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Public Citizen

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Joan Claybrook, President

Dear consumer:

In response to your recent request, we are enclosing information about the use of bone screws in the pedicle of the spine. If you would like a copy of the complete report *Investigation of Pedicle (Spinal) Screw Implantation*, it is available for $10 (for consumers & public interest groups) or $50 (for attorneys or other groups). Please send a check (payable to Health Research Group) and we will get the report to you as soon as possible.

If you have been injured by pedicle screw implantation, it is imperative that you notify the Food and Drug Administration (FDA) about your injuries. It is important that the agency become aware of how serious the situation is with this type of surgery. We are enclosing a **MedWatch** reporting form for your convenience. Send it to the FDA (and a copy to us, if possible) as soon as you can.

We have recently established a Clearinghouse for attorneys who are handling litigation against the manufacturers. While we do not recommend individual attorneys, we will be able to provide a list of attorney members that you may wish to contact concerning your individual situation. We expect the Clearinghouse to be operating by the end of February, so feel free to contact us at that time for a list of attorney members.

For your information, Public Citizen Health Research Group is a non-profit consumer research and advocacy organization that provides advice and oversight regarding drugs, medical devices, health services and occupational health. Thank you for contacting us.

Sincerely,

THE HEALTH RESEARCH GROUP

Ralph Nader, Founder

2000 P Street NW • Washington, D.C. 20036 • (202) 833-3000

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Joan Claybrook, President

December 20, 1994

Dr. David Kessler
Commissioner, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler,

The enclosed report asks you to call for a moratorium of most uses of pedicle screw fixation systems because of a lack of evidence that in most cases where they are being used, the risks are outweighed by the benefits. We also ask FDA to initiate other regulatory actions to stop this epidemic of dangerous spinal surgery with unapproved medical devices.

During the past ten years, unapproved pedicle screw fixation systems (screws used along with plates or rods to increase the likelihood of fusion of two vertebrae) have been implanted into the spines of an estimated 350,000 patients in the United States. An additional 50,000 to 70,000 patients per year are now having such devices implanted.

We have examined FDA documents, analyzed results of a survey that we conducted of injured pedicle screw implant patients, reviewed medical literature concerning spinal surgery using pedicle screw systems and obtained many documents including depositions of orthopedic surgeons who have implanted pedicle screws. We have also interviewed several prominent spinal surgeons who are severe critics of pedicle screws, none of whom had previously been contacted by FDA.

The primary culprits in this disaster, which has resulted in thousands of injuries, are the companies making and promoting pedicle screws (advertisements were found in recent orthopedic journals by Danek, Smith & Nephew, Depuy Motech, Acromed, EBI Medical Systems, and Corin Medical) and those orthopedic surgeons who have greatly profited by implanting these unproven, dangerous and expensive devices for indications for which there is no evidence they are effective. But the findings of our investigation - detailed in the enclosed report *Public Citizen Health Research Group Investigation of Pedicle (Spinal) Screw Implantation* - also implicate FDA because of its negligent response to the problem. At present,

the devices are almost completely unregulated by FDA. Among our findings are the following:

- The very high prevalence of low back pain among the adult population in this country has set the stage for pedicle screw systems to be grossly overused (pp.1-3 of report).

- Pedicle screw fixation devices have a prohibitively high complication rate (33 percent), and a high breakage rate (10 percent)(pp.6-8).

- The vast majority of patients who received the systems were not given anything remotely resembling informed consent as required. Thus, the pedicle screw debacle amounts to a practice of widespread experimentation upon most of the more than 350,000 Americans so far, to their serious and permanent detriment (p.12).

- Fusion without internal fixation is as effective as and safer than fusion with pedicle screw instrumentation (pp.4-6).

- Instrumentation during fusion confers a **twofold increased risk** for reoperation compared with fusion without instrumentation (p.5).

- According to Dr. James Bayley, an orthopedic surgeon, pedicle screws are inserted "blindly; in other words, you can't see where the tip of the screw is going," thus they are difficult to insert optimally (p.10). Yet many surgeons who use them learned the procedure during two- and three-day seminars taught by doctors with a financial interest in the companies (pp.14-16).

- Manufacturers have been blatantly and illegally promoting the screws for use in the pedicle (spine) for eight years, despite FDA's express notification that they are not approved for any use in the spine. Such promotion continues because the FDA has failed to criminally prosecute companies or impose civil penalties despite repeat violations (p.11). As a result, physician users of the screws were commonly unaware of the lack of FDA approval.

- Pedicle screw surgery is tremendously profitable for everyone involved: manufacturers, orthopedic and neurosurgeons, neurologists, hospitals and radiologists (p.16). There seems to be a conspiracy of silence about the risks among members of industry and much of the medical and hospital communities because of the profitability and a fear of litigation.

- The Orthopedic Surgery community has threatened to blackball any surgeon who speaks against the use of pedicle screws (p.16).

- Much of the published literature related to pedicle screws was authored by orthopedic surgeons who have financial interests in the manufacturers (pp.17-18).

- The FDA Orthopedic Device Advisory Committee Panel's July 22, 1994

recommendation to downclassify pedicle screw devices from Class III to class II was based on seriously flawed retrospective studies (pp.18-20).

- Survey results from members of two support groups for pedicle screw patients showed that 75 percent of the respondents had received the screws for herniated, ruptured or slipped discs, and other conditions where the use of the devices is not supported by any known scientific evidence. Furthermore, an additional 14 percent received the screws for spondylolisthesis (a forward displacement of one vertebra over a lower one)(p.20). According to three spinal surgery experts we consulted, only 10 percent (maximum) of patients with this condition (spondylolisthesis) are expected to respond favorably to treatment with pedicle screw systems. Thus, nearly 90 percent of the respondents underwent what data indicates to be dangerous and unwarranted pedicle screw implantation.

We urge the FDA to take the following measures without further delay:

1. declare a moratorium on most uses of bone screws in the spine until manufacturers can show that they are safe and effective.

2. reject the July 22, 1994 FDA Orthopedic Device Advissory Committee Panel's recommendation to downclassify pedicle screw devices from class III to class II (for spinal fractures and degenerative spondylolisthesis only), and require manufacturers to conduct prospective randomized controlled trials to demonstrate the safety and effectiveness of the devices for each use where it is not clear there is a benefit.

3. immediately move for substantial criminal or civil penalties against each manufacturer that illegally promoted the pedicle screw systems.

4. require that large box warnings, such as the following, be placed on the labeling for each bone screw to alert the surgeon that if he or she uses it in the spine, he or she does so with full knowledge that it is not approved for that use, and does so at his or her own risk:

WARNING!

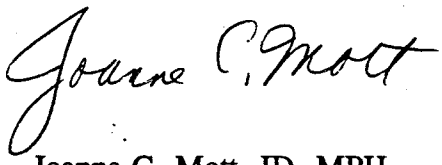
This device is approved for use in long bones (arms and legs) only! It is contraindicated for use in the spine, except under investigational (experimental) use!

Use of this device in the pedicle of the spine has the following complications: neurologic deficits, vascular (blood vessel) injuries, epidural hematoma (collection of blood in the space around the spinal cord), device breakage, device slippage, device migration, device malpositioning, wound complications, infection, cauda equina syndrome (progressive paralysis and/or weakness of the lower extremities), cerebrospinal fluid leakage, neurogenic bladder/bowel control problems, skin breakdown, and pseudoarthrosis (area in the fusion mass that does not heal).

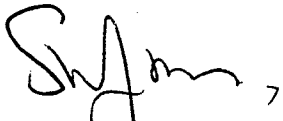
5. require that every patient hereafter implanted with a pedicle screw fixation device sign an FDA-approved informed consent sheet. The sheet must state that (a) the device is contraindicated for use in the spine except as part of investigational studies, (b) the use of the devices confers a two-fold higher risk of reoperation than noninstrumented fusion, and (c) there is a significant risk of complications as set forth in the above box warning.

1,000 to 1,350 people are being implanted with these devices weekly in the United States. For most of these people, the risks greatly outweigh the unproven benefits. We look forward to your prompt effort in addressing this urgent situation for which FDA must accept a share of the blame.

Sincerely,

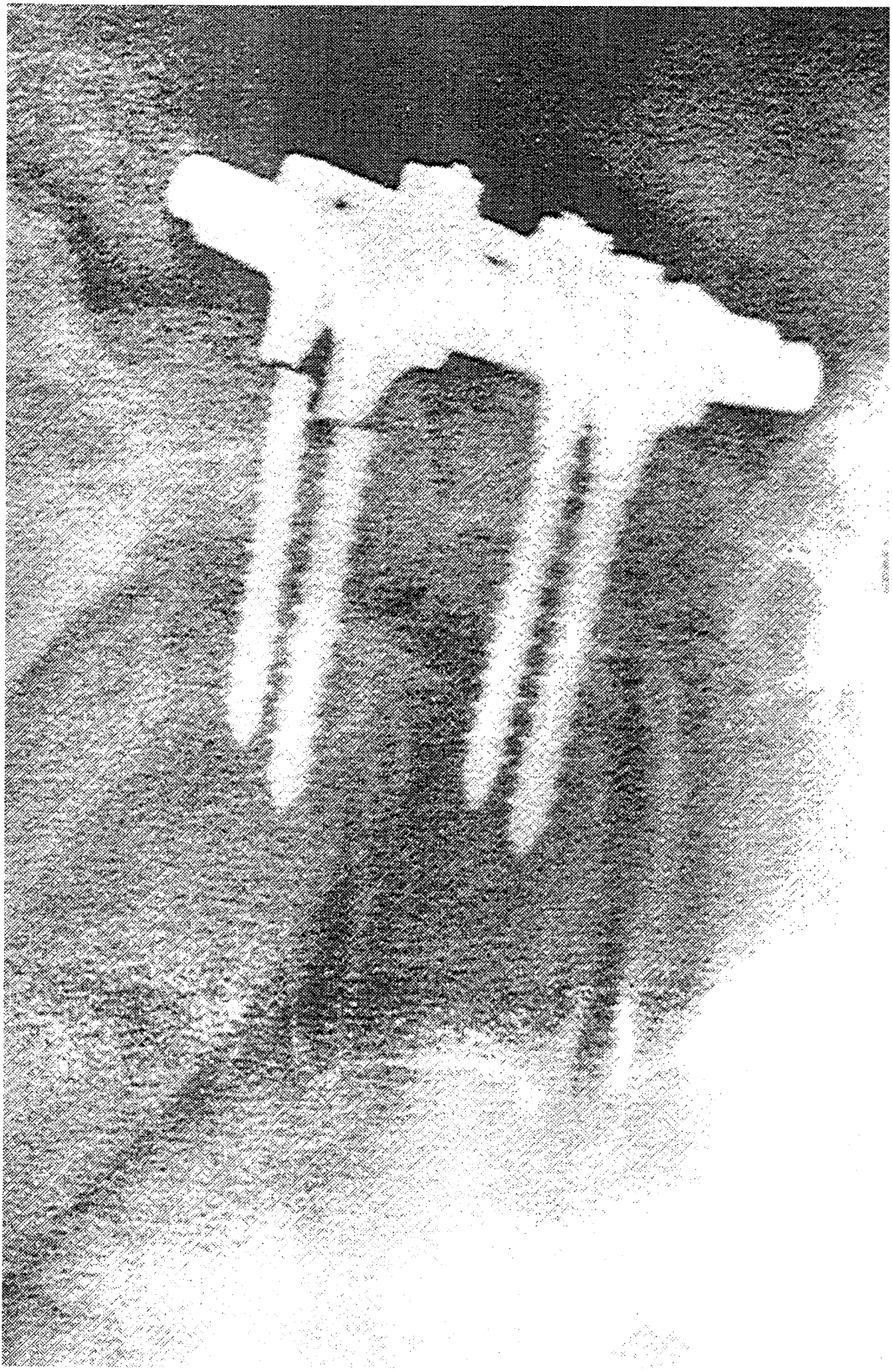


Joanne C. Mott, JD, MPH
Staff Attorney



Sidney M. Wolfe, MD
Director

PUBLIC CITIZEN HEALTH RESEARCH GROUP



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

A. Patient information

1. **Patient identifier**
In confidence

2. **Age at time of event:**
or
Date of birth:

3. **Sex**
☐ female
☐ male

4. **Weight**
____ lbs
or
____ kgs

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)
☐ death _____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: _____

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

4. **Date of this report** (mo/day/yr)

5. **Describe event or problem**

6. **Relevant tests/laboratory data,** including dates

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)

1. **Name** (give labeled strength & mfr/labeler, if known)
#1
#2

2. **Dose, frequency & route used**
#1
#2

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
#1
#2

4. **Diagnosis for use** (indication)
#1
#2

5. **Event abated after use stopped or dose reduced**
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
#1
#2

7. **Exp. date** (if known)
#1
#2

8. **Event reappeared after reintroduction**
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. **NDC #** (for product problems only)
– –

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

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

4. **Operator of device**
☐ health professional
☐ lay user/patient
☐ other: _____

5. **Expiration date** (mo/day/yr)

6.
model #
catalog #
serial #
lot #
other #

7. **If implanted, give date** (mo/day/yr)

8. **If explanted, give date** (mo/day/yr)

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 of 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 identity disclosed to the manufacturer, place an " X " in this box.** ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

***or* FAX to:**
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Joan Claybrook, President

Copies of this report are available for:

$10.00 (consumers and public interest groups)
$50.00 (others) from:

Public Citizen Publications
2000 P St., NW
Suite 600
Washington, DC 20036

Ralph Nader, Founder

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Joan Claybrook, President

January 10, 1995

Dear Consumer,

Thank you very much for participating in our Pedicle Screw Survey. Enclosed is the report that Public Citizen Health Research Group submitted to Dr. David Kessler, Commissioner of the Food and Drug Administration (FDA), on December 20, 1994. Your input was valuable in compiling the report.

We have also enclosed a MedWatch form, and suggest that you fill it out and send it to the FDA, if you have not already done so. Please send us a copy of your completed MedWatch form. It is very important that the FDA become aware of the serious problems and injuries suffered by people who have been implanted with pedicle screws.

Sincerely,

Joanne C. Mott, MPH
Staff Attorney

Sidney M. Wolfe, MD
Director

PUBLIC CITIZEN HEALTH RESEARCH GROUP

Ralph Nader, Founder

2000 P Street NW • Washington, D.C. 20036 • (202) 833-3000

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

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MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787