

In Re: ACCUTANE LITIGATION) **SUPERIOR COURT OF NEW JERSEY LAW**
) **DIVISION: ATLANTIC COUNTY**
)
) **Case Code No.** _____
)
) **PLAINTIFF'S SUPPLEMENTAL**
) **FACT SHEET**
)
) **Plaintiff:** _____

In cases where forms of isotretinoin other than Accutane® were used, this Supplemental Plaintiff's Fact Sheet ("Supplemental PFS") must be completed by plaintiff or plaintiff's personal representative. It is to be completed in conjunction with, and as a supplement to, the primary Plaintiff's Fact Sheet approved for use by the Court in cases involving only Accutane® use ("Primary PFS"). To avoid unnecessary duplication of effort by plaintiff, it is understood and agreed to by all parties that in cases where this Supplemental PFS is required, the following questions set forth in the Primary PFS that reference to the word "Accutane" will be understood to mean "isotretinoin" more generally: all questions in section III; all questions in section IV(G); and all questions in sections V(P), V(Q), and V(R).

To avoid the need for an additional and/or supplemental Plaintiff's Confidential Fact Sheet, all parties further understand and agree that in cases where this Supplemental PFS is required, all references to Accutane® contained in Plaintiff's Confidential Fact Sheet, as approved for use by the Court in cases involving only Accutane® use, will be understood to mean "isotretinoin" more generally.

Finally, to avoid the need for an additional and/or supplemental list of topics for potential electronic discovery, it is understood and agreed to by all parties that in cases where this Supplemental PFS is required, all references to Accutane® or "Accutane® User" contained in the List of Topics For Electronic Documents For Discovery From Plaintiffs' Computers For Plaintiffs Alleging Systemic Injuries approved for use by the Court in cases involving only Accutane® use, will be understood to mean "isotretinoin" or "isotretinoin user" more generally.

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®, Amnesteem®, and other forms of isotretinoin, excluding 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, 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?

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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.)
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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, 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 the 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(s) 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.

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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(s) 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 _____ Don't Know _____

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

II. ISOTRETINOIN PRESCRIPTION INFORMATION

PLEASE NOTE: With regard to each and every one of your answers in this Section II. "Isotretinoin Prescription Information," please provide separate and specific information for each and every form of isotretinoin you took or were prescribed, including separate specific information relating to your use of and/or prescriptions for (1) Claravis®, (2) Amnesteem®, (3) Sotret® and (4) any other forms of isotretinoin you took or were prescribed, excluding Accutane®.

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 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(s) with whom you had such discussions.

Name

Address (if not otherwise provided)

[If discussed with more than one doctor, please copy and complete Item 7 for each.]

8. State whether you requested that any doctor or clinic provide you with Claravis® or with 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:

d. Approximate date you received the written instructions or warnings:

e. 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 Supplemental Fact Sheet) including, but not being 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. 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 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(s) with whom you had such discussions.

Name

Address (if not otherwise provided)

[If discussed with more than one doctor, please copy and complete Item 7 for each.]

8. State whether you requested that any doctor or clinic provide you with Amnesteem® or with 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:

d. Approximate date you received the written instructions or warnings:

e. 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 Supplemental Fact Sheet) including, but not being 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.

C. 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 were you living when you took Sotret®?

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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(s) with whom you had such discussions.

Name

Address (if not otherwise provided)

[If discussed with more than one doctor, please copy and complete Item 7 for each.]

8. State whether you requested that any doctor or clinic provide you with Sotret® or with 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:

d. Approximate date you received the written instructions or warnings:

e. 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 Supplemental Fact Sheet) including, but not being 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.

D. OTHER FORMS OF ISOTRETINOIN

1. Who prescribed isotretinoin for you?

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

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

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

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

6. Pharmacy Information. If you received a prescription for isotretinoin, 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 isotretinoin?

Yes _____ No _____

If yes, identify the doctor(s) with whom you had such discussions.

Name

Address (if not otherwise provided)

[If discussed with more than one doctor, please copy and complete Item 7 for each.]

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

Yes _____ No _____

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

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:

d. Approximate date you received the written instructions or warnings:

e. Summary of instructions/warnings received:

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

11.

- a. To the best of your recollection, what other medications (other than those set forth elsewhere in the Supplemental Fact Sheet) including, but not being limited to, oral contraceptives (as applicable) and over-the-counter medication had you taken five (5) years before you took isotretinoin, 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 isotretinoin? 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.

III. DOCUMENTS AND THINGS

Attach copies of the following unprivileged documents and things to this declaration to the extent that such materials currently are in your possession, custody, or control, in the possession, custody, or control of your parents, guardians or spouse, or in the possession, custody, and 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, or 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 any brand of isotretinoin used by plaintiff, excluding Accutane®, that were obtained from the Food and Drug Administration or other government agencies.
- C. 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 any brand of isotretinoin were filled.
- D. Copies of all advertisements or promotional materials for any brand of isotretinoin received or reviewed before filing this action.
- E. 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 Supplemental Fact Sheet is true and correct to the best of my knowledge and that I have supplied all the documents requested in Section III of this Supplemental Fact Sheet 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 Supplemental Fact Sheet. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Print Name
(Plaintiff)

Signature

Date

Print Name
(Loss of Consortium Plaintiff)

Signature

Date