Prescription Drug Ads
ProCon.org

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35 FDA-Approved Prescription Drugs Later Pulled from the Market

Below are the 35 drugs we could find that have been recalled from the US market since the 1970s, some that had been in use since the 1930s. A sample of advertisements for only some of the drugs are included because there is a scarcity of ads for withdrawn drugs online due to manufacturers removing ads for withdrawn drugs as part of the agreement to no longer market the drugs.

According to the FDA, a "drug is removed from the market 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." The FDA also takes into account the number of people taking a drug being considered for removal so as to not harm those patients.

1. Accutane (Isotretinoin)

on the market for
27
YEARS
1982 to June 2009

Use: Acne

Manufacturer: Hoffman-La Roche

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

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

2. Baycol (Cerivastatin)

on the market for
3
YEARS
1998 to Aug. 2001

Use: Cholesterol reduction

Manufacturer: Bayer A.G.

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)

3. Bextra (Valdecoxib)

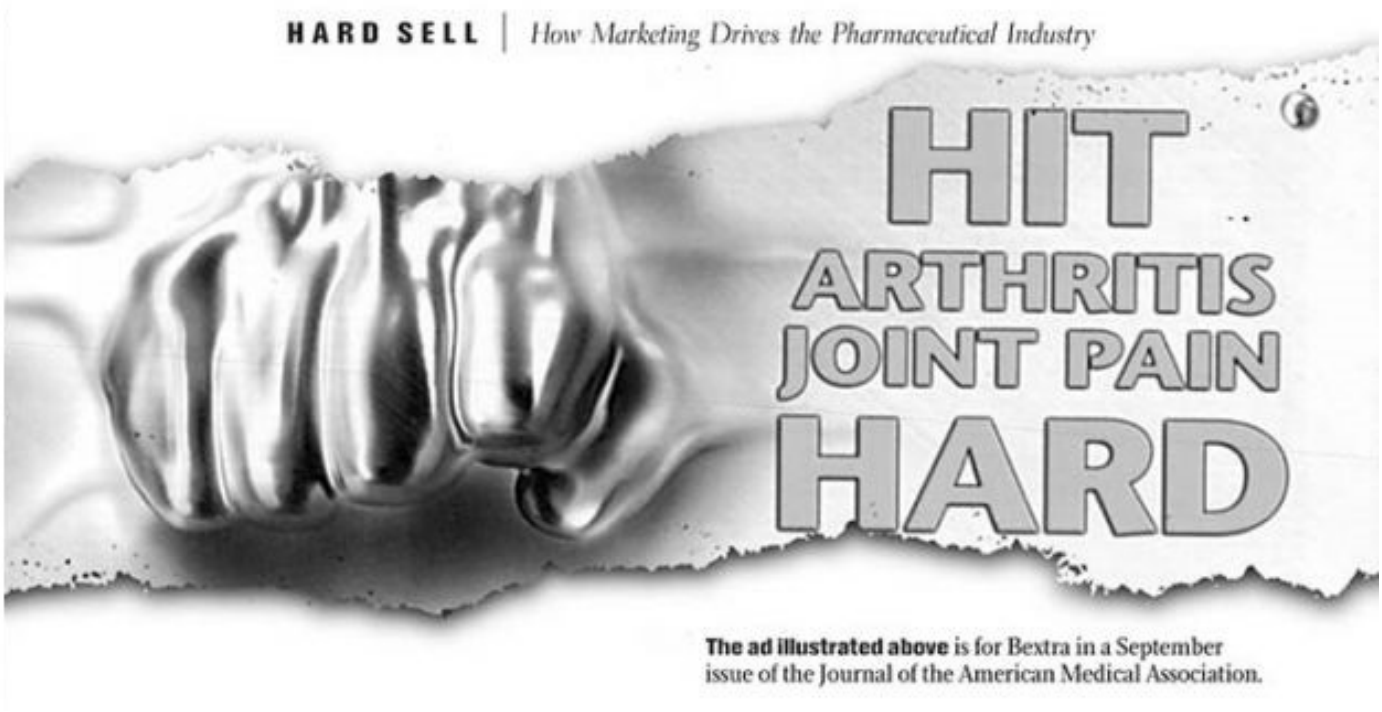
on the market for
3.3
YEARS
Nov. 20, 2001 to Apr. 7, 2005

Use: NSAID (pain relief)

Manufacturer: G.D. Searle & Co.

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

The FDA determined that Bextra showed no advantage over other NSAID pain relievers on the market.



Bernadette Tansey, "Hard Sell: How Marketing Drives the Pharmaceutical Industry/The Side Effects of Drug Promotion/Aggressive Ads for Painkillers Left More Patients Exposed to Risk," www.sfgate.com, Feb. 27, 2005

4. Cylert (Pemoline)

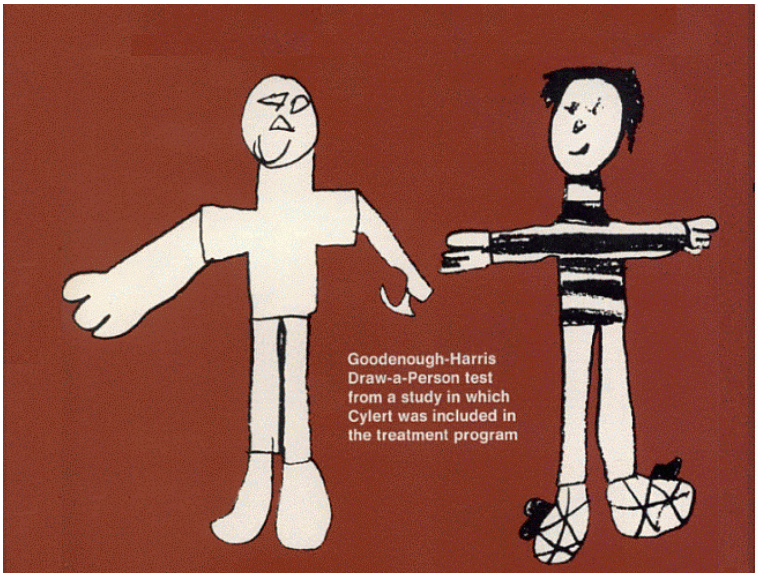
on the market for
30
YEARS
1975 to Oct. 2010

Use: Central nervous system stimulant to treat ADHD/ADD

Manufacturer: Abbott Laboratories

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.



Cylert (pemoline) will not in itself "enhance learning" or resolve difficult behavioral problems. But it can increase attention span in the hyperkinetic child and reduce the impulsivity that often interferes with the learning process.

Cylert® (pemoline) C IV

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. 238 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
- The Wide Range Achievement Test (WRAT) (reading and arithmetic)
- The Lincoln-Oseretsky Motor Performance Test Factor II

Overall results
Approximately two out of three patients were significantly improved by treatment with Cylert as reflected by global ratings.

1. Conners, C. K., ed., *Clinical Use of Stimulant Drugs in Children*, Excerpta Medica, 1974, p. 98.
2. Page, J. G., et al., J. Learning Disabilities, 7:498, Oct., 1974.

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.

Please see last page of this advertisement for Prescribing Information.

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

For the child		For the adults
No drug in child's possession while at school	⟷	Control of medication remains with parents
Avoids situation in which child is repeatedly singled out as being "different"	⟷	Obviates need for nurse or teacher to supervise taking of mid-day doses
Helps prevent possible variations in effect caused by missed, forgotten or delayed 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.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.

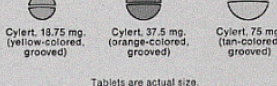
When not to use Cylert

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)



Tablets are actual size.

Cylert (PEMOLINE) C IV

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. In 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 minimal sympathomimetic effects. Pemoline is structurally dissimilar from the amphetamines and methylphenidate. Although the exact mode of pharmacodynamic action is undetermined in man, pemoline has been reported to increase the rate of synthesis of dopamine in rat 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 at several dose levels indicate that serum levels plateau in approximately three days. Cylert and its metabolites are primarily excreted by the kidneys with approximately 75% of an oral dose appearing in the urine within a 24-hour period. Approximately 43% of pemoline is excreted unchanged. Metabolites include pemoline dione, conjugated pemoline and mandelic acid.

Cylert (pemoline) has a gradual onset of action in children with minimal brain dysfunction. Using the recommended schedule of dosage titration, significant clinical benefit may not be evident until the third or fourth week of drug administration.

Indications: MINIMAL BRAIN DYSFUNCTION IN CHILDREN—as adjunctive therapy to other remedial measures (psychological, educational, social).

Special Diagnostic Considerations:
Specific etiology of minimal brain dysfunction (MBD) is unknown, and there is no single diagnostic test. Adequate diagnosis includes the use not only of medical but of psychological, educational, and social resources.

Characteristics commonly reported include: A chronic history of moderate to severe hyperactivity, short attention span, distractibility, emotional lability, and impulsivity. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present. The diagnosis of MBD must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with MBD. In the primary therapy of MBD, appropriate educational placement is essential and psychosocial intervention is generally necessary. When these measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis.

Contraindication: Cylert (pemoline) is contraindicated in patients with known hypersensitivity or idiosyncrasy to the drug. (See PRECAUTIONS)

Warnings: Cylert is not recommended for children under six years of age since safety and efficacy in this age group have not yet been established.

Since Cylert (pemoline) and its metabolites are excreted primarily by the kidneys, caution should be observed in administering the drug to children with significantly impaired renal function.

Sufficient data on safety and efficacy of Cylert administration for periods beyond two years duration in children with minimal brain dysfunction are not yet available. Although a definite causal relationship has not been established, some temporary suppression of predicted growth pattern(i.e., weight 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. Standard studies of fertility, teratology and reproduction were conducted 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 following long-term misuse of pemoline taken orally 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 symptomatology has 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 was transient in nature or responded to 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 stomachache, skin rash, irritability, mild depression, nausea, dizziness, headache, drowsiness, and hallucinations. Mild adverse reactions appearing early in treatment often remit with continuing 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 improvement with Cylert is gradual. Using the recommended schedule of dosage titration, significant benefit 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 restlessness. The treatment of acute massive overdosage with pemoline is essentially the same as that for overdosage with any drug having CNS stimulatory effects. Management is largely symptomatic and may include induction of emesis, gastric lavage or other measures as appropriate.

How Supplied: Cylert (pemoline) is supplied as monogrammed, grooved tablets in three dosage strengths:
18.75 mg. tablets (yellow-colored) in bottles of 100 (**NDC** 0074-6025-13)
37.5 mg. tablets (orange-colored) in bottles of 100 (**NDC** 0074-6057-13)
75 mg. tablets (tan-colored) in bottles of 100 (**NDC** 0074-6073-13)

ABBOTT LABORATORIES
North Chicago, IL60064

Abbott Laboratories, "Cylert," American Journal of Diseases of Children, www.bonkersinstitute.org, 1976

5. Darvon & Darvocet

(Propoxyphene)

on the market for

55

YEARS

1955 to
Nov. 19, 2010

Use: Opioid pain reliever

Manufacturer: Xanodyne

Cause for recall:

serious toxicity to the heart; between 1981 and 1999 there were over 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.

A non-narcotic analgesic with the potency of codeine

DARVON (Dextro Propoxyphene Hydrochloride, Lilly) is equally as potent as codeine yet is much better tolerated. You will find it helpful in any condition associated with pain. Because 'Darvon' is non narcotic, it is safe to use in chronic conditions requiring long-term therapy. Side effects are minimal. The usual adult dose is 32 mg. every four hours or 65 mg. every six hours as needed. Available in 32 and 65-mg. pulvules.

DARVON COMPOUND (Dextro Propoxyphene and Acetylsalicylic Acid Compound, Lilly) combines the antipyretic and anti-inflammatory benefits of 'A.S.A. Compound'* with the analgesic properties of 'Darvon.' Thus, it is useful in relieving pain associated with recurrent or chronic disease, such as neuralgia, neuritis, or arthritis, as well as acute pain of traumatic origin. The usual adult dose is 1 or 2 pulvules every [illegible] hours as needed.

Each Pulvule 'Darvon Compound' provides:

'Darvon'	*32 mg.*
Acetophenetidin	*162 mg.*
'A.S.A.' (Acetylsalicylic Acid, Lilly)	*227 mg.*
Caffeine	*32.4 mg.*

*'A.S.A. Compound' (Acetylsalicylic Acid and Acetophenetidin Compound, Lilly)

ELI LILLY AND COMPANY • INDIANAPOLIS 6, INDIANA, U.S.A.

Christian Sinclair, "Are You Glad Darvocet Got Pulled by the FDA? Are You Sure?," www.pallimed.org, Nov. 30, 2010

6. DBI (Phenformin)

on the market for
19
YEARS
1959 to Nov. 1978

Use: antidiabetic

Manufacturer: Ciba-Geigy

Cause for recall:
lactic acidosis (low pH in body tissues and blood and a buildup of lactate) in patients with diabetes

7. DES (Diethylstibestrol)

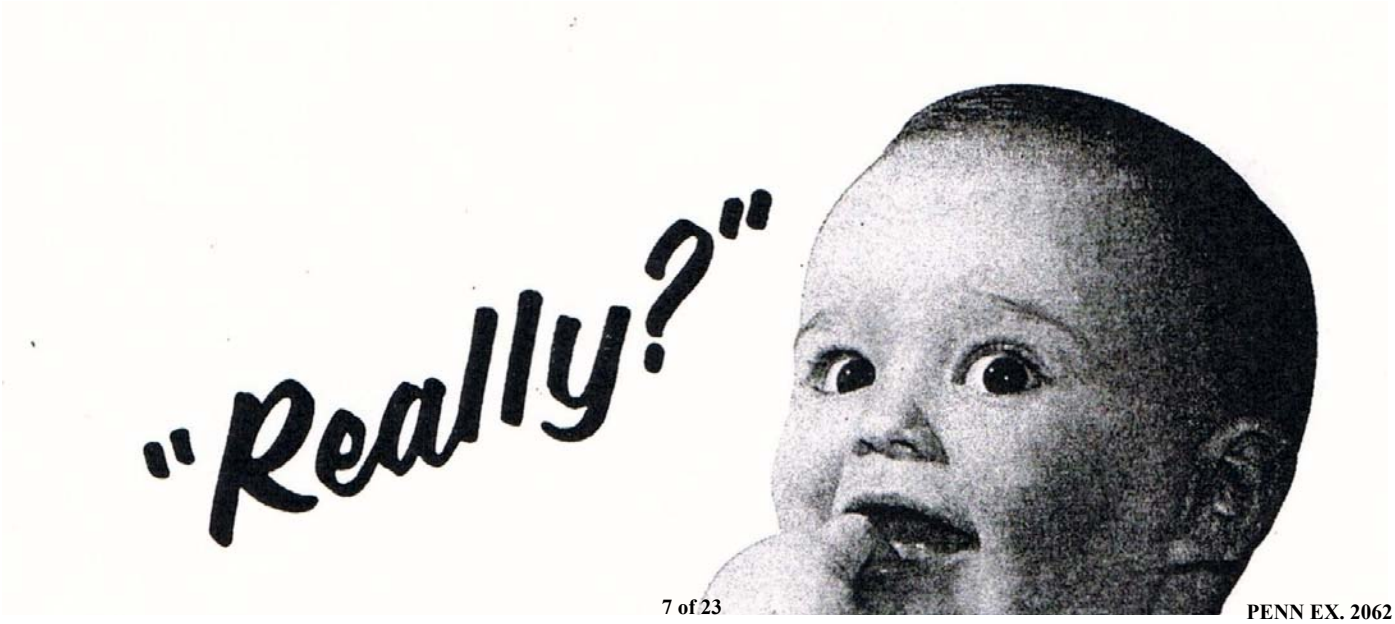
on the market for
31
YEARS
1940 to 1971

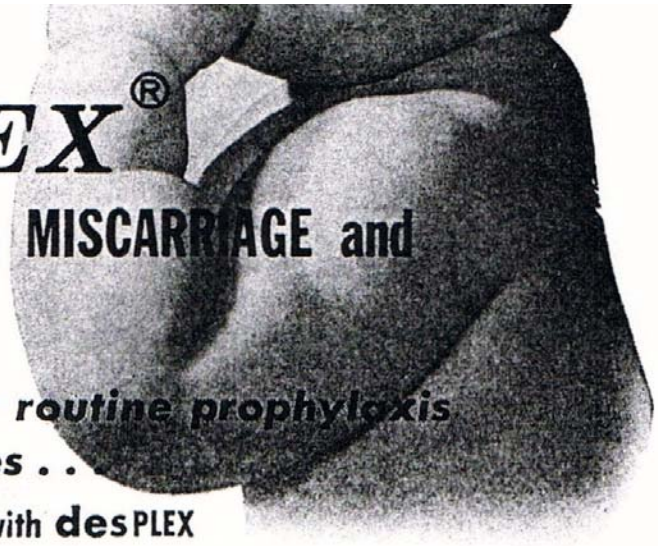
Use: synthetic estrogen to prevent miscarriage, premature labor, and other pregnancy complications

Manufacturer: Grant Chemical Co.

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) but they are unclear as studies are just beginning

Studies in the 1950s showed the drug was not effective at preventing miscarriages, premature labor, or other pregnancy complications.





Yes...

desPLEX®

to prevent ABORTION, MISCARRIAGE and PREMATURE LABOR

recommended for routine prophylaxis in ALL pregnancies . .

96 per cent live delivery with **des**PLEX
in one series of 1200 patients[4]—
— bigger and stronger babies, too.[cf. 1]

No gastric or other side effects with **des**PLEX
— in either high or low dosage[3,4,5]

(Each **des**PLEX tablet starts with 25 mg. of diethylstilbestrol, U.S.P., which is then ultramicronized to smooth and accelerate absorption and activity. A portion of this ultramicronized diethylstilbestrol is even included in the tablet coating *to assure prompt help in emergencies.* **des**PLEX tablets also contain vitamin C and certain members of the vitamin B complex to aid detoxification in pregnancy and the effectuation of estrogen.)

For further data and a generous trial supply of **des**PLEX, write to:
Medical Director

REFERENCES

1. Canario, E. M., et al.: Am. J. Obst. & Gynec. 65:1298, 1953.
2. Gitman, L., and Koplowitz, A.: N. Y. St. J. Med. 50:2823, 1950.
3. Karnaky, K. J.: South. M. J. 45:1166, 1952.
4. Peña, E. F.: Med. Times 82:921, 1954; Am. J. Surg. 87:95, 1954.
5. Ross, J. W.: J. Nat. M. A. 43:20, 1951; 45:223, 1953.

GRANT CHEMICAL COMPANY, INC., Brooklyn 26, N.Y.

Barbara Hammes and Cynthia Laitman, "Pharmaceutical Company Advertisement for DES by the Grant Chemical Company, Brooklyn, NY, Printed in the *American Journal of Obstetrics & Gynecology* in 1957," *Journal of Midwifery and Women's Health*, www.medscape.com, 2003

8. **Duract** (Bromfenac)

Use: Pain killer

Manufacturer: Wyeth-Ayerst Laboratories

on the market for

1

YEAR

July 1997 to June 26, 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.

9. Ergamisol (Levamisole)

on the market for
11
YEARS
May 8, 1989 to 2000

Use: Worm infestation; colon and breast cancers; rheumatoid arthritis

Manufacturer: Janssen Pharmaceutica

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.

10. Hismanal (Astemizole)

on the market for
11
YEARS
1988 to Aug. 13, 1999

Use: Antipsychotic

Manufacturer: Janssen Pharmaceutica

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)

11. Lotronex (Alosetron)

on the market for
0.8
YEAR
Feb. 9, 2000 to Nov. 28, 2000

Use: Irritable bowel syndrome (IBS) in women

Manufacturer: Prometheus Laboratories, Inc.

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.

Irritable Bowel Syndrome Self Help and Support Group, "Lotronex," www.ibsgroups.org (accessed Jan. 6, 2014)

12. Meridia (Sibutramine)

on the market for
13
YEARS
Nov. 1997 to Oct. 2010

Use: Appetite Suppressant

Manufacturer: Knoll Pharmaceuticals

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, calling the drugs "another Vioxx."

13. Merital & Alival (Nomifensine)

on the market for
3
YEARS
1982 to 1985

Use: Antidepressant

Manufacturer: Hoechst AG (now

Sanofi-Aventis)

Cause for recall:
haemolytic anemia; some deaths due to immunohemolytic anemia

14. Micturin (Terodiline)

on the market for
2
YEARS
Aug. 1989 to
Sep. 13, 1991

Use: Bladder incontinence

Manufacturer: Forest Labs

Cause for recall:
QT prolongation and potential for cardiotoxicity

15. Mylotarg (Gemtuzumab Ozogamicin)

on the market for
10
YEARS
May 2000 to
June 21, 2010

Use: Acute myeloid leukemia (AML, a bone marrow cancer)

Manufacturer: Wyeth

Cause for recall:
increased risk of death and veno-occlusive disease (obstruction of veins)

16. Omniflox (Temafloxacin)

on the market for
0.3
YEAR
Jan. 31, 1992 to
June 5, 1992

Use: Antibiotic for pneumonia, bronchitis, and other respiratory tract infections; prostatitis and other genitourinary tract infections; skin ailments

Manufacturer: Abbot Laboratories

Cause for recall:
3 deaths; severe low blood sugar; hemolytic anemia and other blood cell abnormalities; kidney disfunction (half of the cases required renal dialysis); allergic reactions including some causing life-threatening respiratory distress

17. Palladone (Hydromorphone hydrochloride, extended-release)

on the market for
0.5

YEAR
Jan. 2005 to
July 13, 2005

Use: Narcotic painkiller

Manufacturer: Purdue Pharma

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

18. Permax (Pergolide)

on the market for
19
YEARS
1988 to Mar. 29, 2007

Use: Parkinson's disease

Manufacturer: Valeant

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.

19. Pondimin (Fenfluramine)

on the market for
24
YEARS
1973 to
Sep. 15, 1997

Use: Appetite suppressant

Manufacturer: Wyeth-Ayerst

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.

20. Posicor (Mibefradil)

on the market for
1
YEAR
June 1997 to
June 1998

Use: Calcium channel blocker (used to treat hypertension)

Manufacturer: Roche Laboratories

Cause for recall:

fatal interactions with at least 25 other drugs (ex: 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 anti-hypertensive 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.

21. Propulsid (Cisapride)

on the market for
7
YEARS
1993 to July 14, 2000

Use: Severe nighttime heartburn associated with gastroesophageal reflux disease (GERD)

Manufacturer: Janssen Pharmaceutica

Cause for recall:
more than 270 cases of serious cardiac arrythmias (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.

22. PTZ & Metrazol (Pentylenetetrazol)

on the market for
48
YEARS
1934 to 1982

Use: Convulsive therapy for schizophrenia and other psychiatric conditions

Manufacturer: not known

Cause for recall:
uncontrollable seizures; pulled muscles; fractured bones; spine fractures in as many as 42% of patients

23. Quaalude [Marketed as: Optimal, Sopor, Parest, Somnafac, and Bi-Phetamine T] (Methaqualone)

on the market for
23
YEARS
1962 to 1985

Use: Sedative and hypnotic

Manufacturer: William H. Rorer Inc. & Lemmon Company

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).

A good morning after a sleep-through night

That's how a patient feels after a restful night's sleep provided by Quāālude-300 (methaqualone).

He wakes up alert and ready to face the demands of the day (Quāāludc patients usually awaken easily and without evidence of "hangover")...because he slept well all night (Quāālude usually helps produce 6 to 8 hours of restful sleep)...and he didn't have to lie awake for a long period of time before he went to sleep (Quāālude can induce sleep in 10 to 30 minutes). Now the physician has one less tired, sleepy and apprehensive patient to contend with.

Non-barbiturate Quāālude-300 is chemically unrelated to other sedative-hypnotics. Its therapeutic value has been established in controlled clinical studies and by wide usage of methaqualone throughout the world.

Side effects reported have been mild, transient, and have often proved to be statistically insignificant when compared to placebo effects. (See brief summary on last page of advertisement.)

For these reasons, maybe the prescribing physician sleeps a little better, too.

a non-barbiturate
Quāālude®-300 300 mg. tablets
(methaqualone)

WILLIAM H. RORER, INC.
Fort Washington, Pa. 19034

For additional prescribing information, please turn page.

A good morning after a sleep-through night

Sleeping and awakening with Quāālude®-300 (methaqualone) can be a pleasant experience—patients enjoy a sleep-through night, usually without "drugged" after-effects in the morning.

Quāālude is chemically unrelated to barbiturates and glutethimide.

Side effects reported have been mild, transient, and often statistically insignificant when compared to placebo effects. (See *Adverse Reactions* section below.)

Patients appreciate this gentle way to sleep:
sleep usually within 10-30 minutes
sleep duration—6-8 hours
the awakening—pleasantly alert—
usually no "hung-over" feeling

Quāālude®-300 300 mg. tablets
(methaqualone) a non-barbiturate

Brief Summary of Prescribing Information

Indications:
Sleep. Daytime sedation.

Usual Adult Dose:
For sleep, 150-300 mg. at bedtime. For patients previously on other hypnotics, 300 mg. for five to seven nights. *For sedation,* 75 mg. t.i.d. or q.i.d. Not recommended in children. Dosage should be individualized for aged, debilitated or highly agitated patients.

Overdosage:
Acute overdosage may result in delirium and coma, with restlessness and hypertonia, progressing to convulsions. Evacuate gastric contents, maintain adequate ventilation and support blood pressure, if necessary. Dialysis may be helpful. Analeptics are contraindicated. Succinylcholine accompanied by assisted respiration has been proposed for prolonged convulsions. Overdoses of methaqualone appear to be less often associated with cardiac or respiratory depression than are overdoses of oral barbiturates, but shock and respiratory arrest may occasionally occur.

Contraindications:
Contraindicated in women who are or may become pregnant; or patients with known hypersensitivity.

Warnings:
Take hypnotic dose only at bedtime. Not recommended in children. Warn patient on Quāālude against driving a car or operating dangerous machinery. Care needed when administered with other sedative, analgesic or psychotropic drugs or alcohol because of possible additive effects. Pending longer clinical experience, Quāālude should not be used continuously for periods exceeding three months. *Psychological dependence* occasionally occurs. *Physical dependence* rarely reported. However, caution needed with addiction-prone patients.

Precautions:
Use with caution and prescribe small quantities in patients with anxiety states where impending depression or suicidal tendencies exist. Give in reduced doses, if at all, in patients with impaired hepatic function.

Adverse Reactions:
Neuropsychiatric: headache, hangover, fatigue, dizziness, torpor, transient paresthesia of the extremities. An occasional patient has experienced restlessness or anxiety. *Hematologic:* aplastic anemia possibly related to methaqualone has been very rarely reported. *Gastrointestinal:* dry mouth, anorexia, nausea, emesis, epigastric discomfort, diarrhea. *Dermatologic:* diaphoresis, bromhidrosis, exanthema. Urticaria has been particularly well documented.

Supplied:
Quāālude-150 (150 mg. white, scored tablets). Quāālude-300 (300 mg. white, scored tablets).

Consult complete literature before prescribing.

WILLIAM H. RORER, INC.
Fort Washington, Pa. 19034

Res Obscura, "From Quacks to Quaaludes: Three Centuries of Drug Advertising," www.resobscura.blogspot.nl, June 11, 2012

24. Raplon (Rapacuronium)

on the market for
2
YEARS
1999 to
Mar. 27, 2001

Use: Non-polarizing neuromuscular blocker (used in anesthesia

Manufacturer: Organon Inc.

Cause for recall:
bronchospasms and unexplained deaths

25. Raptiva (Efalizumab)

on the market for
6
YEARS
2003 to
Apr. 8, 2009
(completely
withdrawn by
June 8, 2009)

Use: Psoriasis

Manufacturer: Genentech

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)

26. Raxar (Grepafloxacin)

on the market for
2
YEARS
1997 to
Nov. 1, 1999

Use: Antibiotic for bacterial infections

Manufacturer: Glaxo Wellcome

Cause for recall:
cardiac repolarization; QT interval prolongation; ventricular arrhythmia (torsade de pointes)

27. Redux (Dexfenfluramine)

on the market for
1
YEAR
1996 to Sep. 15,
1997

Use: Appetite suppressant

Manufacturer: Wyeth-Ayerst

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.

28. Rezulin (Troglitazone)

on the market for
3.25
YEARS
Jan. 29, 1997 to Mar. 21, 2000

Use: Antidiabetic and anti-inflammatory

Manufacturer: Parke-Davis/Warner Lambert (now Pfizer)

Cause for recall:
at least 90 liver failures; at least 63 deaths

About 35.000 personal injury claims were filed against the manufacturer (Pfizer).

29. Selacryn (Tienilic acid)

on the market for
3
YEARS
May 2, 1979 to 1982

Use: blood pressure

Manufacturer: SmithKline

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"

30. Seldane (Terfenadine)

on the market for
13
YEARS
1985 to Feb. 1, 1998

Use: Antihistamine

Manufacturer: Hoechst Marion Roussel (now Sanofi-Aventis)

Cause for recall:

life-threatening heart problems when taken in combination with other drugs (specifically erthromycin (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.

31. Trasylol (Aprotinin)

on the market for
15 (48) YEARS
1993 (but used since the 1960s) to Nov. 5, 2007 (marketing suspension request to phase it out of the market); May 14, 2008 (manufacturer announced complete removal from market)

Use: antifibrinolytic to reduce blood loss during surgery

Manufacturer: Bayer

Cause for recall:
increased chance of death, serious kidney damage, congestive heart failure, and strokes

On Feb. 8, 2006, the FDA issued a public heath advisory to surgeons who perform heart bypasses, alerting them of possible fatal side effects.

32. Vioxx (Rofecoxib)

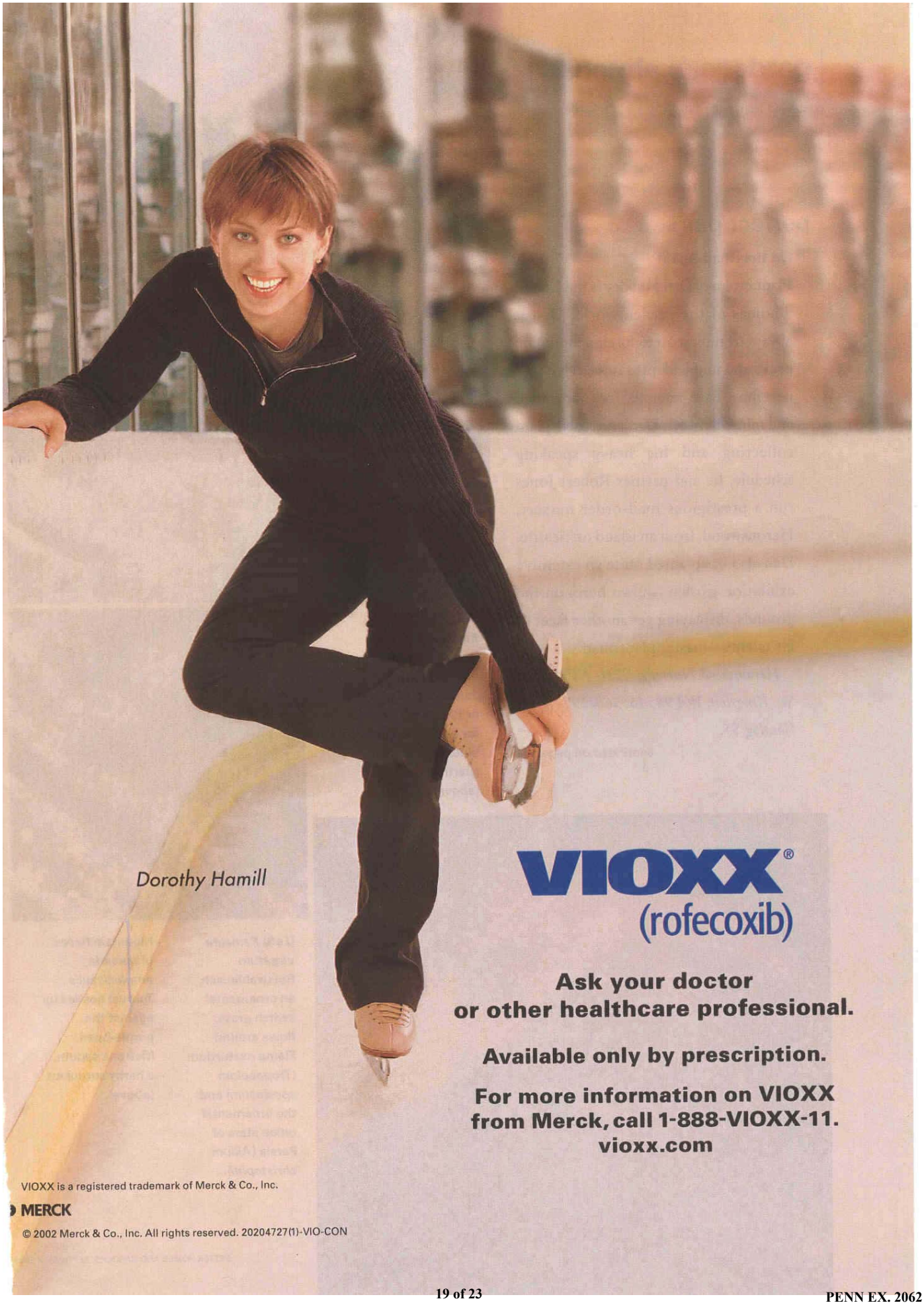
on the market for
5.3 YEARS
May 20, 1999 to Sep. 30, 2004

Use: NSAID (pain relief)

Manufacturer: Merck

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

Ads for Vioxx features Olympic gold medalists Dorothy Hamill and Bruce Jenner. Vioxx was prescribed to more than 20 million people.



Today's Seniors Network, "This Is Patient Education?," www.todaysseniorsnetwork.com (accessed Jan. 7, 2014)

33. Xigris (Drotrecogin alfa (activated))

on the market for
10
YEARS
Nov. 2001 to Oct. 25, 2011

Use: Severe sepsis and septic shock

Manufacturer: Eli Lilly & Company

Cause for recall:
no survival benefit

34. Zelmid (Zimelidine)

on the market for
0
YEARS
1982 to 1982 (withdrawn by the FDA before being released in the US market)

Use: Anti-depressant

Manufacturer: Astra AB (now AstraZeneca)

Cause for recall:
Guillain–Barré syndrome; higher risk of suicide

35. Zelnorm (Tegaserod maleate)

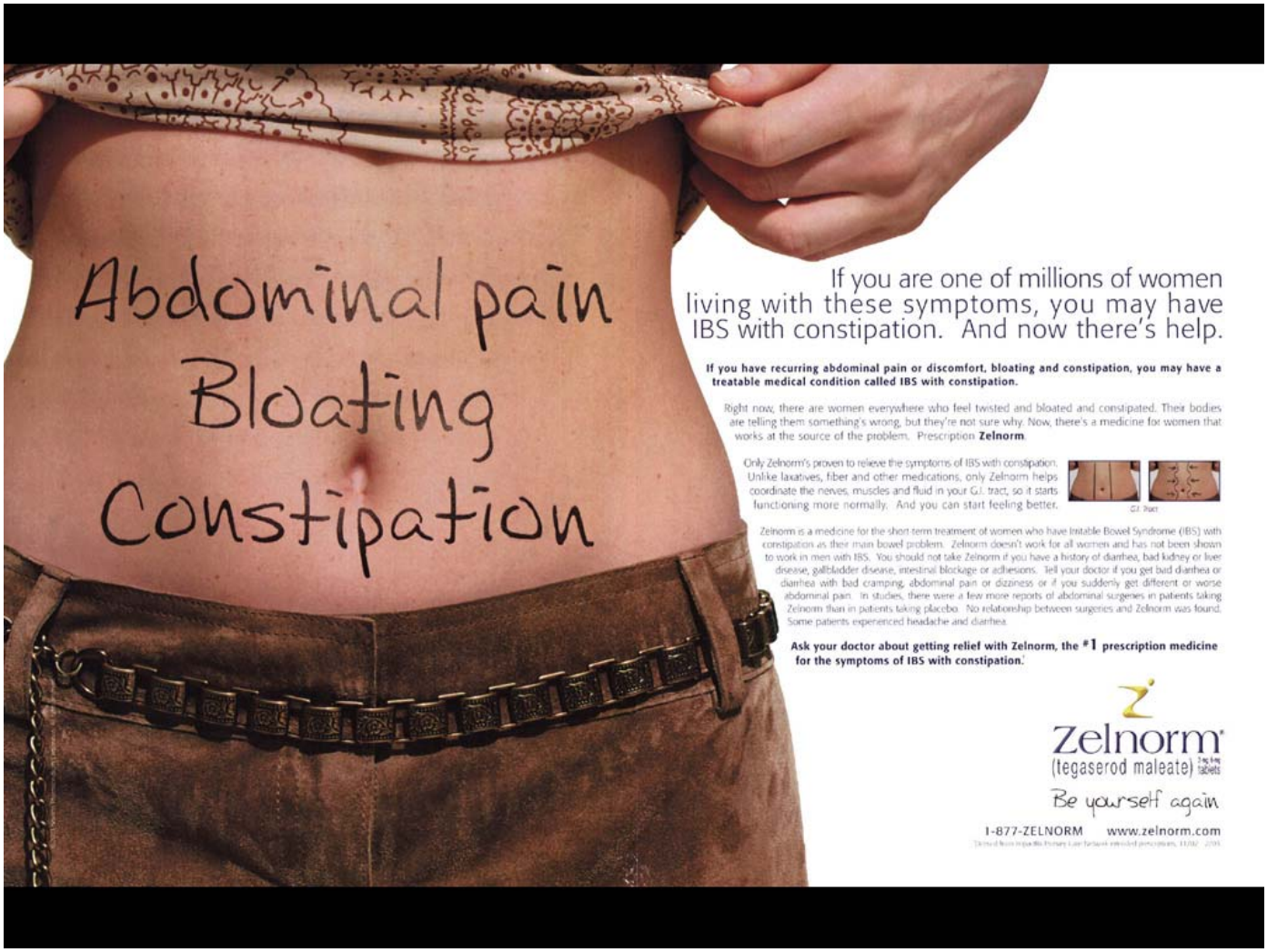
on the market for
4.6
YEARS
July 24, 2002 to Mar. 30, 2007

Use: irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in women younger than 55

Manufacturer: Novartis

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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