Scharen, Hilda

From: Tom Scherer, Civil Rights Activist [redacted]
Sent: Monday, January 10, 2005 1:15 PM
To: Scharen, Hilda
Subject: Re: Mevocor OTC?

I hope at this meeting, you reject any attempt to make this dangerous product available to the general public, without:
a) the oversight of a learned intermediary, and
b) known and unknown risks with such a product, and
c) untested risks with such a product
d) bogus claims that are unsupported by statin mfg. companies.

Concurrently, I am in email communication with Janet Woodcock on a lack of warning given to those concurrently on antifungals such as Loprox or its generic equivalent and a statin. The statin companies warn of not concurrently taking an antifungal, but the antifungal mfg. companies to do in turn, warn their consumers, patients, or learned intermediaries about concurrent use of statins and antifungals.

In summary, what I am seeing in clinical data and post-marketing surv. (Phase IV) is most mfg. companies do not adequately address the high risk of concurrent medications with their products. Such as SSRI products and statins. Naturally, when our drug crazed nation and it's consumers are on multiple products (drugs) concurrently, this compounded risk becomes a factorial that is staggering.

If the FDA wants to protect the public interest, there is this desperate need to address more adequately, concurrent use of prescription products.

I hope you understand that, in this meeting on Jan. 13, 2005. And if you ask Merck those tough questi[illegible]arding Mevachor on dolichols, neuropeptides, DNA and RNA, they will look bewildered.

I am cutting a pasting some communication I have from a former astronaut and flight surgeon (USAF) below that discuss[illegible] adequately, his opinion regarding the unknown and untested dangers of statins.

****

Tom, you are doing pretty good for a law student. Dolichols are five carbon derivatives of the mevalonate pathway of cholesterol biosynthesis and, of course, are c[illegible]mpromised by statins on a "collateral damage" basis as is ubiquinone. Dolichols are vital toThe function of the Golgi apparatus, thereby leading to diminished neuropeptide formation when not readily availabile (our entire Beta endorphin system).
Statins affect the mitochondrial energy process via ubiquinone inhibition leading : 1) To decreased ATP production - interference with electron transfer and 2) increased oxidative damage due to greater free radical producion without the anti-oxidant effect of ubiquinone. Duane

****

And your hearing is considering with this knowledge and expert opinion, allowing Mevachor to be sold OTC?

1/11/2005

I think not.
Tom Scherer, Civil Rights Activist,
Law Student

IN THE DISTRICT COURT
OF JOHNSON COUNTY, KANSAS
10th JUDICIAL DISTRICT OF KANSAS

THOMAS E SCHERER, Petitioner **Vs.** [redacted] Defendant, **AND** [redacted] **Defendant, in his individual capacity, for acts/omissions outside the scope of his employment with the Veterans Administration** **AND** **The State of Kansas,** **Defe[illegible]**	**Chapter 60** **Case No. 04 CV _____**

PETITION PURSUANT TO CHAPTER 60
CIVIL COMPLAINT AND DEMAND FOR RELIEF/REMEDY

I. Parties to this civil action:

A. **Thomas E. Scherer, Petitioner**
[redacted]
Phone: [redacted]

[redacted], **Inc., Defendant**
[redacted]
P.O. Box [redacted]
[redacted]
Phone: [redacted]
Fax: [redacted]

B. [redacted], **Defendant**
[redacted]
Res. Tel.: [redacted]

C. **The State of Kansas, Defendant**
120 SW 10th Ave.
Topeka, KS 66612
Phone (785) 296-2215

D. **Related parties[1] may include the following entities:**

1) **The United States of America, by acts (commissions or omissions) of federal agency officials, in their official or individual capacity, which would include the Veterans Administration (VA) and the Food and Drug Administration (FDA) officials, as well as related federal entities, such as the VHA, the Topeka VA Medical Center, etceteras, not named explicitly[2].**
2) **Washburn University including Washburn University School of Law officials, students, and affiliated organizations.**
3) **Any other individual, who desires to be added as a complainant, or intervenor in this class action petition, who similarly has been injured by the acts and/or omissions of the defendant(s) in the entire class of statin products.**

E. **Requests to allow supplementation and/or amendment to this petition to add any/all necessary individuals or entities to allow for a final and fair adjudication.**

---

[1] This claim is independent and separate (severable liability) of any other claims that may be asserted in the future regarding the related parties under K.S.A. § 60-213. I cannot permissively join the related parties until I have exhausted administrative remedy/relief under an assertion of comparative negligence However, this does not bar [redacted] from asserting a cross-claim for contributory negligence

[2] There is currently on-going and pending, administrative agency action against the contribution to injury and property damages by the acts/omission of the FDA and the VA. It is anticipated that administrative action should theoretically be completed on/around January 17, 2005

ABSTRACT OF THIS PETITION

This is a petition for relief/remedy for acts/omissions to act by several defendants. The failures contained herein are systemic and indicative of a broad federal and state administrative process that has failed to protect the citizens of our nation, as well as the citizens of the State of Kansas from the drug industry. So much so, that there were congressional hearings in Washington D.C. In that congressional inquiry, committee members recommended that there be the creation of an independent agency outside the Food and Drug Administration (November 19, 2004). The purpose of such an independent agency separate from the FDA is necessary to protect consumers and learned intermediaries from drug companies that apparently have chosen economic profit, rather than the safety of its products in the public interest, as it's top priority. In addition, this petition is broad and far-reaching in effect to many, warranting justice; as well as judicial and jury oversight going forward, to protect the future and public interest for many Kansas citizens.

This petition is taking a look at some of those actors [redacted], a doctor, and state regulatory agencies) taking into consideration, the laws and regulations of Kansas. There is separate administrative action taken on a federal, rather than a state level. The authority of our state court to provide relief and remedy under Kansas State law is what is important in this case. I cannot reasonably address each and every person and agency that has failed to do what is required under the law. Therefore, for brevity and manageability, only a few will be stated as the defendants.

Federal relief/remedy will be sought separately against federal agencies and their officials, either in their official and/or individual capacity separately under Federal laws and regulations. There is no logical requirement or law requiring consolidation of federal issues, with state issues. Both the state and the federal government have separate jurisdiction, depending on the defendants involved. In plain language, a complainant or petitioner has the right to seek relief/remedy at the state level and separately at the federal level. The only thing this petitioner cannot do, is obtain duplicate relief/remedy twice. And as the complainant and/or petition, I have a duty to advise this court of concurrent administrative relief/remedy obtained at a federal level (if any).

A failure of federal agencies to take appropriate action and/or provide relief/remedy will be deemed exhaustion of administrative relief/remedy. A failure to take appropriate action at the federal level by, or around January 17, 2005, will result in a federal action taken before a federal judge with different defendants that those contained in this petition.

[redacted], as the learned intermediary and prescribing doctor can be considered in his official capacity, as well as in his individual capacity (one capacity subject to state law and the other official capacity subject to federal law). This petition is related to his individual capacity subject to Kansas's laws and regulations based on his license and consent to practice his profession in the state of Kansas, regardless of the location of some of his employment. To wit, he is doctor licensed by the state to render medical services, regardless of where he is physically subjecting him to Kansas State laws and regulations. The VA's attorneys to date refuse to state the scope and capacity of [redacted] acts necessitating action at both state and federal levels.

In this petition, with three defendants, Mr. Scherer is requesting the jury to assign the percentage of comparative negligence. One of the difficulties in doing so is that the defendant [redacted] warned of some risks and potential for adverse events attributable to its products. On the other hand, [redacted] did not disclose or warn of other known risks to learned intermediaries such as defendant [redacted].

[redacted] cannot he held responsible for what [redacted] failed to warn him, and other learned intermediaries about. Such as the known risks of inhibition of additional enzymes such as Q10 (addressed more fully in the petition), as well as more recent scientific and academic findings of risks related to statins and [redacted]'s statin products, although [redacted] had superior knowledge of that, and subsequent and addition risks.

[redacted] on the other hand, can not be responsible for [redacted]'s negligent acts/omissions. Thereby not allowing Scherer to give informed consent by advising Scherer about internal and known risks, as well as manufacturer warnings regarding drug-drug interaction. In such a scenario, it is proper for the jury/trier of fact to apportion a percentage of comparative negligence based on this series of events to each defendant based on how much the acts of each defendant contributed to injuries and damages of Scherer.

Moreover, it would seem warranted to assign a certain amount of negligence to acts/omissions of federal agency and state agency officials. Their contribution played a role or had a lesser indirect factor in contributing to those injuries and property damage by having not taken appropriate and reasonable action proactively to protect the public interest prior to Scherer taking prescribed products that resulted in injury and property damage to Scherer.

In conclusion, this case is more focused on the public interest and the protection of Kansas citizens against those who choose priorities such as economic profit over our public interest and safety. This is to distinguish that this case is not focused on the economic self-interest of Mr. Scherer in attempting to recover compensation and punitive damages for his personal injuries and damages. Mr. Scherer is of the belief that protecting his and other Kansas citizens is far more valuable than any economic damages or compensation. One cannot place an economic number on a person's rights to be protected and not have to fear products from companies that do business in the state of Kansas. It is my hope that this petition results in some reasonable amount of justice and improvement in this broad systemic failure to protect the public interest by several actors.

So help me God. Signed and dated this the fifteenth day of December 2004.

_____
Thomas E. Scherer
Petitioner

JURY DEMAND: Mr. Scherer demands a trial be one before his peers by jury trial.

DAMAGE AMOUNT: In Excess of $75,000

DEMAND FOR CLASS ACTION CERTIFICATION-

AS PROVIDED UNDER THE KANSAS CONSUMER PROTECTION ACT, K.S.A. 50-634(c) and (d) for a declaratory judgment, an injunction, and appropriate ancillary relief in addition to claims for relief/remedy as provided under the Kansas Product Liability Act.

II. SHORT AND PLAIN STATEMENT FOR A CLAIM FOR REMEDY AND/OR RELIEF K.S.A. § 60-208(a)(1))

This is a product liability claim against the defendant, [redacted], as well as the second defendant [redacted], and finally, state officials of Kansas for failing to protect my, or other Kansas citizen's interests within the intent of the Kansas legislature. As well any unnamed but necessary additional defendants as needed, as provided under the Kansas Products Liability Act (K.S.A. § 60-3301 et seq.) and the Kansas Consumer Protection Act (K.S.A. § 50-623 et seq.) based on strict liability, as well as negligence, breach of express or implied warranty, and breach of or failure to discharge duty to warn or instruct. This claim asserts that [redacted] committed both a design defect[3] (alternative and more reliable product was available) and a marketing defect[4] (failure to warn). In addition, other relevant Kansas statutes are provided in Chapters 65 (Public Health), 77 (Administrative Rules, Regulations and Procedures), and 84 (U.C.C.).

Scherer was prescribed two products by [redacted]. In that regard, this petition is also a professional liability action as provided in K.S.A. §§ 60-3401-3414, *et seq.*, commonly referred to as malpractice including negligence. The prescribed products were manufactured and distributed by the defendant, [redacted]. Those products were prescribed by [redacted], which in turn, caused (proximate cause and cause in fact)[5] personal injury and damage to the petitioner.

[1] *See* Restatement Third of Torts, Section 2(b) and 2(c) on categories of product defect which provides that [A product] is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor. (Merck has a combination product of simvastatin and coenzyme CoQ10. Merck does not market that superior or more reasonable alternative product.. 2(c) states that {A product] is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provisions of reasonable instructions or warnings by the seller or other distributor . . . and the omission of the instructions or warnings renders the product not reasonably safe. Specifically refer to Comments (i) inadequate instructions or warnings and (j) warnings: obvious and generally known risks; (m) Reasonably foreseeable uses and risks in design and warning. All comments which apply in this instant petition.

[4] *See* Restatement Third of Torts, Section 6(b) that provides that a prescription drug or device is not reasonably safe due to inadequate instructions or warnings regarding foreseeable risks of harm not provided. See Comment (a-h) in this section in entirety.

[5] If necessary and prudent, Scherer can reestablish the products were the causation by merely repeating the taking of the prescriptions products.

Scherer in addition to taking two of [redacted] products was taking several other prescriptions concurrently. Scherer was initially prescribed lovastatin (Mevacor)[6] on April 14, 2003 by a state-licensed practitioner at the Topeka VA, [redacted] M.D. The Topeka VA Pharmacy provided that initial prescription in a bottle with labeling instructions. On May 1, 2004, a second prescription was given for a different statin prescription, simvastatin (Zocor). On July 7, 2003, the prescription for simvastatin was doubled, despite the reporting of several symptoms on several dates. Scherer took the prescriptions as directed on the labels. There was no warning given regarding:

a) Critical and high risk of a drug-drug interaction, although from documents obtained under the Freedom of Information Act, in appears both [redacted] and the pharmacist had information regarding a critical and high risk of a drug-drug interaction. Neither the doctor nor pharmacist complied with a duty to warn of a potential drug-drug interaction. Nor did either professional warn about manufacturer's warnings of a danger in a drug-drug interaction, specifically while a consumer was also taking a prescription for ketconazole.

b) A possible risk of depletion/reduction of a coenzyme, CoQ10 based on the inhibition of this coenzyme by statin products. A known effect not warned by the defendant in prescribing information, although that effect is reported in patent information by [redacted], as well as by published medical/scientific experts including petitions filed and pending by others with the FDA.

The failure of a duty to warn, in addition of the doctor or pharmacist as state regulated and licensed professionals, to follow the VA computer system warning or, as a learned intermediary by failing to follow prescribing information by the warnings of the defendant [redacted], resulted in a serious, potentially life threatening, serious expected and unexpected adverse event. That included an emergency room visit requiring medication intervention on April 24, 2003. Initially, the ER did not properly attribute the adverse event with the medication.

Scherer continued to take those products and suffer personal injury and damages including pain, agony, emotional distress and the loss of normal functioning--a *disability* as defined by the regulations enforced by the FDA (21 C.F.R. 600.80), until he was advised by a different doctor, [redacted] at the Kansas City VA to stop taking that ordered prescription product on October 24, 2003.

After stopping that prescription, some of the symptoms that are attributed to this product, stopped within three days. Although some symptoms remain to date, including chronic fatigue requiring further medical intervention, treatment, and on going medical tests. Some of the injury suffered by Scherer may in fact, be found to be both permanent and irreparable.

This petition deals with in part, the superior and constructive product knowledge of the manufacturer, [redacted] as the defendant in their capacity as manufacturer, applicant, and distributor. [redacted] failed to warn intermediaries of known, but unreported risks attributable to the inhibition by these two products, lovastatin and simvastatin on the coenzyme CoQ10.

[6] Lovastatin is the active ingredient. The proprietary product name is Mevacor. Simvastatin is the active ingredient. The propriety name is Zocor.

[redacted] failed to take prudent action in warning intermediaries of this known risk in prescribing information. [redacted] is subject to strict liability for a marketing defect and the failure to warn those intermediaries for any/all injuries/damages suffered, or will be suffered by Scherer. The two products are the cause in fact and the proximate cause of those injuries and subsequent or concurrent damages. In regard to the defendant, [redacted]:

1. [redacted] **had superior and constructive product knowledge of high risks** and the potential for adverse events that are attributed to lovastatin or simvastatin including the high risk attributed to depletion of coenzyme CoQ10[7] and reported that information in patents to the United States Patent Office.[8]

2. [redacted] **intentionally, knowingly, and willfully, negligently and with reckless endangerment, failed to test for, and/or failed to inform the FDA during the IND process, clinical trials or any other part of the NDA process, or in supplemental filings**[9], of this known risk related to CoQ10 and the corresponding potential for an adverse event to users of lovastatin or simvastatin despite that superior and constructive knowledge as stated in its patent applications.

3. [redacted] intentionally, knowingly, and willfully, negligently and with reckless endangerment, failed to conduct, test, or report during its clinical trials, or after approval of this product for consumer use, reports that were known or subsequently reported after FDA approval (December, 1991), to this known foreseeable risk and likely potential for an adverse event (depletion or reduction in coenzyme Coq10, despite having a superior or constructive knowledge of that risk contained in several patents filed with the U.S. Patent Office, as well as reported Research in public and scientific reports by the Director of for [redacted] for twenty years, [redacted] during the time period from 1990 through 1994, *et al*.

4. [redacted] **intentionally, knowingly, and willfully, negligently failed with reckless endangerment to adequately inform intermediaries** of this known and foreseeable risk, and the corresponding potential for an adverse event related to reduction/depletion of coenzyme CoQ10 in prescribing information (marketing defect) nor did it give instructions with specificity to this known risk, or provide to intermediaries how they were supposed to determine this risk, or diagnose events pertaining to that risk with specific instructions regarding tests to confirm or deny that risk. This is a breach of, or failure to discharge [redacted]'s duty to foreseeably warn or instruct under *the learned intermediary doctrine*,[10] to licensed practitioners in Kansas. *Also See* Restatement of Torts, 3d Product Liability.

5. [redacted] **failed to modify or change prescribing information** with full, superior, and constructive knowledge of petitions filed and pending with the FDA[11] pertaining to potential risks attributable to lovastatin or simvastatin

6. [redacted] **breached the implied and express warranties of merchantability**. *See* Restatement of Torts, 2d §§ 2-314 and 315.

[redacted] officials would include [redacted], General Counsel for [redacted], his assistant, [redacted] (refuses to provide a last name).

Under the Kansas Product Liability Act, and the Kansas Consumer Protection Act, this court and jury should find [redacted] liable for those foreseeable injuries and damages. In doing so, the court and jury will be protecting the public interest in ensuring that this manufacturer, or any other manufacturer does not fail to provide to intermediaries, important and foreseeable facts necessary to adequately prescribe medications, or warn of known risks.

In regard to the second named defendant, [redacted]

1. [redacted] as a state licensed practitioner[12] failed to provide adequate warnings to a known and high risk of a drug-drug interaction in his individual capacity as a learned intermediary.

2. The failure to warn of known risks and warnings is a failure to obtain *informed consent* from the consumer, Scherer.

3. The failure to warn of known risks and warnings (specifically a drug-drug interaction) that resulted in injury and/or property damage to a consumer is an act of malpractice and/or negligence under Kansas's statutes.

4. A person who commits malpractice and/or negligence in the state of Kansas is subject to liability for those acts/omissions under Kansas's statutes.

---

[7] *Also referred* to as ubiquinone, coenzyme Q sub.10, Co-enzyme Q10 or simply Q10. *Hereafter* referred to as CoQ10 in this document).

[8] Patents include 1) 4,444,784, Antihypercholesterolemic compounds, (April 24, 1984) regarding the patenting of a manufacturing process that includes SIMVASTATIN 2) 4,929,437, Coenzyme Q sub.10 with HMG-CoA reductase inhibiters (May 29, 1990), regarding the combining of statins with CoQ10 3) 4,933,165, Coenzyme Q sub.10 with HMG-CoA reductase inhibiters, (June 12, 1990) regarding the need to counteract myopathy (muscle damage from statins)/ 4) 5,082,650, Amelioration of reductions of coenzyme A sub.10 in cardiomyopathy patients receiving Lovastatin (January 21, 1992) 5) 5,316,765, Use of coenzyme Q sub.10 in combination with HMG-CoA inhibitor therapies (May 31, 1994), by Karl Folkers, *et al*, regarding the methods to inhibit side effects related to HMG-CoA inhibitors including Lovastatin and SIMVASTATIN.

[9] *Refer to* new drug application (NDA) 19-766 and related supplemental filings on simvastatin at http //www fda gov/cder/approval/z htm.

[10] *See apposite case*, Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 681 P.2d 1038 Kan., (1984) which fully addresses the duty to warn, as well as the learned intermediary doctrine. Attached as a citation of authority.

[11] *See* FDA petitions 02P-0243/CP1 and 02P-244/CP1 (date-stamped November 14, 2002) recommending supplementation of enzyme CoQ10. *Also see* 01P-0372/CP1 (dated August 27, 2001) filed by Public Citizen regarding four specific recommendations on statin therapies regarding "Black box warning labels" and adverse events attributable to ZOCOR and other statin products. *Also see* 02N-0115 (June 10, 2002) regarding a medical doctor reporting of an adverse event attributed to ZOCOR

[12] The petition naming [redacted] is for acts/omissions in his individual capacity, acting outside the scope of his duty as a doctor for the Veteran's Administration. A separate administrative claim is filed for acts/omissions in his official capacity. The attorney acting for [redacted], refuses to state whether the acts/omissions are considered by the VA as acting within or outside his capacity.

A. ISSUES OF FACT TO BE DECIDED BY A JURY OF PEERS

1. Does the acts/omissions of the defendant [redacted], by failing to adequately and [redacted]ly warn of a known, but unreported risk relating to Q10, the cause of personal injury and damages to Scherer as the petitioner?

2. Did the acts/omissions of [redacted] constitute negligence and/or malpractice outside the scope of his official duty, and fail to act prudently within the standard of duty owned to Mr. Scherer, resulting in injury and property damage?

B. ISSUES OF LAW TO BE DECIDED BY A TRIER OF FACT

1. Did [redacted] knowingly, intentionally, and willfully fail to report a spontaneous consumer report to the FDA as mandated by federal regulations (21 CFR 600.80)?

2. Did the State of Kansas by acts/omissions/failure to act protect Mr. Scherer and other Kansas citizens by failing to take reasonable steps to ensure licensed Kansas doctors and pharmacists were in compliance with Kansas statutes and regulations? And if the state did not act reasonably in protecting Kansas citizens, did that contribute to Mr. Scherer's injuries and property loss?

3. Was that regulatory failure of the state of Kansas agency officials sufficient to warrant a declaratory judgment, as well as assessing punitive damages in the public interest to Scherer as a private attorney general?

III. A DEMAND FOR JUDGMENT FOR WHICH THE PETITIONER IS ENTITLED K.S.A. § 60-208(a)(2)

1. Mr. Scherer requests a summary judgment for relief/remedy as provided under state statutes, and their corresponding regulations under a theory of strict liability from the defendant [redacted]. That relief/remedy includes compensatory and punitive damages for personal injury and property damages including negligent infliction of emotional distress for pain, suffering, and agony. In addition, punitive damages should be asserted against [redacted] for its failure to adequately warn intermediaries of known, but unreported risks.

2. Mr. Scherer requests a summary judgment for relief/remedy as provided under Kansas statutes, and their corresponding regulations under a theory of negligence/malpractice against [redacted] for his acts/omissions outside the scope of his official duty (individual capacity)including the relief and remedy compensatory and punitive damages for personal injury and property damages including negligent infliction of emotional distress for pain, suffering, and agony.

3. Mr. Scherer requests a declaratory judgment against the state of Kansas for failing to take reasonable steps in compliance with the intent of the Kansas legislature

4. Mr. Scherer asks the trier of fact/jury to apportion the amount of contribution of each defendant to Scherer's injuries and damages.

IV. RELEVANT FACTS OF THE CLAIM AGAINST [redacted], [redacted], AND THE STATE OF KANSAS AS DEFENDANTS

a) Facts about the Petitioner

FACT 1 Mr. Scherer is a permanent resident of Merriam, (Johnson County) Kansas. He has and still maintains a permanent residency at [redacted] since around 1992 as a homeowner. Scherer was and is a registered voter in Johnson County, paid personal and real property taxes, as well as paid utility bills on that permanent residence at the time he took products manufactured and distributed by the defendant.

FACT 2 Mr. Scherer is a divorced father and has one son named [redacted]. Scherer was born on [redacted] (age 49 at start of taking the product), in [redacted] Kansas and is an honorably discharged veteran; currently rated 30% service connected disability and is the petitioner. He was also considered a person with a disability by the Social Security Administration and by an ALJ effective September 7, 1994. He also is considered disabled based on a chronic skin condition by the Veterans Administration retroactive to 1976.

FACT 3 Scherer was prescribed and took as directed on labels, two products manufactured by the defendant, lovastatin and simvastatin during the period of time from April 14, 2003 until he stopped taking simvastatin on October 24, 2003, based on a VA doctor order ([redacted]) Scherer therefore has the right to petition this court based on that permanent residency. Therefore, this district court has general, personal, and subject matter jurisdiction; as well as venue; in a timely petition filed against the defendant, a corporation doing business in Kansas including as provided under K.S.A. 60-604 (3), et al. In addition, the state of Kansas has a significant interest and duty in protecting our Kansas citizens.

FACT 4 Scherer was prescribed both of these statin products manufactured and distributed by [redacted] in 2003. (*See* **Exhibit** 4). Scherer was prescribed by doctor order, lovastatin by a medical doctor with the Topeka VA[13], [redacted], Primary Care Blue Team, a licensed physician licensed authorized to practice medicine in the state of Kansas on April 14, 2003. [redacted] prescribed Simvastatin on May 1, 2003. [redacted] doubled the dosage of simvastatin on July 7, 2003. Both [redacted] and the registered pharmacist at the Topeka VA failed their duty to adequately and timely warn of a known critical and high risk including warnings provided by the manufacturer, [redacted] at the time of prescribing on both April 14 and again on May 1, 2003, regarding concurrently prescribing a statin product while at the same time, a consumer was taking ketoconazole.

[13] The Topeka VA will be used for convenience herein to indicate the VA medical center as an entity and its officials. The official entity is VA Eastern Kansas HCS, Department of Veterans Affairs, Colmery-O'Neil VA Medical Center 2200 Gage Blvd., Topeka, KS 66622-0001. The Kansas City VA will be stated the KC VA to distinguish between the two different VA medical centers that are referred to in this petition *hereafter*.

FACT 5 Scherer provided a notice to [redacted]s Office of General Counsel, a certified letter dated November 18, 2003. That letter includes a request for [redacted] to provide relief and/or remedy. [redacted] received that letter (see United States Form PS-3811. And did not respond to that letter until December 16, 2003. (***See* Exhibit 5**)/

FACT 6 Mr. Scherer had previously been prescribed and was actively taking several other active prescription medications when he was prescribed Lovastatin or SIMVASTATIN starting on April 14, 2003 and continuing until October 24, 2003, including the following:

a) Ketoconazole Creme
b) Busiprone
c) Lithium
d) Thiordidazine
e) Fluticasone
f) Diphenhydroamine
g) Nicotine Patch

That information was available and reported on the Topeka VA Computer medical records and therefore was in constructive knowledge, possession, and available for the prescribing and treating medical doctors at the VA. *See* **exhibit** 4.

FACT 8 Scherer was originally given an initial prescription for Lovastatin by [redacted], his primary care physician (Blue Team) at the Topeka VA on April 14 2003, (an event called a actual medication error). This was while as I treated at the Topeka Kansas VA during the period of time I was attending Washburn University School of Law as a temporary, but not a permanent resident of Topeka, Kansas.

FACT 9 The taking and subsequent symptoms from taking the products lovastatin and simvastatin as directed, was a significant mitigating factor in Scherer's actual performance at Washburn University School of Law including final exams on May 6 through May 9, 2003.

FACT 10 [redacted], M.D. the prescribing licensed practitioner, appears on the bottle containing the prescription product Rx 513566875, dated 5/1/03 and again on 7/7/03 and will be presented as a physical exhibit.

FACT 11 The purpose of [redacted] prescribing Scherer to take the prescription Lovastatin was to treat a condition/diagnosis of hypercholesterolemia (commonly referred to as high cholesterol levels). Despite his prescription order, the Topeka VA pharmacy instead, substituted a non-prescribed product, simvastatin (active ingredient) or Zocor (proprietary name) on May 1, 2003. The reason for the substitution was related more to product availability, rather than reported emergency intervention and consumer reported product symptoms.

FACT 12 [redacted] failed to warn on April 14, or thereafter about any possible risks associated with concurrent taking of ketaconazole 2% crème despite the prescribing information specific and explicit information regarding the combining of these two products.

FACT 13 On April 24, 2003, Scherer went to the Topeka VA emergency room to be treated and diagnosed for pain in my stomach, and other symptoms. Scherer could not concentrate on legal studies and was very concerned about that since final exams were scheduled in less than two weeks at the Washburn University School of Law. On that date, Scherer did not know what was causing the gastro-intestinal problem nor did he attribute that pain to the taking of the prescription LOVASTATIN and/or SIMVASTATIN.

FACT 14 Scherer was treated in the VA ER on April 24, by both a Nurse practitioner [redacted] and by the ER supervisor, [redacted]. Their incorrect diagnosis was constipation, a symptom, rather than diagnosing what was causing the pain. I was prescribed docusate (stool softer) and magnesium citrate and took these prescriptions as directed. I obtained short-term relief for about three days when the symptoms returned.

FACT 15 From April 18, to May 15, 2003, Scherer stopped taking some of his prescribed medications believing some of those medications were causing his symptoms. He did continue to take simvastatin however, until October 24, 2003.

FACT 16 Scherer continued taking simvastatin as instructed on the prescription bottle from around May 1, 2until October 24, 2003 when a nurse, acting on behalf of [redacted], Assistant Professor, IM/ Geriatrics at the Kansas City VA Primary Care Green team, and my new primary care doctor, ordered me to stop taking that prescription. The rationale for stopping that prescription was based on what I believe is generally described by the FDA and others, as a serious adverse event attributable to taking this prescription.

FACT 17 On or around April 29, 2003, [redacted] negligently, and a second medical error, ordered a new or initial prescription for simvastatin. Ordering a prescription, when the prescribing information or, the Topeka VA provides a warning about possible drug-drug interactions is commonly referred to in federal regulations, as well as by other authority, as *a medication error*.

FACT 18 On May 15, 2003, Mr. Scherer stopped taking most prescribed medications in an attempt to isolate which prescription might be causing the pain and discomfort, with the exception of simvastatin, busiprone for extreme anxiety situations as needed, and Ketaconazole 2% crème for active new skin lesions when they initially appeared.

FACT 19 On July 7 2003, I reported to [redacted] the pain and discomfort. Instead of adequately attributing that pain and symptoms to simvastatin, [redacted] negligently instead increased the prescription level. That pain, suffering, and negligent infliction of emotional distress continued until around October 27 2003, three days after I stopped taking the simvastatin. My appetite returned to levels that are more normal and finally my gastro-intestinal symptoms returned in part. I did however, and continue to date continue to have chronic muscle aches and fatigue.

FACT 20 On September 26, 2003, I met with [redacted] in the KCVA Mental Health Clinic. I reported to [redacted] that I was feeling fatigued in pain and experiencing suicidal ideation.

FA **21** Since October 24, 2003, I have done exhaustive legal and scientific research, [redacted]e the chronic fatigue pertaining to adverse events attributable to simvastat[redacted]in drug therapy, and the class of statin products. I continue to do legal and sc[redacted]esearch, as well as taking diagnostic tests to determine the nature and exten[redacted] of [redacted]jury and corresponding damages. By doing that research, I have found severa[redacted] pr[redacted] that cause me concern regarding the safety of this product.

F[redacted] **22** Since October 24, 2003, I have attempted to act in good faith with variou[redacted] [redacted]fficials by regarding simvastatin and VA administrative processes pertaining [redacted]dverse events and the reporting of those adverse events,; the FDA (Janet Woodcock), and her designee Mitchell Weiztman, Attorney at Law; as well as the drug manu[redacted]urer, [redacted], Inc.

FA[redacted] 23 On November 16, 2003, consumers Medwatch report was filed with the FDA via fax. An acknowledgment was received from the FDA of that Medwatch report dated December 16, 2003. (**Exhibit 6**).

FACT 24 On November 16, 2003, a notice was sent to the manufacturer of lovastatin and simvastatin, [redacted], Office of General Counsel via certified mail, return receipt. (**Exhibit 5**).

FACT 25 On November 17, 2003, I started taking a multi-vitamin, multi-mineral supplement (ABC Complete hoping there was some kind of nutritional deficiency related to malabsorption that may have directed related from the taking of SIMVASTATIN.

FACT 26 On December 8, 2003, a letter was sent certified mail, return receipt, and restricted delivery, to the Topeka VA Director, [redacted] (carbon copy to the Secretary of the VA, [redacted]. That letter requested a writing that asked specific action to be taken, including the filing by VA officials of an adverse event with the FDA, as well as copies to be provided to me of that reporting. Director [redacted] signed the receipt on December 13, 2003. To date, there has been no response, by any VA official to that official letter.

FACT 27 On December 18, 2003, [redacted] and a medical resident, [redacted], interviewed me. [redacted] recommended more diet modifications including Benecol spread (contains plant stenol esters, a known product that lowers cholesterol) and fish oil supplement (omega 3 fatty acid). I purchased the Benecol spread the same day. And several days later, purchased a fish oil concentrate at the local K-Mart store, softgel capsules, 1000 mg., with 600 mg. omega-3 fatty acids (360 mg. of EPA, 240 mg. DHA).

FACT 28 On December 29, 2003, I was informed by telephone call that [redacted] was the General Counsel by [redacted], Topeka VA Patient Representative. I contacted Mr. [redacted] on that date, regarding no production under the FOIA, or no communication from Director [redacted] to my letter dated December 8, 2003 regarding the reporting either internally, or externally on my adverse events. [redacted] informed me he would investigate and call back. He did not call back, nor did any other VA official.

FACT 29 On January 9, 2004 I was informed by a staff nurse [redacted] at the KC VA primary care team, who works under [redacted], that a VA lab supervisor had stated that the VA lab can check CoQ10 enzyme levels, a diagnostic test several VA officials had previously stated they could not do, on several occasions.

FACT 30 On January 12, 2003, after the KC VA lab, took a blood sample for submission of a baseline CoQ10 level, I started a scientific test for CoQ10 by taking an OTC supplement from GNC of CoQ10, 100 mg. water-soluble capsules, one time per day.

FACT 31 On Tuesday, January 20, 2004, I contacted the Regional Counsel's staff in St. Louis. Prior communication with VA officials on whom to send the SF-95 claim form created confusion on who was the proper official to receive service on behalf of the Veterans Administration. The Topeka VA Patient Representative had previously informed me [redacted] in Wichita was the Regional Counsel. The Kansas City VA insisted their office was the regional counsel. The fact was that neither office was the Regional Council. The Regional Counsel is located in St. Louis, MO.

FACT 32 On Wednesday, January 20, 2003, [redacted] an attorney who works for the Regional Counsel, contacted me on the telephone and assured me that I would receive a response pertaining to the letter I had written and sent to Topeka VA Director [redacted], and documents I had requested in an official valid FOIA request would be sent to my residence by Saturday, January 24, 2004. No documents or writings were provided.

FACT 33 The Topeka FOIA officer, the acting FOIA officer, or the interim or new FOIA officer is therefore in violation of the FOIA (5 U.S.C. 552) in not timely producing requested documents (10 working days) under that act. There is no exception that has warranted a delay in production under that act. There has been no acknowledgment letter or any letter in writing requesting an extension of time regarding production.

FACT 34 The ordering and subsequent taking as directed of lovastatin and simvastatin products manufactured and distributed to the VA by [redacted] are the cause in fact, and the proximate cause of the subsequent injury and damages suffered by Scherer as the petitioner.

FACT 35 On January 27, 2004, I received an implausible letter from Director [redacted] stating that a committee met and determined my actual medications errors, and subsequent unexpected and expected, potentially life threatening, serious adverse event was not deemed to be *significant*.

FACT 36 On January 30, 2004, a reply and notice of appeal and error was sent in response to that ludicrous assertion that my experience was not significant.

FACT 37 To date, I have requested aggregate documents and data from several VA and FDA officials, public documents under the Freedom of Information Act 5 U.S.C. § 552 pertaining to the reporting of adverse events and specific documents related to my own specific situation regarding the prescribing and treatment related to simvastatin.

This includes:

a) Letter(s) dated November 13, December 4, and again on December 16, 2003 to [redacted] as Freedom of Information Officer, Topeka VA. To date there have been no records provided under those requests related to treatment records on April 29, 2003, or records from the pharmacy dated April 14, 2003.

b) Letter dated January 14, 2004 to Secretary [redacted] VHA FIOA officer, Washington, D.C.

c) Letter dated January 6, 2004 to FDA Commissioner [redacted] Director, c/o [redacted], Freedom of Information Officer.

d) An email was sent to [redacted] with receipt, including carbon copies to several officials with the FDA.

Initially, the prescribing of Lovastatin was an actual medication error by the precise and unambiguous federal regulations. The substitution by the Topeka VA Pharmacy on April 14, 2003 for Lovastatin was a second medication error. There was no prescribing information or warnings given on the substituted prescription product.

The first medication error can be established by referring to the prescribing information. The prescribing information for simvastatin gives a specific warning regarding the concurrent taking of simvastatin and Ketaconazole 2% crème. [redacted] prescribing information specifically and explicitly states this combination should be avoided. See Merck prescribing information (**Exhibit 2** at pg. 11-12).

Finally, Scherer as the petitioner has to date, been variously diagnosed with several conditions such as myalagia, chronic fatigue, (July 2004) peripheral neuropathy September 2004) , and most recently with a form of leukemia (October 2004). Scherer in turn, believes this warrants advisement to the trier of fact, there may periods of Scherer being in a state of fatigue. In such an event, Scherer in good faith will advise the trier in that event.

b) Facts about the defendant [redacted]

FACT 38 [redacted] & Co., Inc., *hereafter referred to as* [redacted]) is a business entity incorporated in the state of Delaware (Restated Certificate of Incorporation dated September 1, 2000). [redacted] maintains their principal place of business at their corporate facilities and offices located in [redacted], New Jersey. [redacted] is registered with the Kansas Secretary of State as a business entity I.D. No. [redacted] with the intent to distribute its products in the stream of commerce within the state of Kansas sufficient for this court to exercise subject matter jurisdiction. [redacted] has a resident agent for service of process in the state of Kansas.

FACT 39-The registered agent for service of process for the defendant is:

The Corporation Company, Inc.
[redacted].
Topeka (Shawnee County), Kansas
[redacted]

FACT 40 [redacted] develops, patents, tests, manufactures, and distributes biological products intended for human consumption. Two of those products include active [redacted]ient referred to as Lovastatin and Simvastatin. The two products are also referred to by their registered names Mevacor (Lovastatin) and Zocor (simvastatin). [redacted] in addition has patented the manufacturing process related to these products including the combination of a statin product with a coenzyme CoQ10. [redacted] does not manufacture or produce a product that combines a statin with this coenzyme. No other manufacturer can infringe on [redacted]'s patent and combine a statin product with CoQ10. [redacted] has filed an application and received approval for these products with the FDA. The FDA in turn considers [redacted] in addition to being a manufacturer, to also be considered by the FDA, as an applicant.

FACT 41 [redacted] officials **must** file an FDA form 3500A (15 day adverse event report) with the FDA upon receipt of a spontaneous consumer letter informing the manufacturer of a serious adverse event, under required federal regulation (*See* 21 C.F.R.. § 600.80).

FACT 42 [redacted] failed to adequately or reasonably warn intermediaries of a known risk associated with statin therapy-the risk related to a reduction/depletion of a coenzyme CoQ10. By failing to adequately warn the FDA or intermediaries of this known risk, [redacted] in marketing that product in failing to warn of that known risk, has defectively marketed statin products--a marketing defect. [redacted] has a duty to warn intermediaries of known risks.[14]

[14] ***See apposite case*** Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 681 P.2d 1038 Kan., (1984) that discusses in depth, many of the issues that will be presented in this case, including the *learned intermediary doctrine*, and a manufacturer's *duty to warn of known risks*, including those risks as reported by others such as in petitions filed with the FDA and as reported and published by national and international scientific medical experts.

c) FACTS ABOUT DEFENDANT [redacted]
IN HIS INDIVIDUAL CAPACITY

FACT 43- [redacted] is a licensed medical doctor. He is licensed to practice medicine in the state of Kansas with the Kansas Board of Healing Arts (License No. [redacted]).

Fact 44 [redacted] resides at the following residential address:

Fact 45 [redacted] is employed with the Topeka VA Hospital in Topeka, KS part of the time. On the other hand, he is a licensed practitioner all of the time.

Fact 46 [redacted] is not entitled to immunity for acts that exceed the scope of his duty, or exceed the standard of care required of a licensed practitioner under Kansas statutes and regulations for acts of negligence and/or malpractice.

Fact 47 This is not a petition relating to [redacted] in his official capacity as a licensed medical practitioner employed by the Veteran's Administration.

Fact 48 [redacted] was aware of, or should have reasonably been aware of a pending complaint against him, for acts/omissions related to his treatment of Mr. Scherer, the petitioner. In written rep[eats to Kansas Board of Healing Arts, in Item 13(g), [redacted] made a false statement on June 10, 2004.

Fact 49 There is a separate pending administrative claim(s)for acts/omissions against [redacted] in his official capacity as a medical doctor within the scope of his employment relationship with the Veterans' Administration. This administrative action is not a part of this petition.

Fact 50 [redacted] was aware, or should have been aware that Mr. Scherer was prescribed and actively taking several other medications at the time of prescribing Mr. Scherer both Lovastatin and Simvastatin.

Fact 51 [redacted] was aware or should have been aware of internal system warnings regarding a high and critical risk of a drug-drug interaction with lovastatin and ketoconazole. (*See* **Exhibit. 1**)-VA critical and high risk drug-drug warning).

Fact 52 [redacted], as a learned intermediary, was aware or should have been aware of prescribing information pertaining to adverse events and product warnings from the manufacturer [redacted] regarding not prescribing Lovastatin or Simvastatin to a consumer (Scherer) concurrently being prescribed ketoconazole.

Fact 53 The prescribing of lovastatin and simvastatin (when there was reasonable and sufficient information from both the manufacturer [redacted] as well as internally within the VA) is a mistake, medication error, and is the cause of injury and damage to Mr. Scherer.

Fact 54 The prescribing of lovastatin and simvastatin in error is sufficient to be classified as an act of negligence and/or malpractice warranting the relief and remedy requested in this petition from [redacted]

Fact 55 [redacted] cannot use federal tax dollars or federal government attorneys for representing him in this individual capacity action for acts/omissions outside the scope of his employment.

d) FACTS ABOUT THE DEFENDANT, THE STATE OF KANSAS

Fact 56 The State of Kansas has regulatory agencies that regulate and protect the interests of citizens of Kansas as provided by the authority of the Kansas State legislature.

Fact 57 The State of Kansas has a regulatory agency that regulates and protects Kansas citizens from licensed practitioners such as the Kansas State Board of Healing Arts. The physical address for the Kansas Board of Healing Arts is 235 S. Topeka Boulevard, Topeka, Kansas 66603-3068. This agency maintains a website that includes those state regulations under the authority at www.ksbha.org. The telephone number for this agency is (785) 296-7413. The executive director of this agency is Lawrence T. Buening, Jr.

Fact 58 The State of Kansas has a regulatory agency that regulates and protects Kansas citizens from licensed pharmacists such as the Kansas Board of Pharmacy.

Fact 59 Both state agencies, acting for the State of Kansas failed to perform their regulatory duty pertaining to registered and licensed doctor and pharmacists practicing within the state of Kansas.

Fact 60 The failure of these state agencies and their officials to protect my, and other Kansas citizens by conducting reasonable regulatory action is shocking to the conscious of a prudent or reasonable person in accordance with the legislature of the State of Kansas.

Fact 61 Mr. Scherer filed regulatory complaints with both state agencies. Both agencies have failed to take reasonable, prudent, and timely action on those regulatory complaints.

Fact 62 Mr. Scherer has reasonably and constructively exhausted attempts to obtain administrative remedy/relief from these state administrative agencies.

Fact 63 Both state agencies refuse to allow or provide Mr. Scherer with any notice of action taken to date, despite Scherer having a right to know, hiding behind their lack of action by claiming privileged and confidential investigation on his administrative complaints.

Fact 64 Any Kansas citizen who files an administrative complaint has the right to both notice of acts taken by a state regulatory agency. To allow a state agency to act, without any notice to the complainant, ensures that a state agency can in fact, do nothing or very little subject to its own discretion without any oversight by acts/failures to act by the state agency.

Fact 65 It is an inherent fact and right for a Kansas citizen to be able to determine the status of a regulatory complaint to ensure a state agency is performing it's regulatory function within the intent of the Kansas state legislature.

Fact 66 The failure of these two state agencies to conduct an administrative action is shocking to the conscious of a reasonable and prudent person.

Fact 67 It is the public interest of Kansas citizens for these administrative agencies to allow judicial inspection of what acts they have, or have not taken pertaining to Mr. Scherer's administrative complaints.

e) FACTS THAT ARE RELEVANT AND PRODUCT SPECIFIC

FACT 68-Ubiquinone, (also known as Q10, coenzyme Q10, CoQ10) are by similar metabolized derivatives is an essential component is the mitochondria as human cells (DNA). Ubiquinone in turn, is used by all cells in the human body and is necessary for energy production. A low, depleted, or reduced level of Q10 would explain scientifically or medically, some of the chronic fatigue Scherer, and others would experience from taking a statin product.

FACT 69 Lovastatin and simvastatin, as well as the entire class of statin products is known as a HMG CoA reductase inhibitor. It is also well known by the mfg. [redacted] that statin products also inhibit ubiquinone in the liver.

FACT 70 [redacted] does not warn or inform intermediaries in prescribing information of the high risk of inhibition of ubiquinone or Q10. In plain language, [redacted] fails to warn of this known corresponding inhibition.

FACT 71 Scherer attempted to address this issue with the defendant [redacted] General Counsel in good faith, rather than seek judicial relief and remedy. In addition Scherer is pursuing administrative remedy/relief from the potential related parties with their respective FDA and VA agency officials. Scherer has exhausted administrative remedy with the Washburn University School of Law and is presenting pursuing administrative remedy with the Dept. of Education Civil Rights Division in Kansas City, MO and in a timely complaint filed with the Kansas Human Rights Commission.

f) FACTS PERTAINING TO PENDING, AND/OR REASONABLE CONSTRUCTIVE OR ACTUAL EXHAUSTION OF REMEDY/RELIEF WITH EITHER DEFENDANT, OR REGULATORY AGENCIES OF THE FEDERAL OR STATE GOVERNMENT, OR ITS REGULATORY OR REPRESENTATIVE OFFICIALS.

Fact 72 There is a pending administrative tort claim filed against both the Food and Drug Administration and the Veterans Administration, federal government agencies dated Aug. 2004. This is not included in this state petition.

Fact 73 There is a pending claim with the Veterans Administration pending with the Wichita VA regional office that is not included in this state petition.

Fact 74 There have been administrative complaints filed with the Kansas Board of Healing Arts and the Kansas Board of Pharmacy for acts of either doctors or pharmacists. For the most part, these administrative complaints have been exhausted either actually, or constructively, with no good faith acts taken by either state agency.

Fact 75 There has been an administrative complaint filed with the Joint Commission of Accreditation of Hospitals (JCAH). That administrative complaint was closed without any reasonable action taken.

Fact 76 There has been additional complaints or requests for administrative action to various entities including the Topeka VAMC officials, the National Center for Patient Safety (VA as a federal agency) as well as acts/documents with the Food And Drug Administration, and non-profit consumer agencies and groups.

FACT 77 There are additional petitions pending with the Food And Drug Administration pertaining to better labeling and warnings to intermediaries by other individuals or consumer protections groups regarding statin products such as Public Citizen, and [redacted] *et. al.*

V. ANTICIPATED DISCOVERY PROBLEMS IN THIS CASE INCLUDING DEFENDANT AFFIRMATIVE DEFENSES

A. **MEDICAL EXPERTS-**[redacted], in anticipation, will try to assert an affirmative defense pertaining to whom [redacted] considers is, or is not, a qualified medical expert. [redacted] refuses to provide in response to a writing, whom their General Counsel would consider to be a medical expert with sufficient product knowledge, or the necessary qualifications. [redacted] should be barred from raising this affirmative defense since their officials have refused to identify whom they would consider to be a medical expert, or the necessary qualifications to be regarded as a medical expert.[15] *Alternatively*, should the trier of fact require medical experts, some of whom may be international, or national, Scherer requests under Kansas Supreme Court Rule 145 (2001 Edition Annotated at pg. 198), that he be allowed with the trial court's discretion, the use of telephone conference calls for interviewing, depositions, and the recording of testimony from national and international medical experts that the trier of fact finds necessary and relevant under a Daubert-type analysis.

Alternatively, the court has the discretion and authority to provide for a screening panel as provided under K.S.A. 60-3502-3509 at the request of any of the parties. Scherer anticipates making such a request for that convening as provided under that Kansas statute by filing a timely and reasonable memorandum to that effect.

B. There is already abundant and public reported studies by national and international scientific and medical experts concerning the need for supplementation of statin therapy sufficient for the jury and the trier of fact to the known dangers of statins and a subsequent reduction/depletion of coenzyme Q10. In addition, I have at my disposal, public statements made by [redacted] own former director of research for twenty years, [redacted] who regarded statin therapy without supplementation to be *"expensive and downward spiral of death"*. Those reported studies and publications including as reported by [redacted] former director of research are sufficient and fully comport with the four factors contained in a *Daubert*-type analysis, without need for additional, timely, and costly petitioner, defendant, or independent court-appointed medical experts.

C. In anticipation, [redacted] may frivolously seek removal to federal court under a theory of complete federal preemption. Other Kansas courts have previously decided that issue.[16]

D. In anticipation, [redacted] will do everything in their power to ensure the general public and intermediaries do not become informed of the known, but unreported information that [redacted] has, pertaining to statins. [redacted], in their most recent reports filed

---

[15] See Millet v. Pfizer, Inc. filed Feb. 4, 2004, Case No. 02-3092 (10th Cir. 2004). Listing the four factors contained in a Daubert analysis pertaining to medical expert testimony and distinguishing general, specific and proximate causation

[16] *See* Fort Trial & Insurance Practice Law Journal, American Bar Association, Winter 2003, Vol. 38, Number 2 at 638-40. Also see pgs. 567-581 on federal preemption, both express and implied; duty to warn; pharmacist liability as an intermediary, the Emergency Medical Treatment and Active Labor Act, et al. Theories of federal preemption based on a fraud to the FDA only provide for federal preemption on medical devices, not drug products, when a claim of fraud against a federal agency is asserted. *Also see* Eve v. Sandoz Pharmaceutical Corp., pg.575, Caraker v. Sandoz Pharmaceuticals Corp., at pg. 576-77 and Ohler v. Purdue Pharma, L.P. at 577on point including related footnotes (citations omitted)

with t... ..., anticipates worldwide sales of statin products in 2004 to be in the range of four billion dollars. Merck's primary motivation is economic, rather than a moral or ethical sense of responsibility to the public interest, including Kansas citizens. It is incumbent and the duty of this court, to ensure the public, and intermediaries in Kansas are informed regarding these statin products manufactured by the defendant.

L. Attorneys for the Veterans Administration have refused to date, to state whether or not the acts/omissions of [redacted] was within, or outside the scope of his official duty. Therefore, it is necessary until the attorneys for the Veterans Administration make a declaration of fact pertaining to [redacted] whether or not he is subject to Kansas statutory and regulatory law in his individual capacity. Therefore, this declaration pertaining to [redacted] is to ensure that after the fact, the Veterans Administration may not resort to after the fact defense that acts/omissions of David Barry were outside the scope of his official duty, and therefore, are his individual acts/omissions, rather than official acts.

The naming of [redacted] is this petition, is therefore to ensure that his acts/omis... are not permitted, without justice being addressed, regardless of his capacity and affirmative defenses. Mr. Scherer, as the petitioner, will object to any/all attempts at removal to a federal court of law and states there is no complete federal preemption. The VA attorneys have assured me that they will seek a removal action of [redacted], even though this petition is related to his capacity as an individual. In the case that such an event occurs, or is requested, the VA is required to state factually, his scope of duty in regard to a removal action. Moreover, in a removal action to federal ...rt, then the petitioner ask... the court for bifurcation of the defendants, rather than a removal of all defendants to a federal court.

VI. SUBJECTIVE PATIENT REPORTING vs. OBJECTIVE MEDICAL

REPORTED SYMPTOMS AND TREATMENT

It is important to distinguish between what I know, as the patient or as the consumer, vs. the objective information attributed to the resulting unexpected, and expected serious, potentially life threatening adverse event after taking lovastatin and/or simvastatin. It seems warranted for me as the person that was most knowledgeable, to put a human face on what it was really like. The medically reported symptoms is subjectively reported by treating doctors and medical staff, based on their memory of the interview, later after that interview has been completed. Their reporting is limited by time pressures, memory recall and their subjective opinion on what to report in a concise and relevant method necessary only as it related to documenting their treatment, and need for any subsequent treatment. In plain language, I would tell the treating official the symptoms and they in turn would only report what they considered to be objective. In order to clearly and subjectively state what it was like, I need to state from my perspective, what the pain, suffering, agony, loss of functioning, loss of pleasure and other related and corresponding symptoms and subsequent treatments and medical intervention were like.

After the initial start of lovastatin, shortly followed by simvastatin, I could not produce a bowel movement. I started to experience what is commonly referred to as gastric bloating or gastroparesis[17]. That gastric bloating in turn, made it almost impossible to urinate, all within three days of taking this product. In turn, I could not concentrate on my legal studies due to these symptoms. The flu-like symptoms and pain became so severe, I finally called the Topeka VA ER staff, and subsequently reported per their direction to the Topeka Emergency Room on Sunday, April 24, 2003.

The emergency room Nurses' practitioner and the supervising doctor attempted to diagnose what was causing this pain. They diagnosed a symptom (constipation) rather than determine with any objective tests, what was really causing the pain. In turn, there was a prescription given for docusate, a stool softener, and a laxative, magnesium citrate. I started both the same day. Initially, the magnesium forced a bowel movement.

That treatment relieved symptoms such as gastrointestinal bloating and the inability to urinate for about three days. The symptoms returned several days later. What was happening apparently is that I would eat food. The food would for the most part, stay in the stomach instead of moving into the intestines. This would cause the bloating and the pain. Sometimes diagnosed by medical professionals as a condition called dyspepsia.

---

[17] **Gastroparesis**-means the paralysis of the stomach. Under this condition, food is not thoroughly ground and does not empty into the intestine normally. This can be caused by diseases of the stomach muscles or the nerves that control those muscles. A side effect is malnutrition by food not being absorbed in the intestine. **Myopathy** or muscle damage is broken into three areas based on severity and lab tests. 1) **Fibromylagia**-muscular disease with no increased CK or CKP elevation noted. 2) **Myositus**-muscular diseases that cause degeneration of muscle tissue resulting in decreasing strength, and making even the simplest physical activities difficult. Generally indicated by a CK level > 3 times the ULN. **Rhabdomyolysis**-muscular disease that is diagnosed when CK level is >10 times the ULN. **Severe Constipation**-Infrequent occurrence of bowel movements.

In addition, over the long term, the failure of food to pass into the intestinal tract, would in turn cause malabsorption or a nutritional deficiency. There are two muscles that control the passage of food and liquids from the stomach. I speculate after months and attempts to modify diet, use medical products, or OTC products that the lovastatin, and simvastatin inhibited the ability of those muscles to move food from the stomach into the intestinal tract.

I tried several things to alleviate this pain, suffering, loss of function, and agony. I stopped taking most prescribed medications May 15 because I suspected a possible drug-drug interaction. I tried a couple of things that did work (June and July 2003). For example, if I consumed huge amounts of water (32-64 fluid oz.) in excess of my normal intake (such as coffee [32 fluid oz. and beverages 36 fluid oz.) I could produce a bowel movement. I also could produce a bowel movement with eating almost exclusively raisin bran (August, 2003), regardless of fluid intake. After relieving the gastric bloating symptoms by one of several methods, the flu-like symptoms would go away for about three days. I would have a small fever and the muscle aches, particularly in the legs would return.

For emergency measures, when all else failed, I would purchase magnesium citrate. I did this on four separate occasions from May to October 2003. Although it does state on the warning instructions, that this product should not be used frequently. Once the bloating happened, I could only eat small portions of food. If I ate, I knew that when I went to bed, I would have pain on almost a daily basis throughout the night. I would prop pillows in an attempt to minimize the pain at night.

My normal **functioning** was severely impacted, while at law school and after I finished finals in May of 2003. I could no longer perform simple household tasks. I could not engage in pleasurable activity with my son. And if I did, I would be exhausted or fatigued by simple things such as just going out for a meal. Prior to this statin therapy, I used to work six days a week, 12 to 14 hours per day. After the therapy, I was lucky if I could be productive in any way for more than six hours a day. Generally, I would be so fatigued by 2:30 in the afternoon. I measured the amount of productive effort I could accomplish in a given day for months. I was hoping to increase the amount of productive effort/day in hours of time.

I could not perform common simple household **tasks** such as raking leaves, cutting grass, or general cleaning, for example. I could not perform **recreational activities** such as playing racquetball, or going fishing, or taking my dog for a walk, all pleasurable activities that I engaged in routinely prior to taking these prescriptions. My typical day after starting this statin therapy April 14, 2003 therefore was get up, try to be productive until the fatigue set in. Eat when I had to or could, and then deal with the pain until I went to bed in the evening. I could not assist my parents who were dealing with their own serious health issues--my stepfather had a laryngecotomy in February 2003. He was unable to speak. I had no desire to travel or meet with family or friends. It was a miserable experience and had a significant impact on the relationship I had with my son, my immediate family and friends. Generally this is referred to as loss of pleasure.

For the most part, I would not leave my home, except for tasks that had to be performed-such as groceries or medical appointments. My civil rights work came to a abrupt halt. I was unable to timely respond or file legal documents in related court cases. To summarize, all I could perform was mainly things that had to be done.

In regard to **treatment**, and initial acceptance that these symptoms were permanent, I become disappointed with treatment by professional medical individuals. They would treat symptoms, but not diagnose what was causing the symptoms. They would merely prescribe more medications, suggest diet modifications, or exercise. I do think and reported that I experienced heart irregularities within minutes after taking this prescription. I had my EKG taken to ensure there was no apparent heart muscle damage in January 2004. During the summer months, I did try my own tests and other things to improve my stamina and ability to function to a more normal level. I tried diet modification, OTC supplements, vitamin and mineral supplementation. I researched medical and scientific data from the Internet.

Finally, I was scheduled for a doctor examination on October 24, 2003. I had received documentation from the VA that instructed me to provide information at that appointment, current medications. At that point, I started to pull information from the Internet at each prescription. At that point, I started to read information about possible symptoms attributable to ZOCOR. I noticed my right upper arm had lost most of muscle mass and was starting to look strange. On October 24, I called and my new primary care doctor, [redacted], acting through his nurse, Lazano gave me an order to stop taking ZOCOR.

Within three days after stopping ZOCOR on October 24,the gastrointestinal problems went away. My appetite returned. I was able to eat a full meal. The gastrointestinal bloating has not returned. **This makes it reasonable to attribute the gastrointestinal problems that I suffered for eight months to ZOCOR (cause in fact and proximate cause)**. However, the fatigue, as well as any myopathy remains. And continue to date. Which in turn believes me to suspect that there was and is quite possibly, permanent and irreparable damages in the cell structure. This is reported in some scientific documents that once cell damage has occurred, it cannot be repaired. I continued to do research regarding this prescription product ZOCOR. There is significant data reported by national and international scientific and medical experts that highly suggests that this fatigue and gastrointestinal symptoms may be caused in fact, by a depletion of coenzyme CoQ10[redacted] in turn, knows of this, has reported it to the U.S. Patent office, and apparently does not inform the FDA of this known effect. It does not warn or describe this effect in prescribing information.

I finally was able to meet with [redacted] on December 18, 2003. I gave a complete description of symptoms, medications, and other data in hard copy. He did want those documents. I advised him, as well as showed him what documentation I would need to supplement the SF-95. He would not provide any supplementary documents. He did however, at my request, order some lab tests. He has not however, ordered a test for a CPK level or CoQ10 level. I had to then obtain on my own, a lab that would perform a test for CoQ10. After I had obtained the name of that lab, the contact person and the doctor who would test that level, the VA primary nurse then calls, and informs me that the VA staff was in error, and can perform the lab test for Q10.

On January 12, 2004, after obtaining a blood sample for making baseline measurement of CoQ10 at the KC VA lab seventy-eight days after stopping the

simvastatin, I started a scientific test of taking this enzyme supplement. Whether that will rest[redacted] urn my CoQ10 enzyme levels to normal is unknown.

On January 27, 2003, an international expert on statins and CoQ10, [redacted], contacted me on the telephone.. I was referred to contact him by another national expert, [redacted], at the Whitaker Wellness Institute in California. He did state to me, these symptoms pertaining to statins are well known by several scientific experts on statin therapy, in addition to those individuals at [redacted]. He was not surprised by my injury or the damage, or with the inadequacies of the FDA or VA pertaining to statin therapy. In other words, he stated it was fairly common. He also stated he personally had known [redacted]'s former director of research and informed me that he had passed in 1997. [redacted] had filed scientific research both independently, and with [redacted]'s former Director of Research

To date, I cannot find one exact and specific disease for my symptoms. Fibromyalgia is similar. I cannot claim mystitus or rhambodylsis since there is apparently no elevated CK levels reported in lab tests to date. However, one should note the lab tests were not performed until almost seventy-eight days after stopping the simvastatin. This lab test for CK, CKP, and Q10 should have been ordered immediately upon stopping the simvastatin. A failure to order that lab test may also be an issue of malpractice.

Finally, in regard to reported medical statements, those statements will be provided as exhibits at the appropriate time.

VII. SPECIFIC RELIEF REQUESTED BY THE PETITIONER

Mr. Scherer requests the court grant the following remedies and/or relief:

1. Award damages for gross negligence[18], breach of implied and express warranty, and breach of or failure to discharge duty to warn or instruct. This award should include compensatory and punitive damages for injuries and damages incurred by Scherer including those for loss of function, mental anguish, pain, suffering, emotional distress, and loss of familial pleasure.

2. Order and award court costs, as well as related costs with the defendants, such as expenses for medical experts, other related costs for supplemental products, and costs for future treatment, diagnosis, and related medical intervention needed to alleviate symptoms attributable to these products.

3. Issue a declaratory judgment that [redacted] has defectively marketed lovastatin and simvastatin, and any other combination using one of these active ingredients.

4. Issue a declaratory judgment that [redacted] has defectively designed lovastatin and simvastatin, and any other combination using one of these active ingredients when a safer product, which [redacted] has a patent on, was available, but not marketed for the general public consumption. Nor can any other manufacturer due to [redacted]'s patents.

5. Order [redacted], via a temporary or permanent injunction, to suspend the marketing of statin products such as lovastatin, simvastatin, or any combination including these active ingredients such as Vyortin (compounded statin product (simvastatin with a bile sequesterant (Ezitimbe)(until sufficient warnings pertaining to a known, but unreported risk related to coenzyme CoQ10 is provided to intermediaries.

Mr. Scherer alleges that [redacted] as the defendant, is continuing the practices as stated in the complaint including marketing and design defects and failing to warn intermediaries of known, but unreported risks attributed to these statin products. Mr. Scherer claims and requests actual damages. Mr. Scherer claims and requests punitive damages.

In regard to relief/remedy against the defendant, [redacted], Mr. Scherer asks the court to provide the following:

1. Find and award damages[19] for the acts of this doctor in his individual capacity for his acts/omissions.

---

[18] The purpose of this case is primarily the public interest, rather than the amount of damages in self-interest. In the spirit of this petition, even nominal damages would be considered as an appropriate remedy in that spirit. I cannot be more specific or explicit in assuring the trial of fact, my purpose is the public interest, rather than self-interest.

[19] It is my humble opinion [redacted] is a good person. He simply made mistakes that resulting in my injuries. It is the failure of the VA, and its officials to acknowledge and apologize for those mistakes that is a fundamental and important judicial issue rather than the competency or qualifications of [redacted]

In regard to the State of Kansas as defendant, the following relief/remedy is requested:

1. Declaratory judgment finding the acts of the Kansas State Board of Healing Arts and the Kansas Board of Pharmacy failed shockingly to the conscious of a reasonable or prudent person standard, to perform its regulatory function in protecting Kansas consumers including the petitioner.

2. Order the state of Kansas agencies make available for inspection, all documents pertaining to acts taken in regard to Mr. Scherer's administrative complaint, or lack thereof, including all communication, oral or written in any format with the respondent, if any.

_____

Signature of the Petitioner

Thomas E. Scherer
[redacted]
Merriam, KS [redacted]
Telephone Number [redacted]

VIII. DESIGNATION OF PLACE OF TRIAL

Petitioner designates Olathe, (Johnson County) Kansas as the location for the trial in this matter.

_____

Signature of the Petitioner

Mr. Scherer requests a trial by a jury of his peers.

_____

Signature of the Petitioner

Dated this 15th day of December 2004

IX. NOTICE OF SERVICE-PETITION AND SUMMONS

Mr. Scherer, by his signature below, states the facts as pleaded in this petition are true and accurate to the best of his knowledge and belief.

In addition, by his signature below states affirmatively that a original copy of this petition, summons, and exhibits, were served to the defendants at the addresses given below via certified mail, return receipt.

Original copy of the petition and summons were provided to the defendants at the following addresses via certified mail:

The Corporation Company, Inc. (for the first defendant, [redacted])
515 S. Kansas Ave.,
Topeka (Shawnee County), Kansas,
66603-0000

[redacted], Defendant,
[redacted],
Lawrence, KS [redacted]

State Of Kansas,
Kansas Attorney General
Phill Klein, acting on behalf of the state of Kansas,
120 SW 10th Ave.,
Topeka, KS 66612

Signed and dated this the fifteenth day of December, 2004

Thomas E. Scherer, petitioner
7916 W. 60th St.
Merriam, KS 66202-3009

X. RELEVANT PHOTOCOPIES OF EXHIBITS IN SUPPORT OF THE FACTS[20]

a) Mfg. Product and Prescribing Information

1. [redacted] prescribing information on Lovastatin
2. [redacted] prescribing information on Simvastatin
3. [redacted] patents filed with the U.S Patent Office
4. [redacted] Manuals accessible at http://www.merck.com.
5. [redacted] Manual, Second Edition, Section 12, Chapter 157 at [redacted] on statins, the mechanism, indications and statin side effects. Accessed on 12/17/03.

b) International and Scientific Research

6. Excerpts from Multifactorial Prevention, Lovasatin Therapy and Ubiquinone Supplementation in Coronary Heart Disease, Ari Palomaki, Academic Dissertation (Nov. 8th 2002), Medical School of the University of Tampere, Finland. This document summarizes in one document, all prior studies related to Q10 and lovastatin by other scientists and medical research officials.
7. Ely and Crane (attached).

c) Petitioner Specific Evidence

Written communication to and from Merck

8. Certified letter, return receipt, including a U.S. Postal Form PS 3811 confirming receipt by [redacted], titled Legal Notice and Request for relief/remedy dated November 16 2003. Signed receipt dated November 21, 2003
9. Letter from [redacted], dated December 18, 2003.
10. Letter to [redacted] Office of General Counsel, first class mail, postage prepaid dated January 2, 2004.
11. Letter to [redacted], first class mail, postage prepaid, dated January 12, 2004

Written communication to and from VA or FDA officials

12. VA Form 0246, showing active prescriptions with a statement date of 05/18/2003
13. Certified letter, return receipt, restricted delivery to [redacted], Director, Topeka VA dated December 8, 2003 with proof of receipt, PS Form 3811.
14. Faxed letter with return receipt dated January 6, 2004 to Betty Dorsey, and FDA Commissioner Mark McClennan for documents under the FOIA.
15. FDA acknowledgment letter of FOIA request dated January 8, 2004
16. Certified letter, return n receipt to Secretary of Veterans Affairs, c/o FOIA officer Clay Johnson for FOIA documents. Signed receipt dated January 20, 2004
17. Letter from Topeka VA, dated May 1, 2003 signed by [redacted], Supervisor on substitution of simvastatin for lovastatin.

[20] All references to documents or exhibits are photocopies or documents that lay in the public domain. I retain the originals for presentation to a jury, including obtaining certification when necessary to comport with rules pertaining to evidentiary documents

19. Excerpts from my confidential and private Topeka VA medical records with details pertaining to symptoms and prescribing information furnished by the Topeka VA under a FOIA request.

d) Other miscellaneous and relevant exhibits

20. Physicians Desk Reference (PDR). Also accessible at http://www.pdrhealth.com/drug_info/index.html.
21. Pending petitions filed with the FDA regarding statin products including either simvastatin or lovastatin.
22. Medwatch Consumer Report filed with the FDA November 18, 2003.
23. USP Medication Errors Report, web ID 2047, reported by Scherer dated February 2, 2004.
24. United States General Accounting Office, Report to Congressional Requesters, ADVERSE DRUG EVENTS: THE MAGNITUDE of HEALTH RISK Is UNCERTAIN BECAUSE OF LIMITED INCIDENCE DATA, GAO/HEHS-00021 (January 2000).
25. VA Directive and associated handbook, 1050.1 dated January 30,.2002
26. FDA draft Guidance for Industry, Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines, (March 2001).
27. A Brief Update on Ubiquinone (Coenzyme Q10), John T. A. Ely and Cheyl A. Krone. Journal of Orthomolecular Medicine 2000; 15 (2):64-68. This document includes references to many international and national authorities, with particular emphasis on references 32,42, and 43 which includes references to public documents that were published by Merck's former director of research for twenty years, Karl Folkers. Mr Folkers passed in 1997. Additional data on Q10 can be accessed at: **http://fac .washington.edu/ely/coenzq10abs.html**. For an easy-to-read link on Q10, reference or background information that is not so scientific can be obtained from this link, and its associated web pages, see http://shop.store.yahoo.com/epic4health/index.html.
28. Any other necessary exhibits not specifically mentioned above needed to ensure justice is served in the public interest.

XI. STATUTORY ADDENDUM

The attached portion of this section is to aid the trier of fact and the jury of relevant statutory sections that include federal and state statutes and regulations that provide definitions of terms that are relevant, or alternatively, were violated by the defendant.

1. **Kansas Product Liability Act K.S.A. § 60-3301 et seq.**
2. **Kansas Consumer Protection Act, K.S.A. § 50-617 as supplemented, amended and annotated (2002) et seq. with particularity to § 50-626 (defective marketing)) and 50-634 (private remedies).**
3. **21 CFR 600.80-relevant regulatory definitions and reporting and mandatory reporting guidelines in post-marketing surveillance in effect at the time of taking the prescription products.**
4. **Proposed modifications to the Code of Federal Regulations that provide further elaboration and clarification of terms and definitions that apply in this instant case as reported in the Federal Register/ Vol. 68, No 50/Friday, March 14, 2003, pg. 12405-12497 [FDA Docket No. 00N-1484]. Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule. Due to the length of that document, only relevant excerpts that clarify, or better define terms as proposed and understood by the FDA will be provided. I also understand that proposed rules do not have the force of the law until codified. However, in this instant petition, the intent of the FDA can be considered by the trier of fact in any decision that attempts to harmonize existing and proposed federal regulations, with Kansas statutes and regulations in a court decision or memorandum order.**

XII. CITATIONS OF AUTHORITY

Most of the relevant issues in this complaint have previously been addressed by the state of Kansas courts in the attached citation of authority. Additional authority or guidance (not contained with this petition) that may be relevant is provided in Restatement of the Law Third, Torts, Product Liability (1997 as amended). Particularly, but not exclusively limited to § Section 2 (j) or. formerly to Restatement of Torts 2D, Chapter 14 § 402(A)(g), (h), and (n) on strict liability as applied to a corporation such as the defendant.

1. Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 681 P.2d 1038 Kan., (1984).

2. FDA pending petition filed by or on behalf of Julian Whitaker, M.D. at http://www.fda.gov/ohrms/dockets/dailys/02/May02/052902/02p-0244-cp00001-01-vol1.pdf

3. Any other authority not specifically contained herein.

ABSTRACT AND PARTIAL EXCERPT OF RELEVANT COPY OF KANSAS PRODUCT LIABILITY ACT STATUTES[21]

Home > Kansas Statutes > Kansas Statute No. 60-3302

60-3302
Chapter 60.--PROCEDURE, CIVIL
Article 33.--ACTIONS RELATING TOCOMMERCIAL ACTIVITY
60-3302. Definitions. (a) "Product seller" means any person or entity that is engaged in the business of selling products, whether the sale is for resale, or for use or consumption. The term includes a manufacturer, wholesaler, distributor or retailer of the relevant product, but does not include a health care provider, as defined in subsection (f) of K.S.A. 40-3401 and amendments thereto, who utilizes a product in the course of rendering professional services.

(b) "Manufacturer" includes a product seller who designs, produces, makes, fabricates, constructs or remanufactures the relevant product or component part of a product before its sale to a user or consumer. It includes a product seller or entity not otherwise a manufacturer that holds itself out as a manufacturer, or that is owned in whole or in part by the manufacturer.

(c) "Product liability claim" includes any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any action based on, strict liability in tort, negligence, breach of express or implied warranty, breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent, misrepresentation, concealment or nondisclosure, whether negligent or innocent, or under any other substantive legal theory.

(d) "Harm" includes: (1) Damage to property; (2) personal physical injuries, illness and death; (3) mental anguish or emotional harm attendant to such personal physical injuries, illness or death. The term "harm" does not include direct or consequential economic loss.

History: L. 1981, ch. 231, § 2; L. 1992, ch. 307, § 5; July 1.

---

[21] The convention used in providing this abstract is for the convenience of the trier of fact and the jury. Shading will be employed on the most relevant portions applied in the context of this petition. Excerpts will be marked in bold at the beginning of any statute or regulation. Some of these statutes and regulations are quite lengthy and the entire regulation or statute can be obtained via the Internet, or upon request in full length rather than as an excerpt. There is no attempt here to take an excerpt out of context from the intent of the respective regulation or statute. In addition each regulation or statute will begin on a separate page to the greatest extent possible. All Kansas statutes were obtained from: http://www.kslegislature.org/cgi-bin/statutes/index.cgi. Last accessed on February 7, 2004. This is not to be considered as all and every relevant Kansas state statute or regulation. For example, I have not included any applicable state regulations from state licensing agencies such as the Kansas Board of Healing Arts, Kansas Board of Pharmacy, or the Kansas Board of Nursing, although I could. Or from the Joint Comm. On Accreditation (JCAH). At some point, after filing this petition the differing medical standards of review by different federal and state authority will need to be addressed. For the purposes of filing this petition, to do so is premature.

Home > Kansas Statutes > Kansas Statute No. 60-3304

60-3304 [**EXCERPT**]
Chapter 60.--PROCEDURE, CIVIL
Article 33.--ACTIONS RELATING TOCOMMERCIAL ACTIVITY

60-3304. Legislative regulatory standards or administrative regulatory safety standards or mandatory government contract specifications; defenses. (a) When the injury-causing aspect of the product was, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed not defective by reason of design or performance, or, if the standard addressed warnings or instructions, the product shall be deemed not defective by reason of warnings or instructions, unless the claimant proves by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions.

(b) When the injury-causing aspect of the product was not, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design, performance, warnings or instructions, the product shall be deemed defective unless the product seller proves by a preponderance of the evidence that its failure to comply was a reasonably prudent course of conduct under the circumstances.

History: L. 1981, ch. 231, § 4; July 1.

Home > Kansas Statutes > Kansas Statute No. 60-3305

60-3305. Manufacturer's or seller's duty to warn or protect against danger, when. In any product liability claim any duty on the part of the manufacturer or seller of the product to warn or protect against a danger or hazard which could or did arise in the use or misuse of such product, and any duty to have properly instructed in the use of such product shall not extend: (a) To warnings, protecting against or instructing with regard to those safeguards, precautions and actions which a reasonable user or consumer of the product, with the training, experience, education and any special knowledge the user or consumer did, should or was required to possess, could and should have taken for such user or consumer or others, under all the facts and circumstances;

(b) to situations where the safeguards, precautions and actions would or should have been taken by a reasonable user or consumer of the product similarly situated exercising reasonable care, caution and procedure; or

(c) to warnings, protecting against or instructing with regard to dangers, hazards or risks which are patent, open or obvious and which should have been realized by a reasonable user or consumer of the product.

History: L. 1981, ch. 231, § 5; July 1.

RELEVANT ABSTRACT/EXCERPT OF COPIES FROM THE KANSAS CONSUMER PROTECTION ACT

Home > Kansas Statutes > Kansas Statute No. 50-626

Kansas Statute No. 50-626 **[Relevant EXCERPT]**

50-626
Chapter 50.--UNFAIR TRADE AND CONSUMER PROTECTION
Article 6.--CONSUMER PROTECTION
50-626. Deceptive acts and practices. (a) No supplier shall engage in any deceptive act or practice in connection with a consumer transaction.

(b) Deceptive acts and practices include, but are not limited to, the following, each of which is hereby declared to be a violation of this act, whether or not any consumer has in fact been misled:

(2) the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact;

(3) the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact;

History: L. 1973, ch. 217, § 4; L. 1976, ch. 236, § 3; L. 1991, ch. 159, § 2; L. 1993, ch. 177, § 1; L. 2000, ch. 167, § 1; July 1.
Page Last Modified Friday, December 05, 2003 12:09 PM

Home > Kansas Statutes > Kansas Statute No. 40-3401 **[Excerpt]**

40-3401
Chapter 40.--INSURANCE
Article 34.--HEALTH CAREPROVIDER INSURANCE
40-3401. Definitions. As used in this act the following terms shall have the meanings respectively ascribed to them herein.

(a) "Applicant" means any health care provider.

(b) "Basic coverage" means a policy of professional liability insurance required to be maintained by each health care provider pursuant to the provisions of subsection (a) or (b) of K.S.A. 40-3402 and amendments thereto.

(f) "Health care provider" means a person licensed to practice any branch of the healing arts by the state board of healing arts . . ., a pharmacist licensed by the state board of pharmacy,

(m) "Medical care facility" means the same when used in the health care provider insurance availability act as the meaning ascribed to that term in K.S.A. 65-425 and amendments thereto, except that as used in the health care provider insurance availability act such term, as it relates to insurance coverage under the health care provider insurance availability act, also includes any director, trustee, officer or administrator of a medical care facility.

History: L. 1976, ch. 231, § 1; L. 1977, ch. 165, § 1; L. 1979, ch. 186, § 22; L. 1980, ch. 142, § 1; L. 1981, ch. 199, § 1; L. 1982, ch. 207, § 1; L. 1984, ch. 177, § 1; L. 1985, ch. 166, § 1; L. 1986, ch. 183, § 14; L. 1986, ch. 229, § 24; L. 1986, ch. 231, § 4; L. 1986, ch. 184, § 1; L. 1986, ch. 181, § 2; L. 1986, ch. 181, § 3; L. 1986, ch. 181, § 4; L. 1987, ch. 176, § 1; L. 1987, ch. 177, § 1; L. 1987, ch. 242, § 1; L. 1987, ch. 178, § 1; L. 1987, ch. 178, § 2; L. 1988, ch. 246, § 12; L. 1989, ch. 143, § 1; L. 1990, ch. 174, § 1; L. 1990, ch. 175, § 1; L. 1991, ch. 139, § 1; L. 1992, ch. 156, § 2; L. 1994, ch. 181, § 3; L. 2000, ch. 162, § 14; L. 2001, ch. 204, § 1; L. 2003, ch. 128, § 19; Apr. 1, 2004.

Page Last Modified Friday, December 05, 2003 12:09 PM

Home > Kansas Statutes > Kansas Statute No. 60-19a01

60-19a01
Chapter 60.--PROCEDURE, CIVIL.
Article 19a.--**LIMITATION ONDAMAGES FOR PAIN AND SUFFERING**

60-19a01. Personal injury action defined; limitation established; itemization of verdict; no jury instruction on limitation to be given; wrongful death limitation not affected; application limited. (a) As used in this section, "personal injury action" means any action for damages for personal injury or death, except for medical malpractice liability actions.

(b) In any personal injury action, the total amount recoverable by each party from all defendants for all claims for pain and suffering shall not exceed a sum total of $250,000.

(c) In every personal injury action, the verdict shall be itemized by the trier of fact to reflect the amount awarded for pain and suffering.

(d) If a personal injury action is tried to a jury, the court shall not instruct the jury on the limitations of this section. If the verdict results in an award for pain and suffering which exceeds the limit of this section, the court shall enter judgment for $250,000 for all the party's claims for pain and suffering. Such entry of judgment by the court shall occur after consideration of comparative negligence principles in K.S.A. 60-258a and amendments thereto.

(e) The provisions of this section shall not be construed to repeal or modify the limitation provided by K.S.A. 60-1903 and amendments thereto in wrongful death actions.

(f) The provisions of this section shall apply only to personal injury actions which are based on causes of action accruing on or after July 1, 1987, and before July 1, 1988.

History: L. 1987, ch. 217, § 1; L. 1988, ch. 216, § 2; July 1.

Page Last Modified Friday, December 05, 2003 12:09 PM

RELEVANT FEDERAL REGULATIONS[22] ABSTRACT/EXCERPT/COPY PERTAINING TO IMPORTANT REGULATORY DEFINITIONS USED IN THIS PETITION INCLUDING ADVERSE EVENTS AND REPORTING OF THOSE ADVERSE EVENTS

[Code of Federal Regulations]
[Title 21, Volume 7]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR600.80]

[Page 14-18]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 600--BIOLOGICAL PRODUCTS: GENERAL--Table of Contents

Subpart D--**Reporting of Adverse Experiences**

Sec. 600.80 Postmarketing reporting of adverse experiences.

Source: 59 FR 54042, Oct. 27, 1994, unless otherwise noted.

(a) Definitions. The following definitions of terms apply to this section:

Adverse experience. Any adverse event associated with the use of a biological product in humans, whether or not considered product related, including the following: An adverse event occurring in the course of the use of a biological product in professional practice; an adverse event occurring from overdose of the product whether accidental or intentional; an adverse event occurring from abuse of the product; an adverse event occurring from withdrawal of the product; and any failure of expected pharmacological action.

Blood Component. As defined in Sec. 606.3(c) of this chapter.

Disability. A substantial disruption of a person's ability to conduct normal life functions.

Life-threatening adverse experience. Any adverse experience that places the

---

[22] The actual federal regulations in their entirety under Title 21 can be obtained on the Internet at the following address: http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321. Last revised on April 1, 2003. Last accessed on Feb. 7, 2004.

[[Page 15]]

patient, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred, i.e., it does not include an adverse experience that, had it occurred in a more severe form, might have caused death.

Serious adverse experience. Any adverse experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Unexpected adverse experience: Any adverse experience that is not listed in the current labeling for the biological product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents. ``Unexpected,'' as used in this definition, refers to an adverse experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

(b) Review of adverse experiences. Any person having a biologics license under Sec. 601.20 of this chapter shall promptly review all adverse experience information pertaining to its product obtained or otherwise received by the licensed manufacturer from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. Licensed manufacturers are not required to resubmit to FDA adverse product experience reports forwarded to the licensed manufacturer by FDA; licensed manufacturers, however, must submit all followup information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse experiences to FDA.

(c) Reporting requirements. The licensed manufacturer shall report to FDA adverse experience information, as described in this section. The licensed manufacturer shall submit two copies of each report described in this section for nonvaccine biological products, to the Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200 N., Rockville, MD 20852-1448. Submit all vaccine adverse experience reports to: Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849-1100. FDA may waive the requirement for the second copy in appropriate instances.

(1)(i) Postmarketing 15-day ``Alert reports''. The licensed manufacturer shall report each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the licensed manufacturer.

(ii) Postmarketing 15-day ``Alert reports''--followup. The licensed manufacturer shall promptly investigate all adverse experiences that are the subject of these postmarketing 15-day Alert reports and shall submit followup

[[Page 16]]

reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover.

(iii) Submission of reports. The requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section, concerning the submission of postmarketing 15-day Alert reports, shall also apply to any person whose name appears on the label of a licensed biological product as a manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or any other participant involved in divided manufacturing. To avoid unnecessary duplication in the submission to FDA of reports required by paragraphs (c)(1)(i) and (c)(1)(ii) of this section, obligations of persons other than the licensed manufacturer of the final biological product may be met by submission of all reports of serious adverse experiences to the licensed manufacturer of the final product. If a person elects to submit adverse experience reports to the licensed manufacturer of the final product rather than to FDA, the person shall submit each report to the licensed manufacturer of the final product within 5 calendar days of receipt of the report by the person, and the licensed manufacturer of the final product shall then comply with the requirements of this section. Under this circumstance, a person who elects to submit reports to the licensed manufacturer of the final product shall maintain a record of this action which shall include:

(A) A copy of all adverse biological product experience reports submitted to the licensed manufacturer of the final product;

(B) The date the report was received by the person;
(C) The date the report was submitted to the licensed manufacturer of the final product; and-
(D) The name and address of the licensed manufacturer of the final product.
(iv) Report identification. Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report," or "15-day Alert report-followup."
(2) Periodic adverse experience reports. (i) The licensed manufacturer shall report each adverse experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The licensed manufacturer shall submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of issuance of the biologics license) and each annual report within 60 days of the anniversary date of the issuance of the biologics license. Upon written notice, FDA may extend or reestablish the requirement that a licensed manufacturer submit quarterly reports, or require that the licensed manufacturer submit reports under this section at different times than those stated. Followup information to adverse experiences submitted in a periodic report may be submitted in the next periodic report.
(ii) Each periodic report shall contain:
(A) A narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval (all 15-day Alert reports being appropriately referenced by the licensed manufacturer's patient identification number, adverse reaction term(s), and date of submission to FDA);
(B) A form designated for Adverse Experience Reporting by FDA for each adverse experience not reported under paragraph (c)(1)(i) of this section (with an index consisting of a line listing of the licensed manufacturer's patient identification number and adverse reaction term(s)); and
(C) A history of actions taken since the last report because of adverse experiences (for example, labeling changes or studies initiated).
(iii) Periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse experience information obtained from postmarketing studies (whether or not conducted under an investigational new drug application), from reports in the

scientific literature, and from foreign marketing experience.
(d) Scientific literature. (1) A 15-day Alert report based on information from the scientific literature shall be accompanied by a copy of the published article. The 15-day Alert reporting requirements in paragraph (c)(1)(i) of this section (i.e., serious, unexpected adverse experiences) apply only to reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial.
(2) As with all reports submitted under paragraph (c)(1)(i) of this section, reports based on the scientific literature shall be submitted on the reporting form designated by FDA or comparable format as prescribed by paragraph (f) of this section. In cases where the licensed manufacturer believes that preparing the form designated by FDA constitutes an undue hardship, the licensed manufacturer may arrange with the Division of Biostatistics and Epidemiology (HFM-210) for an acceptable alternative reporting format.
(e) Postmarketing studies. (1) Licensed manufacturers are not required to submit a 15-day Alert report under paragraph (c) of this section for an adverse experience obtained from a postmarketing clinical study (whether or not conducted under a biological investigational new drug application) unless the licensed manufacturer concludes that there is a reasonable possibility that the product caused the adverse experience.
(2) The licensed manufacturer shall separate and clearly mark reports of adverse experiences that occur during a postmarketing study as being distinct from those experiences that are being reported spontaneously to the licensed manufacturer.
(f) Reporting forms. (1) Except as provided in paragraph (f)(3) of this section, the licensed manufacturer shall complete the reporting form designated by FDA for each report of an adverse experience (FDA Form 3500A, or, for vaccines, a VAERS form; foreign events including those associated with the use of vaccines, may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form).
(2) Each completed form should refer only to an individual patient or single attached publication.
(3) Instead of using a designated reporting form, a licensed manufacturer may use a computer-generated form or other alternative format (e.g., a computer-generated tape or tabular listing) provided that:
(i) The content of the alternative format is equivalent in all elements of information to those specified in the form designated by FDA; and
(ii) the format is approved in advance by MEDWATCH: The FDA Medical Products Reporting Program; or, for alternatives to the VAERS Form, by the Division of Biostatistics and Epidemiology.
(4) Copies of the reporting form designated by FDA (FDA-3500A) for nonvaccine biological products may be obtained from the Center for Biologics Evaluation and Research (address above). Additional supplies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Rd., Landover, MD 20785. Supplies of the VAERS form may be obtained from VAERS by calling 1-800-822-7967.
(g) Multiple reports. A licensed manufacturer should not include in reports under this section any adverse experience that occurred in clinical trials if they were previously submitted as part of the biologics license application. If a report refers to more than one

biological product marketed by a licensed manufacturer, the licensed manufacturer should submit the report to the biologics license application for the product listed first in the report.

(h) Patient privacy. For nonvaccine biological products, a licensed manufacturer should not include in reports under this section the names and addresses of individual patients; instead, the licensed manufacturer should assign a unique code number to each report, preferably not more than eight characters in length. The licensed manufacturer should include the name of the reporter from whom the information was received. The names of patients, health care professionals, hospitals, and geographical identifiers in

[[Page 18]]

adverse experience reports are not releasable to the public under FDA's public information regulations in part 20 this of chapter. For vaccine adverse experience reports, these data will become part of the CDC Privacy Act System 09-20-0136, ``Epidemiologic Studies and Surveillance of Disease Problems.'' Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal

(i) Record keeping. The licensed manufacturer shall maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences.

(j) Revocation of biologics license. If a licensed manufacturer fails to establish and maintain records and make reports required under this section with respect to a licensed biological product, FDA may revoke the biologics license for such a product in accordance with the procedures of Sec. 601.5 of this chapter.

(k) Exemptions. Manufacturers of the following listed products are not required to submit adverse experience reports under this section:

(1) Whole blood or components of whole blood.

(2) In vitro diagnostic products, including assay systems for the detection of antibodies or antigens to retroviruses. These products are subject to the reporting requirements for devices.

(l) Disclaimer. A report or information submitted by a licensed manufacturer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect. A licensed manufacturer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the biological product caused or contributed to an adverse effect. For purposes of this provision, this paragraph also includes any person reporting under paragraph (c)(1)(iii) of this section.

[59 FR 54042, Oct. 27, 1994, as amended at 62 FR 34168, June 25, 1997; 62 FR 52252, Oct. 7, 1997; 63 FR 14612, Mar. 26, 1998; 64 FR 56449, Oct. 20, 1999]

FEDERAL REGULATIONS ABSTRACT/EXCERPT/COPY PERTAINING TO LABELING AND RELEVANT TO THIS INSTANT CASE

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR201.5]

[Page 11-12]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN
SERVICES (CONTINUED)

PART 201--LABELING--Table of Contents

Subpart A--**General Labeling Provisions**

Sec. 201.5 Drugs; adequate directions for use.

Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines ``intended use.'') Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a

[[Page 12]]

practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(f) Route or method of administration or application.

(g) Preparation for use, i.e., shaking, dilution, adjustment of temperature, or, other manipulation or process.

[41 FR 6908, Feb. 13, 1976]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED) **[EXCERPT]**

PART 201--LABELING--Table of Contents

Subpart B--Labeling Requirements for Prescription Drugs and/or Insulin

Sec. 201.57 Specific requirements on content and format of labeling for human prescription drugs.

Each section heading listed in Sec. 201.56(d), if not omitted under Sec. 201 56(d)(3), shall contain the following information in the following order:

(a) Description. (1) Under this section heading, the labeling shall contain:

(i) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug;

(ii) The type of dosage form and the route of administration to which the labeling applies;

(iii) The same qualitative and/or quantitative ingredient information as required under Sec. 201.100(b) for labels;

(iv) If the product is sterile, a statement of that fact;

(v) The pharmacological or therapeutic class of the drug;

(vi) The chemical name and structural formula of the drug;

(vii) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(2) If appropriate, other important chemical or physical information, such as physical constants, or pH, shall be stated.

(b) Clinical Pharmacology. (1) Under this section heading, the labeling shall contain a concise factual summary of the clinical pharmacology and actions of the drug in humans. The summary may include information based on in vitro and/or animal data if the information is essential to a description of the biochemical and/or physiological mode of action of the drug or is otherwise pertinent to human therapeutics. Pharmacokinetic information that is important to safe and effective use of the drug is required, if known, e.g., degree and rate of absorption, pathways of biotransformation, percentage of dose as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier. Inclusion of pharmacokinetic information is restricted to that which relates to clinical use of the drug. If the pharmacological mode of action of the drug is unknown or if important metabolic or pharmacokinetic data in humans are unavailable, the labeling shall contain a statement about the lack of information.

(2) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section of the labeling only under the following circumstances:

(i) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement ``The following in vitro data are available but their clinical significance is unknown.''

(ii) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled clinical studies, as defined in Sec. 314.126(b) of this chapter, to be pertinent to clinical use may be used only if a waiver is granted under Sec. 201.58 or Sec. 314.126(b) of this chapter.

(c) Indications and Usage. (1) Under this section heading, the labeling shall state that:

(i) The drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, e.g., penicillin is indicated for the treatment of

[[Page 22]]

pneumonia due to susceptible pneumococci; and/or

(ii) The drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, e.g., chlorothiazide is indicated for the treatment of edema in patients with congestive heart failure; and/or

(iii) The drug is indicated for the relief of symptoms associated with a disease or syndrome, e.g., chlorpheniramine is indicated for the symptomatic relief of nasal congestion in patients with vasomotor rhinitis; and/or

(iv) The drug, if used for a particular indication only in conjuction with a primary mode of therapy, e.g., diet, surgery, or some other drug, is an adjunct to the mode of therapy.

(2) All indications shall be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in Sec. 314.126(b) of this chapter unless the requirement is waived under Sec. 201.58 or Sec. 314.126(b) of this chapter.

(3) This section of the labeling shall also contain the following additional information:

(i) If evidence is available to support the safety and effectiveness of the drug only in selected subgroups of the larger population with a disease, syndrome, or symptom under consideration, e.g., patients with mild disease or patients in a special age group, the labeling shall describe the available evidence and state the limitations of usefulness of the drug. The labeling shall also identify specific tests needed for selection or monitoring of the patients who need the drug, e.g., microbe susceptibility tests. Information on the approximate kind, degree, and duration of improvement to be anticipated shall be stated if available and shall be based on substantial evidence derived from adequate and

well-controlled studies as defined in Sec. 314.126(b) of this chapter unless the requirement is waived under Sec. 201.58 or Sec. 314.126(b) of this chapter. If the information is relevant to the recommended intervals between doses, the usual duration of treatment, or any modification of dosage, it shall be stated in the ``Dosage and Administration'' section of the labeling and referenced in this section.

(ii) If safety considerations are such that the drug should be reserved for certain situations, e.g., cases refractory to other drugs, this information shall be stated in this section.

(iii) If there are specific conditions that should be met before the drug is used on a long-term basis, e.g., demonstration of responsiveness to the drug in a short-term trial, the labeling shall identify the conditions; or, if the indications for long-term use are different from those for short-term use, the labeling shall identify the specific indications for each use.

(iv) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective, the Food and Drug Administration may require that the labeling state that there is a lack of evidence that the drug is effective for that use or condition.

(v) Any statements comparing the safety or effectiveness, either greater or less, of the drug with other agents for the same indication shall be supported by adequate and well-controlled studies as defined in Sec. 314.126(b) of this chapter unless this requirement is waived under Sec. 201.58 or Sec. 314.126(b) of this chapter.

(d) Contraindications. Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities shall be listed, e.g., if hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication. If no contraindications are known, this section of the labeling shall state ``None known.''

[[Page 23]]

(e) Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the ``Indications and Usage'' section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectivenes for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the ``Adverse Reactions'' section of the labeling.

(f) Precautions. Under this section heading, the labeling shall contain the following subsections as appropriate for the drug:

(1) General. This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug, e.g., precautions not required under any other specific section or subsection of the labeling.

(2) Information for patients. This subsection of the labeling shall contain information to be given to patients for safe and effective use of the drug, e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects. Any printed patient information or Medication Guide required under this chapter to be distributed to the patient shall be referred to under the ``Precautions'' section of the labeling and the full text of such patient information or Medication Guide shall be reprinted at the end of the labeling. The print size requirements for the Medication Guide set forth in Sec. 208.20 of this chapter, however, do not apply to the Medication Guide that is reprinted in the professional labeling.

(3) Laboratory tests. This subsection of the labeling shall identify any laboratory tests that may be helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information shall be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be done before, during, and after therapy.

(4)(i) Drug interactions. This subsection of the labeling shall contain specific practical guidance for the physician on preventing clinically significant drug/drug and drug/food interactions that may occur in vivo in patients taking the drug. Specific drugs or classes of drugs with which the drug to which the labeling applies may interact in vivo shall be identified, and the mechanism(s) of the interaction shall be briefly described. Information in this subsection of the labeling shall be limited to that pertaining to clinical use of the drug in patients. Drug interactions supported only by animal or in vitro experiments may not ordinarily be included, but animal or in vitro data

may be used if shown to be clinically relevant. Drug incompatibilities, i.e., drug interactions that may occur when drugs are mixed in vitro, as in a solution for intravenous administration, shall be discussed under the ``Dosage and Administration'' section of the labeling rather than under this subsection of the labeling.

(ii) Drug/laboratory test interactions. This subsection of the labeling shall contain practical guidance on known interference of the drug with laboratory tests.

[44 FR 37462, June 26, 1979, as amended at 55 FR 11576, Mar. 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998]

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR208.3]

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR208.1]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 208--MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS--

Table of Contents

(a) This part sets forth requirements for patient labeling for human prescription drug products, including biological products, that the Food and Drug Administration (FDA) determines pose a serious and significant public health concern requiring distribution of FDA-approved patient information. It applies primarily to human prescription drug products used on an outpatient basis without direct supervision by a health professional. This part shall apply to new prescriptions and refill prescriptions.

(b) The purpose of patient labeling for human prescription drug products required under this part is to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products.

(c) Patient labeling will be required if the FDA determines that one or more of the following circumstances exists:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects.

(2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product.

(3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 208--**MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS--**
Table of Contents

Subpart A--**General Provisions**

Sec. 208.3 Definitions.

For the purposes of this part, the following definitions shall apply:

(a) Authorized dispenser means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

(b) Dispense to patients means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c) Distribute means the act of delivering, other than by dispensing, a drug product to any person.

(d) Distributor means a person who distributes a drug product.

(e) Drug product means a finished dosage form, e.g., tablet, capsule, or solution, that contains an active drug ingredient, generally, but not necessarily, in association with inactive ingredients. For purposes of this part, drug product also means biological product within the meaning of section 351(a) of the Public Health Service Act.

(f) Licensed practitioner means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice.

(g) Manufacturer means for a drug product that is not also a biological product, both the manufacturer as described in Sec. 201.1 and the applicant as described in Sec. 314.3(b) of this chapter, and for a drug product that is also a biological product, the manufacturer as described in Sec. 600.3(t) of this chapter.

[[Page 112]]

(h) Medication Guide means FDA-approved patient labeling conforming to the specifications set forth in this part and other applicable regulations.

(i) Packer means a person who packages a drug product.

(j) Patient means any individual with respect to whom a drug product is intended to be, or has been, used.

(k) Serious risk or serious adverse effect means an adverse drug experience, or the risk of such an experience, as that term is defined in Secs. 310.305, 312.32, 314.80, and 600.80 of this chapter.

SELECTED PINPOINTS FROM THE Federal Register/ Vol. 68, No. 50/Friday, March 14, 2003, pg. 12405-12497 [FDA Docket No. 00N 1484]. <u>Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule.</u> The entire document can be obtained from the following web address: http: [illegible]

Pinpoints to relevant definitions and terms used in the context of this [illegible]

1. Spontaneous Consumer Report at 1242[illegible], [illegible]
2. Actual Medication Error defined at 124[illegible]
3. Adverse Drug Experience at 124[illegible]
4. Serious adverse drug experience at 12419
5. Life-threatening serious adverse drug [illegible]
6. Applicant defined at 1247[illegible] in contrast to manufacturer
7. Post-marketing report at 1248[illegible]
8. Disability defined at 12412

Journal of Orthomolecular Medicine 2000, 15(2):63-68.

A Brief Update on Ubiquinone (Coenzyme Q10)

John T. A. Ely, Ph.D.
Radiation Studies, University of Washington, Seattle, WA 98195
and
Cheryl A. Krone, Ph.D.
Applied [illegible], [illegible], NZ

Abstract
Ubiquinone is one of the two most important essential nutrients (the other being ascorbic acid). These two molecules, [illegible] other essential nutrients, have been rejected as unpatentable and unprofitable by certain "authorities" and interests, according to expose's by Pauling and others.[1,2] This has been one of the most lethal errors of modern medicine because no cell, organ, function, remedy, etc. can avoid failure unless essential nutrients, especially these two, are [illegible]. Supplementation of both is mandatory: for ascorbate [illegible] humans can't synthesize it); for ubiquinone, increasingly with age. In this update, to facilitate study of ubiquinone, we seek to assemble in one place vital information that is not widely known.

Introduction

Ubiquinone [illegible] years is an essential nutrient in the Physicians' Desk Reference [illegible] and the many clinical trials that established [illegible] described in 1995 by one of the leaders in [illegible] in his "Introduction to Coenzyme Q10". In [illegible] the full text is not in print.[1] With his [illegible] on a web site[5] with much other material in [illegible] selected reports to the bibliography here and [illegible] controlled clinical trials;[6-14] nine [illegible] trials,[15-22] including the 2664 patient multicenter study in Italy reported by Baggio [23] and the Proceedings of eight international symposia.[24-31] The [illegible] "Physicians' Update on Coenzyme Q10", was made in response to the request from Clinical Chemistry that we determine the demand for blood tests. Clinical Chemistry would need to robot (automate) the complex 14 step HPLC assay (provided to Ely by Karl Folkers) sufficiently to make it efficient to run and affordable. To determine if the demand for the ubiquinone blood test justifies this considerable effort, the web site asks that physicians accomplish the extremely brief electronic questionnaire linked to the site.

Ubiquinone Turnover

Naturally, many details concerning the pharmacokinetics and clinical use of ubiquinone have been learned since the 1970s in the cited clinical trials, symposia and in related research. Possibly the most important details are those related to ubiquinone body pool [illegible] supplementation. Adult human body pool has been [illegible] requires replacement of about 0.5 [illegible] turnover rate of about 4 days in various tissues.[34] This [illegible] or from exogenous sources. Synthesis

ressively in humans above age [illegible]. Furthermore, the average ubiquinone western diet [illegible] than 5 mg/day.[35] Thus, ubiquinone supplementation the only way for older people, and certainly the ill, to obtain the major he 0.5 gram/day need. Failure to supplement by the aged, ill or stressed, consequences in the form of irreversible damage in the brain, other ochon[illegible] everywhere[36,37]. In addition to production of adenosine TP, molecules for energy), and maintenance of cellular and mitochondrial lity, ubiquinone has a possibly even greater value. This is its free radical ty (50 times greater than vitamin E), that prevents the above mentioned tative damage. In Professor Littarru's authoritative 91 page book, he s (71%) to ubiquinone's defense against free radical damage [38] He knowledge of mitochondrial aging in unsupplemented mammals has been 1985.[39] In this aging mechanism he and others have stated that low inone permit oxidative damage to the DNA of mitochondria, permanently ability to function. If, by supplementation, the ubiquinone level is restored ue, the rate of oxidative damage will be lessened, but the impairment t it appear that physicians who tell their patients not to take ubiquinone, e more rapidly have more health problems including cardiopathy, urment (especially strokes), etc, and die early"? Isn't this what is erica today

inone

ale clinic. [illegible]is, oral ubiquinone has been shown to be safe and ood levels of about 4 ppm (considered pharmacologic and attained by addition, even at levels of 80 ppm measured [illegible] Japanese in 1984 inone preparation, only beneficial effects were reported. A new mal ubiquinone is available from Eisai. A caveat: in patients with ichs, oral Candida can colonize upper gut (potentially lethal); before uinone, their physicians should study Marshall et al.[39] Our studies inone enhance growth of Candida albicans [40]

udies of stroke in three animal models (dog, rat, gerbil) ubiquinone was ving complete protection and this was over two times more often than at (naloxone) of the many tested to date. Some of the animals were me post-stroke (less than 12 hrs). None of the 50+ synthetic stroke umans has yet proven successful as of February 2000. If mainstream humanistic motivation, why doesn't it use ubiquinone in the interim?

bservation using ubiquinone was in a patient predicted by the very e specialists in a large California facility to remain permanently e recovered completely after about 10 days in coma.[41] She had been memory problem with oral ubiquinone 400 mg/day for a month prior to trauma with massive hemorrhage. In a second case (unpublished), a , the mother of Dr Fudenberg's former secretary had a similar stroke gnosis of permanently vegetative; he traveled from South Carolina to patient out of hospital and gave her 400 mg ubiquinone b.i.d. (starting oke, which we felt would be too late) and she recovered to much better condition (near mental acuity, speech agility, equal to what she had

experienced in her 40's). There has been a third case which we "do not advertise" because it is extremely important to elevate ubiquinone as rapidly as possible to minimize the ischemic reperfusion injury. This is a 70 year old male professional dancer in Seattle who was given ubiquinone in similar oral dosing starting on the 11th day and made progress much above predicted; he regained speech and ability to do dance steps but had difficulty with names and his recovery plateaued after a few weeks; his stroke was not comatose and his recovery was not complete to his pre-stroke condition. Can't the medical (and lay) readers of this journal help stimulate a grass-roots evaluation of this simple innocuous treatment?

We emphasize that we are not advising people to self-treat. However, everyone must realize that, each year in the U.S. alone, over 650,000 families have a loved one hospitalized for stroke. Only 1/4 of these escape death or permanent disability. The families have a right to know that ubiquinone exists at their health food stores, has the properties described above and appears likely to avert the tragic prognoses. If you readers pass this information to such families, many, in their desperation, may elect ubiquinone. We request the readers suggest (1) this be done with the best open-minded preventive medicine supervision available, and (2) the supervising physician report by email (tapresi@aol.com) the patient identification, date of stroke, treating stroke center, prognosis, time delay before ubiquinone (swallowed or intubation), dosage including other agents, and progress up to 4 weeks post-stroke.

Ubiquinone in Cardiology

Negative "Studies." A very few negative "studies" from the early 1990's up to present have reported lack of beneficial effects of ubiquinone for congestive heart failure (CHF). Fundamentally, these negative studies have been criticized as cases of too little ubiquinone, for too short a time and too late in the course of CHF in the trial patients. Correct treatment should include the essential nutrients (ubiquinone, vitamin E, and ascorbic acid) and no statins. Self-appointed "experts" who have no experience in treating CHF correctly have praised these few negative "studies" while ignoring the vastly greater literature cited above including the large scale trials demonstrating the positive aspects of ubiquinone. Could the negative studies have been "designed" to produce failures? Is this action designed to oppose acceptance of the low cost (unprofitable), non-toxic (endogenous), versatile ubiquinone modality. Certainly the investigators and extollers of these negative "trials" appear to be totally oblivious of the fundamental physiology of ubiquinone requiring its constant replacement at 500 mg/day by synthesis from exogenous substrate or by supplementation.

Positive Studies. Clinical observations of cardiologists who have had extensive experience with the use of ubiquinone (such as Peter Langsjoen) find dramatic improvements in heart function in CHF patients treated with ubiquinone prior to the development of irreversible damage. While the optimal dose of ubiquinone in the treatment of congestive heart failure is not established, it has become clear over the past 15 years, that 100 mg per day (the dose used in some of the negative studies) is suboptimal for the majority of patients. A higher dose of ubiquinone for a longer period of time has demonstrated highly significant benefit in many previously published trials. An extensive review of ubiquinone use for cardiovascular disease (CVD) in 34 controlled clinical trials and several open-label and long-term studies has recently been published.42

Statins: Toxic Misuse. Karl Folkers, the frequently honored chemist who first determined the structure of ubiquinone in 1958 and was Director of Research for Merck for 20 years, warned in 1990[43], that heart disease is caused or worsened by the depression of ubiquinone that is associated with statin use and that ubiquinone must be supplemented adequately in patients given statins. Others have also documented this high level mandate for use of ubiquinone with statins.[32,42] Theoretically curable CVD patients on statins will progressively decompensate and decrease ejection fraction if given only 100mg ubiquinone/d or less. They can reverse these losses and recover if given sufficiently greater than 200mg ubiquinone/d. If the lethal effects of violating this higher need for ubiquinone created by statins are overlooked, CVD patients are trapped in an **expensive downward spiral to death** and vastly more dollars are spent on their care than if given adequate ubiquinone. Ironically, statins may only be needed in the truly rare familial hypercholesterolemias. It is well known that: (1) cholesterol is not a risk factor for CVD unless LDL is oxidized; and (2) this is simply prevented by vitamin E in nearly all humans.[44,45]

Ubiquinone and Ascorbic Acid (AA). There can be little expectation for significant improvement in ejection fraction or any other parameter of cardiovascular function without high AA levels. These levels are necessary for hydroxylation reactions in the constant restoration of the structural proteins, collagen and elastin.[46] Virtually all unstressed mammals need roughly 50 mg AA/kg body weight daily, or ~3.5 g/70kg human. Of course, CVD patients may not be exactly "unstressed". If AA intake is only 60 mg or 200 mg (the current and proposed RDA's for AA), patients would likely not have frank clinical scurvy. However, at these low intakes, it is extremely unlikely that they could restore or maintain youthful elasticity of blood vessels to increase ejection fraction, even though ubiquinone is supplied. Moreover, glycemic level must be controlled; AA cannot enter cells of hyperglycemic tissues because glucose competitively inhibits its insulin-medicated active transport (Ely, 1972 unpublished). Thus, modest hyperglycemia can cause scorbutic conditions to exist in the intimal surface of blood vessels even when plasma AA levels are reasonable.

Glycation and Aging
Ely discovered in animal model work (and confirmed with Warner et al in a study of 300 human patients) that elevated plasma AA levels antagonize glycation of hemoglobin and all other proteins, which improves health and slows aging.[47] Unfortunately, we are then faced with the nuisance that glycated hemoglobin reads falsely low when used as a measure of average blood glucose level for purposes of glycemic control. Bliznakov demonstrated restoration of youthful thymic response against viruses and tumors and major increases in lifespan of very old mice given ubiquinone.[48]

There is ample evidence that high levels of ubiquinone, and AA, slow the detrimental biochemical, structural and other changes that occur with aging in all mammals. Ubiquinone may reverse some age-related bioenergetic degradation that acutely affects the systems with the highest energy demand (cardiovascular and immune). Failure in these systems is a major cause of morbidity and mortality in the elderly. However, it has been known since 1985 that mitochondrial aging (in all systems) that accumulates in intervals when ubiquinone is low, especially the brain, is not reversible. Supplementation of ubiquinone and AA with glycemic control should be considered by all adults,

especially the elderly, ill and stressed. Amounts of AA needed in health and disease have been discussed previously.[2]

Acknowledgements
Support from Applied Research Institute and the assistance of H. F. Krone are gratefully acknowledged.

References
1. Pauling LJ: How to live longer and feel better. New York, Avon Books, 1987; 413.
2. Ely JTA: Ascorbic Acid and Some Other Modern Analogs of the Germ Theory, J Orthomol Med, 1999; 14: 143-156.
3. Physicians Desk Reference, 42nd Edition, Medical Economics, 1988; 2154.
4. Physicians Desk Reference, 51st Edition, Medical Economics, 1997; 2769.
5. Langsjoen, PH: Introduction to Coenzyme Q10, 1995. On Univ of Wash web site http://faculty.washington.edu/ely
6. Hiasa Y, Ishida T, Maeda T, Iwano K, Aihara T, Mori H: Effects of coenzyme Q10 on exercise tolerance in patients with stable angina pectoris. In eds. Folkers K, Yamamura Y: Biomedical and Clinical Aspects of Coenzyme Q, vol. 4, Elsevier, 1984; 291-301.
7. Kamikawa T, Kobayashi A, Yamashita T, Hayashi H,Yamazaki N: Effects of coenzyme Q10 on exercise tolerance in chronic stable angina pectoris. Am J Cardiol, 1985; 56: 247-251.
8. Langsjoen Per H, Vadhanavikit S, Folkers K: Response of patients in classes III and IV of cardiomyopathy to therapy in a blind and crossover trial with coenzyme Q10. Proc Natl Acad Sci USA,1985, 82: 4240-4244.
9. Judy WV, Hall JH, Toth PD, Folkers K: Double blind-double crossover study of coenzyme Q10 in heart failure. In eds. Folkers K, Yamamura Y: Biomedical and Clinical Aspects of Coenzyme Q, vol. 5, Elsevier, 1986; 315-323.
10. Rossi E, Lombardo A, Testa M, Lippa S, Oradei A, Littarru GP, Lucente M, Coppola E, Manzoli U: Coenzyme Q10 in ischaemic cardiopathy. In eds. Folkers K, Yamamura Y, Littarru GP: Biomedical and Clinical Aspects of Coenzyme Q, vol. 6, Elsevier,1991; 321-326.
11. Morisco C, Trimarco B, Condorelli M: Effect of coenzyme Q10 therapy in patients with congestive heart failure: A long-term multicenter randomized study. In eds. Folkers K, Mortensen SA, Littarru GP, Yamagami T, Lenaz G: Seventh International Symposium on Biomedical and Clinical Aspects of Coenzyme Q, The Clinical Investigator, 1993; 71:S 34-S136.
12. Schneeberger W, Muller-Steinwachs J, Anda LP, Fuchs W, Zilliken F, Lyson K, Muratsu K, Folkers K: A clinical double blind and crossover trial with coenzyme Q10 on patients with cardiac disease. In eds. Folkers K, Yamamura Y: Biomedical and Clinical Aspects of Coenzyme Q, vol. 5, Elsevier, 1986; 325-333.
13. Schardt F, Welzel D, Schiess W, Toda K: Effect of coenzyme Q10 on ischaemia-induced ST-segment depression: A double blind, placebo-controlled crossover study. In eds. Folkers K, Yamamura Y, Littarru GP: Biomedical and Clinical Aspects of Coenzyme Q, vol. 6, Elsevier,1991; 385-403.
14. Swedberg K, Hoffman-Berg C, Rehnqvist N, Astrom H: Coenzyme Q10 as an adjunctive in treatment of congestive heart failure. 64th Scientific Sessions American Heart Association, 1991; Abstract 774-6.
15. Mortensen SA, Vadhanavikit S, Folkers K: Deficiency of coenzyme Q10 in myocardial failure. Drugs Exptl Clin Res,1984; 10(7): 497-502.

16. Mortensen SA, Vadhanavikit S, Baandrup U, Folkers K: Long term coenzyme Q10 therapy: a major advance in the management of resistant myocardial failure. Drugs Exptl Clin Res, 1985; 11(8): 581-593.
17. Langsjoen PH, Folkers K, Lyson K, Muratsu K, Lyson T, Langsjoen PH: Effective and safe therapy with coenzyme Q10 for cardiomyopathy. Klin Wochenschr, 1988; 66: 583-593.
18. Langsjoen PH, Langsjoen, PH, Folkers, K: Long term efficacy and safety of coenzyme Q10 therapy for idiopathic dilated cardiomyopathy. Amer J Cardiol, 1989; 65: 521 - 523.
19. Mortensen SA, Vadhanavikit S, Muratsu K, Folkers K: Coenzyme Q10: Clinical benefits with biochemical correlates suggesting a scientific breakthrough in the management of chronic heart failure. Intl J Tissue React, 1990; 12 (3): 155-162.
20. Ursini T, Gambini C, Paciaroni E, Littarru GP: Coenzyme Q10 treatment of heart failure in the elderly: Preliminary results. In eds. Folkers K, Yamamura Y, Littarru GP: Biomedical and Clinical Aspects of Coenzyme Q, vol. 6, Elsevier, 1991; 473-480.
21. Poggessi L, Galanti G, Comeglio M, Toncelli L, Vinci M: Effect of coenzyme Q10 on left ventricular function in patients with dilative cardiomyopathy. Curr Ther Res, 1991; 49: 878-886.
22. Langsjoen HA, Langsjoen PH, Langsjoen PH, Willis R, Folkers K: Usefulness of coenzyme Q10 in clinical cardiology, a long-term study. In eds. Littarru GP, Battino M, Folkers K: Eighth International Symposium on Biomedical and Clinical Aspects of Coenzyme Q, The Molecular Aspects of Medicine, 1994; 15:S165-S175.
23. Baggio E., Gandini R., Plancher A.C., Passeri M., Carmosino G. Italian multicenter study on safety and efficacy of coenzyme Q10 adjunctive therapy in heart failure. In eds. Littarru GP, Battino M, Folkers K: Eighth International Symposium on Biomedical and Clinical Aspects of Coenzyme Q, The Molecular Aspects of Medicine, 1994; 15: S287-S294.
24. Biomedical and Clinical Aspects of Coenzyme Q. Eds. Folkers K, Yamamura Y, Elsevier, 1977; 1-315.
25. Biomedical and Clinical Aspects of Coenzyme Q, Vol. 2. Eds.Yamamura Y, Folkers K, Ito Y, Elsevier, 1980; 1-456.
26. Biomedical and Clinical Aspects of Coenzyme Q, Vol. 3. Eds. Folkers K, Yamamura Y, Elsevier, 1981; 1-414.
27. Biomedical and Clinical Aspects of Coenzyme Q, Vol. 4. Eds. Folkers K, Yamamura Y, Elsevier, 1983; 1-432.
28. Biomedical and Clinical Aspects of Coenzyme Q, Vol. 5. Eds. Folkers K, Yamamura Y, Elsevier, 1986; 1-410.
29. Biomedical and Clinical Aspects of Coenzyme Q, Vol. 6. Eds. Folkers K, Yamagami T, Littarru GP, Elsevier, Amsterdam, 1991; 1-555.
30. Seventh International Symposium on Biomedical and Clinical Aspects of Coenzyme Q. Eds. Folkers K, Mortensen SA, Littarru GP, Yamagami T, Lenaz G, The Clinical Investigator, 1993; 71(8): S51-S177.
31. Eighth International Symposium on Biomedical and Clinical Aspects of Coenzyme Q. Eds. Littarru GP, Battino M,Folkers K, The Molecular Aspects of Medicine, 1994; 15: S1-S294.
32. Bliznakov EG, Wilkins DJ: Biochemical and clinical consequences of inhibiting Coenzyme Q10 biosynthesis by lipid-lowering HMG-CoA reductase inhibitors (statins): A critical overview. Advances in Therapy, 1998; 15(4), 218-28.
33. Kalen A, Appelkvist E-L, Dallner G: Age related changes in the lipid composition of rat and human tissue. Lipids, 1989; 24: 579-584.
34. Ernster L, Dallner G: Biochemical, physiological and medical aspects of ubiquinone function. Biochim Biophys Acta, 1995; 1271: 195-204.
35. Weber C, Bysted A, Holmer G: The coenzyme Q10 content of the average Danish diet. Int J Vitam Nutr Res. 1997; 67: 123-129.
36. Bliznakov E. Aging, mitochondria, and coenzyme Q10: The neglected relationship. Biochimie, 1999; 81:1131-1132.
37. Linnane AW, Kovalenko S, Gingold EB: The universality of bioenergetic disease: age associated cellular bioenergetic degradation and amelioration therapy. Ann NY Acad Sci, 1998; 854: 202-213.
38. Littarru GP: Energy and Defense. Roma, Casa Editrice Scientifica Internazionale. 1995; 91. ISBN 88-86062-24-9.
39. Marshall JC, Christou NV, Horn R, Meakins JL: The microbiology of multiple organ failure. The proximal gastrointestinal tract as an occult reservoir of pathogens. Arch. Surg . 1988; 123: 309-15.
40. Krone CA, Elmer GW, Ely JTA, Fudenberg HH, Thoreson J: Does gastrointestinal Candida albicans prevent ubiquinone absorption? Med Hypotheses in press.
41. Ely JTA, Fudenberg HH, Bliznakov EG, Branch JD: Hemorrhagic Stroke in human pretreated with coenzyme Q10: Exceptional recovery as seen in animal models. J Orthomol Med, 1998; 13(2): 105-109.
42. Langsjoen PH, Langsjoen AM: Overview of the use of CoQ10 in cardiovascular disease. BioFactors, 1999; 9: 273-284. available at http://wwwcsi.unian.it/coenzymeQ/article.html
43. Folkers K, Langsjoen P, Willis R, Richardson P, Xia L-J, Ye C-Q, Tamagawa H: Lovastatin decreases coenzyme Q levels in humans, Proc Natl Acad Sci USA, 1990; 87: 8931-8934.
44. Gey KF, Puska P, Jordan P, Moser U: Inverse correlation between plasma vitamin E and mortality from ischemic heart disease in cross-cultural epidemiology. Am J Clin Nutr, 1991; 53:326s-334s.
45. Esterbauer H, Dieber-Rothender M Striegl G, et al: Role of vitamin E in preventing oxidation of low-density lipoprotein. Am J Clin Nutr, 1991; 53: 314s-321s.
46. Myllyla R, Majamaa K, Gunzler V, Hanuska-abel HM, Kivirikko KI: Ascorbate is consumed stoichiometrically in the uncoupled reactions catalyzed by propyl-4-hydroxylase and lysyl hydroxylase. J Biol Chem, 1984; 259: 5403-5405.
47. Ely JTA, Warner GA, Read DH, Santisteban GA: Protein glycation: ascorbate antagonism (abstract). Bull APS (Div of Biol Phys), 1988; 33(3): 296.
48. Bliznakov EG: Effect of stimulation of the host defense system by coenzyme Q10 on dibenzpyrene-induced tumors and infection with Friend leukemia virus in mice. Proc. Natl. Acad. Sci. USA, 1973; 70: 390-4.

Proceed to Science of Essential Nutrients or Coenzyme Q10 Research

---

Updated October 2002

Friday, August 06, 2004, via certified mail, return receipt

Attn: Regional Counsel, David Davenport
Department of Veterans Affairs, as well as separately and concurrently to the General Counsel for the Secretary of the VA, Tim S. McClain
1 Jefferson Barracks Dr.
Building 25,Room 308
St. Louis, MO 63125

As well as Wayne Hill, Wichita VARO

ABSTRACT OF CLAIMS FOR INJURY AND PROPERTY DAMAGE

Per Congressman Dennis Moore's staff official (Paul Davidson) advisement this date, this one page document (abstract) serves as an official signed and dated writing (notice) constituting and supplementing both a claim for injury and property damage (VA Form 21- 4138 dated July 7, 2004) under 38 U.S.C. § 1151, as well as other state and federal laws. This abstract also serves as actual notice, as well, as an inter-agency claim against the VA and the FDA (Form SF-95)(Included). This abstract incorporates other documents already provided by any means, and is not limited to merely the documents, attachments, forms, or any other writing, not provided herein.

Both claims are attributable to acts and/or omissions regarding residual effects resulting in injury and property damage, more fully described in other documents. The taking of prescription products (lovastatin and simvastatin), while taking other medications concurrently) proscribed by the Topeka VA Hospital staff, without timely or adequate warning, as well as a medication errors, has resulted in the need to file both of these claims. The onset of the injury and damages started with the prescribing of these medications on/around April 14, 2003 continuing with additional prescriptions until I was advised to stop taking simvastatin on/around October 24, 2003 by a new primary care doctor's advisement [redacted] M.D.

After several requests for written documentation to [redacted] I was finally able to obtain a diagnosis of this statin-induced injury. [redacted] in writing, stated he believed I met the criteria for chronic fatigue syndrome (under CDC Guidelines), as well as myalagia. For the most part, a better or additional diagnosis that is more accurate is/may be statin-induced peripheral neuropathy. Finally, I continue to suffer from this statin-induced injury.

In anticipation, I will be assembling evidence in a separate document at a later date.

Signed and dated, this the 6th day of August, 2004

Thomas E. Scherer, Claimant and veteran
[redacted] Merriam, KS. 66202[redacted]
SSN (Claim No.) [redacted]
ATTACHMENTS INCLUDING FORM SF-95

BVA Docket No. 0105380A

MOTION FOR SUBMISSION OF ADDITIONAL MATERIAL FACTS AND RELEVANT EVIDENCE

Mr. Scherer as the claimant and veteran, requests by formal motion and consideration, the attached document marked as Exhibit 1. Exhibits in support as referenced in the attached document will be provided as evidence at the hearing afforded under the principles and concepts of due process.

Veteran

Ts (electronic signature, good as original)
Thomas E. Scherer, Pro Se

Friday, August 06, 2004, by certified mail, return receipt

Attn: Regional Counsel, David Davenport
Department of Veterans Affairs, as well as separately and concurrently to the General Counsel for the Secretary of the VA, Tim S. McClain[1]
1 Jefferson Barracks Dr.
Building 25,Room 308
St. Louis, MO 63125
Re: Standard Form SF-95, Claim for damage and injury

Dear Mr. Davenport and McClain,

NOTICE AND A CLAIM FOR DAMAGES AND INJURIES

This letter, the enclosed Standard Form SF-95, and any/all attachments or exhibits, as well as any future amendments/diagnostic tests/documents, separate claims, information provided from expert witnesses, or any other future supplemental writing, if any, shall constitute my new and timely claim and notice, separate and irrespective of any other existing claims, remands, or any other VA administrative processes. Nor should this claim interfere in existing, prior, or current pending VA claims, BVA remands, or requests for a personal hearing before the BVA dated March 30, 2004 via certified letter, return receipt.

This new claim is pertaining to and including any/all damages (both property and personal) for injuries that I have suffered; am presently cognizant of; or become aware of, or will occur or suffer from in the future related to treatment with statin products[2] at the Topeka, KS VA Medical facility in 2003. The proximate cause, and cause in fact pertaining to this claim has resulted from the distribution, ordering of, and subsequent taking, of a prescribed prescription products known commonly as LOVASTATIN AND ZOCOR (proprietary name) or as Simvastatin (active ingredient) by me. That prescribing constitutes an *actual medication error*, resulting in a subsequent *unexpected and serious adverse event* (or experience)[3] that has resulted in this claim. There was a failure by learned intermediaries (doctors and/or pharmacists) to give a reasonable and timely warning of a critical and high risk of a drug-drug interaction to the consumer. This document does include some risks known by the drug manufacturer [redacted], that are not warned or included, in the manufacturer's prescribing information. For example, *see* **Exhibit 2**, letter including prescribing information for ZOCOR applicable at the time of dispensation.

[1] Title 38 is ambiguous in how or whom to effectuate proper service of a SF-95 claim. An original copy will be provided to both General Counsel, acting for the VA Secretary, as well as to Regional Counsel as directed.

[2] There was an initial prescription given and dispensed on April 14, 2003 for Lovastatin. On May 1, 2003, the VA officials substituted Zocor (Simvastatin) for the Lovastatin. All further references will be to one or the other prescription product In the context of this document and claim. Specificity as needed, will be provided. Statins as a class refer to all prior, current, or new statin products approved by the FDA.

[3] Adverse events are also defined as sentinel events by the VA and Joint Commission on Accreditation

In addition, this notice and claim includes specific acts, that constitute negligent or wrongful acts, or omissions by specific VA officials (learned intermediaries) relating to subsequent events after the prescribing of that product that are related to any diagnostic tests, diagnosis, treatment, warnings, or any other act(s) in treating the reported symptoms that are attributed to either product LOVASTATIN or ZOCOR either independently, or in contribution.

[redacted][4] (hereafter [redacted]) manufactures the prescribed products, LOVASTATIN AND ZOCOR. ZOCOR was prescribed and distributed to me, by officials acting for, or on behalf of the Veterans Administration without warning of a high risk of a drug-drug interaction by any intermediary in either their individual or official capacity, under the *learned intermediary doctrine*,[5] for the period of time starting April 14, 2003, and continuing until I stopped taking ZOCOR by doctor order on/around October 24, 2003.[6] Claims for damages and personal injury regarding product liability will be addressed separately and independently with the drug manufacturer, Merck. Claims against learned intermediaries in their individual capacity (doctors and pharmacists) will be addressed separately as well.

Finally, this filing serves as a notice of an interagency claim against the United States Food and Drug Administration (*hereafter* referred to as FDA) for its failure to:

a) protect my or the public interest, regarding unknown, known but not reported life-threatening risks, and known and reported risks, that result in potential or

[4] [redacted], is incorporated in the state of Delaware. [redacted] is a global research-driven pharmaceutical products and services company that discovers, develops, manufactures and markets a broad range of products to improve human and animal health, directly and through its joint ventures. Its principal corporate office and address of record is [redacted] 0100[redacted] is registered to conduct business with the Secretary of State, the state of Kansas, as a business entity, ID Number[redacted] including having a registered agent.

[5] The *learned intermediary doctrine* is fully discussed, as well as other apposite and relevant issues discussed in this claim, are contained in Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 681 P.2d 1038 Kan., (1984). For legal terms used in the context of this document, terms are adopted from applicable federal regulations and the Federal Register to the greatest extent possible applicable on the time of the medication error and corresponding adverse events. *Also refer* to VA Directive 1050.1 and its associated handbook, Patient Safety Improvement at http://www.va.gov/publ/direc/health/handbook/1051r1hk.pdf.

[6] Statutory authority for federal agencies including federal officials such as the VA and the FDA in their official, as well as individual capacity, is provided under Federal Tort Claims Act, 28 U.S.C. §§ 2671-80, as well as to the VA and its officials under 38 U.S.C. § 1151 and 5107, et al. *Also refer to* Kansas statutory authority which includes the Kansas Tort Act, K.S.A. 75-6101, et seq. regarding liability of public officials; the Kansas Product Liability Act, K.S.A. § 60-3301 et. seq., and the Kansas Consumer Protection Act regarding manufacturer liability. A denial of administrative relief includes judicial review including 5 U.S.C. § 702 and 28 U.S.C. § 2412, et al. It is anticipated and provided for, that separate actions will be filed shortly in either/both state and federal courts within the statute of limitation time period, if there is not a quick and proper administrative relief/remedy provided by August 26, 2004. For all practical purposes, administrative action in Kansas has been constructively exhausted against intermediaries There is no administrative agency or statutory requirement for relief/remedy from a drug manufacturer such a[redacted]

actual serious adverse events or experiences that are attributable to the class of statin drugs[7], including LOVASTATIN and/or ZOCOR[8]; or

b) Implement modifications or suggested product recommendations to statin drugs including better warning labels (referred to as Black Box warning labels), or

c) Order better and more specific baseline and diagnostic anticipatory tests to known potential risks; better diagnostic tests regarding patient reported symptoms or side effects, or

d) Order better prescribing information for intermediaries in response to reported risks and potential adverse events that address known risks and adverse events that include a substantial number of reported deaths, damages, and injuries, related to this class of statin products including LOVASTATIN AND ZOCOR[9].

The purpose of this letter therefore, and all other documents, is two-fold. **First**, I need to address my own personal injuries and damages, some of which may be permanent and irreparable. Hence, this constitutes sufficient and reasonable notice of a claim for damages and injuries. **Second**, I want to ensure that other veterans on statin therapies, as well as the general public, are better informed and protected regarding medication errors, risks, and potential or actual adverse events, attributable to the taking of statin products. In that regard, I am actively working with several federal agencies, [redacted], the manufacturer of ZOCOR, as well as with elected officials, federal and state regulatory agencies, consumer protection groups, national and international experts, regarding the entire class of statins. I start with a bold assertion that attempts in one statement to factually summarize into one concise and precise term statement on the next page:

[7] Statin class of products include proprietary products or active ingredients such as ZOCOR, Lipitor, Baycol (recalled 2001), Mevacor, Lescol, Pravachol and Advicor Atorvastatin; Cerivastatin; Fluvastatin; Lovastatin ; Pravastatin; Simvastatin

[8] *See* 28 C F R. 14.2 as it relates to the duty of a regional counsel when claims of damages/injury against more than one federal agency are involved.

[9] *See* FDA petitions 02P-0243/CP1 and 02P-244/CP1 (date-stamped November 14, 2002) recommending supplementation of enzyme CoQ10. *Also see* 01P-0372/CP1 (dated August 27, 2001) filed by Public Citizen regarding four specific recommendations on statin therapies regarding "Black box warning labels" and adverse events attributable to ZOCOR and other statin products. *Also see* 02N-0115 (June 10, 2002) regarding a medical doctor reporting of an adverse event attributed to ZOCOR

WHAT REALLY HAPPENED FACTUALLY, IS THERE WAS AN INITIAL ACTUAL MEDICATION ERROR (PRESCRIBING LOVASTATIN; FOLLOWED BY A SECOND MEDICATION ERROR (SUBSTITUTION OF ZOCOR FOR LOVASTATIN; BOTH OF WHICH WERE NOT PROVIDED WITH ADEQUATE OR APPROPRIATE PRODUCT SPECIFIC WARNING(S), EITHER TIMELY OR REASONABLY, ORALLY, OR IN WRITING, WITH A THIRD MEDICATION ERROR OF INCREASING THE MEDICATION (ZOCOR), DESPITE PRIOR REPORTED SYMPTOMS INCLUDING EMERGENCY ROOM TREATMENT FOR THOSE SYMPTOMS. ALL OF WHICH ARE REQUIRED UNDER A PRE-EXISTING DUTY AND STANDARD INDUSTRY TRADE PRACTICES; BY MORE THAN ONE PROFESSIONAL PERSON (DOCTOR OR PHARMACISTS) TO KNOWN (AND UNKNOWN) CRITICAL RISKS INCLUDING MANUFACTURERS AND INTERNAL KNOWN DRUG-DRUG INTERACTION WARNINGS.

THAT THOSE ERRORS RESULTED IN BOTH AN EXPECTED AND UNEXPECTED, SERIOUS, ADVERSE EVENT (PROXIMATE CAUSE AND CASE IN FACT). THAT DUE TO THOSE ERRORS, AND LACK OF PRE-EXISTING DUTY TO WARN, SUBSEQUENT ERRORS RESULTED WHICH INCLUDED ACTS OF COMMISSIONS/OMISSIONS, WHICH IN TURN, CAUSED OR RESULTED IN SERIOUS PERSONAL INJURY AND DAMAGE INCLUDING LOSS OF FUNCTION (SENTINEL EVENT). THERE IS PRELIMINARY INDICATIONS AS WELL, THAT THOSE SERIES OF EVENTS CONSTITUTING ONE TRANSACTIONAL SERIES, MAY INCLUDE A PERMANENT LOSS OF FUNCTION AS A FINAL RESULT. FINALLY, THIS MEDICATION ERROR AND SUBSEQUENT EVENTS THAT OCCURRED AFTER THE TAKING OF THE PRESCRIBED PRODUCTS LOVASTATIN AND SIMVASTATIN HAS RESULTED IN ACTUAL DAMAGES RESULTING IN, AND CONTINUING TO BE INCURRED. WITH A CORRESPONDING HIGH RISK OR PROBABILITY, THAT SIMILARLY SITUATED PATIENTS OR CONSUMERS AT THE VA, ARE LIKELY TO ALSO EXPERIENCE SERIOUS, EXPECTED, AND UNEXPECTED, ADVERSE AND SENTINEL RISKS FREQUENTLY, GOING FORWARD, PROVIDED THAT THERE IS NO FURTHER MORAL, ETHICAL, MANDATORY, AND/OR VOLUNTARY, REGULATORY ACTION, SUCH AS REPORTING AND ROOT CAUSE ANALYSIS.

I. CLAIMS ATTRIBUTABLE TO THE VA (AS USER-FACILITY AND DISTRIBUTOR/DISPENSER) INCLUDING VA OFFICIALS IN THEIR OFFICIAL AND INDIVIDUAL CAPACITY:

GENERALLY REFERRED TO UNDER FEDERAL GUIDELINES AS A TORT(S) AND UNDER KANSAS STATE LAW AS ACTS OF MEDICAL MALPRACTICE

This claim, and the claimed damages and injuries, are attributed (cause in fact and proximate cause) to the taking and prescribing of prescription medication(s), LOVASTATIN AND ZOCOR (proprietary name) or simvastatin (active ingredient). The location or occurrence of events pertaining to this claim is the state of Kansas. LOVASTATIN AND ZOCOR are prescription products manufactured by Merck; a product that is known to have risks and causes serious adverse events. The prescribing information to intermediaries includes some contradictions and product warnings[10].

This claim includes negligent, or wrongful act(s)/failure to act by VA officials, in their official, as well as individual capacity, independently and/or collectively, for claims of damages and injury caused by negligence/malpractice in a series of related transactions or a or chain of events pertaining to

a) My taking of that prescribed and ordered medication (actual medication error), without being provided reasonable or adequate warning of a critical and high risk possibility of a VA known drug-drug interaction (*See* **Exhibit 1**).

b) Prescribing LOVASTATIN AND SUBSEQUENTLY ZOCOR negligently, and wrongfully, when the prescribing information supplied by the drug manufacturer provides warnings to not give ZOCOR, to someone who is concurrently taking Ketoconalzole Crème, Rx No. 10261491, that constitutes an actual medication error resulting in an unexpected and serious adverse event or experience. Then, subsequently failing to warn of known risks under a duty to warn when taking this anti-fungal prescription at the same time as LOVASTATIN AND ZOCOR. *See* ZOCOR prescribing information warnings at pg. 10-11 **(Exhibit 2)**.

c) The Topeka VA pharmacy substituting ZOCOR for Lovastatin on/around May 1, 2003. (**Exhibit 3**). The prescription bottle labels on the ZOCOR contained spaces for marking warnings. But there are no warnings marked on the May 1 and July 7, 2003 prescription bottle labels.

d) Subsequently and negligently not treating/timely diagnosing the unexpected symptoms attributable to ZOCOR when that prescription resulting in an unexpected, serious adverse event.

[10] *See* the FDA application, patents, trials, contraindications, warnings and known adverse events related to more detailed information regarding the product ZOCOR (prescribing information attached as Exhibit 1).

e) Topeka VA Director [redacted] and other VA officials, in their individual and official capacity, for failing negligently to report those actual medication error and resulting serious, unexpected, adverse events attributable to my taking of ZOCOR. This is for my protection, as well as the protection of the public interest, both internally with the VA locally at the Topeka VA, as well as with the National Center for Patient Safety (*hereafter* NCPS); or external to the VA, with the drug manufacturer, or with the FDA, despite a patient request being received by the Topeka VA Director [redacted], via United States Postal Service, restricted mail, certified delivery, return receipt dated December 8, 2003.

Officials in either there individual or official capacity would include staff members of the primary care team, the Topeka VA Head Pharmacist, [redacted], and/or unknown employees on his pharmacy staff; the Topeka VA safety officer Voos; staff members of the Topeka VA Emergency Room; the Topeka VA patient representative [redacted], the Topeka VA former FOIA, as well as the interim and new FOIA officer, the Director of the Topeka VA, [redacted], any other unnamed officials at the Topeka VA involved in protecting patient safety and reporting adverse events or the participation in the reporting of adverse events to the NCPS, the FDA or the drug manufacturer, Merck.

Officials at the NCPS, and at the VA and VHA Central Office in Washington, D.C., including the Secretary of the Veterans Administration, Anthony J. Principi, General Counsel Tim S. McClain and Secretary Principi's staff members,, the Executive Office including Melina Carrington (Jan. 8, 2004), his FOIA officer, J.C. Finley (VHA on Jan. 8, 2004) and/or Clay Johnson, as well as Jenifer Legley, Health Administration Specialist (VHA on Jan. 12, 2004). It would seem unnecessary at this point to specifically name each and every individual, describing each and every act or omission performed by each and every individual at each point in time at this stage of the claim process. I will however name specific acts and individuals pertaining to negligent, wrongful, or acts of omission. In addition, the aggregate acts of all individuals constitute a chain of acts or events that would constitute a negligent or wrongful act(s).

The VA is indisputably, the largest provider of health care services in the nation. It is a user-facility and distributor of prescription products including ZOCOR. It is therefore imperative that the VA, as the nation's largest health care provider, provides accurate reporting of potential risks and reported adverse events to the FDA, or the drug manufacturer including those attributable to the taking or prescription medications[11]. The VA is also aware of similar and related adverse events related to cholesterol medication[12]

[11] *See* News Release by United States Department of Health and Human Services, Secretary Thompson, Secretary Thompson announces steps to reduce medication errors, (March 13, 2003) pertaining to the need for improved safety reporting due to medication errors and the need for improved reporting making adverse event reporting mandatory within 15 calendar days by companies such as Merck, the manufacturer of ZOCOR.

[12] *See* Heath Update Cholesterol Medications Can Cause Muscle Disease, Douglas J. Lanska, M D., VA Medical Center, Tomah, WI (January 28th, 2003

The VA is also aware of similar claims for damage and injury, as well prior cases docketed in the United States Court of Appeals for Veterans Claims, related to statin therapies including ZOCOR.[13] The VA therefore has constructive knowledge of adverse events attributable to ZOCOR. It is apparently clear the VA in turn, does not report the majority of those adverse events to the FDA or to the product manufacturer, Merck. The reporting of adverse events by the VA should be mandatory since the VA is in effect, a one of the major distributors of this product. A failure to report adverse events by the VA with the FDA, or the manufacturer, Merck, leads to a serious and disproportionate under-reporting of adverse events.

II. CLAIMS AGAINST THE FDA

The FDA as a federal agency and its officials has had specific knowledge regarding risks (including reported risks and adverse events) pertaining to a class of drugs commonly referred to as statins. The FDA approves for national distribution, products including prescription drugs used for human consumption. The FDA protects consumers from both risks including potential and actual serious adverse, as well as merely adverse events attributed to prescription drugs including statins. From a broad perspective, the Commissioner of the FDA stated recently that:

> The prevalence of avoidable health complications that involve the use of FDA-regulated products presents a challenge for the Agency. A 1999 Institute of Medicine (IOM) report estimated that as many as 100,000 Americans die each year as a result of medical errors, which are projected to rank as the eighth leading cause of death in the United States. Misuse of pharmaceuticals is associated with about 3 million hospital admissions a year. Drug-related adverse events in the ambulatory population cost Americans approximately $75 billion annually. FDA's central public health role is to ensure that medical products (drugs, biologics, and devices) are proven safe and efficacious prior to marketing, and that these products continue to be safely used once approved and marketed.[14]

FDA is a federal agency within Department of Health and Human Services (DDHS). FDA's mission is to implement the federal Food Drug and Cosmetic Act. 21 U.S.C. § 393. Among its duties are protecting the public health by ensuring that human drugs are safe and effective. Id. at §§ 393 and 355. Under the Federal Tort Claims Act, the United States is liable in the same manner and to the same extent as a private individual under like circumstances. 21 U.S.C. § 2674. The United States is the Defendant for claims for money damages for injury or loss of property or personal injury or death caused by the

[13] *See* Board of Veterans Appeals, Docket No. 00-17 558, Citation No. 0120429 (August 9, 2001) at http://www.va.gov/vetapp01/files03/120429.txt . for disability claim attributable to ZOCOR and a mass in the left lower abdominal quadrant; as well as Board of Veterans Appeals, Docket No. 99-02 771, Citation No. 0026513 (October 4, 2000) See http://www.va.gov/vetapp00/files3/0026513-claim for disability in the left upper extremity as a result of an increased dosage of medication (ZOCOR)

[14] See http://www.fda.gov/oc/mec/cellm/adverse.html, accessed Feb. 2, 2004

negligent or wrongful act or omission of any employee of the agency while acting within the scope of his or her office or employment. 21 U.S.C. § 2672.

The FDA has a reporting system pertaining to adverse events referred to as Adverse Event Reporting System (AERS) that includes the Medwatch program and Phase IV post-marketing surveillance program (PMS) to monitor and report adverse events on prescriptions products that are already approved by the FDA and in the stream of commerce.[15]

The FDA approved ZOCOR for human consumption December 23, 1991 as part of FDA regulator process. In 1997, the FDA ordered a voluntary recall of a different, but similar statin prescription, Baycol due to a high number of reported deaths in 2001[16] There have been several reports and petitions filed with the FDA regarding this class of statin drugs including serious adverse events related more specifically to ZOCOR.

From a broad perspective that is indicative of the inadequate systems currently in place in our nation, in the year 2002, there was processing and evaluating 320,860 reports of adverse drug events, including 20,455 submitted directly from individuals.[17] The FDA, out of fear, does not want an adequate or effective consumer/patient reporting system. Their fear is there would be abundance of reported data. Fear, is never a justifiable basis for refusing to collect public information that would serve the national interest.

The FDA has not timely responded to prior petitions in a reasonable manner regarding statins and ZOCOR. The standard FDA response generally to petitions is a canned response that the FDA is evaluating the petition. Sometimes, that evaluation takes years while individual consumers continue to be victims, and experience and report adverse events. In regard to my instant claim, had the FDA timely responded to those recommendations and adverse events, perhaps my prescribing doctor would have been better informed had the FDA done a better job. Therefore, the FDA by its omissions and delays has played a contributing part in my claim for damages and injury.

The FDA officials have not investigated, or sent a warning letter to Merck for not submitting a timely ADE 15 day alert report (within 15 calendar days), or for Merck officials failure to conduct a prompt and adequate investigation of a serious and unexpected adverse event not reporting in prescribing information, as provided under 21 C.F.R. 314.80(c)(1) and 310.305(c).

The FDA FOIA officials did not timely respond to FOIA requests until congressional intercession was initiated. After congressional intercession (Congressman

[15] *See* GAO Report to Congressional Requesters, Adverse Drug Events, reporting that the magnitude of health risks by organizations such as the FDA and VA is uncertain (inferring inadequate) because of limited incidence data. United States General Accounting Office, Health, Education, and Human Services Division GAO/HEHS-00-21 (B-281822 (January 18, 2000).

[16] *See* FDA Talk Paper, dated Aug. 8, 2001 regarding the recall of Baycol at http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01095.htm

[17] See http://www.fda.gov/cder/reports/rto2002/rto2002-3.HTM, accessed Feb. 2, 2004

Dennis Moore), the FDA provided some, but not all requested data pertaining to adverse events reported on ZOCOR. On May 14, 2004, the FDA provided some aggregate reported Medwatch events from November 1997 to around April 2004 on ZOCOR or SIMVASTATIN. That data reports there were 11,719 adverse events reported including 419 deaths on this one statin product alone.

FDA officials acting in their individual or official capacity would include FDA Commissioner, Mark B. McClennan, M.D., Ph.D., Janet Woodcock, M.D, Office of the Center Director, her designee, Mitchell Weitzman, attorney at law, Office of Regulatory Compliance, Chris Bechtel RN, MSN, CDER Executive Operations Staff, and the FDA FOIA Officer.

III. CLAIMS AGAINST THE MANUFACTURER, MERCK & CO., INC.[18]

1. [redacted] **had superior product knowledge of high risks** and the potential for adverse events that are attributed to both LOVASTATIN AND ZOCOR including the high risk attributed to depletion of coenzyme CoQ10[19] and reported that information in patents to the United States Patent Office.[20]

2. [redacted] **intentionally, knowingly, and willfully, negligently and with reckless endangerment, failed to inform the FDA during the NDA process, or in supplemental filings**[21], of this known risk and potential for an adverse event to users of ZOCOR, despite that knowledge as stated in its patent applications.

3. [redacted] intentionally, knowingly, and willfully, negligently and with reckless endangerment, failed to conduct, or report during its clinical trials, or after approval of this product for consumer use, reports that were known or subsequently reported after approval, to this known risk and potential for an adverse event (depletion or reduction in

[18] The claims against [redacted] as a manufacturer, as well as individuals in their individual capacities such as learned intermediaries under state laws and regulations of the state of Kansas are asserted outside the context of this claim and are merely included for a complete understanding of the issues involved and the inter-relationship between the manufacturer, the learned intermediaries (doctors and pharmacists), the regulatory agency, and the user-facility/distributor in the stream of commerce in this product distribution cycle.

[19] *Also referred* to as ubiquinone, coenzyme Q.sub.10, Co-enzyme Q10 or simply Q10. *Hereafter* referred to as CoQ10 in this document).

[20] Patents include 1) 4,444,784, Antihyercholesterolemic compounds, (April 24, 1984) regarding the patenting of a manufacturing process that includes ZOCOR 2) 4,929,437, Coenzyme Q.sub.10 with HMG-CoA reductase inhibiters (May 29, 1990), regarding the combining of statins with CoQ10 3) 4,933,165, Coenzyme Q.sub.10 with HMG-CoA reductase inhibiters, (June 12, 1990) regarding the need to counteract myopathy (muscle damage from statins) reported *infra* and at great length within this document 4) 5,082,650, Amelioration of reductions of coenzyme A.sub.10 in cardiomyopathy patients receiving Lovastatin (January 21, 1992) 5) 5,316,765, Use of coenzyme Q.sub.10 in combination with HMG-CoA inhibitor therapies (May 31, 1994), by Karl Folkers, *et al*, regarding the methods to inhibit side effects related to HMG-CoA inhibitors including Lovastatin and ZOCOR.

[21] Refer to new drug application (NDA) [redacted] and related supplemental filings on ZOCOR at http://www.fda.gov/cder/approval/z.htm

coenzyme Coq10, despite having a superior or constructive knowledge of that risk contained in several patents filed with the U.S. Patent Office, as well as reported by the Director of Research, [redacted], including the time period from 1990 through 1994, *et al*.

4. [redacted] **intentionally, knowingly, willfully, and negligently, failed with reckless endangerment, to adequately inform intermediaries** of this known risk and potential for an adverse event related to reduction/depletion of coenzyme CoQ10 in prescribing information (marketing defect) nor did it give instructions with specificity to this known risk, or provide to intermediaries how they were supposed to determine this risk, or diagnose events pertaining to that risk with specific instructions regarding tests to confirm or deny that risk. *See* Restatement of Torts, 3d Product Liability.

5. [redacted] **failed to modify or change prescribing information** with full and constructive knowledge of petitions filed and pending with the FDA pertaining to potential risks attributable to ZOCOR.

6. [redacted] **failed to file a required manufacturer report (Form 3500A) to the FDA timely** (within fifteen calendar days or in any other mandatory timeframe), after being informed of my serious, life-threatening, unexpected adverse event by a certified letter, return receipt, dated November 16, 2003.

7. [redacted] **breached the implied and express warranties of merchantability.** *See* Restatement of Torts, 2d §§ 2-314 and 315.

[redacted] officials would include [redacted], General Counsel for [redacted], his assistant, [redacted]. (refuses to provide a last name).

ATTEMPTS AND REASONABLE AND CONSTRUCTIVE EXHAUSTION OF INCLUDING STATE ADMINISTRATIVE COMPLAINTS, INVESTIGATIONS, AND REQUESTS FOR RELIEF/REMEDY

1. State administrative complaints were filed against the Topeka primary care doctor and Topeka VA pharmacists with:

   a) Kansas Board of Healing Arts (dated March 9, 2004) and
   b) Kansas State Board of Pharmacy (dated March 4, 2004).

2. Neither state administrative agency has conducted or will communicate with me, regarding any investigation or notice to the respondents of the complaint and apparently are not, or will not conduct an investigation, despite state administrative regulations and statutes. I have reasonably and constructively exhausted state administrative relief.

OTHER MISCELLANEOUS ADMINISTRATIVE AND REGULATORY COMPLAINTS AND REQUESTS FOR INVESTIGATION

1. A regulatory complaint was filed with the Joint Commission of Accreditation of Hospitals and received by them on March 3, 2004. The Topeka VA responded on April 22, 2004 and there was a JCAH closure on the same date. The JCAH official, [redacted] refuses to give information or a basis for the investigative closure. Very little, if anything occurred as a result.
2. A complaint was filed with United States Pharmacopoeia, who acknowledged and forwarded information to the FDA.
3. A complaint was filed with the VA's Nation Center for Patient Safety (NCPS).
4. There has been written communication with legal counsel for [redacted] in attempts to obtain remedy/relief partially from the manufacturer of these prescribed products.

COMMUNICATIONS WITH RECOGNIZED INTERNATIONAL OR NATIONAL EXPERTS

I have communicated with several international and national experts pertaining to statins and supplementation of statin therapy with co-enzyme Q10. This includes:

1. Dr. [redacted], M.D., (Tyler, Tx) and
2. Dr. [redacted], (Pennyslvania)
3. Dr. [redacted], (California)
4. Dr. [redacted], (Washington)
5. Dr. [redacted], (Cleveland, OH).

I have also communicated with attorneys at law (Ermond and Associates, Washington, DC) who have provided a retainer agreement as well as having agreed to provide professional representation and assistance with expert testimony, if needed.

IV. BRIEF STATEMENT OF KNOWN FACTS TO DATE PERTINENT TO THE PRESCRIBING, ORDERING CONSTITUING A MEDICATION ERROR AND SUBSEQUENT TAKING OF THE PRESCRIBED PRODUCT ZOCOR INCLUDING THE SUBSEQUENT UNEXPECTED, SERIOUS ADVERSE EVENTS, NEGLIGENCE AND FAILURE TO DIAGNOSE OR TREAT THE SYMPTOMS

1. Mr. Scherer is a divorced father, born on [redacted] (age 49 at start of taking the product), an honorably discharged veteran; currently rated 30% service connected disability and is the claimant. Scherer has maintained a permanent residence since/around April, 1992 at [redacted]. Merriam (Johnson County) Kansas. He received the products LOVASTATIN/ZOCOR, at that permanent residence, as well as treatment for adverse events attributed to taking LOVASTATIN/ZOCOR during the period of time dated April 14, 2003 to the end of taking that product on/around October 24, 2003, by doctor order.

2. Mr. Scherer had previously been prescribed and was actively taking several other active prescription medications when he was prescribed Lovastatin starting on April 14, 2003 and shortly thereafter substituted with ZOCOR on/around May 1, 2003 and continuing taking prescribed LOVASTATIN or ZOCOR until October 24, 2003, while concurrently taking other prescriptions including the following:

a) Ketoconazole Creme
b) Busiprone
c) Lithium
d) Thiordidazine
e) Fluticasone
f) Diphenhydroamine

That information was available, known, and reported on the Topeka VA Computer medical records and therefore was in constructive knowledge, possession, and available for the prescribing and treating medical doctors, as well as the pharmacists at the Topeka VA.

3. I was originally given an initial prescription for Lovastatin by [redacted] M.D., my primary care physician (Blue Team) on April 14, 2003, (an event called a actual medication error *infra*) without reasonable or adequate warning orally, or in writing of a possible, critical and known high risk of a known drug-drug interaction. This was while as I treated at the Topeka Kansas VA during the period of tine I was attending Washburn University School of Law as a temporary, but not a permanent resident of Topeka, Kansas.

4. The purpose of [redacted] prescribing me to take the prescription Lovastatin was to treat a condition/diagnosis of hypercholesterolemia (commonly referred to as high cholesterol levels). Despite his prescription order, the Topeka VA pharmacy instead, substituted a non-prescribed product, ZOCOR (proprietary name) or simvastatin (active ingredient) on the same day. I continued taking either LOVASTATIN (until May 1, 2003) ZOCOR (beginning May 1 until October 24, 2003) as instructed on the

prescription bottle until October 24, 2003 when a nurse, acting on behalf of [redacted], Assistant Professor, IM/Geriatrics at the Kansas City VA Primary Care Green team, and my new primary care doctor, ordered me to stop taking that prescription. The rationale for stopping that prescription was based on what I believe is generally described by the FDA and others, as a serious adverse event attributable to taking this prescription.

5. The bottle and the attached VA label of the ZOCOR prescriptions dated May 1 and July 7, 2003 contained a space for warnings, but there was no warnings or warning instructions, despite there being known by learned intermediaries, of a critical and high risk drug-drug interaction. (*See* **physical exhibit 1 and 2**, photocopy attached).

6. [redacted] failed to warn on April 14, or thereafter about any possible critical or high risks of a drug-drug interaction associated with concurrent taking of Ketaconazole 2% crème despite the prescribing information specific and explicit information and VA specific critical warnings known by VA intermediaries regarding the combining of these two products (Ketoconazole with Lovastatin and/or ZOCOR).

7. On April 24, 2003, I went to the Topeka VA emergency room to be treated and diagnosed for pain in my stomach, and other symptoms. I could not concentrate on legal studies and was very concerned about that since final exams were scheduled in less than two weeks at the law school. At the time, I did not know what was causing the gastro-intestinal problem nor did I attribute that pain to the taking of the prescription ZOCOR.

8. I was treated in the VA ER on April 24, by both a Nurse practitioner [redacted] and by the ER supervisor, [redacted]. Their incorrect diagnosis was constipation, a symptom, rather than diagnosing what was causing the pain. I was prescribed docusate (stool softer) and magnesium citrate and took these prescriptions as directed. I obtained short-term relief for about three days when the symptoms returned.

9. On April 29, 2003, [redacted] negligently ordered a new or initial prescription for ZOCOR.

10. On May 1, 2003, ZOCOR was substituted by the Topeka VA Pharmacy, and a new prescription of ZOCOR was mailed and received by Mr. Scherer. There was no warning on the mailed prescription container label on the prescriptions on May 1, 2003(or July 7, 2003). *See* **physical exhibits 1 and 2**.

11. On May 15, 2003, Mr. Scherer stopped taking most prescribed medications in an attempt to isolate which prescription might be causing the pain and discomfort, with the exception of ZOCOR, busiprone for extreme anxiety situations as needed, and Ketaconazole 2% crème for active new skin lesions when they initially appeared.

12. On May 15, 2003, Mr. Scherer left his temporary residence in Topeka and returned to his permanent residence in Merriam, KS. He had to hire a moving company to move his personal property in Topeka back to his permanent residence at a cost of

$1700 due to fatigue.. Prior to statins, Mr. Scherer was able to move his personal property without assistance.

13. On July 7 2003, I reported to [redacted] the pain and discomfort. Instead of adequately attributing that pain and symptoms to ZOCOR, Dr. Barry negligently instead increased the prescription level. That pain, suffering, and negligent infliction of emotional distress continued until around October 27 2003 when I stopped taking the prescription. My appetite returned to levels that are more normal and finally my gastro-intestinal symptoms returned in part. I did however, and continue to date continue to have chronic muscle aches and fatigue.

14. On September 26, 2003, I met with Dr. [redacted] in the KCVA Mental Health Clinic. I reported to him feeling fatigued, in pain and experiencing suicidal ideation.

15. Since October 24, 2003, I have done exhaustive legal and scientific research pertaining to adverse events attributable to ZOCOR and statin drug therapy. I continue to do legal and scientific research. As well as taking diagnostic tests to determine the extent of damages. By doing that research, I have found several practices that cause me concern regarding the safety of this product.

16. Since October 24, 2003, I have attempted to act in good faith with various VA officials by regarding ZOCOR and VA administrative processes pertaining to adverse events and the reporting of those adverse events,; the FDA (Janet Woodcock M.D. and her designee Mitchell Weiztman, Attorney at Law; the drug manufacturer, [redacted], Inc.

17. On November 16, 2003, a consumer Medwatch report was filed with the FDA via fax. An acknowledgment was received from the FDA of that Medwatch report dated December 16, 2003. **(Exhibit 4)**

18. On November 16, 2003, a notice was sent to the manufacturer of ZOCOR, [redacted], Office of General Counsel via certified mail, return receipt. **(Exhibit 5)**

19. On November 17, 2003, I started taking a multi-vitamin, multi-mineral supplement (ABC Complete hoping there was some kind of nutritional deficiency related to malabsorption that may have directed related from the taking of ZOCOR.

20. On December 8, 2003, a letter was sent certified mail, return receipt, and restricted delivery, to the Topeka VA Director, Robert Malone Jr. (carbon copy to the Secretary of the VA, Anthony J. Principi). That letter requested a writing that asked specific action to be taken, including the filing by VA officials of an adverse event with the FDA, as well as copies to be provided to me of that reporting. Director Malone signed the receipt on December 13, 2003. To date, there has been no response, by any VA official to that official letter. **(Exhibit 6)**

21. On December 18, 2003, [redacted], and a medical resident, [redacted], interviewed me. [redacted] recommended more diet modifications including Benecol spread (contains plant stenol esters, a known product that lowers cholesterol) and fish oil supplement (omega 3 fatty acid). I purchased the Benecol spread the same

day. And several days later, purchased a fish oil concentrate at the local K-Mart store, softgel capsules, 1000 mg., with 600 mg. omega-3 fatty acids (360 mg. of EPA, 240 mg. DHA).

22. On December 29, 2003, I was informed by telephone call that [redacted] was the General Counsel by [redacted], Topeka VA Patient Representative. I contacted Mr. [redacted] on that date, regarding no production under the FOIA, or no communication from Director [redacted] to my letter dated December 8, 2003 regarding the reporting either internally, or externally on my adverse events. Mr. [redacted] informed me he would investigate and call back. He did not call back, nor did any other VA official.

23. On January 9, 2004 I was informed by a staff nurse ([redacted]) at the KC VA primary care team, who works under Dr. [redacted], that a VA lab supervisor had stated that the VA lab can check CoQ10 enzyme levels, a diagnostic test several VA officials had previously stated they could not do, on several occasions.

24. On January 12, 2003, after the KC VA lab, took a blood sample for submission of a baseline CoQ10 level, I started a scientific test for CoQ10 by taking an OTC supplement from GNC of CoQ10, 100 mg. water-soluble capsules, one time per day.

25. On Tuesday, January 20, 2004, I contacted the Regional Counsel's staff in St. Louis. Prior communication with VA officials on whom to send the SF-95 claim form created confusion on who was the proper official to receive service on behalf of the Veterans Administration. The Topeka VA Patient Representative had previously informed me [redacted] in Wichita was the Regional Counsel. The Kansas City VA insisted their office was the regional counsel. The fact was that neither office was the Regional Council. The Regional Counsel is located in St. Louis, MO.

26. On Wednesday, January 20, 2003, [redacted], an attorney who works for the Regional Counsel, contacted me on the telephone and assured me that I would receive a response pertaining to the letter I had written and sent to Topeka VA Director Robert Malone, and documents I had requested in an official valid FOIA request would be sent to my residence by Saturday, January 24, 2004. No documents or writings were provided.

27. The Topeka FOIA officer, the acting FOIA officer, or the interim or new FOIA officer is therefore in violation of the FOIA (5 U.S.C. 552) in not timely producing requested documents (10 working days) under that act. There is no exception that has warranted a delay in production under that act. There has been no acknowledgment letter or any letter in writing requesting an extension of time regarding production.

28. To date, I have contacted the following VA officials pertaining to this adverse event. Patient reps [redacted], Director [redacted], and his executive staff, Safety Officer [redacted], the VA Director of the Topeka VA Pharmacy who has not returned phone calls, all at the Topeka VA. I have contacted [redacted] as Regional Counsel, as well as the VISN 15 office in Kansas City whose staff also claimed to be regional counsel. I was and was assured that Sherrie Rae at the KC VISN office would

call on January 20, 2004, and she did not. I contacted officials at the Kansas City VA including the Chief of Staff, [redacted], Assistant Chief of Staff, Dr. [redacted] as well as [redacted] and [redacted], Patient Representative (or advocate). I have contacted and communicated with the Executive Office of the Secretary of the VA, General Counsel [redacted] (Washington DC), Regional Counsel (St. Louis, MO), [redacted] (Attorney, Wichita, KS VA office), Vision 15 Counsel and the VHA including [redacted] FOIA Officer (VA CO), as well as [redacted] (VHA). And finally, I have been communication with several key federal officials with the FDA including Janet Woodcock, M.D., and her designee, Michael Weitzman, Attorney at law.

29. On January 26, 2004, I had a telephone conversation with internationally recognized and published authority on statin products, [redacted]. Dr. [redacted] stated that he frequently encountered victims of statin therapy and suggested I start taking coenzyme supplements Q10 from Tischon. In regard to whether the statins were the cause of permanent and irreparable damages, he stated that by taking Q10 supplementation, any temporary damages that were permanent and irreparable should disappear after discontinuing the product and supplementation within three to six months.

30. On January 27, 2004, I received an implausible letter from Director [redacted] stating that a committee met and determined my actual medications errors, and subsequent unexpected and expected, potentially life threatening, serious adverse event was not deemed to be *significant*. **(Exhibit 7)**

31. On January 30, 2004, a reply and notice of appeal and error was sent in response to that ludicrous assertion that my experience was not significant. **(Exhibit 8)**.

32. In May, 2004, I received under the FOIA, reported data on adverse events attributed to Zocor (Simvastatin) reported to the FDA via Medwatch from November 1997 to April 2004. That data reports there have been over 11,000 adverse event reports filed including 419 deaths (Excerpt provided as **Exhibit 9**).

33. On May 20, 2004, in a written letter General Counsel for the Secretary, [redacted] states in my letter appealing a failure to produce documents under FOIA by its officer [redacted], FOIA officer, that the VA CO and/or the VA Secretary Principi have no aggregate data and suggests in the letter, I file suit to compel the production of adverse events under FOIA for that aggregate data. **(Exhibit 10)**.

34. On June 9, 2004, I requested as advised from the FDA via fax, fax receipt, detailed data to supplement the FOIA request. To date, the FDA has not provided the detailed data.

35. On July 8, 2004, I had an appointment with my VA primary doctor, [redacted], MD, Assoc. Professor, Internal Medicine. [redacted] stated he was of the opinion that I had myalagia, with full knowledge that I was recording that statement. Myalagia is a disease that can be attributed or associated with statin prescriptions and is referred to as myopathy. I requested he provide documentation of that diagnosis and

prognosis for outside agents such as the DOE, FDA and state regulatory authorities, et al. [redacted] refused to provide written documentation to what he stated orally concerning myalagia.

36. On July 8, 2004, a new claim form was submitted with the assistance of the C&P staff officials at the VAMC in Kansas City, MO.

37. On July 9, 2004, I met with various KC VA officials regarding the refusal by Dr. [redacted] to provide to me, necessary documentation needed for federal and state regulatory authorities, as well as for General Counsel of [redacted]. Those KC VA officials included:

a) Leslie, the assistant to the Exec. Director for the KC VA regarding the refusal of Dr. [redacted] to provide to me, a written diagnosis, prognosis or treatment plan for myalagia or other condition such as chronic fatigue syndrome, or any other appropriate and relevant diagnosis.
b) Dr. [redacted] assistant to the Chief of Medical Staff ([redacted]) my former primary care doctor, supervisor of all KC VA medical doctors, and regarding the refusal of [redacted] to provide to me, a written diagnosis, prognosis, or a plan for treatment for submission to various federal and state agencies.
c) Chief Pathologist, [redacted] regarding the validity of the lab results on a Q10 assay from Metametrix. [redacted] was of the opinion the lab results were valid, despite the calibration warning.
d) VA Compensation and Benefit Representatives regarding the filing and submission of a new claim for compensation needed for external organizations based on the injury and property damage I incurred as a result of the statin treatment.
e) VA Patient Representative, [redacted] on the refusal of [redacted] to provide adequate documentation for various internal and external purposes.

38. On July 24, 2004, I received under the FOIA, documents from both my primary care doctor, [redacted], as well as [redacted], medical records. [redacted] in those records states that I have chronic fatigue syndrome (based on CDC criteria), as well as myalagia(s) *See* **Exhibit 15**.

39. On July 29, in response to an acknowledgement letter of a new claim for compensation attributable to residual effects of statin treatment, I requested via fax, a request for a C&P exam by a qualified doctor in order to submit medical diagnosis, prognosis and treatment plan for consideration of that claim.

40. To date, I have requested documents and data from several VA and FDA officials, public documents under the Freedom of Information Act 5 U.S.C. § 552 pertaining to the reporting of adverse events and specific documents related to my own specific situation regarding the prescribing and treatment related to ZOCOR.

This includes:

a) Letter(s) dated November 13, December 4, and again on December 16, 2003 to [redacted] as Freedom of Information Officer, Topeka VA. To date there have been no records provided under those requests related to treatment records on April 29, 2003, or records from the pharmacy dated April 14, 2003.
b) Letter dated January 14, 2004 to Secretary Principi, c/o [redacted] VHA FIOA officer, Washington, D.C.
c) Letter dated January 6, 2004 to Commissioner Mark McClennan: Director, c/o Betty Dorsey, Freedom of Information Officer.
d) An email was sent to [redacted], with receipt, including carbon copies to several officials with the FDA.

41. [redacted] is licensed and registered with the Kansas Board of Healing Arts (State of Kansas) and is subject to those state statutes and regulations.

42. There are three separate pharmacists that dispensed prescription medications called either lovastatin or simvastatin at the VAMC in Topeka, KS. These pharmacists are licensed with the state of Kansas by the Kansas Board of Pharmacy and is subject to those state statutes and regulations.

43. The VA has no regulatory authority under Kansas law pertaining to the licensing, regulation, and investigation, of both doctors and/or pharmacists under Kansas statutes. Doctors and pharmacists in some of these facts, are employees of the VAMC located in Topeka, KS.

Initially, the prescribing of Lovastatin was an actual medication error by the precise and unambiguous federal regulations. The substitution by the Topeka VA Pharmacy on April 14, 2003 for Lovastatin was a second medication error. There was no prescribing information or warnings given on the substituted prescription product.

The first medication error can be established by referring to the prescribing information from the manufacturer, [redacted], as well as a internal VA high and critical warning to learned intermediaries of a drug-drug interaction. The prescribing information for ZOCOR gives a specific warning regarding the concurrent taking of ZOCOR and Ketaconazole 2% crème. [redacted] prescribing information specifically and explicitly states this combination should be avoided. *See* [redacted] prescribing information (**Exhibit 2** at pg. 11-12).

V. SUBJECTIVE PATIENT REPORTING vs. OBJECTIVE MEDICAL REPORTED SYMPTOMS, DIAGNOSIS, PROGNOSIS, AND TREATMENT

It is important to distinguish between what I know, as the patient, vs. the objective information attributed to the resulting unexpected, serious and adverse event after taking LOVASTATIN AND ZOCOR. The medically reported symptoms is subjectively reported by treating doctors and medical staff, based on their memory of the interview, later after that interview has been completed. Their reporting is limited by time pressures, memory recall and their subjective opinion on what to report in a concise and relevant method necessary only as it related to documenting their treatment, and need for any subsequent treatment. In plain language, I would tell the treating official the symptoms and they in turn would only report what they considered to be objective. In order to clearly and subjectively state what it was like, I need to state from my perspective, what the pain, suffering, agony, and corresponding symptoms and subsequent treatments were like.

It is equally important to distinguish diagnosis of a disease with a cluster of symptoms. Diagnosing a disease is more an art, than an exact science. And in this claim, trying to apply one exact diagnosis to the cluster of symptoms involving a drug-drug interaction can involve several diagnosed diseases being applied to symptoms at a given point in time. There are several diagnosis that are similar or could be applied at a precise point in time. However, the exact or perfect diagnosis is not as critical in determining causation or injury in this claim. There are several that could be applied or are similar. Generally, the scientific and academic community in various publications refer to peripheral neuropathy caused by statins.[22] When the CK and CKP levels are within normal range, the symptoms I have are called a statin-induced myopathy termed myalagia. What complicates a complete and exact diagnosis is the concurrent treatment with other drug products. Although there is sufficient data and warnings given regarding drug-drug interaction with anti-fungal agents such as ketoconazole, both from Merck and the VA.

There is some in the academic and scientific community who believe statin-induced myopathy is permanent and irreversible. *See*. Ely, et al. **(Exhibit __)**. On the other hand, statin-induced neuropathy resulting in myalagia is believed to be reversible by some(not causing permanent and irreparable injury) in some situations. However, this situation is more complicated because of the drug-drug interaction. In addition, recent data reports that simvastatin penetrates both the CNS and brain barriers per MRI studies. In addition, there is significant research that more than likely, the co-hibition of Q10 and cholesterol by statins in the liver would in addition, result in changes at the cellular level (DNA mitochondria). Q10 as metabolized in the liver through lipid metabolism, is one of the primary elements of DNA. More than likely this co-hibition would result in impacting the Cox compound in the DNA electron transport chain (ETC) resulting in the opposite effect of reducing oxidation damages in various organs within the body. The

[22] *See* Statin Associated Myopathy with Normal Creatine Kinase Levels. Phillips, et al., Annals of Internal Medicine, 1 October 2002, Vol. 137, Issue 7, pgs 581-85, *et al*

purpose of statins is to reduce damages from oxidation, rather than merely lowering cholesterol levels.

After the initial start of LOVASTATIN (April 2003) (AND SUBSEQUENTLY ZOCOR (May 1, 2003), I could not produce a regular bowel movement. I started to experience what is commonly referred to as gastric bloating or gastroparesis[23]. That gastric bloating in turn, made it almost impossible to urinate, all within three days of taking this product. In turn, I could not concentrate on my legal studies due to these symptoms. The symptoms and pain became so severe, I finally called the Topeka VA ER staff, and subsequently per their direction went to the Topeka Emergency Room on April 24, 2003.

The emergency room Nurses' practitioner (Martin) and the supervising doctor (Welsh) attempted to diagnose what was causing this pain. They diagnosed a symptom (constipation) rather than determine with any objective tests, what was really causing the pain. In turn, there was a prescription given for docusate, a stool softener, and a laxative, magnesium citrate. I started both the same day. Initially, the magnesium forced a bowel movement.

That treatment relieved symptoms such as gastrointestinal bloating and the inability to urinate for about three days. The flu-like symptoms returned several days later. What was happening apparently is that I would eat food. The food would for the most part, stay in the stomach instead of moving into the intestines. This would cause the bloating and the pain. Sometimes diagnosed by medical professionals as a condition called dyspepsia. In addition, over the long term, the failure of food to pass into the intestinal tract would in turn cause malabsorption or a nutritional deficiency. There are two muscles that control the passage of food and liquids from the stomach. I speculate after months and attempts to modify diet, use medical products, or OTC products, that the Zocor inhibited the ability of those muscles to move food from the stomach into the intestinal tract.

I tried several things to alleviate this pain, suffering, and agony. I stopped taking most prescribed medications May 15 because I suspected a possible drug effect. I tried a couple of things that did work (June and July 2003). If I consumed huge amounts of water (32-64 fluid oz.) in excess of my normal intake (such as coffee and beverages) I could produce a bowel movement. I also could produce a bowel movement with eating almost exclusively raisin bran (August). After relieving the gastric bloating symptoms by

[23] **Gastroparesis**-means the paralysis of the stomach. Under this condition, food is not thoroughly ground and does not empty into the intestine normally. This can be caused by diseases of the stomach muscles or the nerves that control those muscles. A side effect is malnutrition by food not being absorbed in the intestine. **Myopathy** or muscle damage is broken into three areas based on severity and lab tests. 1) **Fibromylagia**-muscular disease with no increased CK or CKP elevation noted. 2) **Myositus**-muscular diseases that cause degeneration of muscle tissue resulting in decreasing strength, and making even the simplest physical activities difficult. Generally indicated by a CK level > 3 times the ULN. **Rhabdomyolysis**-muscular disease that is diagnosed when CK level is >10 times the ULN. **Severe Constipation**-Infrequent occurrence of bowel movements

one of several methods, the flu-like symptoms would go away for about three days. I would have a small fever and the muscle aches, particularly in the legs. And then return.

For emergency measures, when all else failed, I would purchase magnesium citrate. I did this on four separate occasions from May to October 2003. Although it does state on the warning instructions, that this product should not be used frequently. Once the bloating happened, I could only eat small portions of food. If I ate, I knew that when I went to bed, I would have pain on almost a daily basis throughout the night. I would prop pillows in an attempt to minimize the pain at night.

My **functioning** was severely impacted, while at law school and after I finished finals in May of 2003. I could no longer perform simple household tasks. I could not engage in pleasurable activity with my son. And if I did, I would be exhausted or fatigued by simple things such as just going out for a meal. Prior to this statin therapy, I used to work six days a week, 12 to 14 hours per day. After the therapy, I was lucky if I could be productive in any way for more than six hours a day. Generally, I would be so fatigued by 2:30 in the afternoon. I measured the amount of productive effort I could accomplish in a given day for months. I was hoping to increase the amount of productive effort/day in hours of time.

I could not perform common simple household **tasks** such as raking leaves, cutting grass, or general cleaning, for example. I could not perform **recreational activities** such as playing racquetball or going fishing which I had normally done prior to taking this prescription. My typical day therefore was get up, try to be productive until the fatigue set in. Eat when I had to or could, and then deal with the pain until I went to bed in the evening. I could not assist my parents who were dealing with their own serious health issues. I had no desire to travel or meet with family or friends. It was a miserable experience and had a significant impact on the relationship I had with my son, my immediate family and friends.

For the most part, I would not leave my home, except for tasks that had to be performed-such as groceries or medical appointments. My civil rights work came to a abrupt halt. I was unable to timely respond or file legal documents in related court cases. To summarize, all I could perform was mainly things that had to be done.

In regard to **treatment**, and initial acceptance that these symptoms were permanent, I become disappointed with treatment by professional medical individuals. They would treat symptoms, but not diagnose what was causing the symptoms. They would merely prescribe more medications, suggest diet modifications, or exercise. I do think and reported that I experienced heart irregularities within minutes after taking this prescription. I had my EKG taken to ensure there was no apparent heart muscle damage in January 2004. During the summer months, I did try my own tests and other things to improve my stamina and ability to function. I tried diet modification, OTC supplements, vitamin and mineral supplementation. I researched medical and scientific data from the Internet.

Finally, I was scheduled for a doctor examination on October 24, 2003. I had received documentation from the VA that instructed me to provide information at that

appointment, current medications. At that point, I started to pull information from the internet at each prescription. At that point, I started to read information about possible symptoms attributable to ZOCOR. I noticed my right upper arm had lost most of muscle mass and was starting to look strange. On October 24, I called and my new primary care doctor, [redacted] acting through his nurse, [redacted], gave me an order to stop taking ZOCOR.

Within three days after stopping ZOCOR on October 24, 2003, the gastrointestinal problems went away (bloating and gastroparesis), although some symptoms indicating temporary or permanent injury remain. My appetite returned. I was able to eat a full meal. The gastrointestinal bloating has not returned. This makes it reasonable to attribute the gastrointestinal problems that I suffered for eight months to ZOCOR. However, the fatigue, as well as any myopathy remains. And continue to date. Which in turn believes me to suspect that there was and is quite possibly, permanent and irreparable damages in the cell structure. This is reported in some scientific documents that once cell damage has occurred, it cannot be repaired. I continued to do research regarding this prescription product ZOCOR. There is significant data reported by national and international scientific and medical experts that highly suggests that this fatigue and gastrointestinal symptoms may be caused in fact, by a depletion of coenzyme CoQ10. [redacted] in turn, knows of this, has reported it to the U.S. Patent office, and apparently does not inform the FDA of this known effect. It does not warn or describe this effect in prescribing information.

I finally was able to meet with [redacted], on December 18, 2003. I gave a complete description of symptoms, medications, and other data in hard copy. He did want those documents. I advised him, as well as showed him what documentation I would need to supplement the SF-95. He would not provide any supplementary documents including a diagnosis, prognosis, or treatment plan. He did however, at my request, order some lab tests. He has not however, ordered a test for a CPK level or CoQ10 level. I had obtain on my own, a lab that would perform a test for CoQ10 levels. After I had obtained the name of that lab, the contact person and the doctor who would test that level, the VA primary nurse then calls, and informs me that the VA can perform that lab test.

On January 12, 2004, after obtaining a baseline measurement of CoQ10 at the KC VA lab, I started a scientific test of taking this enzyme supplement. Whether that will restore or return my CoQ10 enzyme levels to normal is unknown.

On January 27, 2003, an international expert on statins and CoQ10, Dr. [redacted], contacted me on the telephone. I was referred to contact him by another national expert, [redacted], at the Whitaker Wellness Institute in California. He did state to me, these symptoms pertaining to statins are well known by several experts on statin therapy. He was not surprised by my injury or the damage, or with the inadequacies of the FDA or VA pertaining to statin therapy. In other words, he stated it was fairly common. He also stated he personally had known [redacted], [redacted]'s former director of research and informed me that he had passed in 1997.

On February 9, 2004, I met with [redacted], in consultation. [redacted] did an initial evaluation and declined to provide documentation.

On February 9, 2004, I received an alleged Form 3500A from [redacted].

In March 2004, a regulatory complaint was filed in the state of Kansas with both the Board of Healing Arts (doctors and physician assistant, as well as the Board of Pharmacy (pharmacists).

In March, 2004, a regulatory complaint was also filed with the Joint Commission of Accreditation of Hospitals (JCAH).

On July 8, 2004, I had an appointment with my current primary care doctor, Dr. [redacted]. I informed and requested from him in his official capacity, a diagnosis and prognosis needed for submission to various federal and state agencies, as well as General Counsel for [redacted], documentation. To which [redacted] refused to provide. [redacted] told me to go to Benefits and Compensation staff who would provide me with documentation needed for external entities. Benefits and Compensation stated they did not provide documentation to external agencies nor were they familiar with filing a claim form (SF-95) for injuries and damages attributed to treatment.

To date, I cannot find one exact and specific disease for my symptoms. Chronic Fatigue Syndrome and myalagia is similar. I cannot claim myostitus or rhambodylsis since there is apparently no elevated CK levels reported in lab tests to date. However, one should note the lab tests were not performed until almost forty-five days after stopping the medication. This lab test for CK and CKP should have been ordered immediately upon stopping this medication. A failure to order that lab test may also be an issue of malpractice.

On July 8, 2004, I was finally able to have a primary care doctor state in writing, that he considered I had met the CDC criteria for chronic fatigue syndrome, as well as various myalagia.

VI. DETAILED EXPLANATION TO SUPPLEMENT INFORMATION REQUESTED ON THE FORM SF-95

1. The SF-95 requests a claimant to state the nature and extent of the injury. The nature of the injury in this claim includes injury that is described as chronic fatigue; chronic fatigue syndrome pain; emotional distress including pain, suffering and agony; permanent and irreparable damages to mitochondria (cell structure); myopathy including myalagia. Based on those injuries and the extent of those injuries and loss of property (pertaining to a legal education), Mr. Scherer has incurred several types of damages. Those damages include:

a) Punitive damages from [redacted] for not updating warnings to intermediaries
b) Intentional/Negligent infliction of emotional distress, pain, agony, suffering.
c) Economic damages related to future earnings
e) Permanent and irreparable damages that could include muscle damage not yet discovered including organs such as the heart, liver and kidney)

f) Future medical expenses including treatment, tests, drugs
g) Property damage (pursuit of education-education is a type of property)
h) Loss of pleasure and happiness; loss of consortium with family
i) Incurred and future expenses for OTC Supplements, vitamins and minerals
j) Time and labor for treatments, diagnosis, medical costs and preparation of this claim and costs associated with documenting, preparing, consulting with medical and scientific experts, and any other costs, not specifically claimed.
k) Any unknown, but future damage that may occur.

2. The instructions of the SF-95 request specific and perhaps ambiguous requests for information. *See* the back of SF-95.

3. The SF-95 requests a *sum certain*. This is difficult, costly, but not impossible to determine or estimate. The figures I have provided are therefore, reasonable estimates of a sum certain. To that request, I have provided two estimates on Box 12, one for property damage (Box 9) and one for personal injury (Box 10).

4. (Box 9) is related to the nature and extent of damage to property which in this situation, pertains to my property rights including a legal education, a property right defined under common law, including how that property rights includes claims pertaining to future pay. I have provided a rough estimate including future pay.

5. (Box 10) on the SF-95 requests the claimant to state the nature and the extent of the personal injury. The nature of the personal injury is due to the taking of a prescription ZOCOR. The extent of the injury that forms the basis for the claim would include the taking of the prescription product and a series of events following that event (fully described within this document). The extent to the injuries include pain, suffering, anxiety, permanent and irreparable damages; loss of pleasure and familial consortium; negligent infliction of emotional distress; chronic fatigue; future medical expenses including prescriptions, dietary supplements, future diagnostic tests, expert witnesses as needed, and any future treatment.

6. The SF-95 instructions provide the following statement:

> The amount claimed should be substantiated by competent evidence as follows:
> (a)In support of the claim for personal injury . . . the claimant **should** submit a written report by the attending physician, showing the nature and the extent of the injury, the nature and extent of treatment, the degree of permanent disability, if any, the prognosis, and the period of hospitalization, or incapacitation attaching itemized bills for medical, hospital or burial expenses actually incurred.

I explicitly requested in person to [redacted] at the KC VA, with his internist resident [redacted], as witness on December 18, 2003, to provide the documentation as the attending physician. I showed him the SF-95 including the instructions of what he should provide. He has to date, refused to provide that data or documentation. When that occurred, I contacted and spoke directly to [redacted], Counsel at the Wichita VA Regional office on the telephone on December 29, 2003 specifically to those instructions. Mr. Copp stated to me over the telephone that the word

should did not mean that it was mandatory pertaining to having documentation provided at the time of filing this claim. Therefore, I have done everything reasonable possible to provide that documentation not once but twice-December 2003 and again in July 2004. [redacted] advised me to submit this form and documents in support without [redacted] providing this requested documentation.

On July 8, 2004, I again requested [redacted] to provide a diagnosis and prognosis for this claim, as well as other federal and state regulatory agencies, and General Counsel for [redacted] refused. However, he did state he believed that I did have myalagia (a specific disease where CK and CKP levels are within normal ranges. He would not put that diagnosis in writing despite my requests.

On July 9, 2004, I met with various VA officials at the Kansas City VA regarding and pertaining to [redacted]'s second refusal to give to me, any documentation for submission with this, or any external organization's requests for information from my primary care doctor. This violates the VA's published and promise to patients that includes coordination of medical information with entities external to the VA. This also constitutes malfeasance, medical malpractice and constitutes or infers to a reasonable person, federal statutory violations of law for acts of conspiracy, interference, and obstruction. The only plausible rationale for [redacted]'s refusal to provide a diagnosis, prognosis, or treatment plan, for these reported symptoms, is to protect fellow VA physicians and pharmacists. In turn, a reasonable person could infer by that refusal, the facts of this claim are true.

VII. THERE IS CURRENTLY AN INADEQUATE VA INTERNAL, NATIONAL OR EXTERNALPROCESS FOR REPORTING INDIVIDUAL OR AGGREGRATE ADVERSE EVENTS

The current process in place at the VA hospitals almost guarantees inadequate reporting of adverse events to NCPS, the drug manufacturer, or the FDA, adverse events attributed to prescriptions dispensed by the VA pharmacies[24]. The drug manufacturer provides compiled data on adverse events on each prescription. There should be a proportional number of adverse events/prescription reported by patients, and in turn a proportionate amount of reports filed by the VA officials to either the manufacturer, or the FDA.

For example, if a prescription such as Lovastatin has a 3-5% known adverse events in a population of 1000 individuals, there should be a corresponding indication of that adverse event in veterans taking that prescription. If the number of adverse events attributed to a prescription is not reported to the FDA, the manufacturer, or the NCPS, by the VA adverse event reporting process, there is a dilution in accurately reporting of

[24] *See* http://www.va.gov/OCA/testimony/mather108.htm regarding improvements needed pertaining to VA Risk Management. Also Refer to the VA Manual M-2, Chapter 35 on risk management. *Also see* the VHA Handbook 1051/1and its associated directive changing risk management to Patient Safety Improvement (January 13, 1998) at pg. 2 that specifically states at 3(b) that "Studies of incident reporting have consistently found that most adverse events are not reported".

adverse [redacted] This inhibits the FDA, NCPS, or the manufacturer from adequately compiling [redacted]gate data from all sources. Moreover, since the VA is indisputably the nation's [redacted]ealth care provider, that failure to adequately or timely report adverse events is a [redacted]cant and dilutive event.

[redacted]Th[redacted]nt VA process is layered and the result is inadequate reporting to any regulatory [redacted] adverse events attributed to prescriptions. The VA process requires the patient to [redacted] this process to either the treating doctor, or his staff. Alternatively, the patient can [redacted]ct the VA patient rep. Under either scenario, the reporting is optional rather than [redacted]latory. At the next level, a safety committee or team is formed that reviews vo[redacted]ily reported adverse events. The team then makes a determination on what action [redacted]ny is to be taken. The team is then supposed to report to the VHA in Washington DC. These bureaucratic layers are ineffective in adequately reporting adverse events and leads to under-reporting of medication or prescription-related adverse events.

Secretary Tommy Thompson, Health and Human Resources suggested in public documents, that this process of reporting adverse events attributable to medications become a mandatory process, rather than a voluntary process[25]. His suggestion was that intermediaries should report adverse events to the drug manufacturers, and then it should be mandatory that the drug manufacturers in turn report that known adverse event to the FDA within fifteen calendar days. In this situation apparently neither the VA nor the manufacturer [redacted] has reported this known adverse event to the FDA.

VIII. PHARMACOLOGY, PHARMOCOKINETICS, PHARMACOGNETICS AND PHARMOCODYNAMICS OF ZOCOR

For the most part, the above terms refer to what happens to a prescription in the human body, after ingesting that prescription. It is well known, as well as included in several patents filed on behalf of [redacted], that ZOCOR inhibits the absorption of cholesterol. Hence, it is known as an Hmg CoA reductase inhibitor. It is metabolized in the liver and the kidney. This occurs by turning cholesterol into mevelonate, which is then excreted by the body during digestion, rather than being absorbed. Another well-known side effect is that that ZOCOR also inhibits simultaneously, the coenzyme, CoQ10 during that metabolizing process[26].

On an least five separate occasions, various VA officials ([redacted] his staff nurse(s) [redacted], as well as the Chief Pathologist [redacted] at the KC VA Lab and a lab technician), informed me the VA labs do not have a testing mechanism in place to check CoQ10 enzyme levels. (*See* **Exhibit 11**). I then made arrangements with a [redacted] a neuropharmacologist in Cincinnati, Ohio who stated he would run a lab test for this specific enzyme level and gave me specific instructions and a contact person for the VA to contact regarding shipping a blood sample.

[25] *See* http://hhs.gov/news/press/2003pres/20030313.html, Secretary Thompson announces steps to reduce medication errors; News Release dated March 13, 2003.

[26] *See* FDA Docket No. 02P-243/CP1 and 02P-0244/CP1 et. al. I have multiple sources from international experts, including data submitted by [redacted] in patents on ZOCOR, regarding this known inhibition of CoQ10, as well as the potential damage and adverse events that can be caused by this inhibition.

The KC VA primary care team nurse [redacted], then calls me back on January 9, 2004 informing me now, they can check this enzyme level at the VA lab (Lab No. 80394). She stated she was informed of that fact by a lab supervisor that the VA can in fact, check these coenzyme levels by inputting a specific computer code. Therefore, it has been impossible for VA doctors to date, to know clinically, based on scientific data, whether there has been a depletion of this enzyme in VA patients taking statin therapies.

I have done my own research regarding the clinical testing of this enzyme, and are in the process of having those experts test my CoQ10 levels. I will be making some specific suggestions that the VA adopt known scientific and clinical processes for the testing of this enzyme for all veterans undergoing statin therapy. As well as suggest to the FDA, they make that testing mandatory, in addition to the current liver tests that are done. As well as have the FDA require statin manufacturers, inform intermediaries of the need to check this enzyme level on patients on statin therapies.

The VA treating and diagnosing doctors, by not knowing within their own diagnostic processes, how to check this enzyme level for individuals on statin therapies raises several issues.

First, [redacted] the manufacturer of ZOCOR, knows there is a good possibility of depletion of this enzyme, CoQ10. In fact, [redacted] has a patent that combines a statin with this coenzyme. Yet [redacted] does not market such a product, nor can any other drug manufacturer other then [redacted] since [redacted] holds the patent to this combination. [redacted] in addition, does not inform intermediaries in any documents to check for possible depletion of his enzyme, despite knowing that condition is likely to occur. [redacted] announced a joint venture on November 17, 2003 recently has filed documents with the FDA seeking a new drug application for an ezetibmibe/simvastatin tablet. This is due to [redacted] patent on ZOCOR expiring in the next two years. There are several well-known adverse events with ezetibmibe. in addition to the known adverse events described *infra*. The FDA should reject this application based on the combined adverse events, as well as based on [redacted]'s knowledge and a failure to warn intermediaries about known, but unwarned adverse events.

[redacted] merely informs intermediaries to run liver tests without specificity to which liver tests should be completed. I specifically asked [redacted] to specify what diagnostic tests should be run in a letter to [redacted] General Counsel dated November 16, pg. 2, item 2. [redacted] refused to answer that question and in circular fashion, wrote back in a letter dated stating to ask the treating doctor--who has not been given sufficient information regarding this high likelihood of depletion of this specific enzyme. [redacted] in addition states in its warnings, one of the possible side effects is fatigue. Nevertheless, [redacted] does explain or provide intermediaries, this broad symptom. [redacted] product data on ZOCOR needs to be more specific on what specific liver tests should be checked. [redacted] needs to more specific then merely informing intermediaries that there is the possibility of fatigue, without explaining or defining that overly broad term. For example, how do you objectively measure fatigue? When the intermediary starts statin therapy, a baseline on this coenzyme should be taken, and again checked at a three month interval after starting statin therapy in addition to the more standard liver function tests.

Second, the FDA has been informed in petitions filed of this possible risk. *See* FDA Docket No. 02P-0243/CP1 and 02P-0244/CP1 (Nov. 14, 2002) urging the FDA to recommend supplementation of this enzyme, as well as referring to how [redacted] has patents and knowledge of this enzyme depletion. Therefore, the FDA knows about this depletion, but has not directed drug manufacturers to warn about this possible depletion. The FDA needs to order statin manufacturers to inform intermediaries about this possible enzyme depletion. One improvement that could be made in the FDA regulatory process, is to require drug manufacturers to publish known and currently pending petitions filed with the FDA in warning labels given to intermediaries while the FDA considers those petitions. This would let the intermediaries know of these pending petitions, while the FDA does this lengthy evaluation process.

Third, the VA needs to make checking for a depletion of this CoQ10 enzyme, a standard part of their diagnostic testing procedure, in addition to other lab tests for patients taking statin type therapies.

Finally, in conclusion, I have taken reasonable steps in a co-operative manner with the VA, the FDA, and the drug manufacturer, [redacted] & Co. The testing of the coenzyme CoQ10 indicates that diagnostic test, before starting statin therapy is a better predictor of adverse events from statin therapy. A test of that coenzyme would give a better indication of potential or actual damages including known damage diagnosed at a myopathy (muscle damage) including fibromygalia (normal creatine levels), myostitis, (elevated creatine levels) or rhambadolysis (creatine levels in excess of 10x ULN) much earlier, then currently suggested diagnostic tests such as "liver tests", without specificity to what that ambiguous and overly broad "liver test" means. [redacted] knows of the high risk of depletion of this enzyme. [redacted] fails to warn or instruct intermediaries in prescription information, this known risk of reduction/depletion of CoQ10-an enzyme that is responsible for energy in all cells of the body. Nor is there anything in the prescribing information to alert intermediaries of this risk of reduction/depletion of this enzyme.

My prior experience has shown a big bureaucratic resistance to changing methods or procedures, until someone such as me raises the issue. I understand that the potential for an adverse reaction to any given prescription is possible. However, what shocks the conscious here, is the events that occurred, once a medication error was, or should have been reasonably and prudently discovered. And the subsequent bad faith and failure to act, once alerted to that event on several official levels. The more inaction, non-responsiveness, or a failure to cooperate only makes my resolve and dedication to my mission of improving processes and protecting veterans and the public interest stronger. The VA, the FDA and [redacted] would have found that this process to be a lot smoother, if actions had been done in the spirit of cooperation and collaboration, in the public interest. I should not have to have to go to such lengths. I would be one of the first to admit that our institutions and its professionals have come to a sad state of affairs when in good faith, the first stage of that process requires me, to file a claim for personal injury and damages , in order to compel medical professions to keep their solemn oaths, and that there be moral and ethical action taken before there is compliance with federal and state regulatory authorities.

... summarize in one short, concise and precise phrase, shame on you.

IX. SPECIFIC ACTIONS REQUESTED

1. Please provide acknowledgment that you are the proper person for submission of this claim for damages and injury in writing to my address below, by August 26, 2004.
2. Please provide acknowledgment and receipt of this claim, as well as a timely response by August 26 2004 in writing to my address given below.
3. Provide any orders from the VA, the VHA, or any official with the VA that specifically recommends going forward, the testing of coenzyme CoQ10 as a standard part of statin therapy.
4. Provide suggestions for improvement to the current VA adverse event reporting system including when the VA will report to the FDA, known adverse events attributed to prescriptions.

Submitted, this the 6th day of August, 2004[27]

Thomas E. Scherer
Claimant
[redacted]
Merriam, KS [redacted]
Tel. [redacted]

Cc: Secretary of the Veterans Administration, Honorable Anthony J. Principi
Commissioner of the Food and Drug Administration,

[27] This is not intended or construed to be a legal brief. It does not include references to all relevant federal and state statutes, federal or state regulations, or citations of authority or references to common law.

LIST OF THE MOST RELEVANT EXHIBITS IN SUPPORT TO BE PROVIDED SEPERATELY

INTRODUCTION: I have many exhibits, some of that are the most relevant are provided. This includes exhibits in support of the facts that prove the Topeka VA was cognizant of a critical warning of a high risk of a drug-drug interaction when prescribing Lovastatin and Simvastin. The VA prescribing doctor and the VA pharmacy staff failed to timely warn me as the consumer of those prescribing products, of this high risk of a drug-drug interaction risk. In addition, the manufacturer [redacted] also warns and advises of a risk for a drug-drug interaction in prescribing information.

1. Exhibit Critical and known VA risk of possible drug-drug interaction (Lovastatin and Ketoconazole).
2. Exhibit Letter and attachment from [redacted] dated December 18, 2003 including prescribing information on ZOCOR
3. Topeka VA Pharmacy Letter dated around May 2003 substituting ZOCOR for the original prescription of Lovastation.
4. Exhibit-FDA Medwatch Report dated November 16, 2003
5. Exhibit-Letter to [redacted] Office of General Counsel, dated November 16,2003 titled Legal Notice and Request for Relief/Remedy.
6. Exhibit Certified mail letter to Robert Malone, Topeka VA Director
7. Exhibit Letter from Robert Malone, Topeka VA Director stating adverse event was not significant.
8. Exhibit Appeal of Letter regarding whether the adverse event was significant or not significant.
9. Exhibit FDA FOIA data on adverse events and deaths attributed to ZOCOR (1997-2004).
10. Exhibit VA document stating KC VA cannot check for enzyme Q10 levels
11. Exhibit Letter from VA General Counsel recommending I file suit for aggregate data requested under FOIA.
12. Exhibit Known warning of the Topeka VA regarding a drug-drug interaction An academic article on Ubiquinone (Coenzyme Q10) regarding permanent and irreversable damages attributed to statins, and the failure to supplement statin therapy with Q10.
13. Exhibit-Prescribing Data to confirm ordering and prescription dates of Lovastatin and Simvastatin.
14. Exhibit VA Medical Documents provided under the FOIA regarding treatment in 2003
15. Kansas City VA Diagnostic Notes-[redacted] M.D. dated July 8, 2004 indicating satisfaction of Center for Disease Control criteria for chronic fatigue syndrome as well as myalagia(s).

Possible other exhibits
16. Exhibit-FDA Petitions on ZOCOR
17. Exhibit
18. Exhibit
19. Exhibit
20. Exhibit

MEDICAL, LEGAL TERMS DEFINED INCLUDING ACRONYMS

1. Medication Error- a medication error is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer". There are two types of medication errors, actual and potential as defined in the Fed. Register. A medication error can occur at several steps including product warnings and information, by the prescribed, by the pharmacy that dispenses the product, or by the patient or consumer.
2. Adverse event
3. Serious adverse event
4. Unexpected and serious adverse event
5. Sentinel event (JCAH and VA term for a serious adverse event)
6. Disability
7. Damage (distinguished)
8. Injury (distinguished)
9. Learned Intermediary Doctrine-a doctrine regarding doctors and pharmacists, et al. Being informed and possessing superior knowledge in the treatment of patients
10. Manufacturer (FDA subdivides this into Applicant)
11. NDA-New Drug Application
12. Nature and Extent of Injury
13. Prescribing Information-data supplied from a drug manufacturer containing warnings
14. Medical Guide (on some prescription products)
15. Fatigue, Chronic Fatigue, Chronic Fatigue Syndrome
16. Ubiquinone or (CoQ10); coenzyme Q10;
17. Disease-a common name given to a cluster of medical symptoms
18. Diagnosis-a name applied to a common cluster of medical symptoms
19. Prognosis-the likely forward looking outcome for a disease
20. Treatment Plan-method of treating a particular diagnosis or disease
21. Pathogenesis (Cause of injury by a prescription product)
22. Root Cause Analysis (Process or Procedure that analyzes the causes an adverse event)

OR-NOTES, LEGAL ISSUES, AUTHORITY, THEORIES

PQ LE PARTIES TO EITHER JUDICIAL OR ADMINISTRATIVE PROCESSES

I. Claims ..onst the manufacturer and seller, [redacted]

A) ..fectively marketed the product initially, marketing defect-including a ..ilure to warn intermediaries of possible adverse events from the taking of the product ZOCOR (simvastatin). See Restatement of the Law Third, Torts, Product Liability, Torts, Or change or modify, or notify intermediaries of reported and known risks after the continued marketing after the initial release
B) Gross negligence by failing to inform intermediaries of new and potential dangers reported by consumers and consumer advocacy groups such as Public Citizen (FDA Petition, 2001)(allows for punitive damages)
C) Misrepresented/ concealed risks at the original issuance of the product; plus continuing to adequately report known reasonable risks after product issue
D) Implied warranty the product was safe for consumers
E) Failure to conduct reasonable tests to determine potential adverse actions to the product prior to, and after product release.
F) Vague product warning label and inadequate instruction to intermediaries regarding symptoms relating to the product.
G) Inadequate testing after the start of a consumer taking this product with adequate tests to quickly and adequately determine adverse events attributable to the product. Failure to inform or advise intermediaries regarding updated testing practices

II. Claims against the VA, VA doctors, and the VA pharmacy

A. Medical Malpractice
1. Failure to timely warn of known warnings and dangers associated with statin products (both lovastatin and simvastin) at the time of subscription
2. Failure to have adequate diagnostic tests (measuring CoQ10 enzyme levels for example)
3. Pill splitting is not recommended practice by mfg. Or authorized by Merck et al.
4. Increasing the dosage when contradictions indicated a possible adverse reaction to the prescription.

5. Failure to follow product warning instructions from drug mfg. and order appropriate, reasonable and timely tests for potential adverse events attributable to the drug. CK and CKP levels, Q10, trinanaynlamise levels-kidney, liver, blood.

B. Failure to diagnose or treat-ER, PA and ER doctor, April 24th 2003
C. Failure to warn of a possible drug interaction with Ketazole ointment and ZOCOR
D. Failure to give warnings when Zocor was substituted by the VA Pharmacy when Lovastatin was ordered by the prescribing doctor
E. Failure to report a serious adverse event with the FDA as requested in a certified letter to Director Robert Malone dated December 8 2003.
C. Negligence

III. Claims against the FDA

1. Failure to timely respond or evaluate a petition filed by Public Citizen in 2001[28] or implement or follow the four recommended actions contained in that petition; A failure to timely respond or evaluate several other petitions filed by national experts with the FDA[29]. Failure to protect the public interest.

IV. Claims against individuals in either their individual or official capacity for either acts or failure to act (omission).

V. Claims against State of Kansas and regulatory agencies

a) Kansas Board of Healing Arts-Doctor complaints, March 2004
b) Kansas Board of Pharmacy, March 2004
c) Kansas Attorney General, Consumer Protection Division
d) Joint Commission on Accreditation of Hospitals (JCAH) March 2004

LEGAL ISSUES

General Issues relating to personal injury, product liability and negligence

1. Causation (medically defined as pathogenesis
2. Legal Cause-See Re2nd Torts, 2D, section 430, also see Sec. 457 pertaining to 3rd parties such as the VA, and its doctors
3. Proximate Cause
4. Daubert-medical expert opinion
5. Negligence

Attributable to [redacted]

6. Marketing defect
7. Implied Warranty-there is implied warranty by [redacted] regarding this product is safe for consumers use.

[28] *See* FDA Docket No 01P-0372
[29] *See* FDA Docket No (s) 02P-0243/CP1, 02P-0244/CP1; 02N-0115

8. Defective Product--3 types, mfg., design defect or inadequate instruction or warning. I am claiming a marketing defect and asserting there was an implied warranty. See RE 3d, Product Liability, Sec. 2, Categories of Product Defect.
9. Risk utility balancing-the public interest vs. the risk of product harm. See Re3d, Sec. 2
10. Strict liability, see Restatement of Torts 2D, Chapter 14, Liability of persons supplying chattels for the use of others. Section 402A, replaced by Restatement of Torts, Product Liability (1997). See (j) regarding product directions or warning.
11. Foreseeability and the need to warn including mfg. Keeping current with reported events. See Kansas case (1977) 235 Kan. 387, 681 P.2d 1038, Wooderson v. Ortho Pharmaceutical Corporation (1984).

Attributable to the VA and its officials

12. Learned intermediary doctrine-Doctors responsibility to follow warnings
13. Malpractice
14. Failure to Diagnose
15. Pill Splitting-practice
16. Contributory negligence
17. Contradictions are those who should not take the drug at all
18. Warnings are what to watch for, in those that do take the drug.

ELEMENTS REQUIRED UNDER

1. **Kansas Product Liability Act**
   1.
   2.
   3.

2. **General elements under a theory of negligence**-*see* ReSec Sec. 281, also see sec 284 for negligent conduct by an act or failure to act.
   Statement of the elements of a cause of action for negligence

   A) the interest invaded is protected against unintentional invasion (duty)
   B) the conduct of the actor is negligent with respect to the other, or a class of persons within which he is include, and (breach of duty)(reasonable person std.
   C) the actors conduct is a legal cause of the invasions, and (cause in fact and proximate cause)
   D) the other has not so conducted himself as to disable himself from bringing an action for such invasion (harm or damages).

3. **General elements under a theory of product liability**

Theories of individual and several liability

RELEVANT FACTS

EVIDENCE

1. FDA Medwatch Report, Adverse Event reported by consumer, Nov. 16th 2003
2. Public Citizen Petition, dated 2001 with four specific recommendatons
3. Certified letter, legal notice to Merck, dated November 16th 2003
4. Certified letter to Robert Malone, Topeka VA dated
5. Prescription vials with instructions
6. VA FOIA request and responsive documents received Dec. 10th 2003 (28 pages).
7.

APPOSITE CITATIONS OF AUTHORITY-Cases

a) Federal Courts

1. Sheridan v. Merck & Co. Inc. (E.D. La. Dec. 08,2003) 2003 WL 22902622, No. Civ.A 02-2581

b) U.S. Court for Veterans Appeals

2. U.S Court of Veterans Appeals, Docket No. 00-17 558, Citation No. 0120429 decided 08/09/01. *See* http://www.va.gov/vetapp01/files03/120429.txt. for disability claim attributable to ZOCOR and a mass in the left lower abdominal quadrant

3. U.S Court of Veterans Appeals, Docket No. 99-02 771, Citation No. 0026513, decided 10/04/00. See http://www.va.gov/vetapp00/files3/0026513-claim for disability in the left upper extremity as a result of an increased dosage of medication (ZOCOR)

4. Wooderson v. Ortho Pharmaceutical Corporation 235 Kan. 387, 681 P.2d 1038, (1984). Mfr. Duty to warn, keep abreast of current adverse events and take reasonable action to those events.

STATUTES, REGULATIONS AND OTHER AUTHORITY

1. Restatement of Torts 3D, Product Liability
2. Federal Food, Drug and Cosmetic Act of 1938, as amended 21 U.S.C. 301 et seq.
3. Kansas Product Liability Act, KSA 60-
4. Kansas Consumer Protection Act, 50-601 et seq.
5. United States Code, Chapter 38
6.

Theories and Claims of Damages-Punitive, Compensatory

1. Punitive damages from [redacted] for not updating warnings to intermediaries

2. Intentional/Negligent infliction of emotional distress, pain, agony, suffering.
3. Economic damages related to future earnings
4. Damages for pain, suffering, emotional distress
5. Permanent and irreparable damages-muscle damage, heart, liver, kidney
6. Future expenses including treatment, tests, drugs
7. Property damage (pursuit of education-education is a type of property)
8. Loss of pleasure and happiness
9. Loss of consortium with family

Saturday, November 22, 2003

I. ZOCOR LEGAL SUMMARY AND THEORY

The VA Doctor properly prescribed a statin regimen for high cholesterol. However, the prescription caused adverse events that the VA failed to properly diagnose. In addition, the VA doctor failed to note the potential adverse events regarding another prescription Nicrozal. The doctor also recommended pill splitting which is not recommended by the manufacturer of the product, ZOCOR.

The VA doctors failed to establish a relation to the symptoms reported on April 24th with the prescription ZOCOR-a failure to properly diagnose reported symptoms. The VA doctors failed to adequately diagnose on several occasions reported symptoms such as GI problems, bloating and pain in the abdomen. The VA doctors failed to order diagnostic tests and instead, simply prescribed more prescriptions (Docusate and Citrate of Magnesia).

[redacted] product literature was inadequate in explaining in sufficient detail, the necessary information for doctors to diagnose adverse events caused by the taking of this product. The product literature did not give sufficient information regarding the testing to ensure there would be no muscle damage. This would have been determined by checking CK and CKP levels.

It is my belief the ZOCOR prevented the gastic emptying. This is turn led to malnutrition and mal-absorption in the intestine. That in turn, led to muscle damage, some of which may be permanent and irreparable.

II. PRESCRIPTIONS-Dates of prescription orders:

On Thursday, April 17th, while I was a first-year law student attending Washburn University School of Law, [redacted] my VA Primary Care Physician, Blue Team, Topeka KS VA prescribed Lovastatin, 40 mg. tablets (Rx No. 51330288) for a condition that is commonly referred to as hypercholesterolemia (high cholesterol). The VA Pharmacy at Topeka substituted ZOCOR for the Lovastatin on that same day.

On Thursday, April 24th, I went to the Topeka VA Emergency Room due to intense abdominal pain (stomach bloating). I was given a rectal examination by Dr. [redacted] and prescribed two prescriptions for relief of those symptoms which she believed to be constipation--1) Magnesium Citrate (laxative) (Rx. No. 51332577) and 2) Doucusate (stool softener)(Rx No. 51332576). The magnesium citrate provided some relief from the constipation. However, it soon returned.

On Tuesday, April 29th, I again saw [redacted] who prescribed a prescription for ZOCOR (simvastatin), 20 mg, (Rx. No. 51334142) to be split and taken daily with supper. I advised him that I was having problems with bowel movements.

On Tuesday, May 13th, I moved from Topeka back to Merriam, KS after the completion of finals at Washburn Law School. When I moved back to Merriam, I stopped taking most prescriptions (Lithium, _____) as a test to determine which drug or possible drug was/might be causing GI problems. I discontinued the taking of most drugs with the exception of ZOCOR, Docusate and Busiprone as needed, for anxiety. I would take the ointment, ketoconazole (Nizoral)for skin rashes as skin lesions occurred.

On Tuesday, July 7th, I again saw [redacted] who stated there had been no decrease in the cholesterol level. He then increased the ZOCOR to 80 mg. tablets, (Rx. No. 51356875to be split, taken daily with the evening meal.

On September 26th, I met with [redacted], KC VA, MHC and reported to him, symptoms of fatigue.

On October 24th, after missing an appointment, I called and asked for [redacted] regarding my desire to stop taking ZOCOR after researching the different drugs I had been prescribed. By his nursing assistant, [redacted] approved me from taking the ZOCOR. I requested the VA to do some diagnostic exams relating to CK and CKP levels. The assistant to [redacted] stated I could not see him until December 12th due to other appointments.

At some point in October, I took PROZAC for about a week hoping that would end the fatigue.

Within 3 days after stopping ZOCOR, my appetite returned. I was able to eat a normal meal and started forming developed stools. The bloating and abdominal pain disappeared.

November 17th, I started taking a multiple vitamin hoping to reduce fatigue. I did this under the belief that some of the fatigue might be related to malnutrition.

II. SYMPTOMS RELATED TO GI PROBLEMS

1. I experienced several symptoms that are related to this product.

a) Bloating in the stomach causing pain that would last 3-4 days. That bloating and resulting pain would interfere in my daily activities to the point where I could barely function. This affected by ability to study for finals at law school and the resulting poor performance on law school exams (finals) in May 2003.
b) Muscle Pain/Weakness-I was experiencing fatigue and muscle pain, generally in the legs. I would aspirin for that pain, sometimes daily or twice per day.
c) Vomiting-I did have a few occasions of vomiting. This was only occasionally, and not a daily event.
d) Heart Arrhythmia-I remember have heart arrhythmia almost immediately after taking the medication at my residence in May and June. For some reason, those heart arrythemias did not continue, if I would take the medication prior to eating.
e) No stool formation. I did not have daily bowel movements. If I was able to have a bowel movement, it was not a complete stool formation.
f) Bladder-when I experience the bloating, I could also not urinate.
g) Symptoms after stopping ZOCOR (October 24, 2003). Within three days, the bloating and pain in the stomach stopped. I was able to eat a regular meal and bowel movements returned to a more regular and predictable manner. However, the chronic fatigue continues including problems with concentration.

III. MEDICAL TERMINOLOGY

1. **Gastroparesis**-means the paralysis of the stomach. Under this condition, food is not throughly ground and does not empty into the intestine normally. This can be caused by diseases of the stomach muscles or the nerves that control those muscles. A side effect is malnutrition by food not being absorbed in the intestine.

2. **Myositus**-muscular diseases that cause degeneration of muscle tissue resulting in decreasing strength, and making even the simplest physical activities difficult.

3. **Rhabdomyolysis**-muscular disease that is diagnosed when

4. **Severe Constipation**-Infrequent occurrence of bowel movements.

5. **Hypercholestrerolemia**-High Cholesterol

6. **Creatine kinease** (CK) and **Creatine Phosphoceratine** (CKP)-an enzyme that is measured in the blood to determine muscle related damage.

7. **Trianylmase**-Enzyme that is measured in the blood to determine liver function

8. **Malabsorption** can be the result of a broad spectrum of diseases. Typically, malabsorption can be the failure to absorb specific sugars, fats, proteins, or other nutrients (such as vitamins), or it can include a general nonspecific malabsorption of food. Diarrhea, bloating or cramping, failure to thrive, frequent bulky stools, muscle wasting, and a distended abdomen may accompany malabsorption.

9. **Abdominal bl**oating is a condition in which the abdomen feels full and tight -- usually caused by excessive intestinal gas.

10. **Gastric emptying**-The cycle where food is digested in the stomach and passes to the intestine.

IV. LEGAL TERMS

11. **Serious Adverse Event**-event that could be life threatening, require hospitalization that could result in a disability.

12. **Product Liability**-a situation where a person is damaged by a product and may be ...or any injury or damage caused by such product

13. **Medical Malpractice and Negligent Care**-Caused by a failure to diagnose, or misdiagnose a reported medical condition or disease (diagnostic error) which then causes an adverse event resulting in damages to the patient.

V. REPORTING OF GI SYMPTOMS

I reported symptoms to several individuals. This included [redacted] on April 29th. The ER Doctor and her supervisor (April 24th). The ultrasound technician (July 7th) when I asked if she could detect a mass in the stomach via ultrasound. Dr. [redacted] on September 26th. [redacted]s nurse on October 24th. I reported the symptoms to a nutritionist at the Topeka VA on July 7th. I reported the symptoms to my ex-wife, an RN on several occasions.

VI. DIAGNOSTIC TESTS AND SELF DIAGNOSIS AND TESTS

1. The VA reported to me, that they did perform a 3 month test (must of have been in July) of my blood for liver function. However, they also stated they did not test for CK or CKP levels (creatine).
2. I tried several tests to determine what was causing the GI problems and fatigue:
   a) Water test-tried to drink 32-64 fl. Oz. water
   b) Raisin Bran Test-was able to produce a more developed stool
   c) Atomic Bomb Test-citrate of magnesia when all else failed (did on about 4 occasions.
   d) Modifications to diet, drastically reduced eating dairy products.
   e) Stopping some medications
   f) Tried using metamucil (increase fiber)
   g) Stopped drinking Pepsi (caffeine)
   h) Starting taking vitamin supplement Nov. 17th for fatigue

VII. DRUGS, PRESCRIPTIONS AND OTC MEDICATIONS