

September 9, 1998

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
Docket #98N-339R

5 2 0 8 '98 SEP 16 P2:20

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
FDA MODERNIZATION ACT OF 1997

My name is Marlene Keeling. In 1978 after consulting with my personal physician, I made the decision to get breast implants. It was the worst decision of my life. My implants were removed in 1994 and the pathologist found they were ruptured. It was a silent rupture, which I understand gel-filled implants often are and now I have been diagnosed with demyelinating neuropathy. Something is destroying the myelin sheath around my nerves. If both the FDA and the ASPRS both agree that ruptured implants should be removed immediately, but it can be a silent rupture with no symptoms and no reliable method to detect rupture, how can a woman protect herself?

The purpose of my testimony is to address the issues of informed consent, consumer protection, and adverse event reporting as it might apply to all medical devices.

I would like to read from M55376, a product report problem to the FDA, husband asked if implants rupture "what would the gel do." The doctor answered "Do you think the Govt. would allow them on the market if they would cause harm?" Many women were told by doctors who take an oath to do no harm, implants were safe and would last a lifetime. Many women trusted that the FDA was protecting them as consumers. Our trust has been broken.

A recent survey of 23 plastic surgeon's offices when asked this question - "Are saline implants FDA approved for safety?", everyone, but one (who said she didn't know) said "absolutely, they are FDA approved for safety."

**RECOMMENDATION #1** - Mandate that every breast implant informed consent includes the following: "**The Food and Drug Administration (FDA) has not formally approved these devices as safe and effective because the manufacturers have not provided to FDA adequate scientific evidence to prove their safety and effectiveness. The FDA is concerned about possible health problems from the use of these devices.** (This information should be included with different wording for every device that has not been approved by the FDA, so that consumers will recognize they are part of an experiment and the risks they are taking.)

The FDA is mandated to make sure that medical devices are safe, effective, and accurately labeled. The FDA, manufacturers, and the plastic surgeons have an ethical and moral responsibility not to mislead the public into using harmful toxic devices. Tom Talcott, a former Dow Corning scientist specializing in polymers and silicone elastomers,

98N-339R

C 1

states that almost all silicone elastomers contain at least 4% by weight of migratable or extractable silicone oils, catalyst residues such as PCB's and heavy metals such as tin and platinum.

RECOMMENDATION #2 - Mandate that all chemicals and catalyst residues used in implantable devices be listed in the informed consent along with toxicity information.

Some of the findings in a 1992 Congressional Report on The FDA's Regulation of Silicone Breast Implants are as follows:

1. In 1992, Dow Corning disclosed that the company sold implants to doctors before they were shown to be safe in animals, failed to disclose problems with the implants, and submitted fabricated information about quality control.
2. Patients have been misled about the safety of breast implants for at least the last 15 years.
3. Patients continue to be misled by the FDA-approved informed consent form.
4. FDA's public statements about breast implants minimized the risks.

In 1996 I became a founding director of Chemically Associated Neurological Disorders after networking with thousands of women with implants and hearing many similar diagnoses including peripheral neuropathy, demyelinating neuropathy, organic brain disease, reduced blood flow to the brain from Spect Scans, MRI's showing white lesions on the brain, abnormal nerve conduction tests, dementia, cognitive dysfunction, and memory loss.

Mentor's current product insert states the following regarding Immunological and Neurological Response "The medical literature has raised the possibility that there may be an association between certain immunologically based diseases and silicone breast implants. The diseases most commonly mentioned include scleroderma, rheumatoid arthritis and syndromes which mimic systemic lupus erythematosus. Available information does not permit precise quantification of risk. Neurological problems have been reported in a small number of breast implant patients who also exhibit immunological symptoms." Nowhere is this information mentioned in the informed consent given a patient. Nowhere does it state in either the informed consent or the product insert that the Manual of Allergy and Immunology reports Scleroderma-related disorders superficial to the subcutaneous tissues can be induced by silicone breast implants.

Mentor states that they rely on the surgeon to advise the patient of all potential complications and risks associated with the use of mammary prostheses. Women do not realize they need to ask to see a product insert. The reality is an unethical surgeon can downplay the risks because he has a conflict of interest and could lose one-third of his income from breast implants and the repeat surgeries they require, if he told the truth. In some cases, Surgeons have stated that thirty years of use and large studies by Mayo and Harvard, prove implants are safe. They further state that informed consents are merely a formality caused

by hysterical media and greedy trial lawyers. In some cases informed consent was given to the patient only a few minutes before the surgery process started.

RECOMMENDATION #3 - Mandate that informed consent forms must be given to potential implant candidates at initial consultation along with a mandatory FDA Breast Implant Information Update with consumer and patient information, so that a potential implant candidate can obtain balanced information, if desired. Mandate a seven day "cooling off" period between initial visit and date of surgery, to give patient adequate time to receive information by mail. In order to have true informed consent, mandate that accurate percentages of complication rates and disease rates be included.

The Wall Street Journal in an article dated July 14, 1998 states that 122,285 women got breast implants for cosmetic reasons in 1997 approaching the 1990 peak. We believe this is due to a false sense of safety encouraged by the following statements in the current "so-called" informed consent:

Page 1 - **"Most women implanted have had satisfactory results"** (what percentage after what period of time - six months, one year?) **"This data will be used to collect short-term (5 year) data about possible health problems associated with breast implants. This data will be used to help determine if these implants are both safe and effective."** (With a latency factor of approximately five to fifteen years for symptoms to appear, five years is not long enough to prove implants to be either safe or effective. Tobias Meeker with St. John's Hospital sent a FAX to the FDA concerning serious reservations of the protocols of the Phase II Mentor study and quoted a surgeon as saying the protocol was designed to give the illusion of a study. St. John's currently has patients sign an addendum to Mentor's Informed Consent stating their patients receiving gel-filled implants are not in a strictly controlled scientific study to help determine if implants are safe. I have copies of both these documents.)

Page 2 - **"Complications are uncommon"** (What is the percent of risk? Breast hardening, because of capsular contracture, develops during the first six months after the operation in at least 40% of patients, and can result in a deformity of the breast according to a Women's Health Alert, 1990. The adverse event reports of 115,920 are full of reports of problems.)

Page 3 - **"Calcium deposits cause no problems."** (It is reported that calcium deposits are often razor sharp and may rupture the implant and it also makes it difficult to detect cancer on mammograms.) **"If the envelope containing the saline portion breaks, the saline is absorbed harmlessly by the body within hours."** The research paper titled Microbial Growth Inside Saline-filled Breast Implants, Plast Reconstr Surg 1997 Jul; 100-1:182-196 states "The data show that se-

veral types of bacteria (particularly gram-negative species) and fungi can grow and reproduce in a restricted saline environment for extended periods of time." If the contaminated saline ruptures full of bacteria and fungi, it can overwhelm the immune system. Is this the reason Toxic Shock Syndrome is now mentioned in the product insert but not in the informed consent? What standard of risk for devices does the FDA have? Is the current standard as long as it is mentioned in the product insert, it is an acceptable risk? Has the standard become buyer beware? It is an unworkable society that must do medical research in order to make health decisions and then wonder who financed the research and for what motives.

**"The gel released as a result of rupture may be contained within the capsule surrounding the implant. If the scar envelope also tears, the gel can travel and be squeezed into the breast tissue or into the muscle or fatty tissue next to the breast, abdominal wall or arm. Fortunately this is uncommon. The risks from this escaped gel are unknown."** (It was reported by Dr. Lori Brown from 11 to 23% of ruptures are now found with silicone outside the capsule. Why is there no mention that silicone has been documented in published research in the lymph nodes, fingers, groin, blood and liver and recent evidence documents that it is immunogenic?).

The most egregious false and misleading statement made in the Mentor package insert is "Our product history indicates an overall reported average rupture rate of approximately one percent. The FDA estimates that rupture rates are generally between one to four percent." Protocol violations have been reported to Mentor, the IRB, and the FDA that has allowed Mentor to make this statement. Research published in the *Annals of Internal Medicine*, April 1996 titled Reported Complication of Silicone Gel Breast Implants: An Epidemiologic Review, states "71% of the women in this series had either frank rupture or severe silicone bleed at explantation." Eleven recent research articles documented in *Plastic and Reconstructive Surgery*, July 1997 Failure of Silicone Gel Breast Implants: Analysis of Literature Data for 1652 Explanted Protheses reports a failure rate of 50% at 8 years predicted from their analysis of results for explanted silicone gel protheses from many different research groups. The authors state that the failure master curve shows a significant direct correlation of failure curve with implant time and a failure rate so high that one must seriously question the safety of this device for general clinical use due to biomechanical failure problems alone. Fraud on the part of the manufacturers in under-reporting of complications is serious and cannot be tolerated, along with other protocol violations.

a failure rate so high that one must seriously question the This brings me to the subject of adverse event reporting. Dr. Lori Brown told the recent IOM Committee on the

Safety of Silicone Breast Implants the FDA has received 115,920 adverse event reports on breast implants. Who at the FDA is looking at long term consequences of breast implants? With a reported latency factor of on average five to fifteen years for symptoms to appear, the current MedWatch system is inadequate. It appears it was designed as an early warning system only.

RECOMMENDATION #4 - Design and implement a supplemental information checklist to the MedWatch form on frequent complications and diagnoses on devices suspected of having a long latency period for symptoms to appear for ease of reporting and collection of data for statistical analysis.

I am submitting a supplemental MedWatch form for breast implants, that I would like to leave for your suggestions or implementation. If this would take additional funds from Congress to implement, I am willing to help approach the appropriate committees.

The Wall Street Journal on June 24, 1998, in an article titled MedWatch System Comes Under Fire quotes Brian Strom, chairman of the University of Pennsylvania's biostatistics and epidemiology department as saying "Basically nobody is looking for problems, the system has turned into a big wastebasket. It's convenient for industry, and the FDA because no one is looking over their shoulders."

Well, I'm here to tell you, Dr. Burlington, I'm looking over your shoulder. We have many documents showing how the breast implant manufacturers and the ASPRS agreed to act in concert to keep these devices on the market. I only hope the FDA is not the 3rd part of this unholy alliance. I hold you personally responsible for allowing the experimentation on women for over thirty years to continue. When I tried to make an appointment with you regarding valid concerns that I and the thousands of implanted women whose health has been destroyed by the toxic effects of silicone have, I was denied inspite of congressional intervention on my behalf.

Tell me what to say to the young medical student who tells me her implants are five years old and her lymph nodes stay swollen after many rounds of antibiotics. She reports she is fatigued all the time and doesn't have the money to get her implants removed. Should I reveal to her that Mentor changed their informed consent 002AS-01 to 002AS-02 and added the wording **"Rat studies have suggested that silicone gel similar to that in the implant may have an abnormal effect on the immune system, but the relevance of these tests to humans has not yet been established."**

Should I tell her that while under your leadership at the FDA, Mentor was allowed to sell implants that Dr. Pierre Blais, a noted Canadian Scientist, calls "dirty aquariums" filled with decaying tissue, dead blood cells, and in some cases bacteria because of fundamental design flaws."

RECOMMENDATION #5 - Mandate all manufacturers to halt marketing and require recalls (much like the automobile industry) when good manufacturing practices are violated and until they are corrected.

On October 15, 1997 in response to my citizen's

petition, Dr. Michael Friedman stated that the FDA did not have sufficient information to change the current regulatory policy on silicone gel-filled breast implants at this time but that the public interest is not well served in your current situation.

Your response in a letter dated December 2, 1997 to the President of the ASPRS was to ask for their help in finding additional Plastic Surgeons to put more gel-filled breast implants in women.

May I remind you, Dr. Burlington, that the Nuremberg Code states the following:

1. The voluntary consent of the human subject is absolutely essential. The person involved should have free power of choice, without any element of fraud, deceit, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements involved to be enabled to make an enlightened decision.

2. No experiment should be conducted where there is an a "piori" reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physician also serve as subjects.

3. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death of the experimental subject.

You, Dr. Burlington, are that scientist in charge and I leave with you an Alabama Death Certificate dated April 12, 1994 that lists cause of death Ischemic Colitis, due to or as a consequence of Autoimmune Disease, due to or as a consequence of Systemic Lupus Erythematosus (SLE), due to Silicone Gel Implants.

Sincerely,

Marlene Keeling  
President  
CANDO (Chemically Associated  
Neurological Disorders)  
P.O. Box 682633  
Houston, Tx. 77268-2633  
281/444-0662  
281/444-5468 FAX

FDA Use Only
Triage Unit sequence #

Page \_\_\_ of \_\_\_

### A. Patient information

1. Patient identifier: ② _____	③ Sex <input type="checkbox"/> female <input type="checkbox"/> male	④ Weight _____ lbs or _____ kgs
In Confidence	Date of birth: _____	

### B. Adverse event or product problem

1.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

② Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death _____ (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) **SEE ATTACHED**

④ Date of this report (mo/day/yr) \_\_\_\_\_

5. Describe event or problem

SEE ATTACHED

⑥ Relevant tests/laboratory data, including dates

Biopsy date(s) \_\_\_\_\_

Ct Scan date(s) \_\_\_\_\_

MRI date(s) \_\_\_\_\_

Spect Brain Scan date(s) \_\_\_\_\_

Blood test date(s) \_\_\_\_\_

Other \_\_\_\_\_

⑦ Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

### C. Suspect medication(s)

NOT APPLICABLE

### D. Suspect medical device

USE ATTACHED FORMS

9. Device available for evaluation? (Do not send to FDA)

yes     no     returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment or event)

### E. Reporter (see confidentiality section on back)

① Name, address & phone #

② Health professional?  yes     no

③ Occupation \_\_\_\_\_

④ Also reported to  
 manufacturer  
 user facility  
 distributor

⑤ If you do NOT want your identify disclosed to the manufacturer, place an "X" in this box.

NAME: \_\_\_\_\_

PAGE 2 OF \_\_\_\_\_

**Supplement to MedWatch, the FDA Medical Products Reporting Program  
For Voluntary Reporting by Consumers of Adverse Events and Product Problems  
with  
BREAST IMPLANTS**

Is this additional data to a previously filed Medwatch? Yes \_\_\_ No \_\_\_  
If Yes, date previously filed if known \_\_\_\_\_

Left Breast	Right Breast	[Indicate the numbers in space provided]
_____	_____	Number of times implant(s) replaced
_____	_____	Total number of resulting breast surgeries beginning with first implant surgery.

[Circle Y for Yes OR N for No at left]

Y or N	Y or N	Do you have implants in now?
Y or N	Y or N	Did calcium deposits occur?
Y or N	Y or N	Were biopsies done on any tissue samples examined pathologically. If Yes, please attach copy of report.

Reason for Implant(s):   Cosmetic \_\_\_\_\_   Following Mastectomy for Cancer \_\_\_\_\_  
                                  Following Mastectomy for Fibrocystic Disease \_\_\_\_\_  
                                  Following Mastectomy to Prevent Cancer \_\_\_\_\_  
                                  Other \_\_\_\_\_

Has a medical professional confirmed silicone outside the breast scar tissue capsule? \_\_\_\_\_  
If Yes, give location(s) \_\_\_\_\_

**Note: File a separate MedWatch for each child born after implantation who you suspect may have been affected by your Silicone breast implant(s).**

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	5. Expiration date (mdy)
	7. If implanted, give date
	8. If explanted, give date
9. Device available for evaluation?(Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**PRODUCT MALFUNCTIONS (ABOVE PRODUCT ONLY)**

Implanted in  Right  Left

In surgical area, check if you had:  infection  hematoma  
 Excess fluid  Numbness (nipple or breast)

Condition of Implant:  Ruptured  Intact  Unknown  
 Bleeding through envelope  Other \_\_\_\_\_

Number of capsular contractures(s) (Hard or Tight) \_\_\_\_\_

Number of closed capsulotomies (Pressure applied to break capsule) \_\_\_\_\_

Number of open capsulotomies (Surgical cut scar tissue of capsule) \_\_\_\_\_

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	5. Expiration date (mdy)
	7. If implanted, give date
	8. If explanted, give date
9. Device available for evaluation?(Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**PRODUCT MALFUNCTIONS (ABOVE PRODUCT ONLY)**

Implanted in  Right  Left

In surgical area, check if you had:  infection  hematoma  
 Excess fluid  Numbness (nipple or breast)

Condition of Implant:  Ruptured  Intact  Unknown  
 Bleeding through envelope  Other \_\_\_\_\_

Number of capsular contractures(s) (Hard or Tight) \_\_\_\_\_

Number of closed capsulotomies (Pressure applied to break capsule) \_\_\_\_\_

Number of open capsulotomies (Surgical cut scar tissue of capsule) \_\_\_\_\_

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	5. Expiration date (mdy)
	7. If implanted, give date
	8. If explanted, give date
9. Device available for evaluation?(Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**PRODUCT MALFUNCTIONS (ABOVE PRODUCT ONLY)**

Implanted in  Right  Left

In surgical area, check if you had:  infection  hematoma  
 Excess fluid  Numbness (nipple or breast)

Condition of Implant:  Ruptured  Intact  Unknown  
 Bleeding through envelope  Other \_\_\_\_\_

Number of capsular contractures(s) (Hard or Tight) \_\_\_\_\_

Number of closed capsulotomies (Pressure applied to break capsule) \_\_\_\_\_

Number of open capsulotomies (Surgical cut scar tissue of capsule) \_\_\_\_\_

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
6. model # _____ catalog # _____ serial # _____ lot # _____ other # _____	5. Expiration date (mdy)
	7. If implanted, give date
	8. If explanted, give date
9. Device available for evaluation?(Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

**PRODUCT MALFUNCTIONS (ABOVE PRODUCT ONLY)**

Implanted in  Right  Left

In surgical area, check if you had:  infection  hematoma  
 Excess fluid  Numbness (nipple or breast)

Condition of Implant:  Ruptured  Intact  Unknown  
 Bleeding through envelope  Other \_\_\_\_\_

Number of capsular contractures(s) (Hard or Tight) \_\_\_\_\_

Number of closed capsulotomies (Pressure applied to break capsule) \_\_\_\_\_

Number of open capsulotomies (Surgical cut scar tissue of capsule) \_\_\_\_\_

CHECK IF YOU HAVE BEEN DIAGNOSED WITH ANY OF THE FOLLOWING AFTER IMPLANTATION  
[Exclude any condition that existed before implantation]

BLADDER/URINARY

- Chronic Infections  Intestinal Cystitis

BLOOD PRESSURE

- High or Low

BRAIN/NEUROLOGICAL

- Peripheral Neuropathy
- Demyelinating Neuropathy
- Other Neuropathy
- Carpal Tunnel Syndrome
- Motor Neuron Disease
- Brain Lesions
- Cognitive Changes:
  - Anxiety &/or Depression
  - Organizational Difficulty
  - Lack of Concentration
  - Short-Term Memory Loss
  - Mood Swings
  - Procrastination
  - Getting Lost or Confused
  - Dementia

- Balance Disturbances/Vertigo/Dizziness
- Meningitis (Chemically Induced)
- Multiple Sclerosis
- Atypical M-S
- Stroke
- Organic Brain Syndrome
- Reduced Blood Flow to Brain
- Other \_\_\_\_\_

CANCER

- Multiple Myeloma
- Other Type \_\_\_\_\_
- Other Type \_\_\_\_\_
- Other Type \_\_\_\_\_

CHEST/RIB CAGE

- Pain &/or Burning Sensation
- Inflammation

CHOLESTEROL

- Elevated Cholesterol or Triglycerides

EYES

- Nerve Damage
- Rapid deterioration
- Other \_\_\_\_\_

ENDOCRINE PROBLEMS

- Thyroid Problems  Adrenal Problems
- Other \_\_\_\_\_

EXTREMITIES (Hands &/or Feet)

- Chronic Swelling
- Chronic Pain
- Chronic Discoloration (Red or Blue)
- Heat or Cold Sensitive
- Raynaud's Disease

FEVER

- Frequent Low Grade Fever

GASTROINTESTINAL

- Chronic Diarrhea &/or Constipation
- Esophagitis, Duodenitis &/or Gastritis
- Irritable Bowel Syndrome
- Other \_\_\_\_\_

GYNECOLOGICAL

- Infertility
- Miscarriage &/or Stillbirth
- Hysterectomy
- Other \_\_\_\_\_
- Ovarian Problems

HAIR

- Substantial Hair Loss NOT Connected with Medications

HEADACHES

- Frequent Migraines / Severe Headaches

HEART PROBLEMS

- Type \_\_\_\_\_

HYPERSENSITIVITY OR ALLERGIES TO:

- Chemicals
- Molds, Dust or Pollen
- Insect Bites or Stings

INFECTIONS

- Unusual Chronic Infections

IMMUNE SYSTEM DISEASES

- Connective Tissue Disease
- Lupus
- Atypical Lupus
- Sjogren's Syndrome
- Scleroderma

JOINTS

- Inflammation, Swelling, Pain /Arthralgia
- Rheumatoid Arthritis
- Persistent Joint Stiffness

LIVER PROBLEMS

- Type \_\_\_\_\_

LUNG PROBLEMS

- Asthma
- Type \_\_\_\_\_
- Check if you were/are a Smoker

LYMPH NODES

- Chronic swollen lymph nodes / Lymphadenopathy
  - Under Arms
  - Other \_\_\_\_\_
- Lymph Nodes Removed Location(s) \_\_\_\_\_

MUSCLES

- Chronic Unexplained Muscle Spasms
- Frozen Shoulder
- Muscle Pain & Burning
- Muscle Atrophy
- Fibromyalgia
- Myositis or Polymyositis
- Fascitis
- Other \_\_\_\_\_

SKIN

- Unexplained Rashes
- Sun Sensitive
- Unexplained Severe Itching
- Numerous moles, freckles, etc
- Dermatomyositis

SLEEP

- Chronic Insomnia
- Non-Restorative Sleep

VASCULAR

- Vasculitis
- Thoracic Outlet Syndrome
- Other \_\_\_\_\_

GENERAL

- Chronic Fatigue Syndrome
- Long-Term Extreme Fatigue
- Granulomas or Silicanomas
- Clumsiness/drop things
- Misjudge distance/run into objects
- Sicca

## (Instructions For Sections B)

## ( Instructions For Section E)

# MEDWATCH

## THE FDA NEDUCAL PRODUCTS REPORTING PROGRAM

### WHAT IS A SERIOUS ADVERSE EVENT?

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is **SERIOUS** and should be reported when the patient outcome is:

#### ◆ DEATH

Report if the patient's death is suspected as being a direct outcome of the adverse event.

#### ◆ LIFE-THREATENING

Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.

**Examples:** Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.

#### ◆ HOSPITALIZATION (INITIAL OR PROLONGED)

Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.

**Examples:** Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.

#### ◆ DISABILITY

Report if the adverse event resulted in a significant, persistent, or permanent change, important, damage or disruption in the patient's body function/structure, physical activities or quality of life.

**Examples:** Cerebrovascular accident due to drug-induced hypercoagulability; ototoxicity; peripheral neuropathy.

#### ◆ CONGENITAL ANOMALY

Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

**Examples:** Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.

**Section E:** Reporter - FDA recognizes that confidentiality is an important concern to health care professionals in the context of adverse reporting. The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. However, to allow for timely followup in serious cases, the reporter's identity may be shared with the manufacturer unless requested otherwise in E5. The FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

**E1:** Name, address & phone # - Please provide the name, mailing address and phone number of the person who can be contacted to provide information on the event if followup is necessary. This person will also receive an acknowledgment letter from the MEDWATCH program. This information is necessary for both adverse event and product problem reports.

**E2:** Health professional? - Please indicate whether you are a health professional (e.g., physician, pharmacist, nurse, etc.) or not.

**E3:** Occupation - Please indicate the type of health professional or reporter occupation, and indicate specialty if appropriate.

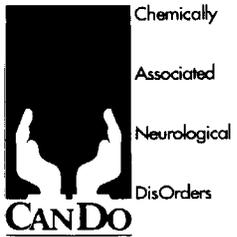
**E4:** Please indicate whether you have also notified or submitted a copy of this report to the manufacturer of the product, the distributor of the product, and/or, for medical device reports only, the user-facility (institution) in which the event occurred. This information helps to track duplicate reports in the Agency data base.

**E5:** Release of reporter's identity to the manufacturer - In the case of a serious adverse event, the Agency may provide, name, address and phone number of the report in E1 to the manufacturer of the suspect product.

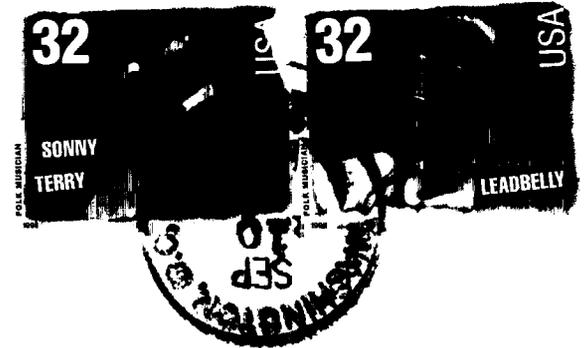
*If you do NOT want your identity released to the manufacturer please put an X in the box.*

E. Reporter (see confidentiality section on back)		
① Name, address & phone #		
② Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	③ Occupation	④ Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
⑤ If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.		<input type="checkbox"/>





P.O. Box 682633  
Houston, Texas 77268-2633



Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Docket #98N-339R