

SAM MAYWOOD, M.D.

ACUTE & CHRONIC PAIN MANAGEMENT
DIPLOMATE AMERICAN BOARD OF ANESTHESIOLOGY
QUALIFIED MEDICAL EXAMINER, STATE OF CALIFORNIA

3444 KEARNY VILLA ROAD, SUITE 305
SAN DIEGO, CALIFORNIA 92123

9536 '00 OCT 24 P2:14

OFFICE (858) 874-0033
FAX (858) 874-8957

October 12, 2000

Dockets Management Branch (HFA/305)
U. S. Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

I am an anesthesiologist who specializes in chronic pain management in San Diego. I am writing to you in regard to the FDA's intention to reclassify implantable spinal cord stimulators from a class III to a class II status. I am vehemently opposed to that reclassification.

I am currently an instructor for several independent foundations who teach spinal cord stimulator implantation to other physicians. We are regarded in our area as being the most experienced in the performance of these implantations. These are extremely complex and dangerous procedures, which involve a high level of surgical skill. The implantation of these stimulators involves either a laminotomy or a percutaneous approach to the epidural space. Movement of a needle or device even as much as 1 mm. could cause serious complications in patients, such as bleeding, infection, paralysis or even death. The spinal cord is obviously one of the most sensitive areas of the body. It takes a highly trained and highly skilled practitioner to be able to perform these relatively dangerous procedures with success.

Secondarily, the devices themselves are electrical devices which again require a high amount of skill in their reprogramming and use. If these devices are turned on at an extremely high level, it can cause shocking pains directly to the spinal cord, which could cause severe and lasting, permanent effects on patients. At the current level of classification, these devices require the highest level of service as well as skill in order to perform the implantation successfully.

I find it extremely difficult to understand why anyone would want to reclassify these and lower the level of safety.

In 1995, the FDA had classified these devices as potentially high risk. I believe that any change would be a potential lowering of standards which

000-1455
00P-0788

C21

U. S. Food & Drug Administration
October 12, 2000
Page Two

could endanger these already fragile patients. The quality of the products produced by the manufacturers at this point is extremely high. I can envision easily that several manufacturers who wish to gain entry into this potentially lucrative market would indeed produce products that would be implanted in the body with a much lower level of quality.

I hope that you will take these comments in the constructive manner in which they are intended. It is not often that I write letters of this type to regulatory bodies, however, my feelings on this subject are sufficiently strong that I felt compelled to respond. If I can provide any further information, please feel free to contact me at (858) 874-0033.

Sincerely yours,



Sam Maywood, M.D.
Diplomate, American Board Of Anesthesiology
Qualified Medical Examiner, State Of California

SM/e

SAM MAYWOOD, M.D.

ACUTE & CHRONIC PAIN MANAGEMENT
DIPLOMATE AMERICAN BOARD OF ANESTHESIOLOGY
QUALIFIED MEDICAL EXAMINER, STATE OF CALIFORNIA

3444 KEARNY VILLA ROAD, SUITE 305
SAN DIEGO, CALIFORNIA 92123

OFFICE (858) 874-0033
FAX (858) 874-8957

October 16, 2000

Gregory Wiener, M.D.
353 Church Avenue
Chula Vista, California 91910

RE: HOPPEL, MARCOS

Dear Dr. Wiener:

Thank you for your kind and thoughtful referral of Marcos Hoppel. The following is my comprehensive pain evaluation of Mr. Hoppel from October 16, 2000.

HISTORY OF INJURY:

Marcos Hoppel is a 43-year-old male with a history of chronic abdominal pain for approximately 12 years. He reports that he was diagnosed with cirrhosis of the liver 12 years ago and underwent a surgical procedure in which a Denver shunt was placed. He reports that he had decreasing abdominal pain following the procedure but he continued to abuse alcohol and had bouts of pancreatitis secondary to that.

The patient reports that, over the past six months, his abdominal pain has progressively worsened. His family doctor has been prescribing Tylenol #3 for his pain, which he reports gives him significant relief but it only lasts for a couple of hours. The patient admits to increasing his Tylenol #3 on his own to 6-7 tablets per day.

The patient has been kindly referred to our office for evaluation and medication management.

CURRENT COMPLAINTS:

The patient describes generalized abdominal pain which is cramping in nature and constant. He reports that the pain increases with activities and decreases with eating. He denies any radiation of pain. He rates his pain as 8-9/10 on the VAS scale. He reports that he has had associated poor appetite.

PAST SURGICAL HISTORY:

Status post crush injury to both legs with pinning of the ankles and knees bilaterally; status post placement of Denver shunt, as above; cholecystectomy; tonsillectomy; surgical repair of the right wrist.

RE: HOPPEL, MARCOS
October 16, 2000
Page Two

PAST MEDICAL HISTORY:

Colitis, hepatitis, cirrhosis of the liver and pancreatitis.

ALLERGIES:

No known allergies.

CURRENT MEDICATIONS:

Bentyl, Lomotil, Pancrease, Remeron, Wellbutrin and Tylenol #3.

SOCIAL HISTORY:

The patient is divorced with no children.

HABITS:

The patient has been sober for 29 days. He smokes 1/2 pack of cigarettes per day and has done so for 20 years.

PHYSICAL EXAMINATION:

An alert, oriented male, well-developed, well-nourished, in no acute distress.

VITAL SIGNS:

Stable.

NECK:

Full range of motion of the neck; no bruits.

CHEST:

Clear to auscultation.

CARDIOVASCULAR:

Regular rate and rhythm; no murmurs.

ABDOMEN:

No abdominal distention; midline, well-healed surgical scar with some diffuse tenderness; positive hepatomegaly; positive varicosities; positive bowel sounds.

BACK:

Range of motion of the lumbar spine reveals forward flexion to 60°; extension to 10°; lateral bending to 10° bilaterally; rotation to 10° bilaterally; no pain on palpation of the posterior lumbar region or bilateral sacroiliac joint areas.

RE: HOPPEL, MARCOS
October 16, 2000
Page Three

EXTREMITIES:

Upper extremity exam reveals normal grip strength; neurological examination within normal limits; full range of motion; reflexes and pulses intact in both upper extremities.

Lower extremity exam reveals negative straight leg raising bilaterally; 5+ strength to plantar and dorsiflexion bilaterally; no sensory loss to pinprick; reflexes and pulses intact in both lower extremities.

DIAGNOSIS:

1. Chronic abdominal pain.
2. History of pancreatitis.
3. Cirrhosis.
4. History of hepatitis.
5. History of alcoholism, sober for one month.

DISCUSSION:

Marcos Hoppel is a 43-year-old male with a long history of chronic abdominal pain secondary to pancreatitis and cirrhosis of the liver. He has obtained some relief with Tylenol #3, however, his pain relief is only transient. He admits to a long history of alcoholism, having been sober for 29 days now.

I would be very cautious in treating this patient with narcotics. However, I believe that his abdominal pain is real. At today's appointment, I have instructed him to discontinue the Tylenol with Codeine secondary to the acetaminophen, which may further damage his liver. I would like to place the patient on a long acting narcotic and have given him a prescription for Oxycontin 20 mg. 1-2 tablets PO q 12 h for pain, dispense 120 with no refills. This is a pure narcotic of oxycodone, without any acetaminophen. It is a sustained release medication and should give him a more stable level of pain control. The patient was instructed not to drink alcohol with this medication. He has signed the narcotic agreement and refill policy at our facility.

I would recommend to Dr. Wiener that we will provide all the patient's prescription refills for his pain medications and monitor his refills at his pharmacy.

It should be noted that I have examined the patient and my conclusions are based on the patient's history, my examination, and the medical records available to me at this time. However, should additional information or medical records become available, in the future, I would reserve the right to change my conclusions, accordingly.

RE: HOPPEL, MARCOS
October 16, 2000
Page Four

I greatly appreciate the opportunity to participate in this patient's care, your confidence and referral.



Michael Moon, M.D.
Diplomate, American Board of Physical Medicine
and Rehabilitation

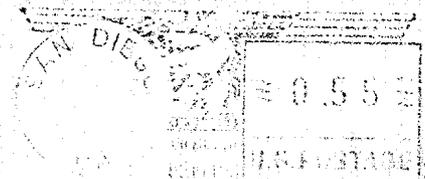


Sam Maywood, M.D.
Diplomate, American Board of Anesthesiology
Qualified Medical Examiner, State Of California

SM/MM/e
D: 10/16/00
T: 10/16/00

SAM MAYWOOD, M.D.

3444 KEARNY VILLA ROAD, SUITE 305
SAN DIEGO, CALIFORNIA 92123



DOCKETS MANAGEMENT BRANCH (HFA/305)
U.S. FOOD + DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MARYLAND 20852