Cholesterol Drugs and Peripheral Neuropathy (PN)* Questionnaire

---These data will be used for research purposes only. Your personal information will not be released.---

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Personal profile:

Last Name:_____   Today's Date:_____
First Name:_____   Date of Birth:_____

Have you ever taken any of the following medications? (Please check)

Chemotherapy (taxol, vincristine, suramin)__, gold__, phenytoin (dilantin)__, amiodarone__,

isoniazid__, ethambutol__, metronidazole (flagyl)__, nitrofurantoin__, chloramphenicol__,

griseofulvin__, dapsone__, cimetidine__, colchicine__, hydralazine__, disulfiram

(antabuse)__, megadose vitamin B6__, thalidomide__, wormwood (artemisia)__

Part I. Cholesterol Drugs and Symptoms

Please write neatly and clearly. Fill out as completely as possible.

A. FIRST CHOLESTEROL DRUG

1. **Name of first cholesterol drug:** _____
2. **Dose of first cholesterol drug:** _____
3. **Duration of use of first cholesterol drug:** _____
4. **Date of use of first cholesterol drug:** _____

5. **Please complete the following table (if known):**

	Before this drug	On this drug
Date of measurement		
Total cholesterol (mg/dl)		
LDL (mg/dl)		
HDL (mg/dl)		
Triglycerides (mg/dl)		

6. **Did you develop symptoms of peripheral neuropathy (PN) on this drug?**
   Yes____   No____

   If you answered no the prior question, please go to the next drug on page 3.

* **Peripheral Neuropathy (PN): Damage to the sensory nerves, commonly of the hands and feet, causing a tingling sensation or a weakened sense of touch in the hands and feet.**

7. **How long after starting this drug did you *first notice symptoms* of PN?**
    _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
    (number)

8. **How long after starting this drug were the PN symptoms *at their worst*?**
    _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
    (number)

9. **How long did you stay on this drug after PN symptoms began?**
    _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
    (number)

10. **Please rate the severity of the PN symptoms at their worst by placing an "X"
    on the line below.**

    No symptoms   Worst possible
    |---|

11. **Did the PN symptoms get better despite continued use of this drug?**
    Yes____   No____

12. **Are you still taking the drug?**
    Yes____   No____

    If you answered "yes" to the prior question, please go on to part II on page 7.

13. **Check one of the following:**
    a. ☐ **You switched to a new cholesterol drug, or different dosage, without
        time to assess improvement?**
        ☐ **Without time off the first drug**
        ☐ **With time off the first drug, but before recovery was complete**
        o **The duration off the first drug was:**
        _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
        (number)

        If you checked "13a", please go on to the next drug on page 3.
    b. ☐ **No improvement occurred after stopping this drug.**
    c. ☐ **The problem got worse after stopping this drug.**
    d. ☐ **Improvement occurred after stopping this drug**

        If you checked "13d", please complete #14. Otherwise, go on to #15.

14. **How complete was your recovery? Check all that apply.**
    a. ☐ **Complete recovery occurred. Recovery was complete after:**
        _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
        (number)
    b. ☐ **Improvement is ongoing now, after stopping this drug for:**
        _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
        (number)
    c. ☐ **Partial recovery occurred after stopping this drug for:**
        _____   ☐ **Day(s) / ☐ Week(s) / ☐ Month(s) / ☐ Year(s)**
        (number)

15. **How much did your PN symptoms improve after stopping this drug? Place an "X" on the line.**

   No Recovery (0%)   50%   Complete recovery (100%)
   |----------------------------------|----------------------------------|

16. **If you had improvement after stopping the drug, please answer the following:**
   a. **How long was it before you *first* noticed improvement in PN symptoms?**
      _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
      (number)

   b. **How long was it before *maximum* improvement in PN symptoms?**
      _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
      (number)

DID YOU TAKE ANOTHER DRUG OR CHANGE THE DOSE?
IF YES, CONTINUE. IF NO, MOVE ON TO PART II, PAGE 7.

B. SECOND CHOLESTEROL DRUG

17. **Name of second cholesterol drug:**_____
18. **Dose of second cholesterol drug:** _____
19. **Duration of use of second cholesterol drug:** _____
20. **Date of use of second cholesterol drug:** _____

21. **Please complete the following table (if known):**

	Before this drug	On this drug
Date of measurement		
Total cholesterol (mg/dl)		
LDL (mg/dl)		
HDL (mg/dl)		
Triglycerides (mg/dl)		

22. **Did you develop symptoms of PN on this drug?**
   Yes____ **No**____
   If you answered "no" the prior question, please move on to the next drug on page 5.

23. **How long after starting this drug did you *first notice symptoms* of PN?**
   _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
   (number)

24. **How long after starting this drug were the PN symptoms *at their worst*?**
   _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
   (number)

25. **How long did you stay on this drug after PN symptoms began?**
   _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
   (number)

26. **Please rate the severity of the PN symptoms at their worst by placing an X on the line below.**

        No symptoms   Worst possible

           |--|

27. **Did the PN symptoms get better despite continued use of this drug?**
     Yes____ No____

28. **Are you still taking the drug?**
     Yes____ No____

> *If you answered "yes" to the prior question, please go on to part II on page 7.*

29. **Check one of the following:**

     a. ☐ **You switched to a new cholesterol drug, or different dosage, without time to assess improvement?**
          ☐ <u>**Without time off**</u> **the first drug**
          ☐ <u>**With time off**</u> **the first drug, but before recovery was complete**
               o **Time off was:**
                 _____ ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
                 (number)

> *If you checked "29a", please go on to the next drug on page 5.*

     b. ☐ **No improvement occurred after stopping this drug.**
     c. ☐ **The problem got worse after stopping this drug.**
     d. ☐ **Improvement occurred after stopping this drug**

> *If you checked "29d", please complete #30. Otherwise, go on to #31.*

30. **How complete was your recovery? Check all that apply.**

     a. ☐ **Complete recovery occurred. Recovery was complete after:**
        _____ ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

     b. ☐ **Improvement is ongoing now, after stopping this drug for:**
        _____ ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

     c. ☐ **Partial recovery occurred after stopping the drug for:**
        _____ ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

31. **How much did your PN symptoms improve after stopping this drug? Place an "X" on the line.**

     No Recovery (0%)   50%   Complete recovery (100%)

        |---------------------------------|---------------------------------|

32. If you had improvement after stopping the drug, please answer the following:

    c. How long was it before you *first* noticed improvement in PN symptoms?

      _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
      (number)

    d. How long was it before *maximum* improvement in PN symptoms?

      _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
      (number)

DID YOU TAKE ANOTHER DRUG OR CHANGE THE DOSE?
IF YES, CONTINUE. IF NO, MOVE ON TO PART II, PAGE 7.

C. THIRD CHOLESTEROL DRUG

33. Name of third cholesterol drug: _____

34. Dose of third cholesterol drug: _____

35. Duration of use of third cholesterol drug: _____

36. Date of use of third cholesterol drug: _____

37. Please complete the following table (if known):

	Before this drug	**On this drug**
Date of measurement		
Total cholesterol (mg/dl)		
LDL (mg/dl)		
HDL (mg/dl)		
Triglycerides (mg/dl)		

38. Did you develop symptoms of PN on this drug?
    Yes____ No____

If you answered "no" and you have no other choleterol drugs to report, please move on to Part II on page 7. If you answered "no" and have other cholesterol drugs to report, please contact the UCSD Statin Study for additional formatted sheets: (858) 558-4950 x215.

39. How long after starting this drug did you *first notice symptoms* of PN?

    _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
    (number)

40. How long after starting this drug were the PN symptoms *at their worst*?

    _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
    (number)

41. How long did you stay on this drug after PN symptoms began?

    _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
    (number)

42. Please rate the severity of the PN symptoms at their worst by placing an X on the line below.

    No symptoms   **Worst possible**

    |--|

43. Did the PN symptoms get better with continued use of this drug?
    Yes____ No____

44. Are you still taking the drug?
    Yes____ No____

If you answered "yes" to the prior question please move on to Part II on page 7.
If you answered "no", but do not have other cholesterol-lowering drug(s) to report, please also move on to Part II on page 7.
If you answered "no" to the prior question and have other cholesterol-lowering drug(s) to report, please contact the UCSD Statin Study for additional sheets: (858) 558-4950 x215.

47. Check one of the following:
    a. ☐ **You switched to a new cholesterol drug, or different dosage, without time to assess improvement?**
        ☐ <u>**Without time off**</u> **the first drug**
        ☐ <u>**With time off**</u> **the first drug, but before recovery was complete**
            o **Time off was:**
            _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
            (number)

If you checked "47a", please call to request additional formatted sheets for additional drug/change of dosage from the UCSD Statin Study: (858) 558-4950 x215.

    b. ☐ **No improvement occurred after stopping this drug.**
    c. ☐ **The problem got worse after stopping this drug.**
    d. ☐ **Improvement occurred after stopping this drug**

If you checked "47d", please complete #48. Otherwise, go on to #49.

48. How complete was your recovery? Check all that apply.
    a. ☐ **Complete recovery occurred. Recovery was complete after:**
        _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

    b. ☐ **Improvement is ongoing now, after stopping this drug for:**
        _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

    c. ☐ **Partial recovery occurred after stopping the drug for:**
        _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

49. How much did your PN symptoms improve after stopping this drug? Place an "X" on the line.

No Recovery (0%)   50%   Complete recovery (100%)
        |--------------------------------|--------------------------------|

50. **If you had improvement after stopping the drug, please answer the following:**

        a. **How long was it before you** *first* **noticed improvement in PN symptoms?**

        _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

        b. **How long was it before** *maximum* **improvement in PN symptoms?**

        _____   ☐ **Day(s)** / ☐ **Week(s)** / ☐ **Month(s)** / ☐ **Year(s)**
        (number)

If you stopped the third drug and have other cholesterol-lowering medication(s) to report, please request additional formatted sheets from the UCSD Statin Study: (858) 558-4950 x215.

Part II. Effects of Symptoms and Doctor's Response

This part of the questionnaire will help us to understand how these symptoms affect people's lives and how doctors respond to concerns about these symptoms.

1. **Please describe your peripheral neuropathy (PN) symptoms and their locations. Characterize the symptoms to the best of your ability (e.g. tingling, burning, numbness, pain, etc.):**

2. **On a scale of 0 to 10, please use the scale below to rate how INTENSE your pain is, if applicable. Place an "X on the line below to describe the instensity of your pain.**

  No Pain |-----|-----|-----|-----|-----|-----|-----|-----|-----|-----| **The most INTENSE**
               0   **1**   **2**   **3**   **4**   **5**   **6**   **7**   **8**   **9**   **10**   **pain sensation imaginable**

3. **Although pain can have a low intensity, it may still feel extremely unpleasant, and some kinds of pain can have a high intensity but be very tolerable. With this scale, please tell us how unpleasant your pain feels by plancing an "X" on the line below.**

  Not Unpleasant |-----|-----|-----|-----|-----|-----|-----|-----|-----|-----| **The most UNPLEASANT**
                0   **1**   **2**   **3**   **4**   **5**   **6**   **7**   **8**   **9**   **10**   **sensation imaginable**
                                                     ("intolerable")

4. **Did anything seem to make your PN symptoms better?**
    Yes_____   **No_____**
    Please describe:

5. Did anything seem to make your PN symptoms worse?
Yes____   No____
Please describe:

6. Did you see your doctor about your PN symptoms?
Yes____   No____

7. Did you or your doctor bring up the possibility of a link between your cholesterol drug use and PN symptoms?
Yes____   No____   **If yes, who brought it up?**   You did____   Your doctor did___
Comments:

8. If cholesterol drug use were discussed in relation to your PN symptoms, what was your doctor's approach to the possible link between cholesterol drugs and your symptoms?
Endorsed/Supported_____   Dismissed_____   Was Neutral_____

9. Were tests performed to diagnose your PN (e.g. electromyography, microfilament test?
Yes____   No____
Please describe:

10. Did your doctor give you a diagnosis of PN?
Yes____   No____
Please describe:

11. Did your doctor determine a cause of your PN?
Yes____   No____
Please describe:

12. Did you receive any treatments for your PN symptoms?
Yes____   No____
Please describe:

13. Please record your most recent cholesterol levels in the table below (if known):

	Date of record	Value (mg/dL)
Total cholesterol (mg/dl)		
LDL (mg/dl)		
HDL (mg/dl)		
Triglycerides (mg/dl)		

Part III. Additional Comments

This part of the questionnaire is very important, and provide the opportunity to add any additional comments about your experience or how it affected you. Include <u>any</u> detail you think may be relevant. We are interested in all you would like to share with us. Please use the additional space provided to attach additional pages if needed. We <u>sincerely</u> thank you for your time and effort.

Please send this questionnaire and the consent form to:
University of California, San Diego
Statin Study
9500 Gilman Drive 0995
La Jolla, CA 92093-0995

End. Thank you.

NEUROPATHY PAIN SCALE

Instructions: There are several different aspects of pain which we are interested in measuring: pain **sharpness**, **heat/cold**, **dullness**, **intensity**, overall **unpleasantness**, and **surface vs. deep** pain.

The distinction between these aspects of pain might be clearer if you think of taste. For example, people might agree on how *sweet* a piece of pie might be (the *intensity* of the sweetness), but some might enjoy it more if it were sweeter while others might prefer it to be less sweet. Similarly, people can judge the loudness of music and agree on what is more quiet and what is louder, but disagree on how it makes them feel. Some prefer quiet music and some prefer it more loud. In short, the *intensity* of a sensation is not the same as how it makes you feel. A sound can be quiet and "dull" or loud and "dull."

Pain is the same. Many people are able to tell the difference between many aspects of their pain: for example, *how much* it hurts and *how unpleasant* or annoying it is. Although often the intensity of pain has a strong influence on how unpleasant the experience of pain is, some people are able to experience more pain than others before they feel very bad about it.

There are scales for measuring different aspects of pain. For one patient, a pain might feel extremely hot, but not at all dull, while another patient may not experience any heat, but feel like their pain is very dull. We expect you to rate very high on some of the scales below and very low on others. We want you to use the measures that follow to tell us exactly what you experience.

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1. Please use the scale below to tell us how **intense** your pain is. Place an "X" through the number that best describes the intensity of your pain.

No pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **intense** pain sensation imaginable

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2. Please use the scale below to tell us how **sharp** your pain feels. Words used to describe "sharp" feelings include "like a knife," "like a spike," "jabbing" or "like jolts."

Not sharp | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **sharp** sensation imaginable ("like a knife")

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3. Please use the scale below to tell us how **hot** your pain feels. Words used to describe very hot pain include "burning" and "on fire."

Not hot | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **hot** sensation imaginable ("on fire")

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4. Please use the scale below to tell us how **dull** your pain feels. Words used to describe very dull pain include "like a dull toothache," "dull pain," "aching" and "like a bruise."

Not dull | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **dull** sensation imaginable

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5. Please use the scale below to tell us how **cold** your pain feels. Words used to describe very cold pain include "like ice" and "freezing."

Not cold | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **sharp** sensation imaginable ("freezing")

6. Please use the scale below to tell us how **sensitive** your skin is to light touch or clothing. Words used to describe sensitive skin include "like sunburned skin" and "raw skin."

Not sen-sitive | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **sensitive** sensation imaginable ("raw skin")

7. Please use the scale below to tell us how **itchy** your pain feels. Words used to describe itchy pain include "like poison oak" and "like a mosquito bite."

Not itchy | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **itchy** sensation imaginable ("like poison oak")

8. Which of the following best describes the **time** quality of your pain? Please check only one answer.

( ) I feel a background pain <u>all of the time</u> **and** occasional flare-ups (break-through pain) <u>some of the time</u>.

Describe the background pain:_____

Describe the flare-up (break-through) pain:_____

( ) I feel a single type of pain <u>all the time</u>. Describe this pain:_____

( ) I feel a single type of pain only <u>sometimes</u>. Other times, I am pain free.

Describe this occasional pain:_____

9. Now that you have told us the different physical aspects of your pain, the different types of sensations, we want you to tell us overall how **unpleasant** your pain is to you. Words used to describe very unpleasant pain include "miserable" and "intolerable." Remember, pain can have a low intensity, but still feel extremely unpleasant, and some kinds of pain can have a high intensity but be very tolerable. With this scale, please tell us how **unpleasant** your pain feels.

Not unpleas-ant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **unpleasant** sensation imaginable ("intolerable")

10. Lastly, we want you to give us an estimate of the severity of your <u>deep</u> versus <u>surface</u> pain. We want you to rate each location of pain separately. We realize that it can be difficult to make these estimates, and most likely it will be a "best guess," but please give us your best estimate.

HOW INTENSE IS YOUR *DEEP* PAIN?

No **deep** pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **intense deep** pain sensation imaginable

HOW INTENSE IS YOUR *SURFACE* PAIN?

No **surface** pain | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | The most **intense surface** pain sensation imaginable