

A deadly dishonor roll

FDA-approved drugs withdrawn from market show fallibility of ‘gold standard’ clinical trials

Reports of safety and effectiveness from doctors who have monitored cannabis use by more than a million US citizens are dismissed by the government and the medical establishment with a simple assertion (that happens to be false): “There have been no randomized controlled trials.”

The reality is that there have been numerous RCTs confirming the safety and efficacy of cannabis in treating various conditions. Elsewhere in this issue Dr. Dustin Sulak refers to 11 RCTs of cannabis in the treatment of pain.

Randomized, placebo-controlled clinical trials are considered “the gold standard” in establishing the safety and effectiveness of a drug. The Food and Drug Administration relies solely on results from RCTs in approving products for the market.

Drug policy reformers often point out that the government has created huge hurdles for researchers who would study cannabis as medicine. But few question the vaunted status of RCTs themselves.

Some 35 drugs whose safety and efficacy were established in randomized, placebo-controlled trials to the satisfaction of the FDA have been removed from the market after patterns of harm emerged in the broader population. We are grateful to Pro-Con.org for listing them.

The FDA orders a manufacturer to stop selling a product “when its risks outweigh its benefits. A drug is usually taken off the market because of safety issues with the drug that cannot be corrected, such as when it is discovered that the drug can cause serious side effects that were not known at the time of approval.”

(It often turns out that a drug’s dangerous side effects were known to the manufacturer, but concealed from the FDA. Manufacturers don’t have to report the result of trials that show little benefit and/or recurrent adverse effects.)

Accutane (Isotretinoin)

Use: Acne
Manufacturer: Hoffman-La Roche
Years on the market: 27 (1982 to 2009)

Cause for recall: increased risk of birth defects, miscarriages, and premature births when used by pregnant women; inflammatory bowel disease; suicidal tendencies

More than 7,000 lawsuits were filed against the manufacturer over the side effects including a \$10.5 million verdict and two \$9 million verdicts.

Baycol (Cerivastatin)

Use: Cholesterol reduction



Manufacturer: Bayer A.G.
Years on the market: three (1998-2001)
Cause for recall: rhabdomyolysis (breakdown of muscle fibers that results in myoglobin being released into the bloodstream) which led to kidney failure; 52 deaths (31 in the US) worldwide; 385 nonfatal cases with most requiring hospitalization; 12 of the deaths were related to taking this drug in combination with gemfibrozil (Lopid).

Bextra (Valdecocixib)

Use: Pain relief
Manufacturer: G.D. Searle & Co.
Years on the market: 3.3 (2001-2005)

Cause for recall: Serious cardiovascular adverse events (death, heart attack, stroke); increased risk of serious skin reactions (like toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme); gastrointestinal bleeding.

The FDA determined that Bextra, a non-steroidal anit-inflammatory drug, showed no advantage over other NSAID pain relievers on the market.

Cylert (Pemoline)

Use: Central nervous system stimulant to treat ADHD/ADD
Manufacturer: Abbott Laboratories
On the market for 35 years (1975-2010)
Cause for recall: liver toxicity
The FDA added a box warning to Cylert in 1999, alerting doctors and patients to the potential of liver damage.

Darvon & Darvocet (Propoxyphene)

Use: Opioid pain reliever
Manufacturer: Xanodyneon
On the market 55 years (1955 to 2010)
Cause for recall: serious toxicity to the heart. Between 1981 and 1999 there were more than 2,110 deaths reported.
The UK banned Darvon and Darvocet in 2005. The FDA was petitioned in 1978 and

again in 2006 to ban the drug by the group Public Citizen.

DBI (Phenformin)

Use: antidiabetic
Manufacturer: Ciba-Geigy
On the market for 19 years (1959-1978)
Cause for recall: lactic acidosis (low pH in body tissues and blood and a buildup of lactate) in patients with diabetes.

7. DES (Diethylstilbestrol)

Use: synthetic estrogen to prevent miscarriage, premature labor, and other pregnancy complications
Manufacturer: Grant Chemical Company
On the market 31 years (1940 to 1971)
Cause for recall: clear cell adenocarcinoma (cancer of the cervix and vagina), birth defects, and other developmental abnormalities in children born to women who took the drug while pregnant; increased risk of breast cancer, higher risk of death from breast cancer; risk of cancer in children of mothers taking the drug including raised risk of breast cancer after age 40; increased risk of fertility and pregnancy complications, early menopause, testicular abnormalities; potential risks for third generation children (the grandchildren of women who took the drug).
Studies in the 1950s showed the drug was not effective at preventing miscarriages, premature labor, or other pregnancy complications.

Duract (Bromfenac)

Use: Pain killer
Manufacturer: Wyeth-Ayerst
On the market July 1997 through 1998
Cause for recall: 4 deaths; 8 patients requiring liver transplants; 12 patients with severe liver damage
Duract was labeled for maximum use of 10 days but patients often received/took more than 10 days worth of pills; all cases of death and liver damage involved patients taking pills for longer than 10 days.

Ergamisol (Levamisole)

Use: Worm infestation; colon and breast cancers; rheumatoid arthritis
Manufacturer: Janssen Pharmaceutica
On the market for 11 years (1989-2000)
Cause for recall: neutropenia (a type of low white blood cell count), agranulocytosis (a type of low white blood cell count), and thrombotic vasculopathy (blood clots in blood vessels) which results in retiform purpura (a purple discoloration of the skin that can sometimes require reconstructive

surgery)
Levamisole is still used to treat animals with worm infestations in the US. It is also being found in street cocaine as an adulterant to increase euphoric qualities.

Hismanal (Astemizole)

Use: Antipsychotic
Manufacturer: Janssen Pharmaceutica
On the market 11 years (1988-1999)
Cause for recall: slowed potassium channels in the heart that could cause torsade de pointes (TdP; a heart condition marked by a rotation of the heart’s electrical axis) or long QT syndrome (LQTS; prolonged QT intervals)

Lotronex (Alosetron)

Use: Irritable bowel syndrome (IBS) in women
Manufacturer: Prometheus Laboratories,
On the market less than a year (Feb. 9, to Nov. 28, 2000)
Cause for recall: 49 cases of ischemic colitis (inflammation and injury of the large intestine); 21 cases of severe constipation (10 requiring surgery); 5 deaths; mesenteric ischemia (inflammation and injury of the small intestine)
Lotronex was reintroduced to the US market in 2002 with restricted indication.

Meridia (Sibutramine)

Use: Appetite Suppressant
Manufacturer: Knoll Pharmaceuticals
On the market 13 years (1997 to 2010)
Cause for recall: increased cardiovascular and stroke risk.
FDA reviewer Dr. David Graham listed Meridia with Crestor, Accutane, Bextra, and Serevent as drugs whose sales should be limited or stopped because of their danger to consumers in Sep. 30, 2004 testimony before a Senate committee,

Merital & Alival (Nomifensine)

Use: Antidepressant
Manufacturer: Hoechst AG (now Sanofi-Aventis)
On the market three years (1982 to 1985)
Cause for recall: haemolytic anemia; some deaths due to immunohemolytic anemia

Micturin (Terodiline)

Use: Bladder incontinence
Manufacturer: Forest Labs
On the market two years (1989 to 1991)
Cause for recall: QT prolongation (irregular heartbeat) and potential for cardio-toxicity.

Cylert® (pemoline)

offers these benefits in a treatment program for MBD

- Single daily dose administration
- Minimal cardiovascular effects
- Mean dosage in long-term studies remained remarkably constant

EFFICACY
Multi-clinic study^{1,2}
21 investigators from 10 states and two provinces in Canada took part in the clinical studies.
Double-blind, placebo control
413 patients were randomly assigned to Cylert or placebo groups. 218 patients met all criteria for evaluation of efficacy.
Psychological test results
Children on Cylert had significantly higher scores statistically than those on placebo on these psychological tests:
• The Wechsler Intelligence Scale for Children (WISC) and its performance IQ Sub-Component Factor II
• The Wide Range Achievement Test (WRAT) (reading and arithmetic)
Overall results
Approximately two out of three patients were significantly improved by treatment with Cylert as reflected by global ratings.

SAFETY
Multi-clinic study (9 weeks); safety data analyzed on 407 patients
There was no significant difference between Cylert and placebo groups in:
• Blood pressure
• Laboratory tests
• Pulse
• Neurological status
Insomnia and anorexia were the most frequently seen side effects and often improved with continuation of treatment or reduction of dosage.
Mean weight loss of 1.1 lbs. was demonstrated in the Cylert group during early weeks of treatment; long-term studies have shown that by 3-6 months, most children return to the normal rate of weight gain for their age group.
Long-term study on Cylert up to 3 years and continuing
Mean dosage . . . remained remarkably constant.
Blood pressure . . . no significant changes attributed to Cylert.
Pulse rate . . . no significant changes attributed to Cylert.
Laboratory examination—mild to moderate increase in transaminase (SGOT and SGPT) levels in 1-2% of patients (no clinical symptoms); levels returned to normal on withdrawal of medication.
No clinically significant abnormalities in the other tests.

1. Coates, C. K., et., Clinical Use of Stimulant Drugs in Children. Excerpta Medica, 1974, p. 98.
2. Page, J. G., et al., Learning Disabilities, 7:149, Oct., 1974.

Please see last page of this advertisement for Prescribing Information.

Abbot’s marketing materials for Cylert appeared in four-page ad inserts in prestigious medical journals. Text in ad at left: “Goodenough-Harris Draw-a-Person test from a study in which Cylert was included in the treatment program. Drawing made prior to treatment.(left). Drawing made at week 5 during treatment.”

Importance of single daily dosage to the child, the parents and the teacher

For the child
No drug in child’s possession while at school
Avoids situation in which child is repeatedly singled out as being “different”
Helps prevent possible variations in effect caused by missed, forgotten or delayed doses

For the adults
Control of medication remains with parents
Obviates need for nurse or teacher to supervise taking of mid-day doses
Helps assure that the prescribed dosage is being given each day

Cylert (pemoline), alone among CNS stimulants used to treat MBD, is inherently long-acting, permitting once-daily dosage.

Cylert can be taken with meals
You can prescribe Cylert a.s.c., p.c., or with meals. Although the speed of absorption is slightly slowed by food, the total absorption is not affected.

Dosage and administration
Cylert is given as a single oral dose each morning. The recommended starting dose is 37.5 mg. per day. This daily dosage should be gradually increased at one-week intervals using increments of 18.75 mg. until the desired clinical response is obtained.
The mean daily effective dose ranges from 56.25 to 75 mg. per day. The maximum recommended daily dose of Cylert is 112.5 mg.
Using the recommended schedule of dose titration, significant benefits may not be seen until the third or fourth week of drug therapy. Side effects may be seen prior to optimum clinical results.

When not to use Cylert
Cylert should not be used for (and will not be effective in) simple cases of overactivity in school-age children.
Neither should it be used in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis.
The physician should rely on a complete history of the child and a thorough description of symptoms from both parents and teacher before postulating a diagnosis of MBD.

The three dosage strengths of Cylert (pemoline)

Cylert, 18.75 mg. (white-coated, gloveless)	Cylert, 37.5 mg. (orange-coated, gloveless)	Cylert, 75 mg. (tan-coated, gloveless)
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Tablets are actual size.

Prescribing Information

Description: Cylert (pemoline) is a white, tasteless, odorless powder which is relatively insoluble (less than 1 mg/ml) in water, chloroform, ether, acetone, and benzene. It is 95% ethyl alcohol, the solubility of pemoline is 2.2 mg/ml.

Actions: Cylert (pemoline) is a central nervous system stimulant. The pharmacologic activity of pemoline is similar to that of other known stimulants but with the sympathetic and metabolic effects. Pemoline is structurally dissimilar from the amphetamines and methylphenidate. Although the exact mode of pharmacodynamic action is undetermined, in many pemoline has been reported to increase the rate of synthesis of dopamine in the brain.
In human subjects, Cylert produces peak blood levels within 2-4 hours. The serum half-life is approximately 12 hours. Multiple dose studies in adults have shown that steady state is achieved after three to five days. Although a definite causal relationship has not been established, some temporary suppression of prepubertal growth/pediatric weight gain and/or height has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

Warnings: Cylert is not recommended for use in children under six years of age. Since safety and efficacy in this age group have not yet been established, extreme caution should be observed in administering the drug to children with significantly impaired renal function.
Sufficient data on safety and efficacy of Cylert in children is not available. In two-year studies in children with minimal mild hyperactivity are not yet available. Although a definite causal relationship has not been established, some temporary suppression of prepubertal growth/pediatric weight gain and/or height has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

Drug Interactions: Interactions between Cylert and other drugs have not been studied in humans. As with most other drugs, concurrent administration with other agents, especially drugs with central nervous system activity, should be carefully monitored.

Usage in Pregnancy: Safety for use in pregnancy has not been established. Studies of fetal development in rats and rabbits. Daily oral doses of pemoline of 18.75 and 37.5 mg/kg beginning at conception produced no abnormalities in the fetuses and did not affect viability at birth. Further studies using similar dose levels with drug administration beginning 14 days before conception demonstrated an increased incidence of stillbirths in these animals.

Drug Dependence: Studies of the drug abuse potential of Cylert (pemoline) in primates have not demonstrated a potential for self-administration. However, the pharmacologic similarities between Cylert and other CNS stimulants with known abuse liability suggest that drug dependence of the stimulant type might occur. There have been isolated reports of transient psychotic symptoms in adults taking only in excessive quantities. Therefore, caution should be observed in emotionally unstable patients considered to have a psychological potential for drug dependence.

Precautions: Delayed hypersensitivity reactions involving the liver have been reported in 1-2% of the patients receiving Cylert usually after several months of therapy. No clinical symptoms have been observed, but mild to moderate increases in transaminase (SGOT and SGPT) levels have occurred in these cases. These effects appear to be completely reversible when drug treatment is discontinued. Transaminase levels should be determined periodically during therapy with Cylert to detect any such reactions.

Adverse Reactions: The most frequently reported adverse reaction with Cylert is insomnia. Insomnia has been observed prior to optimum therapeutic response and in the majority of cases has been observed in patients with dosage reduction. Anorexia with weight loss during the first few weeks of therapy has also been reported. With continuing therapy, a return to a normal weight curve usually occurred within three to six months. Other adverse reactions reported include: headache, nausea, dizziness, headache, drowsiness, nervousness, irritability, mild depression, and constipation. Mild adverse reactions appearing early in treatment often result in discontinuing therapy. If adverse reactions are of a significant or protracted nature, dosage reduction or discontinuation should be considered.

Dosage and Administration: Cylert (pemoline) is administered as a single oral dose each morning. The recommended starting dose is 37.5 mg. per day. This daily dosage should be gradually increased at one week intervals using increments of 18.75 mg. until the desired clinical response is obtained. The mean daily effective dose ranges from 56.25 to 75 mg. per day. The maximum recommended daily dose of pemoline is 112.5 mg.
Clinical improvements with Cylert is gradual. Using the recommended schedule of dosage titration, significant benefits may not be evident until the third or fourth week of drug administration. Drug administration should be interrupted occasionally to determine if behavioral symptoms sufficient to require continuing therapy recur.

Overdosage: Cylert overdosage has been reported to produce symptoms of tachycardia, hallucinations, agitation, or confusion. The treatment of acute massive overdosage with pemoline is essentially the same as that for overdosage with any drug having CNS stimulatory effects. Management should include induction of emesis, gastric lavage or other manipulative procedures.

How Supplied: Cylert (pemoline) is supplied in three dosage strengths: 18.75 mg. (white-coated), 37.5 mg. (orange-coated), and 75 mg. (tan-coated) in bottles of 100 (NDC 0074-0073-13) and 250 (NDC 0074-0073-13) 75 mg. tablet (tan-coated) in bottles of 100 (NDC 0074-0073-13).

Abbott Laboratories
North Chicago, IL 60064

Second ad describes Cylert as a treatment for “MBD,” which readers knew meant “Minimal Brain Damage.” Now it’s dubbed Attention Deficit Disorder (ADD) and Attention Deficit Disorder with Hyperactivity (ADHD). Cylert has given way to Ritalin and Adderall

Withdrawn Drugs continued from previous page

Mylotarg (Gemtuzumab Ozogamicin)
Use: Acute myeloid leukemia (AML, a bone marrow cancer).
Manufacturer: Wyeth
On the market 10 years (2000-2010).
Cause for recall: increased risk of death and veno-occlusive disease (obstruction of veins).

Omniflox (Temafloracin)
Use: Antibiotic for pneumonia, bronchitis, and other respiratory tract infections; prostatitis and other genitourinary tract infections; skin ailments.
Manufacturer: Abbot Laboratories
On the market Jan. 31 to June 5, 1992
Cause for recall: three deaths; severe low blood sugar; hemolytic anemia and other blood cell abnormalities; kidney dysfunction (half of the cases required renal dialysis); allergic reactions including some causing life-threatening respiratory distress.

[The true extent of the damage caused by Omniflox and the vile duplicity of Abbot execs is laid out in a great book by Stephen Fried, “Bitter Pills.” See sidebar *WHERE*.]

Palladone (Hydromorphone hydrochloride, extended-release)
Use: Narcotic painkiller
Manufacturer: Purdue Pharma
On the market January to July 13, 2005
Cause for recall: high levels of palladone could slow or stop breathing, or cause coma or death; combining the drug with alcohol use could lead to rapid release of hydromorphone, in turn leading to potentially fatally high levels of drugs in the system

Permax (Pergolide)
Manufacturer: Valeant
On the market nine years (1988-2007)
Cause for recall: valve regurgitation (a condition that causes the valves to not close tightly, which allows blood to flow backward over the valve) in the mitral, tricuspid, and aortic heart valves, which can result in shortness of breath, fatigue, and heart palpitations
Permax is still available in the U.S. for veterinary use, specifically for pituitary pars intermedia hyperplasia or equine Cushing’s Syndrome (ECS) in horses.

Pondimin (Fenfluramine)
Use: Appetite suppressant
Manufacturer: Wyeth-Ayerst
On the market 24 years (1973 to 1997)
Cause for recall: 30% of patients prescribed the drug had abnormal echocardiograms; 33 cases of rare valvular disease in women; 66 additional reports of heart valve disease
Pondimin is better known as “Fen-Phen” when prescribed with Phentermine.

Posicor (Mibefradil)
Use: Calcium channel blocker (used to treat hypertension)
Manufacturer: Roche Laboratories
On the market 1 year (June ‘97 to June ‘98)
Cause for recall: fatal interactions with at least 25 other drugs, including common antibiotics, antihistamines, and cancer drugs) including astemizole, cisapride, terfenadine, lovastatin, and simvastatin
Posicor was found by the FDA to offer no significant benefit over other antihypertensive or antianginal drugs, which made the risks of drug interactions “unreasonable.” Patients immediately switching from Posicor to another calcium channel blocker were at increased risk of going into shock within 12 hours of the drug switch.

Propulsid (Cisapride)
Use: Severe nighttime heartburn associated with gastroesophageal reflux disease (GERD)
Manufacturer: Janssen Pharmaceutical
On the market seven years (1993-1970).
Cause for recall: more than 270 cases of



serious cardiac arrhythmias (including ventricular tachycardia, ventricular fibrillation, torsades de pointes, and QT prolongation) reported between July 1993 and May 1999, with 70 being deaths.

Propulsid is also banned in India (2011) and available for limited use in Europe. It is still available for use in animals in the US and Canada.

Quaalude (Methaqualone) Marketed as: Optimal, Sopor, Parest, Somnafac, and Bi-Phetamine T.
Use: Sedative and hypnotic
Manufacturer: William H. Rorer Inc. & Lemmon Company
On the market for 23 years (1962 to 1985)
Cause for recall: mania; seizures; vomiting; convulsions; death.

Methaqualone was originally tested in India as a malaria treatment (it was ineffective). The drug is now a schedule 1 drug in the United States (like heroin, marijuana, and LSD).

Raplon (Rapacuronium)
Use: Non-polarizing neuromuscular blocker (used in anesthesia)
Manufacturer: Organon Inc.
On the market for two years (1999-2001)
Cause for recall: bronchospasms and unexplained deaths

Raptiva (Efalizumab)
Use: Psoriasis
Manufacturer: Genentech
On the market six years (2003 to 2009)
Cause for recall: progressive multifocal leukoencephalopathy (PML; a rare and usually fatal disease that causes inflammation or progressive damage of the white matter in multiple locations of the brain)

Raxar (Grepafloxacin)
Use: Antibiotic for bacterial infections
Manufacturer: Glaxo Wellcome
On the market two years (1997 to 1999)
Cause for recall: cardiac repolarization; QT interval prolongation; ventricular arrhythmia (torsade de pointes)

Redux (Dexfenfluramine)
Use: Appetite suppressant
Manufacturer: Wyeth-Ayerst
On the market one year 1996-’97)
Cause for recall: 30% of patients prescribed the drug had abnormal echocardiograms; 33 cases of rare valvular disease in women; 66 additional reports of heart valve disease
Redux is better known as “Fen-Phen” when prescribed with Phentermine.

Rezulin (Troglitazone)
Use: Antidiabetic and anti-inflammatory
Manufacturer: Parke-Davis/Warner Lambert (now Pfizer)
On the market three years 1997 to 2000)
Cause for recall: at least 90 liver failures; at least 63 deaths
About 35,000 personal injury claims were

filed against the manufacturer (Pfizer).

Selacryn (Tienilic acid)
Use: blood pressure
Manufacturer: SmithKline
On the market three years (1979 to 1982)
Cause for recall: hepatitis; 36 deaths; at least 500 cases of severe liver and kidney damage

Anphar Labs (which developed the drug in France and sold rights to sell in US to SmithKline) sent a report to SmithKline in Apr. 1979 (translated in May 1979 to English from French) stating Selacryn damaged livers. On Dec. 13, 1984, SmithKline Beckman plead guilty to “14 counts of failing to file reports with the drug agency of adverse reactions to Selacryn and 20 counts of falsely labeling the drug with a statement that there was no known cause-and-effect relationship between Selacryn and liver damage”

Seldane (Terfenadine)
Use: Antihistamine
Manufacturer: Hoechst Marion Roussel (now Sanofi-Aventis)
On the market 13 years (1985 to 1998)
Cause for recall: life-threatening heart problems when taken in combination with other drugs (specifically erythromycin (an antibiotic) and ketoconazole (an antifungal))

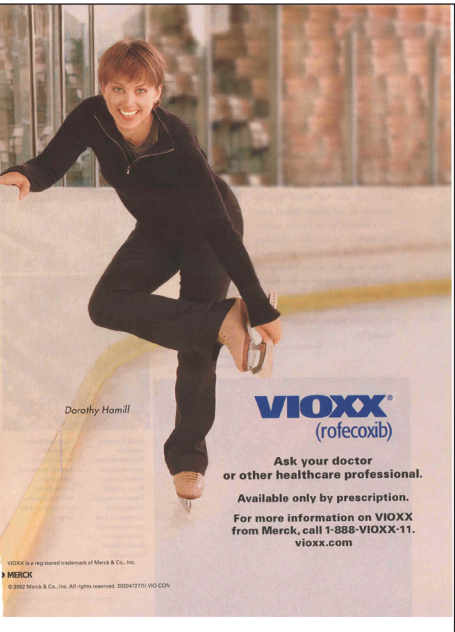
Seldane was not considered an imminent threat. The FDA pulled Seldane from the market because Allegra and Allegra D were produced by the same company and were deemed safer by the FDA.

Trasylol (Aprotinin)
Use: antifibrinolytic to reduce blood loss during surgery
Manufacturer: Bayer
On the market 15 years (1993-2008)
Cause for recall: increased chance of death, serious kidney damage, congestive heart failure, and strokes
On Feb. 8, 2006, the FDA issued a public health advisory to surgeons who perform heart bypasses, alerting them of possible fatal side effects.

Vioxx (Rofecoxib)
Use: NSAID (pain relief)
Manufacturer: Merck
On the market 5.3 years (May 20, 1999 to Sep. 30, 2004)

Cause for recall: increased risk of heart attack and stroke; linked to about 27,785 heart attacks or sudden cardiac deaths between May 20, 1999 and 2003.
[The above from ProCon.org downplays the devastation caused by Vioxx. See sidebar *WHERE*.]

Xigris (Drotrecogin alfa, activated)
Use: Severe sepsis and septic shock
Manufacturer: Eli Lilly
On the market for 10 years (2001-2011)
Cause for recall: no survival benefit



Zelnorm (Tegaserod maleate)
Use: irritable bowel syndrome with constipation and chronic idiopathic constipation in women younger than 55.
Manufacturer: Novartis
On the market for 4.6 years (2002-2007)
Cause for recall: higher chance of heart attack, stroke, and unstable angina (heart/chest pain)
The FDA permitted restricted use of Zelnorm on an emergency basis (with prior case-by-case authorization from the FDA) on July 27, 2007.

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