects of chemotherapy.

Recess 11:50 a.m. – 1:10 p.m.

EXHIBIT: DX-401.I offered and admitted into evidence.

Defense rests.

Jury Out at 4:40 p.m.

EXHIBIT: DX-381.E, DX-381.G, DX-381.L, after the parties reached a stipulation, and DX-381.N admitted into evidence all under Dr. Kopreski's deposition.

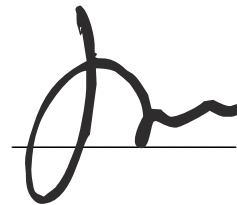
Defense Proffer:

DEFENSE PROFFER 4: *DX-381.K*

DEFENSE PROFFER 5: *DX-381.M*

DEFENSE PROFFER 6: Defendants proffer previously excluded testimony and exhibits via Motion in Limine rulings.

Court recessed at 5:30 p.m. until 8:30 a.m. Thursday, September 26, 2019.

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MINUTE ENTRY
MILAZZO, J.
SEPTEMBER 26, 2019

JS-10: 03:41

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

Civil Action: 16-17144

Barbara Earnest

v. Sanofi S.A. et al

JURY TRIAL – Day 9 (FINAL)
Judge Jane Triche Milazzo presiding

CASE MANAGER: ERIN MOULEDOUS

LAW CLERK: SAMANTHA SCHOTT

COURT REPORTER: KAREN IBOS

APPEARANCES: DARIN SCHANKER, RAND NOLEN, CHRIS COFFIN, DAWN BARRIOS, PALMER LAMBERT, DAVID MICELI, KAREN MENZIES, KYLE BACHUS, ANDRE MURA, DAN MARKOFF, FOR PLAINTIFF
HILDY SASTRE, JOHN STRONGMAN, DOUGLAS MOORE, HARLEY RATLIFF, ADRIENNE BYARD, ILANA EISENSTEIN, FOR DEFENDANTS

Trial resumes at 8:38 a.m.

Parties make motions and argument outside presence of jury:

- Plaintiff moves for Motion to Reopen the Evidence as to the testimony of Barbara Earnest. – **DENIED** by the Court
- Plaintiff moves for Motion for Mis-Trial on defense's violations of Motion in Limine rulings. – **DENIED** by the Court.
- Objections made on the record as to jury charge and verdict form.
- Defendants re-urge their Motion for Judgment as a Matter of Law. – **DEFERRED** - The Court will consider written submissions after a verdict is reached.

After hearing argument from the parties, the Court instructs the clerk that exhibit DX-2331 (Hand written note allegedly written by Dr. Bianchini) will not be admitted into evidence.

All jurors present.

Closings arguments.

Jury charged.

Jury exits to begin deliberation at 12:06 p.m.

JOINT PROFFER 1: The parties have agreed that exhibit PX-250 will not be shown to the jury but instead submitted as a proffer.

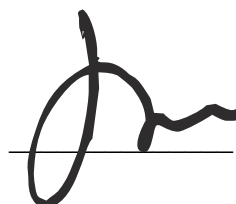
JOINT PROFFER 2: The parties have agreed to a stipulation with regards to a proffer of proposed testimony of Barbara Earnest as set forth on record.

Jury returns with a verdict at 2:47 p.m.

The verdict is read in open Court by the clerk and filed in the record. - **Judgment in accordance with the verdict to follow.**

Jurors are thanked and dismissed.

Court adjourned at 3:00 p.m.

A handwritten signature in black ink, appearing to be 'Jm', is written above a horizontal line.

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

BARBARA EARNEST

CIVIL ACTION

VERSUS

NO: 16-17144

**SANOFI AVENTIS U.S. LLC and
SANOFI US SERVICES, INC.**

SECTION "H" (5)

JURY CHARGE

Members of the jury:

It is my duty and responsibility to instruct you on the law you are to apply in this case. The law contained in these instructions is the only law you may follow. It is your duty to follow what I instruct you the law is, regardless of any opinion that you might have as to what the law ought to be.

If I have given you the impression during the trial that I favor either party, you must disregard that impression. If I have given you the impression during the trial that I have an opinion about the facts of this case, you must disregard that impression. You are the sole judges of the facts of this case. Other than my instructions to you on the law, you should disregard anything I may have said or done during the trial in arriving at your verdict.

You should consider all of the instructions about the law as a whole and regard each instruction in light of the others, without isolating a particular statement or paragraph.

The testimony of the witnesses and other exhibits introduced by the parties constitute the evidence. The statements of counsel are not evidence; they are only arguments. It is important for you to distinguish between the

arguments of counsel and the evidence on which those arguments rest. What the lawyers say or do is not evidence. You may, however, consider their arguments in light of the evidence that has been admitted and determine whether the evidence admitted in this trial supports the arguments. You must determine the facts from all the testimony that you have heard and the other evidence submitted. You are the judges of the facts, but in finding those facts, you must apply the law as I instruct you.

You are required by law to decide the case in a fair, impartial, and unbiased manner, based entirely on the law and on the evidence presented to you in the courtroom. You may not be influenced by passion, prejudice, or sympathy you might have for the plaintiff or the defendant in arriving at your verdict.

BURDEN OF PROOF

Plaintiff Barbara Earnest has the burden of proving her case by a preponderance of the evidence. To establish by a preponderance of the evidence means to prove something is more likely so than not so. If you find that the plaintiff has failed to prove any element of her claim by a preponderance of the evidence, then she may not recover on that claim.

EVIDENCE

The evidence you are to consider consists of the testimony of the witnesses, the documents and other exhibits admitted into evidence, and any fair inferences and reasonable conclusions you can draw from the facts and circumstances that have been proven.

Generally speaking, there are two types of evidence. One is direct evidence, such as testimony of an eyewitness. The other is indirect or circumstantial evidence. Circumstantial evidence is evidence that proves a fact

from which you can logically conclude another fact exists. As a general rule, the law makes no distinction between direct and circumstantial evidence, but simply requires that you find the facts from a preponderance of all the evidence, both direct and circumstantial.

WITNESSES

You alone are to determine the questions of credibility or truthfulness of the witnesses. In weighing the testimony of the witnesses, you may consider the witness's manner and demeanor on the witness stand, any feelings or interest in the case, or any prejudice or bias about the case, that he or she may have, and the consistency or inconsistency of his or her testimony considered in the light of the circumstances. Has the witness been contradicted by other credible evidence? Has he or she made statements at other times and places contrary to those made here on the witness stand? You must give the testimony of each witness the credibility that you think it deserves.

Even though a witness may be a party to the action and therefore interested in its outcome, the testimony may be accepted if it is not contradicted by direct evidence or by any inference that may be drawn from the evidence, if you believe the testimony.

You are not to decide this case by counting the number of witnesses who have testified on the opposing sides. Witness testimony is weighed; witnesses are not counted. The test is not the relative number of witnesses, but the relative convincing force of the evidence. The testimony of a single witness is sufficient to prove any fact, even if a greater number of witnesses testified to the contrary, if after considering all of the other evidence, you believe that witness.

EXPERT WITNESSES

When knowledge of technical subject matter may be helpful to the jury, a person who has special training or experience in that technical field is permitted to state his or her opinion on those technical matters. However, you are not required to accept that opinion. As with any other witness, it is up to you to decide whether to rely on it.

NO INFERENCE FROM FILING SUIT

The fact that a person brought a lawsuit and is in court seeking damages creates no inference that the person is entitled to a judgment. Anyone may make a claim and file a lawsuit. The act of making a claim in a lawsuit, by itself, does not in any way tend to establish that claim and is not evidence.

STIPULATIONS OF FACT

A “stipulation” is an agreement. When there is no dispute about certain facts, the attorneys may agree or “stipulate” to those facts. You must accept a stipulated fact as evidence and treat that fact as having been proven here in court.

Plaintiff Barbara Earnest and Defendant Sanofi have stipulated to the following facts:

1. For the purposes of this trial, Taxotere and docetaxel mean the same thing.
2. Defendant is the “manufacturer” of the Taxotere/docetaxel administered to Mrs. Earnest within the meaning of the Louisiana Products Liability Act (“LPLA”).

3. The use of Taxotere to treat Barbara Earnest's breast cancer in 2011 was a reasonably anticipated use of the product within the meaning of the LPLA.
4. Mrs. Earnest filed this action against Sanofi on December 12, 2016.

DEPOSITION TESTIMONY

Certain testimony has been presented to you through depositions. A deposition is the sworn, recorded answers to questions a witness was asked in advance of the trial. Under some circumstances, if a witness cannot be present to testify from the witness stand, that witness's testimony may be presented, under oath, in the form of a deposition. Some time before this trial, attorneys representing the parties in this case questioned these witnesses under oath. A court reporter was present and recorded the testimony. The questions and answers have been shown to you. This deposition testimony is entitled to the same consideration and is to be judged by you as to credibility as if the witnesses had been present and had testified from the witness stand in court.

CHARTS AND SUMMARIES

Certain charts, summaries and demonstrative aids have been shown to you solely to help explain or summarize the facts disclosed by the evidence. These charts, summaries and demonstrative aids are not evidence or proof of any facts. You should determine the facts from the evidence.

BIAS-CORPORATE PARTY INVOLVED

Do not let bias, prejudice or sympathy play any part in your deliberations. A corporation and all other persons are equal before the law and must be treated as equals in a court of justice.

INSTRUCTIONS

Let me now discuss the law specifically applicable to this case.

As you know, this action arises out of Barbara Earnest's use of Taxotere. Sanofi is the manufacturer of Taxotere. Mrs. Earnest contends that Taxotere prevented her hair from growing back, and that she now has permanent hair loss on her head, eyebrows, eyelashes, and other areas that was caused by Taxotere. Mrs. Earnest also asserts that Sanofi, the manufacturer of Taxotere, did not warn her doctor, Dr. Carinder, about the risk of permanent hair loss associated with Taxotere. Mrs. Earnest seeks damages for her injuries from Sanofi.

Sanofi denies these allegations and contends that it provided adequate warnings to Mrs. Earnest's doctor. Sanofi contends that Taxotere did not cause Mrs. Earnest's alleged injury. Sanofi contends that the approved prescribing information contained accurate, science-based information that enabled Mrs. Earnest's doctor to make an informed decision about the benefits and risks of using Taxotere.

LOUISIANA PRODUCTS LIABILITY ACT

The law applicable to this case is the law of Louisiana. In Louisiana, a products liability action such as this one is governed by the Louisiana Products Liability Act or "LPLA." The LPLA provides that the manufacturer of a product shall be liable to a plaintiff for damage proximately caused by one or more characteristics of the product that render it unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the plaintiff. One of the ways in which a drug can be unreasonably dangerous is by failing to include adequate warnings. In order to recover, the Plaintiff in this case must show that (1) her damages were proximately caused by Defendants'

failure to provide adequate warnings about one or more characteristics of the product that render it unreasonably dangerous, and that (2) her damages arose from a reasonably anticipated use of the product.

REASONABLY ANTICIPATED USE

A “reasonably anticipated use” of a product means a use or handling of a product that the manufacturer should reasonably expect, in this case by a prescribing or treating physician. The parties have stipulated that Mrs. Earnest’s use of Taxotere was a reasonably anticipated use of the product.

LIABILITY BASED ON INADEQUATE WARNING

In order to decide Plaintiff’s failure to warn claim, you must determine whether the Plaintiff has proven by a preponderance of the evidence that Defendants failed to adequately warn Ms. Earnest’s prescribing physician, Dr. Carinder, and, if so, whether Defendants’ failure to warn was a proximate cause of Ms. Earnest’s injuries.

Plaintiff claims that Taxotere is unreasonably dangerous because of inadequate warnings about its potential risk of permanent alopecia.

In order to be successful, Plaintiff must prove by a preponderance of the evidence that:

- (1) Taxotere had a potentially damage-causing characteristic;
- (2) Sanofi failed to use reasonable care to provide an adequate warning to the plaintiff’s prescribing physician about this characteristic and its danger to users of the product;
- (3) Mrs. Earnest’s injuries were proximately caused by an inadequate warning; and

(4) The injury Mrs. Earnest suffered arose from a reasonably anticipated use of the product.

“ADEQUATE WARNING” DEFINITION

An “adequate warning” under the LPLA is defined as a “warning [...]that would lead an ordinary reasonable user or handler of a product such as a prescribing physician to contemplate the danger in using or handling the product and either to decline to use or handle the product, or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made.”

There are certain circumstances, however, under which a manufacturer does not have to provide an adequate warning as described above. A manufacturer does not have to provide such a warning when the prescribing physician already knows or reasonably should be expected to know of the dangerous characteristic of the product that may cause injury.

A manufacturer of a product shall not be liable for damage proximately caused by a characteristic of the product if, at the time the product left the manufacturer’s control, it did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic.

FDA APPROVAL AND LABELING

The FDA is a regulatory body of the United States, and Sanofi is a pharmaceutical company. Pharmaceutical companies are heavily regulated by the FDA. The FDA, however, does not bear the primary responsibility for

creating or updating a drug's label. It is the drug manufacturer who bears the responsibility for the content of its label. In creating or updating a label, the pharmaceutical companies must comply with regulations of the FDA. However, FDA approval, although relevant, does not in and of itself absolve the Defendants of all liability nor does it establish that the warnings provided with the drug were adequate under the standards of Louisiana law.

LEARNED INTERMEDIARY DOCTRINE

Louisiana applies the “learned intermediary” doctrine to warnings cases involving prescription drugs. A drug manufacturer has a duty to provide an adequate warning only to a “learned intermediary,” such as the prescribing physician. It does not have a duty to provide any warning directly to the patient. This is because physicians are generally in a superior position to evaluate the warning and to impart such warning to the patient, and can provide an independent medical decision as to whether use of the drug is appropriate for a particular patient. Although a drug manufacturer's duty to warn about the potential risks of its product is directed only to the physician, the manufacturer is directly liable to the patient for breach of this duty.

The warning must both lead the physician to contemplate the risks in using the product and to (1) advise the patient or (2) decline to use it.

In determining the scope of a manufacturer's duty to warn of risks and dangers of its products, the manufacturer is held to the knowledge and skill of an expert in its field. The manufacturer must keep up with scientific knowledge, discoveries, and advances and is presumed to know what could be learned by doing so. This duty is continuing. If the manufacturer learns of a characteristic or danger that may cause injury after its product is on the market, the manufacturer has a continuing duty to use reasonable care to

provide adequate warning to prescribing and treating physicians concerning such later-discovered matters. That is to say, under the law applicable to this case, drug manufacturers are responsible to draft the initial label for their product, and they have a continuing duty to ensure that the label remains adequate at all times.

It is a physician's duty to remain abreast of a medication's characteristics and to take into account the information contained in a prescription medication's label. The manufacturer may reasonably assume that the prescriber or treater will apply the same knowledge, professional expertise, and good judgment that a reasonable physician would apply in using the product. Providing an adequate warning to the prescribing or treating doctor relieves the manufacturer of its duty to warn the patient regardless of how or if the prescriber or treater warns the patient.

CAUSATION

In order for Plaintiff to prevail on her claims, she must establish that the inadequate warning was the "proximate cause" of Mrs. Earnest's alleged injuries.

Proximate cause means the efficient or direct cause. The law defines proximate cause as something that produces a natural chain of events which, in the end, brings about the injury. In other words, proximate cause is the cause without which the injury would not have occurred. Proximate cause requires proof of both causation-in-fact and legal cause.

Causation-in-fact is proved by establishing that a Plaintiff's injury would not have occurred "but for" the Defendants' actions. In order to prove cause-in-fact in this case, the Plaintiff must show to a reasonable degree of medical probability that Taxotere can cause permanent hair loss, that Taxotere caused

permanent hair loss for Mrs. Earnest, and that the failure to warn Dr. Carinder was the cause of Mrs. Earnest's injury.

Legal cause is proved by establishing foreseeability. The test of foreseeability is whether some injury to another is the natural and probable consequence of the complained-of conduct. The law requires only reasonable foresight. It is not necessary for the Plaintiff to demonstrate that the Defendant should have foreseen the particular event which occurred, but merely that the Defendant should have foreseen that its actions would probably cause injury to someone. The Plaintiff proves legal cause by establishing that the injury in question occurred as a natural and probable consequence of the Defendants' actions or inactions.

Proximate cause does not mean the sole cause. The Defendants' conduct can be a proximate cause if it was at least one of the direct, concurring causes of the alleged injury. However, Plaintiff must show that Defendants' conduct was a substantial contributing factor in bringing about the result. In other words, it is not necessary for Plaintiff to negate all other contributing factors or causes of Mrs. Earnest's injuries, provided they show that Defendants' failure to provide an adequate warning in the Taxotere label substantially contributed to her injuries. Where two or more possible causes for an injury are identified, Plaintiff must establish with reasonable probability that Mrs. Earnest's injury resulted from a cause for which Defendants would be liable. Moreover, Plaintiff must proffer a competent medical expert to testify to a reasonable degree of medical probability that Taxotere was a proximate cause of Mrs. Earnest's injuries.

To recover for the failure-to-warn claim, Plaintiff must prove by a preponderance of the evidence that an inadequate warning itself – in addition to the medication – was the proximate cause of Mrs. Earnest's injury. In other

words, Plaintiff must prove by a preponderance of the evidence that, if an adequate warning had accompanied Taxotere, then Dr. Carinder would have altered his prescribing or treating decision or behavior and Mrs. Earnest would not have suffered her injury.

DAMAGES – GENERAL INSTRUCTION

If you decide that the Plaintiff has established the other elements of her case by a preponderance of the evidence, you must decide the question of whether there has been damage to Plaintiff and if so, the amount of that damage. Louisiana law suggests simple reparation is a just and adequate compensation for injuries. Your award should be designed to fully and fairly compensate the Plaintiff for her injury, if you find one has occurred, and should not go beyond such reparation.

The law recognizes the difficulty of translating personal injuries into a dollars and cents figure, but that is what must be done if you decide Plaintiff has proven her claims by a preponderance of the evidence. You must arrive at a figure that will fairly and adequately compensate the Plaintiff for damages she has suffered. In estimating such damages, you may take into consideration the following elements:

- (1) physical injury;
- (2) pain and suffering;
- (3) loss of enjoyment of life; and
- (4) permanent disability, if any.

Like other parts of the Plaintiff's case, these damages must be established by a preponderance of the evidence. This means, on the one hand, you are not entitled to award speculative damages for injuries which you think the Plaintiff might have experienced or might experience in the future. On the

other hand, it means that you may also make an effort to reasonably approximate the damages which the Plaintiff has proved are more probable than not, even though they cannot be computed with mathematical certainty.

You may award compensatory damages only for injuries that plaintiffs prove were caused by defendants' wrongful conduct. The damages you award must be fair compensation for plaintiffs' damages, no more and no less. Compensatory damages are not allowed as punishment and cannot be imposed or increased to penalize defendants.

If you decide to award compensatory damages, you should be guided by dispassionate common sense. That is to say, you should not be affected by sympathy, compassion, prejudice, or bias. Computing damages may be difficult, but you must not let that difficulty lead you to engage in arbitrary guesswork. On the other hand, the law does not require plaintiffs to prove the amount of their losses with mathematical precision, but only with as much definiteness and accuracy as the circumstances permit.

You must use sound discretion in fixing and award of damages, drawing reasonable inferences where you find them appropriate from the facts and circumstances in evidence.

In reaching a verdict on the question of damages, I caution you not to include anything for the payment of expenses and attorney fees; the law does not consider these as damages experienced by the Plaintiff. If you decide to make an award, follow the instructions I have given you, and do not add or subtract from that award on account of federal or state income taxes.

Finally, let me say that the fact that I have given you these statements about the law of damages does not in any way imply or suggest that I feel or do not feel that any damages are due in this case. Whether or not damages are due is solely for you to determine.

MENTAL ANGUISH

The law recognizes that a plaintiff may experience mental distress and anguish as a result of an injury. You are permitted to consider such consequences as a part of the general damages which you may award. By “mental distress and anguish,” I mean substantial worry or concern, grief and the like.

STATEMENTS BY COUNSEL AS TO DAMAGE

As I have mentioned to you, there is no practical way to introduce evidence as to the general damages which plaintiff claims for pain and suffering and for mental distress. There is no precise standard to fix these damages or assign some kind of value to them. Rather, your job is to determine an amount that will be fair and just on the basis of evidence of plaintiff's injury and treatment that you have heard, and that will fairly compensate plaintiff for any damage he may have suffered.

STATUTE OF LIMITATIONS – ACTUAL OR CONSTRUCTIVE KNOWLEDGE

In this case, it is necessary for you to determine whether the Plaintiff had actual or constructive knowledge of facts indicating to a reasonable person that she was the victim of a tort on or before December 12, 2015. This occurs when the Plaintiff has actual or constructive knowledge of a causal relationship between the object or product and the injury. There is no requirement that a patient be informed by an attorney or physician of a possible claim before prescription begins to run. Rather, prescription begins to run when there is enough notice to call for an inquiry about a claim, not when an inquiry reveals the facts or evidence that specifically outline the claim. The ultimate issue is the reasonableness of the Plaintiff's action or inaction, in light

of her education, intelligence, the severity of the symptoms, and the nature of the Defendant's conduct.

DUTY TO DELIBERATE; NOTES

It is now your duty to deliberate and to consult with one another in an effort to reach a verdict. Each of you must decide the case for yourself, but only after an impartial consideration of the evidence with your fellow jurors. During your deliberations, do not hesitate to re-examine your own opinions and change your mind if you are convinced that you were wrong. But do not give up on your honest beliefs because the other jurors think differently, or just to finish the case.

Remember at all times, you are the judges of the facts. You have been allowed to take notes during this trial. Any notes that you took during this trial are only aids to memory. If your memory differs from your notes, you should rely on your memory and not on the notes. The notes are not evidence. If you did not take notes, rely on your independent recollection of the evidence and do not be unduly influenced by the notes of other jurors. Notes are not entitled to greater weight than the recollection or impression of each juror about the testimony.

When you go into the jury room to deliberate, you may take with you a copy of this charge, the exhibits that I have admitted into evidence, and your notes. You must select a jury foreperson to guide you in your deliberations and to speak for you here in the courtroom.

Your verdict must be unanimous. After you have reached a unanimous verdict, your jury foreperson must fill out the answers to the written questions on the verdict form and sign and date it. After you have concluded

your service and I have discharged the jury, you are not required to talk with anyone about the case.

If you need to communicate with me during your deliberations, the jury foreperson should write the inquiry and give it to the court security officer. After consulting with the attorneys, I will respond either in writing or by meeting with you in the courtroom. Keep in mind, however, that you must never disclose to anyone, not even to me, your numerical division on any question.

You may now proceed to the jury room to begin your deliberations.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:
Civil Action: 16-17144
Barbara Earnest
v. Sanofi S.A. et al

CERTIFICATION OF TRIAL EXHIBITS FOR JURY DELIBERATION

I have reviewed the exhibits admitted during the September 16-26, 2019 trial of this matter and certify that those being sent to the Jury Room should be used by the Jury during their deliberation in this case.

9/26/19
Date

Dawn Barrios
Plaintiff's counsel

9/26/2019
Date

Kelly A. Bland
Defendant's counsel

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 16-2740

SECTION: "H" (5)

This document relates to:

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Barbara Earnest

v. Sanofi S.A. et al

NOTICE FOR REMOVAL OF EXHIBITS

Pursuant to Rule 79.3 of the Local Rules of this Court, all exhibits in the custody of the Clerk will be destroyed after 35 days from final disposition of the case.

LOCAL RULE 79.3 states "All exhibits in the custody of the Clerk shall be removed within 35 days of the final disposition of the case. The party offering exhibits shall be responsible for their removal and shall give a detailed receipt for the Clerk's records. If the parties or their attorneys fail or refuse to remove exhibits within 35 days, the exhibits may be destroyed or otherwise disposed of by the Clerk."

Distributed this 26th day of September, 2019

BY: s/Erin Mouledous
Case Manager