

KATHRYN FLOR

Plaintiff,

v.

MYLAN BERTEK
PHARMACEUTICALS, INC., f/k/a
BERTEK PHARMACEUTICALS, INC.;
MYLAN PHARMACEUTICALS, INC.;
MYLAN, INC. f/k/a MYLAN
LABORATORIES, INC.;
CARDINAL HEALTH 409, INC.
f/k/a R.P. SCHERER CORPORATION;
and GENPHARM

Defendants

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY

DOCKET NO. ATL-L-3795-07

CIVIL ACTION

**APPLICABLE TO ALL
CONSOLIDATED CASES**

PLAINTIFF'S FACT SHEET

Plaintiff: _____
(name)

This Fact Sheet and the attached List of Medical Providers and Other Sources of Information must be completed by each plaintiff who has used isotretinoin or their personal representative. In filling out this form, please use the following definitions:

(1) "Health care provider" means any hospital, clinic, center, physician's office, infirmary, medical or diagnostic laboratory, or other facility that provides medical, dietary, psychiatric, mental, emotional or psychological care or advice, and any pharmacy, counselor, dentist, X-ray department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, physician, psychiatrist, osteopath, homeopath, chiropractor, psychologist, therapist, nurse, herbalist, nutritionist, dietician or other persons or entities involved in the evaluation, diagnosis, care and/or treatment of you or your decedent;

(2) "Document" means any writing or record or any type, however produced and whatever the medium on which it was produced or reproduced, and includes, without limitation,

the original and any non-identical copy (whether different from the original because of handwritten notes or underlining on the copy or otherwise) and all drafts of papers, letters, telegrams, telexes, notes, notations, memoranda of conversations or meeting, calendars, diaries, minutes of meetings, interoffice communications, electronic mail, message slips, notebooks, agreements, reports, articles, books, tables, charts, schedules, memoranda, medical records, x-rays, advertisements, pictures, photographs, films, accounting books or records, billings, credit card records, electrical or magnetic recordings or tapes, or any other writings, recordings, or pictures of any kind of description.

(3) **“Isotretinoin”** means any and all forms of the prescription drug generically known as isotretinoin, including Claravis®, Sotret®, Amnesteem®, and other branded or non-branded versions or forms of isotretinoin, including, but not limited to, Accutane®.

(4) **“Primary care physician”** means the physician or health care provider whom you consult initially for diagnosis and treatment of any condition and upon whom you rely for referrals to specialists or other health care providers, including, but not limited to, physicians designated as your primary care physicians under any health or medical insurance plan.

I. CASE INFORMATION

A. Name of person completing this form: _____

B. Please state the following for the civil action which you filed:

1. Case Caption: _____

2. Case No.: _____

3. Please state the name, address, and telephone number of the principal attorney representing you:

Name

Firm

City, State and Zip Code

Telephone number

4. When did you first contemplate obtaining an attorney regarding any injury(ies) which you now allege is (are) associated with isotretinoin?

5. When did you first contact an attorney regarding any injury(ies) which you now allege is (are) associated with isotretinoin? (This question asks for the first contact with any attorney including, but not limited to, your present attorney.)

C. If you are completing this questionnaire in a representative capacity (e.g., on behalf of the estate of a deceased person or a minor), please complete the following: If not, skip this question.

1. _____
Your name and Social Security Number

2. _____
Maiden or other names used or by which you have been known

3. _____
Street Address
4. _____
City, State and Zip Code
5. If you are in a representative capacity, state which individual or estate you are representing, and in what capacity you are representing the individual or estate:

6. If you were appointed as a representative by a court, state the:

Court	Date of Appointment
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7. Your relationship to deceased or represented person or person claimed to be injured:

8. If you represent a decedent's estate based on a decedent's death, state the date of death of the decedent and the address of the place where the decedent died:

If you are completing this questionnaire in a representative capacity, please respond to the remaining questions with respect to the person who used isotretinoin, unless the question instructs you otherwise. Those questions using the term "You" refer to the person who used the isotretinoin, unless you are instructed otherwise. If the individual is deceased, please respond as of the time immediately prior to his or her death, unless a different time period is specified.

D. Claim Information

1. What bodily injury(ies)/condition(s) do you claim resulted from your use of isotretinoin? If you state severe organ damage, please state specifically which organ and the alleged injury(ies). Be very specific about each and every injury claimed.

2. When do you claim this injury(ies)/condition(s) first occurred?

3. Who diagnosed the condition(s)?

4. Physician/healthcare provider(s) who related condition(s)/diagnosis(es) to isotretinoin.

5. Date of diagnosis for each condition(s) alleged to have been caused by isotretinoin.

6. Did you ever suffer this injury(ies) prior to the date set forth in answer to the prior question? If yes, when and who diagnosed the condition(s) at that time?

7. Do you claim that your use of isotretinoin worsened a condition(s) that you already had or had in the past?

Yes _____ No _____ Don't Know _____

If yes, set forth the injury(ies) or condition(s), whether or not you had already recovered from that injury(ies) or condition(s) before you took isotretinoin, and the date of recovery, if any.

8. Is there a family history of the same or similar condition(s) you claim resulted from your use of isotretinoin?

Yes _____ No _____

If so, who in your family had or has this or a similar condition (father, mother, brother, grandmother, etc.)?

II. PERSONAL INFORMATION OF THE PERSON WHO USED ISOTRETINOIN

A. Last Name: _____
First Name: _____
Middle Name or Initial: _____

B. Maiden or other names used or by which you have been known: _____

C. Social Security Number: _____

D. Present Street Address: _____

City _____ State _____ Zip Code _____

E. Identify each other address at which you have resided during the last ten (10) years, and list when you started and stopped living at each one:

_____	From _____	To _____
_____	From _____	To _____
_____	From _____	To _____
_____	From _____	To _____
_____	From _____	To _____
_____	From _____	To _____

F. Identify each grammar/grade school, high school, college, university or other educational institution you have attended, the dates of attendance, courses of study pursued, and diplomas or degrees awarded and when each was awarded:

G. Employment Information.

1. Current employer (if not currently employed, last employer):

Name

Address

Dates of Employment

Occupation/Job Duties

2. List the following for each employer you have had in the last ten (10) years:

Name

Address

Dates of Employment

Occupation/Job Duties

Name

Address

Dates of Employment

Occupation/Job Duties

Name

Address

Dates of Employment

Occupation/Job Duties

H. Driver's license number and State issuing license: [If you have had driver's licenses in more than one state, list response for each state.]

I. Date and place of birth:

J. Sex: Male _____ Female _____

K. Military Service Information

1. Have you ever served in any branch of the U.S. military?

Yes _____ No _____

If yes, please state:

1. What branch, the dates of service and highest rank achieved:

2. Were you discharged for any reason relating to your physical, psychiatric or emotional condition(s)?

Yes _____ No _____

If yes, identify the condition(s):

2. Have you ever been rejected from military service for any reason relating to your health or physical condition(s)?

Yes _____ No _____

If yes, identify the condition(s):

3. Have you ever served in the military overseas?

Yes _____ No _____

If yes, state location(s) and dates:

L. Insurance/Claim Information

1. Have you ever filed a worker's compensation claim?

Yes _____ No _____

If yes, please state:

1. Month and year when each claim was filed: _____
2. Court/State in which claim was filed: _____
3. Claim/ docket number, if applicable: _____
4. Nature of disability: _____
5. Period of disability: _____
6. Benefits received, if any: _____

[Attach additional sheets if necessary to provide all of the foregoing information for more than one claim]

2. Have you ever filed a social security disability claim (SSI or SSD)?

Yes _____ No _____

If yes, please state:

1. Year claim was filed: _____
2. Where claim was filed: _____
3. Nature of disability: _____
4. Period of disability: _____
5. Benefits received, if any: _____

[Attach additional sheets if necessary to provide all of the foregoing information for more than one claim]

3. Have you ever been denied life insurance or medical insurance for reasons relating to your medical or physical condition(s)?

Yes _____ No _____

If yes, state when, the name of the insurance company, the type or kind of policy involved, and the company's stated reason for denial:

4. ***(Answer this question if you are claiming damages for mental or emotional distress.)*** Have you ever been denied life insurance or medical insurance for reasons relating to your mental or emotional condition(s)?

Yes _____ No _____

If yes, state when, the name of the insurance company, the type or kind of policy involved, and the company's stated reason for denial:

5. Has any insurance or other company provided medical coverage to you (either directly or through a group including any employer of yours) or paid medical bills on your behalf at any time, beginning ten (10) years before your alleged injury(ies) through the present?

Yes _____ No _____

If yes, then as to each company, separately state:

Name of the company: _____

Address of the company: _____

The account/policy number or designation: _____

The claim number, if any: _____

Dates of coverage: _____

When claim was made: _____

6. Have you ever been out of work for more than thirty (30) days for reasons related to your health? If yes, set forth when and the reason for each such occasion:

Yes _____ No _____

When: _____

Reason: _____

7. Have you ever filed a lawsuit or made a claim, other than in the present suit, relating to any bodily injury(ies)?

Yes _____ No _____

If so, state the court in which such action was filed, the caption, case name and/or names of adverse parties, and the civil action or docket number assigned to each claim, action or suit, and a brief description of the claims asserted:

M. Have you ever been convicted of a crime? If yes, set forth where, when and the crime, and, for each such instance, the penalty or sentence imposed and, if you were incarcerated, the name of the institution in which you were incarcerated:

Yes _____ No _____

III. FAMILY INFORMATION

A. List for each marriage the name of your spouse; spouse's date of birth (for your current spouse only), spouse's occupation, date of marriage, date the marriage ended, if applicable, and how the marriage ended (e.g., divorce, annulment, death):

B. List the names and ages of your parents and whether they are still married:

C. List the names and ages of your paternal and maternal grandparents and whether they are still living. If deceased, list date and cause of death for each:

D. To the best of your current knowledge or present recollection, has any parent, grandparent, child, or sibling ever been diagnosed with a condition(s) relating to the same organ or organ system identified in your answer to Section I(D)?

Yes _____ No _____ Don't Know _____

If yes, identify each such person below and provide the information requested:

1. Name: _____
Current age (or age at death): _____
Type of condition: _____
If applicable, cause of death: _____

2. Name: _____
Current age (or age at death): _____
Type of condition: _____
If applicable, cause of death: _____

3. Name: _____

Current age (or age at death): _____
Type of condition: _____
If applicable, cause of death: _____

E. If applicable, for each of your children, list his/her name, age, occupation and address:

F. If you are bringing a survivor cause of action, state whether you have been appointed as the decedent's personal representative authorized to prosecute the decedent's claims, and, if so, when and by whom you were so appointed:

IV. CURRENT MEDICAL CONDITION(S)

A. Do you currently suffer from any physical injuries, illnesses or disabilities other than those you have alleged are the result of your use of isotretinoin?

Yes _____ No _____

B. If the answer is yes, please state the following for each injury(ies), illness or disability:

1. Identify for each such injury(ies), illness or disability, their symptoms and date of onset:

Date of onset: _____

2. By whom were you first diagnosed with this injury, illness or disability?

Name

Address (if not otherwise provided)

Date of diagnosis _____

Medical specialty of diagnosing physician: _____

V. MEDICAL HISTORY AND BACKGROUND

A. Height: _____

B. Current weight: _____
Weight at the time of the injury, illness or disability described in section I(D):

C. Prescription Medications

1. To the best of your recollection, list each prescription medication, including but not limited to oral contraceptives (as applicable) you have taken **regularly** in the last ten (10) years, identifying the medication and the condition(s) for which it was prescribed:

2. To the best of your recollection, list each prescription medication you have taken **intermittently** in the last ten (10) years, identifying the medication and the condition(s) for which it was prescribed:

3. To the best of your recollection, state whether you used any of the following substances at any time ten (10) years prior to the date of the injury(ies) you allege in section I(D) through the present. Circle all medications you have used, state when you took the medication and how frequently, and, if a doctor prescribed or suggested the medication for your use, identify the doctor:

a. NSAIDS (such as):

<u>Substance</u>	<u>When taken and how frequently</u>	<u>Name of prescribing doctor (if any)</u>
Advil	_____	_____
Ibuprofen	_____	_____
Aleve	_____	_____
Naprosyn	_____	_____
Motrin	_____	_____
Orudis	_____	_____
Feldene	_____	_____
Indocin	_____	_____
Toradol	_____	_____
Daypro	_____	_____
Celebrex	_____	_____

b. Herbal remedies or supplements:

<u>Substance</u>	<u>When taken and how frequently</u>	<u>Name of prescribing doctor (if any)</u>
Kava	_____	_____
Ginseng	_____	_____
Ginko Bilboa	_____	_____
St. John's Wort	_____	_____
Sal Palmetto	_____	_____
Other	_____	_____

D. Smoking/tobacco use history (circle whichever is applicable):

1. Never used or smoked cigarettes/cigars/pipe tobacco or chewing tobacco/snuff.
2. Past user or smoker of cigarettes/cigars/pipe tobacco or chewing tobacco/snuff.
 Date on which smoking/tobacco use ceased: _____
 Amount smoked or used: _____ per day for _____ years.
3. Current user or smoker of cigarettes/cigars/pipe tobacco or of chewing tobacco/snuff.

Amount smoked or used: _____ per day for _____ years.

E. Drinking history:

1. Do you now drink or have you in the past drunk alcohol (beer, wine, whiskey, etc.)?

Yes _____ No _____

If no, go to Section F below. If yes, check the following box which represents your greatest alcohol consumption over an extended (6 months or greater) period within the last 10 years:

_____ 1-5 drinks per week

_____ 6-10 drinks per week

_____ 11-14 drinks per week

_____ 15 or more drinks per week

_____ Other (describe) _____

Check the following box which represents your weekly alcohol consumption for the month prior to the first symptom (gastrointestinal or other symptoms related to your injury) you experienced:

_____ 1-5 drinks per week

_____ 6-10 drinks per week

_____ 11-14 drinks per week

_____ 15 or more drinks per week

_____ Other (describe) _____

F. Caffeine and sugar intake history:

1. Do you now or have you in the past consumed caffeinated beverages (coffee, tea, sodas, etc.)?

Yes _____ No _____

If yes, check the following box which represents your greatest caffeine consumption over an extended (6 months or greater) period within the last 10 years:

_____ 1-5 drinks per week

_____ 6-10 drinks per week

_____ 11-14 drinks per week

_____ 15 or more drinks per week

_____ Other (describe) _____

Check the following box which represents your weekly caffeine consumption for the month prior to the first symptom (gastrointestinal or other symptoms related to your injury) you experienced:

- 1-5 drinks per week
 6-10 drinks per week
 11-14 drinks per week
 15 or more drinks per week
 Other (describe) _____

2. Do you now or have you in the past consumed sugared beverages or desserts?

Yes _____ No _____

If yes, check the following box which represents your greatest sugar consumption over an extended (6 months or greater) period within the last 10 years:

- 1-5 items per week
 6-10 items per week
 11-14 items per week
 15 or more items per week
 Other (describe) _____

Check the following box which represents your weekly sugar consumption for the month prior to the first symptom (gastrointestinal or other symptoms related to your injury) you experienced:

- 1-5 items per week
 6-10 items per week
 11-14 items per week
 15 or more items per week
 Other (describe) _____

G. *If you are claiming damages for mental or emotional distress as a consequence of isotretinoin*, state whether you have experienced or been treated for any psychological, psychiatric or emotional problem prior to the use of isotretinoin, including but not limited to, panic attacks, anxiety, post traumatic stress disorder, depression, thoughts of hurting yourself or other people, schizophrenia, bipolar disorder, personality disorders (e.g., obsessive compulsive, paranoid, borderline, histrionic, other), generalized anxiety disorder, social phobia/anxiety disorder, mania, poor sleep, poor concentration, suicidal thoughts/attempts, and drug abuse.

Yes _____ No _____

If yes, state:

1. Name and address of each health care provider who treated you:

Name

Address (if not otherwise provided)

2. Condition(s) for which treated: _____

3. When treated: _____

4. Medications prescribed for such condition(s): _____

H. To the best of your knowledge or understanding, have you ever experienced, or been told by a doctor or other healthcare professional, that you have, may have or had any of the following at any time in your life.

<u>Symptom/Condition</u>	<u>Yes</u>	<u>No</u>	<u>I don't know</u>
Abdominal pain			
Allergic reaction to medication			
Anemia			
Arthritis			
Back pain and/or neck injury			
Bleeding/clotting disorders (hemophilia, Von Willebrand's disease, scurvy, other)			
Blood disorders			
Blood in stool or dark/black stools			
Blurry vision lasting more than a few days			
Bone fracture			
Bone problems/pain/disease			
Calcification of tendons and ligaments			
Cancer (lung, colon, liver, breast, testicular, other)			
Chest pain/angina (at rest or with exertion)			
Chronic Fatigue Syndrome			
Chronic obstructive pulmonary disease/COPD			

<u>Symptom/Condition</u>	<u>Yes</u>	<u>No</u>	<u>I don't know</u>
Colitis			
Congenital heart disease			
Congestive heart failure			
Corneal opacity			
Corneal ulcer			
Coronary artery disease			
Coronary heart disease			
Crohn's Disease			
Deep vein thrombosis/DVT/blood clot in lower legs			
Degenerative disc			
Dermatomyositis			
Diabetes			
Dizziness lasting more than a few days			
Drowsiness lasting more than a few days			
Elevated cholesterol			
Elevated liver enzymes			
Elevated triglycerides			
Esophagus problems (strictures, achalasia, esophagitis, Barrett's esophagus, difficulty swallowing, other)			
Eye hemorrhages			
Fibromyalgia			
Gall bladder problems (gall stones, other)			
Gastrointestinal problems			
Gout			
Headaches lasting more than a few days			
Heart attack/MI/myocardial infarction			
Heart problems (including but not limited to heart attack, heart murmurs, heart valve problems, heart palpitations, heart rate/rhythm problems, congestive heart failure, cor pulmonale, etc.)			
Heartburn/ reflux/ esophageal reflux disease/ GERD			

<u>Symptom/Condition</u>	<u>Yes</u>	<u>No</u>	<u>I don't know</u>
Hepatotoxicity			
Hernia (strangulated or incarcerated)			
High blood pressure/hypertension			
High triglycerides			
Hodgkin's disease/ non-Hodgkin's lymphoma			
Hypoxia (low oxygen saturation)			
Ileitis			
Inflammatory bowel disease			
Insomnia lasting more than a few days			
Intestinal hemorrhage			
Intestinal obstruction (not including constipation)			
Irregular heart rhythm			
Irritable bowel syndrome			
Itching (persistent lasting more than one week)			
Joint pain lasting more than a few days			
Keratitis			
Kidney problems (disease, infection, stones, protein in urine, etc.)			
Leukemia			
Liver disease (hepatitis B/C, cirrhosis, cysts, abnormal enzymes, etc.)			
Lupus			
Lymphadenopathy			
Measles			
Musculoskeletal problems			
Nausea (repetitive bouts lasting more than a few days)			
Night vision loss			
Obesity			
Optic neuritis			
Oral herpes (canker sores)			

<u>Symptom/Condition</u>	<u>Yes</u>	<u>No</u>	<u>I don't know</u>
Osteoarthritis			
Pancreatitis			
Paresthesias			
Peptic ulcer disease			
Peripheral vascular disease			
Premature epiphyseal closure			
Pseudotumor cerebri psychosis			
Pulmonary embolism/blood clot in the lung			
Pyoderma faciale			
Rectal bleeding			
Regional ileitis			
Rheumatic fever (as to you only, if applicable)			
Rhabdomyolysis			
Rheumatoid arthritis			
Scheuermann's Kyphosis			
Seizure disorder			
Shortness of breath not associated with vigorous exercise			
Silent MI			
Skeletal hyperostosis			
Sleep apnea			
Stomach problems (ulcers, perforations, bleeding)			
Stroke			
Swelling/edema/fluid in legs ankles (other than in pregnancy)			
Syncope			
Tendonitis			
Thyroid disorder and/or goiter			
Transient chest pain			
Transient ischemic attack/TIA			

<u>Symptom/Condition</u>	<u>Yes</u>	<u>No</u>	<u>I don't know</u>
Tuberculosis			
Ulcerative colitis			
Urogenital condition(s)			
Vascular problems			
Vascular thrombotic disease			
Vasculitis			
Vision problems lasting more than a few days			
Vomiting lasting more than a few days			

1. If you responded "yes" to any of the above, please identify/state the condition(s), the date of onset, any medication prescribed to treat the condition(s), and the name and address of the physician or other person who made the diagnosis or informed you of the condition(s):

1. Condition(s): _____
 Onset date and medication: _____
 Name and address of physician or other person: _____

2. Condition(s): _____
 Onset date and medication: _____
 Name and address of physician or other person: _____

3. Condition(s): _____
 Onset date and medication: _____
 Name and address of physician or other person: _____

4. Condition(s): _____
 Onset date and medication: _____
 Name and address of physician or other person: _____

5. Condition(s): _____
 Onset date and medication: _____
 Name and address of physician or other person: _____

J. Please indicate whether you have ever received any of the following treatments or diagnostic procedures:

1. Surgeries, including but not limited to the following, and specify for what condition(s) the surgery was performed: open heart/bypass surgery, vascular surgery, intestinal surgery, etc.

Surgery and condition(s) for which it was performed: _____

When: _____

Treating physician: _____

Hospital: _____

2. Treatments/interventions for heart attack, angina (chest pain), or lung ailments, including but not limited to the following: cardiac catheterization, angioplasty (balloon), stenting, electroconversion.

Treatment/intervention: _____

When: _____

Treating physician: _____

Hospital: _____

3. Have you had any of the following tests performed: chest X-ray, CT scan, MRI, any other type of x-ray, colonoscopy, upper or lower GI, EKG, echocardiogram, bleeding scan, endoscopy, lung bronchoscopy, carotid duplex/ultrasound, or CT scan of the head. If so, answer the following:

Diagnostic test: _____

When: _____

Treating physician: _____

Hospital: _____

Reason: _____

K. Have you ever participated in any clinical trials or studies relating to any drugs or treatments for any medical condition(s)?

Yes _____ No _____

If "Yes", please identify: _____

Name of the trial or study: _____

Sponsor of trial or study: _____

Drug or treatment studied: _____

Indicated use(s) of the drug or treatment studied: _____

Name and address of the investigator in charge of your care and treatment in the trial or study: _____

The dates you participated in the trial or study: _____

L. To the best of your knowledge, have your parents, grandparents, children or siblings ever experienced or been diagnosed with, or been told by a doctor or other healthcare professional, that they have, may have or had any of the following (circle all that apply), set forth the name of the individual and their relationship to you next to each condition(s) circled:

<u>Symptom/Condition</u>	<u>Name of Individual</u>	<u>Relationship</u>
Gastrointestinal pain (repetitive bouts)		
Blood in stool or dark/black stools		
Bone pain/problems/disease		
Cancer (lung, colon, liver, breast, testicular, other)		
Depression/psychiatric disorders		
Diabetes		
Elevated cholesterol/lipids		
Heart problems of any kind including atherosclerotic disease		
Any kind of bowel disease/disorder (including Crohn's, ulcerative colitis or irritable bowel syndrome)		
Kidney disease/stones		
Liver disease (hepatitis B/C, cirrhosis, cysts, other)		
Lupus		
Musculoskeletal disease/disorder		

<u>Symptom/Condition</u>	<u>Name of Individual</u>	<u>Relationship</u>
Pancreatitis		
Stroke		
Thyroid disease/disorder (goiter, etc.)		
Vision Disorder		

VI. ISOTRETINOIN PRESCRIPTION INFORMATION

PLEASE NOTE: With regard to each and every one of your answers in this section VI. "Isotretinoin Prescription Information" (subparts A through T), please provide separate and specific information for each and every brand or form of isotretinoin you took or were prescribed, including separate specific information relating to your use of and/or prescriptions for (1) Claravis®, (2) Sotret®, (3) Amnesteem® and (4) any or other branded or non-branded versions or forms of isotretinoin you took or were prescribed, such as Accutane®.

Which of the following brands of isotretinoin did you ingest:

Claravis®

Sotret®

Amnesteem®

Accutane®

Please complete the section(s) for each brand of isotretinoin checked above.

A. CLARAVIS®

1. Who prescribed Claravis® for you?

2. On which dates did you begin to take, and stop taking, Claravis®? If you took Claravis® more than once, list each start and stop date.

3. For what condition(s) were you prescribed Claravis®?

4. Did you renew your prescription for Claravis®? If yes, how many times?

5. Where and with whom were you living when you took Claravis®?

6. Pharmacy Information. If you received a prescription for Claravis®, state for each prescription the name and address of the pharmacy where it was filled, and the number of times it was filled:

7. Have you had discussions with any doctor about whether your claimed injury(ies) is (are) related to the use of Claravis®?

Yes _____ No _____

If yes, identify the doctor or doctors with whom you had such discussions.

Name _____

Address (if not otherwise provided) _____

[If discussed with more than one doctor, please copy and complete Part 2 for each.]

8. State whether you requested that any doctor or clinic provide you with Claravis® or a prescription for Claravis®.

Yes _____ No _____

9. Were you given any written instructions or warnings regarding the use of Claravis®?

Yes _____ No _____

If yes, please state:

- a. When the written instructions or warnings were given to you:

- b. A description of the written warnings or instructions (e.g., package insert, patient product information; pharmacy handout, etc.):

- c. Identify each person or entity from whom you received the warnings or instructions:

Approximate date you received the written instructions or warnings:

Summary of instructions/warnings received:

10. What other medications (including aspirin), if any, were you taking at the same time you were taking Claravis®?

11. a. To the best of your recollection what other medications (other than those set

forth elsewhere in the Fact Sheet) including, but not limited to, oral contraceptives (as applicable) and over-the-counter medication, had you taken five (5) years before you took Claravis®, and when did you take them? Please also state how frequently you took the medication, and, if it was prescribed by a physician, the name and address of the physician.

- b. Do you believe you ever experienced gastrointestinal problems or other adverse side effects from any or all of these other medications? If yes, list the type of adverse side effect, the medication you were taking at the time, and the date(s) on which you experienced the adverse side effect.

- c. Do you believe you experienced any of the adverse side effects listed in your answer to the preceding question while taking Claravis®? If so, set forth which adverse side effect you experienced, when, what treatment you received for the adverse side effect, and who prescribed that treatment.

B. SOTRET®

1. Who prescribed Sotret® for you?

2. On which dates did you begin to take, and stop taking, Sotret®? If you took Sotret® more than once, list each start and stop date.

3. For what condition(s) were you prescribed Sotret®?

4. Did you renew your prescription for Sotret®? If yes, how many times?

5. Where and with whom were you living when you took Sotret®?

6. Pharmacy Information. If you received a prescription for Sotret®, state for each prescription the name and address of the pharmacy where it was filled, and the number of times it was filled:

7. Have you had discussions with any doctor about whether your claimed injury(ies) is (are) related to the use of Sotret®?

Yes _____ No _____

If yes, identify the doctor or doctors with whom you had such discussions.

Name _____

Address (if not otherwise provided) _____

[If discussed with more than one doctor, please copy and complete Part 2 for each.]

8. State whether you requested that any doctor or clinic provide you with Sotret® or a prescription for Sotret®.

Yes _____ No _____

9. Were you given any written instructions or warnings regarding the use of Sotret®?

Yes _____ No _____

If yes, please state:

a. When the written instructions or warnings were given to you:

b. A description of the written warnings or instructions (e.g., package insert, patient product information; pharmacy handout, etc.):

c. Identify each person or entity from whom you received the warnings or instructions:

Approximate date you received the written instructions or warnings:

Summary of instructions/warnings received:

10. What other medications (including aspirin), if any, were you taking at the same time you were taking Sotret®?

11. a. To the best of your recollection what other medications (other than those set

forth elsewhere in the Fact Sheet) including, but not limited to, oral contraceptives (as applicable) and over-the-counter medication, had you taken five (5) years before you took Sotret®, and when did you take them? Please also state how frequently you took the medication, and, if it was prescribed by a physician, the name and address of the physician.

- b. Do you believe you ever experienced gastrointestinal problems or other adverse side effects from any or all of these other medications? If yes, list the type of adverse side effect, the medication you were taking at the time, and the date(s) on which you experienced the adverse side effect.

- c. Do you believe you experienced any of the adverse side effects listed in your answer to the preceding question while taking Sotret®? If so, set forth which adverse side effect you experienced, when, what treatment you received for the adverse side effect, and who prescribed that treatment.

C. AMNESTEEM®

1. Who prescribed Amnesteem® for you?
-
-
-
2. On which dates did you begin to take, and stop taking, Amnesteem®? If you took Amnesteem® more than once, list each start and stop date.

3. For what condition(s) were you prescribed Amnesteem®?

4. Did you renew your prescription for Amnesteem®? If yes, how many times?

5. Where and with whom were you living when you took Amnesteem®?

6. **Pharmacy Information.** If you received a prescription for Amnesteem®, state for each prescription the name and address of the pharmacy where it was filled, and the number of times it was filled:

7. Have you had discussions with any doctor about whether your claimed injury(ies) is (are) related to the use of Amnesteem®?

Yes _____ No _____

If yes, identify the doctor or doctors with whom you had such discussions.

Name _____

Address (if not otherwise provided)

[If discussed with more than one doctor, please copy and complete Part 2 for each.]

8. State whether you requested that any doctor or clinic provide you with Amnesteem® or a prescription for Amnesteem®.

Yes _____ No _____

9. Were you given any written instructions or warnings regarding the use of Amnesteem®?

Yes _____ No _____

If yes, please state:

- a. When the written instructions or warnings were given to you:

- b. A description of the written warnings or instructions (e.g., package insert, patient product information; pharmacy handout, etc.):

- c. Identify each person or entity from whom you received the warnings or instructions:

Approximate date you received the written instructions or warnings:

Summary of instructions/warnings received:

10. What other medications (including aspirin), if any, were you taking at the same time you were taking Amnesteem®?

11. a. To the best of your recollection what other medications (other than those set forth elsewhere in the Fact Sheet) including, but not limited to, oral contraceptives (as applicable) and over-the-counter medication, had you taken five (5) years before you took Amnesteem®, and when did you take them? Please also state how frequently you took the medication, and, if it was prescribed by a physician, the name and address of the physician.

b. Do you believe you ever experienced gastrointestinal problems or other adverse side effects from any or all of these other medications? If yes, list the type of adverse side effect, the medication you were taking at the time, and the date(s) on which you experienced the adverse side effect.

c. Do you believe you experienced any of the adverse side effects listed in your answer to the preceding question while taking Amnesteem®? If so, set forth which adverse side effect you experienced, when, what treatment you received for the adverse side effect, and who prescribed that treatment.

D. ACCUTANE®

1. Who prescribed Accutane® for you?

2. On which dates did you begin to take, and stop taking, Accutane®? If you took Accutane® more than once, list each start and stop date.

3. For what condition(s) were you prescribed Accutane®?

4. Did you renew your prescription for Accutane®? If yes, how many times?

5. Where and with whom were you living when you took Accutane®?

6. Pharmacy Information. If you received a prescription for Accutane®, state for each prescription the name and address of the pharmacy where it was filled, and the number of times it was filled:

7. Have you had discussions with any doctor about whether your claimed injury(ies) is (are) related to the use of Accutane®?

Yes _____ No _____

If yes, identify the doctor or doctors with whom you had such discussions.

Name _____

Address (if not otherwise provided) _____

[If discussed with more than one doctor, please copy and complete Part 2 for each.]

8. State whether you requested that any doctor or clinic provide you with Accutane® or a prescription for Accutane®.

Yes _____ No _____

9. Were you given any written instructions or warnings regarding the use of Accutane®?

Yes _____ No _____

If yes, please state:

- a. When the written instructions or warnings were given to you:

- b. A description of the written warnings or instructions (e.g., package insert, patient product information; pharmacy handout, etc.):

- c. Identify each person or entity from whom you received the warnings or instructions:

Approximate date you received the written instructions or warnings:

Summary of instructions/warnings received:

10. What other medications (including aspirin), if any, were you taking at the same time you were taking Accutane®?

11. a. To the best of your recollection what other medications (other than those set

forth elsewhere in the Fact Sheet) including, but not limited to, oral contraceptives (as applicable) and over-the-counter medication, had you taken five (5) years before you took Accutane®, and when did you take them? Please also state how frequently you took the medication, and, if it was prescribed by a physician, the name and address of the physician.

- b. Do you believe you ever experienced gastrointestinal problems or other adverse side effects from any or all of these other medications? If yes, list the type of adverse side effect, the medication you were taking at the time, and the date(s) on which you experienced the adverse side effect.

- c. Do you believe you experienced any of the adverse side effects listed in your answer to the preceding question while taking Accutane®? If so, set forth which adverse side effect you experienced, when, what treatment you received for the adverse side effect, and who prescribed that treatment.

E. FIRST SYMPTOMS AND MEDICAL CARE, WAGE LOSS, MEDICAL EXPENSES

1. On what date, and in what city and state, did you first experience any symptoms you believe are related to the injury(ies) alleged in your complaint, and what were those symptoms?

2. Were there any witnesses to the symptoms identified above? If so, state their names, addresses, phone numbers and relationships to you.

3. When did you first contact a doctor or healthcare professional concerning this injury(ies)? Whom did you contact?

4. If you were taken to a doctor or health care facility for the injury(ies) alleged in your complaint, state the name and address of the persons, police department, fire department, emergency medical workers, or ambulance company that took you to the doctor or health care facility.

5. **Wage Loss Claims.** Answer these questions if you claim or expect to claim that you lost earnings or impairment of earning capacity as a result of any condition(s) that you believe was caused by your use of isotretinoin: [If you are not claiming lost wages, skip this section.]

a. State the total amount of time you have lost from work as a result of any condition(s) that you claim or believe was caused by your use of isotretinoin and the amount of income that you lost.

b. State your total earned income (including salary, bonus, and benefits) for each of the last 10 years.

Year	Income
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____

6. Have you paid or incurred any medical expenses that are related to any condition(s) that you claim or believe was caused by your use of isotretinoin and for which you seek recovery in the action you have filed?

Yes _____ No _____

If yes, state the total amount of such expenses at this time: \$ _____

7. Has your insurer, or any other entity or person, paid or incurred any medical expenses that are related to any condition(s) that you claim or believe was caused by your use of isotretinoin and for which you seek recovery in the action you have filed?

Yes _____ No _____

If yes, state the total amount of such expenses at this time: \$ _____

8. Emotional Distress Claims. *If you are claiming damages for mental or emotional distress*, describe the kind of injury(ies) you allege and when you allegedly suffered it, and list all individuals from whom you received treatment for such injury(ies) and the dates on which treatment was received.

9. Please identify all person who you believe possess information relevant to your claims in this matter and, for each, state his or her name, relationship address, telephone number and a description of the relevant information you believe he or she possesses.

VII. DOCUMENTS AND THINGS

Attach copies of the following non-privileged documents and things to this declaration to the extent that such materials are currently in your possession, custody, or control, in the possession, custody, or control of your parents, guardians or spouse, or in the possession, custody, or control of your lawyers.

- A. A copy of all prescriptions for isotretinoin, any unused isotretinoin you received as a result of such prescriptions, receipts, physician or office records, drug containers, packaging and other records that show the period during which you have taken isotretinoin, the dosage of isotretinoin and the frequency with which you took isotretinoin.
- B. All documents that refer or relate to isotretinoin obtained from the Food and

Drug Administration or other government agencies.

- C. If you have been the claimant or subject of any worker's compensation, Social Security or other disability proceeding, all documents relating to such proceeding.
- D. Copies of all documents from physicians, hospitals, clinics, or any type of health care provider relating to your medical or mental health history. This includes, but is not limited to, hospital records, diagnostic test or test results, lab work, rehab records, doctor's office charts, etc.
- E. All documents constituting, concerning or relating to product use instructions, product warnings, package inserts, consent forms, pharmacy handouts or other materials distributed or provided to you when your prescriptions for isotretinoin were filled.
- F. Copies of all advertisements or promotional materials for isotretinoin received or reviewed before filing this action.
- G. Executed authorizations for the release of medical, employment, educational and other records.
- H. If you claim you have suffered loss of earnings or earning capacity, all documents that evidence your income/earnings for each of the last ten (10) years.
- I. If you claim any loss from medical expenses, copies of all bills from any physician, hospital, pharmacy or other health care provider, and statements and explanations of benefits from your health care insurer or plan.
- J. Copies of letters testamentary, letters of administration, powers of attorney, guardianship or guardian *ad litem* orders or other documents relating to your status as plaintiff if you are suing on behalf of another individual.
- K. Decedent's death certificate (if applicable).
- L. Report of autopsy, medical examiner, coroner, pathology, toxicology, or other police or investigative reports (if applicable);
- M. Copies of all documents concerning your education including, but not limited to, records of and from all schools attended including but not limited to report cards, progress reports, attendance records, disciplinary reports, transcripts, guidance or counseling records and any class yearbooks.
- N. All documents authored by you which document, record or reflect your physical or mental condition or state of mind before, during and after isotretinoin use, including but not limited to diaries or journals, suicide notes,

and written or electronic communications.

CERTIFICATION

I certify under penalty of perjury that all of the information provided in this Fact Sheet is true and correct to the best of my knowledge, that I have completed the List of Medical Providers and Other Sources of Information appended hereto, which is true and correct to the best of my knowledge, that I have supplied all the documents requested in part VII of this declaration to the extent that such documents are in my possession, custody, or control, or in the possession, custody, or control of my lawyers, and that I have supplied the authorizations attached to this declaration. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Print Name

Signature

Date

Print Name
(Loss of Consortium Plaintiff)

Signature

Date

**LIST OF MEDICAL PROVIDERS
AND OTHER SOURCES OF INFORMATION**

EACH PLAINTIFF IS REQUIRED TO FULLY AND ACCURATELY TO THE BEST OF THEIR RECOLLECTION COMPLETE THIS FORM LISTING MEDICAL CARE PROVIDERS AND OTHER SOURCES OF INFORMATION AS REQUESTED.

List the name and address of each of the following:

A. Your current family and/or primary care physician:

Name

Street Address

City, State, Zip Code

B. To the best of your ability, identify each of your primary care physicians for the last ten (10) years. [See definition as set forth on page 2 of the Fact Sheet]

Name

Approximate Dates

Last Known Address

City, State, Zip Code

Name

Approximate Dates

Last Known Address

City, State, Zip Code

Name

Approximate Dates

Last Known Address

City, State, Zip Code

Name

Approximate Dates

Last Known Address

City, State, Zip Code

Name

Approximate Dates

Last Known Address

City, State, Zip Code

- C. Each hospital, clinic, or healthcare facility where you have received inpatient treatment during the last ten (10) years.

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

D. Each hospital, clinic, or healthcare facility where you have received outpatient treatment (including treatment in an emergency room) during the last ten (10) years.

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

Name

Street Address

City, State, Zip Code

Dates of Admission

Reason for Admission

- E. Each physician or healthcare provider from whom you have received treatment in the last ten (10) years.

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

Name

Specialty

Street Address

City, State, Zip Code

Dates of Treatment

F. Each pharmacy where you filed or obtained prescription medication in the last ten (10) years.

Name

Street Address

City, State, Zip Code

Name

Street Address

City, State, Zip Code

G. If you have submitted a claim for social security disability benefits in the last ten (10) years, state the name and address of the office which is most likely to have records concerning your claim.

Name

Street Address

City, State, Zip Code

H. If you have submitted a claim for worker's compensation benefits, state the name and address of the entity which is most likely to have records concerning your claim.

Name

Street Address

City, State, Zip Code