

# Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

April 2005 ♦ VOL. 21, NO. 4

## George A. Silver, M.D. 1913 - 2005: In Memoriam

*Dr. George Silver, a long-time colleague and close friend of Public Citizen's Health Research Group, died January 7th of this year. He had contributed many articles to the Health Letter over the years. The following is a tribute to Dr. Silver from the Department of Health Policy at George Washington University:*

The Department of Health Policy is honored to have been chosen to serve as a home for a memorial to Dr. George A. Silver, one of the leading figures in 20th century health policy. Dedicated to the belief that medicine and health care could — and should — be understood only in a far broader context of public health and social justice, Dr. Silver was instrumental in shaping U.S. health policy at a critical time in its development.

Dr. Silver came to health policy from a career in medicine beginning with service in the Army medical corps during World War II, where he helped liberate Dachau and other concentration camps. From 1951 through 1965 Dr. Silver served as chief of the Social Medicine Division at Montefiore Hospital.

As Deputy Assistant Secretary for health and scientific affairs for the United States Department of Health Education and Welfare from 1965 to 1968, Dr. Silver was instrumental in shaping U.S. health policy for the poor, the underserved, and the

medically vulnerable. His tenure at HEW saw the initial implementation of Medicare and Medicaid, the desegregation of U.S. hospitals under Title VI of the 1964 Civil Rights Act, the establishment of major federal health programs for low income children, and the early community health center demonstration.

Following his government service, Dr. Silver returned to a long and celebrated career in academic health policy as a member of the public health faculty of the Yale Medical School. A tireless voice for at-risk populations, Dr. Silver was honored for his contributions through memberships in the Institute of Medicine, the World Health Organization's expert committee on medical care, and the National Academy of Social Insurance. Dr. Silver wrote prolifically on a wide range of subjects and throughout his career he remained true to the themes of social medicine, child and family health policy, and health as a form of social justice.

The Department of Health Policy will honor Dr. Silver's memory through an annual Visitorship in Child and Family Policy, scholarships for advanced degree candidates pursuing careers in child and family health policy, and other activities that embody his work. Contributions to the George A. Silver Fund can be sent to:

Department of Health Policy  
2021 K Street NW, Suite 800  
Washington, DC 20006  
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*In 1990, Dr. Silver finished a book concerning the lack of any coherent health policy in this country and the origins of and solutions for this problem. We will periodically reprint excerpts from this unpublished work in Health Letter, the first of which, from the author's preface, follows:*

### **The Archaeology of Health Policy**

My interest in the baffling contra-  
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ditions in the American health care system and the puzzling failure of a wealthy, powerful and democratic nation to formulate a satisfactory national health policy was intensified by my career experiences in the health care system. As a medical student I was faced with the wide gulf between what we did for poor people in the clinics, and in the home deliveries of babies, as compared with the technical excellence and solicitude displayed on behalf of paying patients. It was a time, in the mid-thirties, when there was great agitation for a national health program, and there was professional turmoil even in the cloistered classrooms. Some of my teachers devoted precious lecture time to ranting attacks on President Franklin D. Roosevelt. Others among my clinic teachers had participated in the studies of the Committee on the Costs of Medical Care and were urging system changes.

I have spent my entire professional life in medicine. For a short period at the beginning of my career, I was a general practitioner, giving direct care to patients in a modest lower middle income neighborhood. Poor people could receive services from me without charge or "on account" — usually never paid. But they were hard pressed to obtain laboratory, X-ray or consultation services without payment. I could beg some of these services from colleagues, but not too often. In accordance with the practice of the times, I did a little obstetrics, a little surgery (minor cutting into abscesses and setting of finger and wrist fractures in the office; and no more than appendectomies in the hospital!)

During WW II as a field hospital doctor, I did some clinical work — battle casualty emergency medicine — in a number of military settings overseas. And in the multiple responsibilities expected of field medical officers, I did lots of administrative work as well. Even before the War I had yearned a bit wistfully for social engagement in medical services to people, and had considered public health for a career. My experiences as

a local general practitioner had chilled my enthusiasm for clinical practice, and on leaving the Army, I sought entry to the world of public health opportunities.

A medical school classmate had become wartime director of a large scale, federally sponsored public health program, and after the War ended he took me on to direct the office responsible for providing medical care to migratory farm workers in eleven Northeastern states. This was an educational experience in more than the professional dimension: emotionally wrenching and illuminating for me the harsh realities of life for migrant farm workers, who are the poorest of the rural poor.

Following that experience, I took jobs in other non-clinical medical settings: teaching, research and administration in the medical care field. I have worked in the private sector: at Montefiore Hospital in New York City as chief of the hospital service in social medicine; as professor of public health or social medicine in a number of universities, latterly at Yale; as well as the Health Executive for the National Urban Coalition in its pioneer days, helping to set up community clinics under the auspices of popular local coalitions.

In the public sector, I have served as an official in local government (a teaching district health officer in Baltimore), state government (assistant to a county health officer in Maryland), national government (Deputy Assistant Secretary for Health in the office of the Secretary of Health Education and Welfare) and international health services (consultant to the World Health Organization and to the US Agency for International Development). For some years I served on the Technical Board of the Milbank Memorial Fund, learning about, and dealing with foundation efforts to change and improve medical care in the United States and abroad.

As part of my work, I have lived and studied in many foreign countries, learning about the operation of their health and medical care systems. At the same time, I have had the opportunity to investigate and explore the

medical care system in the United States. My various jobs made it possible to experiment with health service organizational models in an effort to resolve the ambiguities and contradictions of medical practice here. In the 1950s and 1960s I directed a prepaid medical group practice organization (now known as "HMO"). Montefiore Hospital had initiated a well-known and respected Home Care program long before Medicare introduced home health services. It was in this Home Care Program that a "team approach" to medical practice was undertaken. Doctor, nurse and social worker combined forces to look after families. In the group practice, we employed specially trained nurses as complementary to physicians in family medical services. In the approach to family practice we added preventive services in the Family Health Maintenance Demonstration and measured the effect.

In these experiences, it became clearer and clearer that the ambitious programs and modifications I was engaged in were but tiny drops in an ocean of need. The great gap in medical care in the United States was not the failure of a piece or part of the system, or insufficient funding, but the lack of a coherent, overtly expressed national medical policy and program. I was troubled and perplexed that despite nearly fifty years of public debate and argument, no generally acceptable national health policy existed.

The medical community seemed untouched by the societal inequities in medical care. The politicians met narrow periodic challenges with narrow legislative responses. Now, more than eighty years into these debates and political struggle, while the outward forms of medical care service and delivery (and certainly of cost!) have changed, the structure is still unresponsive to societal demands.

Many popular as well as technical books have been published in explanation and proposed resolution of these health problems, endeavoring to analyze and even to redirect the US health care system. On the whole, though, these analyses tend to

emphasize one or another presumed causative factor, related to the special expertise of the author. Economic approaches are very popular, laying the blame on technology and physician overuse of expensive equipment; or on patient misuse of the system, or on popular morbid life style. Sometimes medical education is the whipping-boy, and cure will lie in teaching a better approach to patient care.

Over time, most of the panaceas have been tried, yet the medical care system defies the reformers. Politicians as well as students of health and medical care are puzzled by the apparent helplessness of this vastly wealthy, technically advanced country, so rich in medical resources and in trained and expert people, to provide effective, satisfactory, economical and easily available medical care services of high quality to all its citizens. The point is underlined by the success of other nations, not nearly so wealthy, to offer all its citizens good, easily available medical care. Canada, a close neighbor and linguistic and cultural close cousin, seems to be doing splendidly.

So far, despite the number and variety of approaches recommended in the many volumes on the bookshelves, it is still unclear why we have failed for so long to establish a broad national consensus, why this rich nation suffers from such a luxurious yet insufficiently satisfactory medical care system. The analyses suggest only that there is a defect (or defects), and that we need only eliminate it or them. None supplies a

national policy or suggests what the overall health policy ought to be.

It is not unfair to say that the well-intentioned reformers disregard the complex nature of medical care and of the medical care system. It is not the faulty outer forms that deprive us of an effective and satisfactory medical care system. Simple tinkering will not do. Just as the inner structure of a machine or a building determines the limitations of the external configuration, health policies are shaped by an inner determinant. The basic core with respect to health policy is the traditional format within which health policy is articulated. History can unfold this format for us. Recognition of our failure to follow the traditional pathway to health policy may give us the leverage to develop a national health policy, and thus prepare the way for programming an effective medical care system.

Fundamental reform will follow articulation of clearcut health policy. It is the lack of a framework for an inclusive and integrated national health policy that has obstructed and continues to hobble today's efforts to create a national health program.

The absence of national health policy is evident in the compartmentalized, unintegrated, fragmented, duplicated medical care services. The private sector plays a major role, and has a sizeable financial investment in the multi-billion dollar medical care system. There is little or no programmatic connection between the private and the public sectors, despite the heavy investment of the federal, state

and local governments. Sensible cost control, rational use of resources, avoidance of duplication and assurance of availability in cases and places of need is impossible without integration of the public and private sectors.

Within the public sector, other disjointed efforts obtain. The states justifiably blame the federal government for not providing enough money and the federal establishment blames the states for not imposing discipline, standards and controls to make most efficient use of the money that is provided (also true). Without coordinated effort, a satisfactory solution cannot be reached. The multiplicity of uncoordinated efforts, the lack of a national consensus, paralyzes action.

How can we achieve a national consensus? Our medical care system built up in this century encompasses enormous sums: almost \$700 billion, of which hospitals devour nearly \$300 billion, doctors 150 billion and insurance companies control or mete out nearly \$200 billion is not easily turned around. The personnel alone involved reveal a daunting constituency: 600,000 doctors, 2 million nurses, 7 million health workers all told. In response to the agonized demand for help, hundreds, if not thousands, of academic scholars each of whom has a different, seemingly logical approach and solution. And thousands of legislators and political aspirants, in Washington, and in the state capitals, are listening, arguing, furiously working out their

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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# Misprescribing and Overprescribing of Drugs

The numbers are staggering: in 2003, an estimated 3.4 billion prescriptions were filled in retail drugstores and by mail order in the United States. That averages out to 11.7 prescriptions filled for each of the 290 million people in this country. But many people do not get any prescriptions filled in a given year, so it is also important to find out how many prescriptions are filled by those who fill one or more prescriptions. In a study based on data from 2000, more than twice as many prescriptions were filled for those 65 and older (23.5 prescriptions per year) than for those younger than 65 (10.1 prescriptions per year). Another way of looking at the high rate of prescriptions among older people is the government finding that although

Medicare beneficiaries comprise only 14% of the community population, they account for more than 41% of prescription medicine expenses.

There is no dispute that for many people, prescriptions are beneficial, even lifesaving in many instances. But hundreds of millions of these prescriptions are wrong, either entirely unnecessary or unnecessarily dangerous. Inappropriate prescribing is an academically gentle euphemism for prescriptions for which the risks outweigh the benefits, thus conferring a negative health impact on the patient. A recent comprehensive review of studies of such inappropriate prescribing in older patients found that 21.3% of community-dwelling patients 65 years or older were using at least one

drug inappropriately prescribed. Much more so than age, per se, the total number of drugs being prescribed was an important predictor of inappropriate prescribing, as was female gender. Another study found that, conservatively — using very narrow criteria for inappropriate prescribing — elderly United States patients were prescribed at least one inappropriate drug at an estimated 16.7 million visits to physician offices or hospital outpatient departments in the year 2000. Examples of specific drugs that have been inappropriately prescribed, including studies involving younger adults and children, are given later in this section.

At the very least, misprescribing  
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## SILVER, from page 3

own theories and responses.

Drawing back for a moment, the interested reader may be thinking that this is something like recognizing the need for belling the cat, a hardly useful exercise. If this ideal, toward which public, private and professional interests should be cooperatively linked, hasn't been achieved in eighty years, maybe there are powerful reasons why it can't be done! Surely others over the years must have understood the inadequacy of piecemeal diagnoses and piecemeal solutions! Why hasn't our intelligent, sophisticated, technologically advanced society coordinated health and medical care activities toward a commonly perceived goal?

The obstacles to correction of the American medical care system's defects must be sought within American social and political traditions. If we look at the European countries, similarly wealthy, industrially advanced, and technologically developed, there is a parallel to the divergence of the American medical care experience from the Western (European) pattern in welfare policies as well. It would seem to be essentially the American style of policy making.

American history suggests that

much of what was laid down as social policy in the 18th and 19th centuries continues as social policy today, however much the social factors have changed or developed. Economic improvement, technological advance, changed and enriched medical education, along with enormous transformation by way of urbanization and industrialization, fluctuating political groupings have only marginally influenced the attitudes and values that determine social policies.

Despite our protests of attachment to democratic equity, we see how inequities persist — poverty and race are still powerfully influential in becoming sick, getting medical care and in the kind and quality of care one receives. Once, it was accepted that poor people should be given second-rate care — if any! Even today, despite lip service to equity, Congress fidgets over paying for “equal” access for the poor and the rich. Economists advise us to be content with “Chevrolet” medical care for less well-off people, and “Cadillac” care for the wealthy.

This book grows out of my experiences and my reflections on health policy as a social and political

phenomenon with historic roots. What is offered by way of solution is to call attention to the need for embracing an American approach to any solution. It is intended to provide insight into process, with a kernel of design that will allow a more promising opportunity for achievement of a national health policy.

In that process, the usually overlooked aspect of health policy-making in this country is the traditional and peculiarly American pattern of health — and other social — legislative action. From colonial times, in most instances of health and welfare legislation, state models must precede national action.

In assessing health policy on this principle, it may become clearer why some national social policies that, on the face of things appear desperately needed, and widely longed for, never come to fruition: while others, less desirable, or less desired, are more easily and rapidly achieved.

This book is the result of long pondering a nagging question: of all the Western industrialized nations, why does the solution of America's unsatisfactory medical care system continue to elude us? ■



**PRESCRIBING**, from page 4  
wastes tens of billions of dollars, barely affordable by many people who pay for their own prescriptions. But there are much more serious consequences. More than 1.5 million people are hospitalized and more than 100,000 die each year from largely preventable adverse reactions to drugs that should not have been prescribed as they were in the first place. What follows is a summary of the **seven all-too-often-deadly sins of prescribing**.

**First: The “disease” for which a drug is prescribed is actually an adverse reaction to another drug, masquerading as a disease** but unfortunately not recognized by doctor and patient as such. Instead of lowering the dose of the offending drug or replacing it with a safer alternative, the physician adds a second drug to the regimen to “treat” the adverse drug reaction caused by the first drug. Examples discussed in our book, *Worst Pills, Best Pills*, and on our website, <http://www.worstpills.org>, include drug-induced parkinsonism, depression, sexual dysfunction, insomnia, psychoses, constipation, and many other problems.

**Second: A drug is used to treat a problem that, although in some cases susceptible to a pharmaceutical solution, should first be treated with commonsense lifestyle changes.** Problems such as insomnia and abdominal pain often have causes that respond very well to nondrug treatment, and often the physician can uncover these causes by taking a careful history. Other examples include medical problems such as high blood pressure, mild adult-onset diabetes, obesity, anxiety, and situational depression. Doctors should recommend lifestyle changes as the first approach for these conditions, rather than automatically reach for the prescription pad.

**Third: The medical problem is both self-limited and completely unresponsive to treatments such as antibiotics or does not merit treatment with certain drugs.** This is seen most clearly with viral infections such as colds and bronchitis in otherwise healthy children or adults.

**Fourth: A drug is the preferred**

**treatment for the medical problem, but instead of the safest, most effective and often least expensive treatment, the physician prescribes one of the Do Not Use drugs listed in our book, *Worst Pills, Best Pills*, or another, much less preferable alternative.** An example of a less preferable alternative would be a drug to which the patient has a known allergy that the physician did not ask about.

**Fifth: Two drugs interact. Each on its own may be safe and effective, but together they can cause serious injury or death.**

**Sixth: Two or more drugs in the same therapeutic category are used, the additional one(s) not adding to the effectiveness of the first but clearly increasing the risk to the patient.** Sometimes the drugs come in a fixed combination pill, sometimes as two different pills. Often heart drugs or mind-affecting drugs are prescribed in this manner.

**Seventh: The right drug is prescribed, but the dose is dangerously high.** This problem is seen most often in older adults, who cannot metabolize or excrete drugs as rapidly as younger people. This problem is also seen in small people who are usually prescribed the same dose as that prescribed to people weighing two to three times as much as they do. Thus, per pound, they are getting two to three times as much medicine as the larger person.

### **Evidence of Misprescribing and Overprescribing**

Here are some examples from recent studies by a growing number of medical researchers documenting misprescribing and overprescribing of specific types of drugs:

### **Treating Adverse Drug Reactions with More Drugs**

Researchers at the University of Toronto and at Harvard have clearly documented and articulated what they call the prescribing cascade. It begins when an adverse drug reaction is misinterpreted as a new medical condition. Another drug is then prescribed, and the patient is placed at risk of developing additional adverse effects

relating to this potentially unnecessary treatment. To prevent this prescribing cascade, doctors —and patients— should follow what we call Rule 7 of the Ten Rules for Safer Drug Use (see the section of our book or our web site, <http://www.worstpills.org>, titled “Protecting Yourself and Your Family from Preventable Drug-induced Injury”): Assume that any new symptom you develop after starting a new drug might be caused by the drug. If you have a new symptom, report it to your doctor.

Some of the instances of the prescribing cascade that these and other researchers have documented include:

- The increased use of anti-Parkinson’s drugs to treat drug-induced parkinsonism caused by the heartburn drug metoclopramide (REGLAN) or by some of the older antipsychotic drugs.
- A sharply increased use of laxatives in people with decreased bowel activity that has been caused by antihistamines such as diphenhydramine (BENADRYL), antidepressants such as amitriptyline (ELAVIL) — a **Do Not Use** drug — or some antipsychotic drugs such as thioridazine (MELLARIL).
- An increased use of antihypertensive drugs in people with high blood pressure that was caused or increased by very high doses of nonsteroidal anti-inflammatory drugs (NSAIDs), used as painkillers or for arthritis.

### **Failing to Treat Certain Problems with Nondrug Treatments**

Research has shown that many doctors are too quick to pull the prescription trigger. In one study, in which doctors and nurse practitioners were presented with part of a clinical scenario — as would occur when first seeing a patient with a medical problem — and then encouraged to ask to find out more about the source of the problem, 65% of doctors recommended that a patient complaining of insomnia be treated with sleeping pills even though, had they asked more questions about the patient, they would have found that the patient was not exercising, was drinking coffee in the

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## **PRESCRIBING, from page 5**

evening, and, although awakening at 4 a.m., was actually getting seven hours of sleep by then.

In a similar study, doctors were presented with a patient who complained of abdominal pain and whose endoscopy showed diffuse irritation in the stomach. Sixty-five percent of the doctors recommended treating the problem with a drug—a histamine antagonist (such as Zantac, Pepcid, or Tagamet). Had they asked more questions they would have discovered that the patient was using aspirin, drinking a lot of coffee, smoking cigarettes, and was under considerable emotional stress — all potential contributing factors to abdominal pain and stomach irritation.

In summarizing the origin of this overprescribing problem, the authors stated: “Apparently quite early in the formulation of the problem, the conceptual focus [of the doctor] appears to shift from broader questions like ‘What is wrong with this patient?’ or ‘What can I do to help?’ to the much narrower concern, ‘Which prescription shall I write?’” They argued that this approach was supported by the “barrage” of promotional materials that only address drug treatment, not the more sensible lifestyle changes to prevent the problem.

In both of the above scenarios, nurse practitioners were much more likely than doctors to take an adequate history that elicited the causes of the problems and, not surprisingly, were only one-third as likely as the doctors to decide on a prescription as the remedy instead of suggesting changes in the patient’s habits.

Throughout our book, in the discussions about insomnia, high blood pressure, situational depression, mild adult-onset diabetes, and other problems, you will find out about the proven-effective nondrug remedies that should first be pursued before yielding to the riskier pharmaceutical solutions.

## **Treating Diseases with Drugs That Are Not Effective for Those Problems**

Two recently published studies, based on nationwide data from office

visits for children and adults, have decisively documented the expensive and dangerous massive overprescribing of antibiotics for conditions that, because of their viral origin, do not respond to these drugs. Forty-four percent of children under 18 years old were given antibiotics for treatment of a cold and 75% for treatment of bronchitis. Similarly, 51% of people 18 or older were treated with antibiotics for colds and 66% for bronchitis. Despite the lack of evidence of any benefit for most people from these treatments, more than 23 million prescriptions a year were written for colds, bronchitis, and upper respiratory infections. This accounted for approximately one-fifth of all prescriptions for antibiotics written for children or adults. An accompanying editorial warned of “increased costs from unnecessary prescriptions, adverse drug reactions, and [subsequent] treatment failures in patients with antibiotic-resistant infections” as the reasons to try to reduce this epidemic of unnecessary antibiotic prescribing.

Similar misprescribing of a drug useful and important for certain problems, but not necessary or effective, and often dangerous, for other problems can be seen in another recent study. In this case, 47% of the people admitted to a nursing home who were taking digoxin, an important drug for treating an abnormal heart rhythm called atrial fibrillation or for treating severe congestive heart failure, did not have either of these medical problems and were thereby being put at risk for life-threatening digitalis toxicity without the possibility of any benefit.

A final example in this category involves the overuse of a certain of drugs, in this case calcium channel blockers, which have not been established as effective for treating people who have had a recent heart attack. The study shows that this prescribing pattern actually did indirect damage to patients because their use was replacing the use of beta-blockers, drugs shown to be very effective for reducing the subsequent risk of death or hospitalization following a heart attack. Use of a calcium channel blocker instead of a beta-blocker was associated with a

doubled risk of death, and beta-blocker recipients were hospitalized 22% less often than nonrecipients.

## **Prescribing Do Not Use Drugs**

There are 181 **Do Not Use** drugs listed in our book, *Worst Pills, Best Pills* (available to purchase at <https://www.citizen.org/wpbp>, or see our ad in this issue for ordering information), for which we recommend safer alternatives. Although the original determinations for these Do Not Use drugs were based on their use by older adults, we have concluded that the same warnings apply to use by anyone.

Also included in the book *Worst Pills, Best Pills* are a number of drugs we label **Do Not Use Until Seven Years After Release**. We have applied this warning to drugs that have only recently appeared on the market, for which there is no evidence of their superiority over older drugs about which we have much more information as to long-term safety and effectiveness. Because of incomplete and worrisome safety information, there is a risk that some of these newer drugs will have to be banned. But by the time they have been on the market for seven years, it is much less likely that they will be banned, and it is much more likely that, if they are still being used, there will be much better information about their safety and effectiveness, such as a new black-box warning not present when the drugs were first marketed.

Another category of drugs that is misprescribed even though there are safer alternatives are drugs to which patients are known to be allergic, but about which their physicians have not taken a careful medical history ■

*To be continued in the May issue.*

For more information  
about misprescribed  
drugs, visit  
[www.worstpills.org](http://www.worstpills.org).



# Product Recalls

February 17 — March 16, 2005

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

## DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. A Class I recall is a situation in which there is a probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is [www.fda.gov](http://www.fda.gov).

Name of Drug or Supplement; Class of Recall; Problem	Lot #: Quantity and Distribution; Manufacturer
a) <b>Nefazodone HCl Tablets</b> , 50 mg; b) <b>Nefazodone HCl Tablets</b> , 100 mg; c) <b>Nefazodone HCl Tablets</b> , 150 mg; d) <b>Nefazodone HCl Tablets</b> , 200 mg, Class III, Dissolution failure.	a) Lot 118557A, Exp. Date 6/2005; 949 units; b) Lot 118550, Exp. Date 7/2005; 937 units; c) Lot 118552, Exp. Date 6/2005; 1348 units; d) Lot 118555, Exp. Date 7/2005; 1316 units; nationwide distribution; Ivax Pharmaceuticals, Inc., Northvale, NJ.
a) <b>Pramosone cream</b> 1%, Rx only; b) <b>pramosone cream</b> , 2.5% (hydrocortisone acetate 2.5%, Rx only, Class III, Defective container.	Multiple lots and expiration dates; 561,260 tubes distributed nationwide; Ferndale Laboratories, Inc., Ferndale, MI.
<b>CombiPatch</b> (estradiol/norethindrone acetate transdermal system) 0.05/0.14 mg per day, Rx only, Class II, Impurities/Degradation.	Lot 7364101, Exp. date 04/2005; 20,057 packers distributed nationwide; Novartis Pharmaceuticals, Corp, East Hanover, NJ.
<b>Effervescent antacid and pain medication</b> (aspirin 325 mg, citric acid 1000 mg and sodium bicarbonate 1916 mg), packaged under various store brands, Class III, Stability failure.	Lots 3EP0066, 3EP0067, 3EP0074, 3EP0075, 3EP0076, 3FP0001, 3FP0002, 3FP0003, 3FP0076, 3GP0001, 3GP0002, 3GP0026; 109,804 packages distributed nationwide; Perrigo Company, Allegan, MI.
<b>Imodium Advanced Caplets</b> (Loperamide HCl 2 mg/Simethicone 125 mg), Class III, Dissolution failure.	Lot HPC025, Exp. date 10/31/05; Lot JHF082, Exp. date 6/30/06; 258,750 pouches and 36,888 bottles distributed nationwide; McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA.
<b>Madame Pearl's brand Cough Syrup</b> , OTC product, Class III, product has exceeded the label expiration date, and has been re-labeled with a new production and expiration date without any supporting data.	Old code: PD/BAT 19990805 Exp. date 20011105; New code: PD/BAT 20030805 Exp. date 20070605; 5 cases (6 x 12 bottles) distributed in PA, IL, and MA; Great Kingsland, Inc., Brooklyn, NY.
<b>Megace Oral Suspension</b> (megestrol acetate), 240 mL bottle, Rx Only, Class II, contains microbial contamination: mold and yeast.	Multiple lots and expiration dates; 23,439 bottles distributed nationwide; Bristol Myers Squibb Caribbean Company, Mayaguez, PR.
<b>Premarin</b> 0.625 mg (Conjugated Estrogens Tablets, USP), Rx only, Class III, dissolution failure.	Multiple lots; Exp. date 09/2005; 15,000,600 bottles distributed nationwide; Rx PAK, Memphis, TN.
<b>Ultra Flu and Ultra Cap, Nasal Decongestant, Cough Suppressant, Antihistamine</b> , Class II, label lacks the declaration of pseudoephedrine HCl 30 mg.	Lot #4293, Exp. date 9/2005; 2,342 bottles distributed nationwide; Weeks & Leo, Co., Inc., Urbandale, IA.
<b>Up Your Gas Energy Booster, Dietary Supplement Caplets.</b> Ingredients include extracts of ginseng, guarana seed, kola nut, yerba mate leaf and niacin, Class II, pesticide contamination.	Lot # 109810804, Exp. date 08/07; 3,480 bottles distributed in FL; Nutrition Formulators, Inc., Miami Lakes, FL.

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## CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC Web site is [www.cpsc.gov](http://www.cpsc.gov).

### *Name of Product; Problem*

**ATVs.** On some units, the nut which secures the front upper suspension arm pivot bolt could come loose during vehicle use. Continued use of the vehicle could allow the nut to come off, and the upper suspension A-arm pivot bolt to back partially out. This would result in a loss of steering control, and possibly cause the rider to crash and suffer injury or death.

**ATVs.** Water can enter the throttle lever case and freeze, causing the throttle lever to become stuck and fail to automatically return to the idle position when the rider releases the throttle. The ATV may not slow down as the rider expects. The rider could lose control of the ATV and an accident resulting in injury or death could occur.

**Baby carriers.** The shoulder strap support can detach from the hammock, posing a fall hazard to the baby.

**Baby rattle.** A metal bar on the rattle can break off during use, releasing small round beads and small farm animal figures. The beads can pose an aspiration hazard to young children. The breakage also can create ragged edges on the ring, posing a laceration hazard.

**Bicycle frame.** The frames on these bicycles can crack and fail during use, posing a risk of injury to riders.

**Bicycle suspension seat posts.** The seat post could fail prematurely. A failure could lead to a crack in the bicycle seat post, which may cause the rider to fall or crash.

**Blenders.** The blades can weaken or break during use while making frozen beverages. A broken blade presents a risk of injury if taken into the mouth or swallowed.

**Candle sets.** The birch surrounding the candles, may ignite, posing a fire and burn hazard.

**Carpet.** The carpet does not meet flammability standards as required under the federal Flammable Fabrics Act. The carpet could ignite, posing a serious risk of burn injuries to consumers.

**Dishwashers.** An electrical defect within the dishwashers' wash motor wiring poses a risk of the motor overheating and possibly catching fire.

### *Lot #: Quantity and Distribution; Manufacturer*

Kawasaki Brute Force(tm) 750 4x4i All-Terrain Vehicle (ATV); about 9,500 sold at authorized Kawasaki dealers sold the ATVs from July-Sept 2004; Kawasaki Motors Manufacturing Corp., USA of Lincoln, Neb.; (866) 802-9381.

Suzuki 2004-2005 model year LT-A500F Vinson, LT-F500F Vinson, and LT-A700X 2005 KingQuad ATVs; about 30,000 sold at Suzuki dealers nationwide between July 2003-Feb 2005; American Suzuki Motor Corp., of Brea, California; (800) 444-5077.

Playtex Hip Hammock; about 32,000 sold at stores, nationwide, catalog and internet sites from June 2004-Feb 2005; Playtex Products Inc., of Westport, Conn.; (800) 522-8230 or [www.playtexbaby.com](http://www.playtexbaby.com).

Farm Teether Rattle; about 3,700 rattles sold by Tiffany and Company in its retail stores and from its catalogs and Web site from Nov 2002-Mar 2004; New England Sterling of Attleboro, Mass., for Tiffany and Company of New York, N.Y.; (800) 464-5000.

Titanium bicycle frame for road bicycles; 422 units sold via direct Web site sales from Jan 1997-Dec 2004; CF Roark Welding & Engineering Co. Inc., of Brownsburg, Ind.; (800) 556-3163.

1-X Bicycle Suspension Seat Post; about 1,480 sold at authorized Cannondale dealers nationwide in December 2004; multiple bicycle models affected; Cannondale Bicycle Corporation, of Bethel, Conn.; (800) BIKE-USA.

Black & Decker(r) brand ProBlend(r) blenders; about 500,000 sold at retailers nationwide from Dec 2003-Jan 2005; models BL5000, BL5900 and BL6000; Aplica Consumer Products Inc., of Miramar, Fla.; (800) 385-6686 or [www.regcen.com/blenderrecall](http://www.regcen.com/blenderrecall).

Martha Stewart Everyday Brand Birch Candle Sets; about 4,600 sold at Kmart stores nationwide from Sept 2004-Jan 2005; Kmart Corp., of Troy, Mich.; (866) KMART4U or [www.kmart.com](http://www.kmart.com).

Shaw Industries' "Southern Breezes" Wall-to-Wall Carpet; about 5,000 square yards of carpet sold at certain Menards stores in IL, IN, IA, MI, MN, NE, ND, SD and WI from April 2004-June 1, 2004; Shaw Industries Inc., of Dalton, Ga.; (800) 441-7429.

Whirlpool(r) and Kenmore(r) brand dishwashers; about 162,000 sold at department and appliance stores and through homebuilders nationwide from June 2004-Jan 2005; Whirlpool Corporation, of Benton Harbor, Mich; (866) 769-7260 or <http://repair.whirlpool.com>.



## CONSUMER PRODUCTS *cont.*

### *Type of Product; Problem*

**Dishwashers.** These dishwashers have a connector that can short-circuit and overheat during normal use, posing a fire hazard to consumers.

**Dive sticks.** Children can fall or land on these upright dive sticks in shallow water and suffer impalement injuries. CPSC banned pre-weighted dive sticks in 2001.

**Electrical cord for light fixture.** The cord of the light fixture can drip plasticizer fluid onto the light fixture, which can degrade the acrylic reflector, causing it to crack and fall. Falling pieces of acrylic can injure a person below the fixture.

**Electronic musical toys.** The ball on the end of the drumstick sold with these toys can break off during use, posing a choking hazard to young children.

**Flying saucer toy.** The Flying Saucer can overheat while charging, resulting in the plastic motor cover starting to melt, creating a risk of burns to children handling the toy.

**Glass light shades.** The glass shades can separate from the light fixture, posing a risk that a consumer could be cut by the broken glass if the shade were to fall and break.

**Infant and toddler sweaters.** The zipper-pull mechanism can detach from the zipper, posing a choking hazard to children.

**Infant toy.** The seam on the plastic balls can separate, releasing the small toy inside and posing a choking hazard to young children.

**Light fixtures.** A component in the light fixture can leak fluid, which can degrade the acrylic lenses and reflectors, causing them to crack and fall. Falling pieces of acrylic can injure someone below the fixture.

**Musical candleholder.** The center of the candle has an unexpected high flame and the plastic petals could ignite. The ignited plastic could also spread to nearby combustibles and pose a fire hazard. The battery in the middle of candle could eventually explode.

**Pacifiers.** The pacifiers are banned under federal law. They failed federal safety tests and can pose a choking hazard to infants and small children.

### *Lot #: Quantity and Distribution; Manufacturer*

General Electric Built-in Dishwashers; about 74,300 sold at appliance retail outlets and builder distributors nationwide from Jan 2004-Feb 2005; GE Consumer & Industrial of Louisville, Ky; (800) 804-9802 or [www.GEappliances.com](http://www.GEappliances.com).

Dive sticks in the shape of worms, fish, and seahorses; about 180,000 dive stick packages sold at Dollar General stores nationwide from April 2004 through September 2004; The Dollar General Corp., of Goodlettsville, Tenn; (800) 678-9258 or [www.dollargeneral.com](http://www.dollargeneral.com).

High Intensity Discharge (HID) light fixtures with acrylic reflectors; about 120,000 sold by lighting and electrical supply distributors nationwide from June 1999-May 2002; Lithonia Lighting, of Conyers, Ga.; 866-799-6173 or [www.lithonia.com/HIDCordRecall](http://www.lithonia.com/HIDCordRecall).

"Toy Tunes" Electronic Musical Toys; about 147,600 sold at Dollar Tree, Only \$1, and Dollar Bills stores nationwide from Mar 2004-Jan 2005; Dollar Tree Stores Inc., of Chesapeake, Va.; (800) 876-8077 or [www.dollartree.com](http://www.dollartree.com).

Battery-Powered Flying Saucer Toys; 555 units distributed through school fund-raising programs nationwide from Aug 2004-Sept 2004; QSP Inc., Pleasantville, N.Y.; (800) 966-4540.

The Ginger(r) Kubic(r), K2(r) and Surface(tm) Bathroom Light Fixtures; about 5,900 sold to commercial dealers and consumers through select showrooms and retailers nationwide from Aug 2003-Sept 2004; Ginger(r), of Fort Mill, S.C.; (800) 842-4872 or [www.gingerco.com](http://www.gingerco.com).

Arizona(r) Boys' Zip-Up Cardigan Sweater; 42,000 toddler-size and 15,000 infant size sold at J.C. Penney stores nationwide from Sept 2004-Jan 2005; J.C. Penney Corp., of Plano, Texas; (888) 333-6063 or [www.jcpenney.com](http://www.jcpenney.com).

Baby Connection Reef Rocker infant toys; Sold at Wal-Mart stores nationwide from May 2004 through January 2005; Wal-Mart Stores Inc., of Bentonville, Ark; (800) 925-6278 or [www.walmartstores.com](http://www.walmartstores.com).

High Intensity Discharge (HID) light fixtures with acrylic lenses and/or reflectors; about 93,200 sold by lighting and electrical supply distributors nationwide from April 2002-Feb 2004; Lithonia Lighting of Conyers, Ga.; (866) 345-1194 or [www.lithonia.com/HIDCapRecall](http://www.lithonia.com/HIDCapRecall).

Musical Flower Birthday Candleholder; about 120 sold by Skylighter on their Web site only in sets of two; Skylighter Inc., of Round Hill, Va.; (540) 338-3877 or [lwilkinson@skylighter.com](mailto:lwilkinson@skylighter.com).

Soother Baby Pacifiers; about 34,500 sold at gift shops, discount retail stores and various Hispanic commercial retailers nationwide from Mar 2000-Jan 2005; The Elegant Kids 2000 Inc., of Los Angeles, Calif.; (213) 627-6716.

*continued on page 10*



*Type of Product; Problem*

**Portable cribs.** The crib slats can separate from the headboard, posing an entrapment risk to young children. In addition, children can fall through the slat opening.

**Projection televisions.** An internal electrical connection can cause electrical arcing, charring or smoking inside the television, which pose a fire risk to consumers.

**Rope candle.** The candle has a clamp that, when clamped properly, will extinguish the candle when the burning wick meets the metal clamp. The clamp may sever the wax close enough to the wick to enable the wick. This can lead to the flame continuing down into the coiled section of the candle, which can then ignite and cause fire damage.

**Silver charms.** The recalled metal charms contain high levels of lead, posing a serious risk of lead poisoning to young children.

**Snowmobiles.** The snowmobile wiring harness may be routed in a way that could disconnect the engine stop switch and the throttle safety switch connector. The engine stop and the throttle safety switches will no longer function. This could pose a possible crash hazard. However, the keyed ignition switch will continue to function and will shut down the vehicle when the key is in the OFF position.

**Stuffed bunny.** The eyes and the heart and flower button decorations can detach from the stuffed animal, posing an aspiration hazard to young children.

**Toddler drinking cups.** A container inside the cup holds petroleum distillates, which can leak onto the outside of the cup and could come into contact with the user posing a poisoning hazard to children.

**Women's boots.** The heel on the boot can detach from the sole while in use, causing the consumer to fall.

**Yarn.** Garments constructed of "Fur Out" yarn are dangerously flammable, posing a burn risk to consumers.

**Youth ATVs.** Metal-flange locking nuts securing the tie rod assemblies, integral to the steering system on the Youth ATV, can come loose. The resulting unstable steering condition could result in serious injury or death to a rider.

**Zipper pulls.** The rubber zipper pull-tab can be bitten off and may pose a risk of choking to young children.

*Lot #: Quantity and Distribution; Manufacturer*

Portable Cribs; about 10,000 sold at juvenile furniture stores nationwide from Jan 2004-Feb 2005; model numbers 4464-1, 4464-2, and 4464-4; Delta Enterprise Corp., of New York, N.Y.; (877) 660-3777 or [www.deltaenterprise.com](http://www.deltaenterprise.com).

JVC Rear-projection televisions; 26,500 sold at consumer electronic stores nationwide from July 2004-Jan 2005; JVC Americas Corp., of Wayne, N.J.; (800) 252-5722; [www.jvc.com/support/notification](http://www.jvc.com/support/notification).

Beeswax Rope Candle; about 2,000 sold at Gardener's Supply retail store in Burlington, Vt., and in the Holiday 2004 Gardener's Supply Catalog sold the candles from Oct 20-Nov 12, 2004; Zhongshan Zhongnam Candle Manufacturer Co., Ltd. of China; (800) 876-5520 or [www.gardners.com](http://www.gardners.com).

"Charming Thoughts(tm)" Necklace Charms; about 2.8 million sold at Michaels Stores from July 2002-Feb 2005, at Recollections stores from Oct 2004-Feb 2005, and at Hancock Fabrics stores from Jan 2004-January 2005; Hirschberg Schutz & Co. Inc., of Warren, N.J.; (800) 873-5506 or [charmsrecall@horizongroupusa.com](mailto:charmsrecall@horizongroupusa.com).

Polaris "900 Fusion" "900 RMK" and "900 Switchback" Snowmobiles; about 11,560 sold at Polaris dealers nationwide from Aug 2004-Feb 2005; model no. S05PL8DSD, S05PM8DS(A)(B), S05PN8DS, S05PS8DS, S05MP8DS(A)(B)(C), S05PL8DS(A)(B)(C); Polaris Industries, Inc., of Medina, Minn.; (800) 765-2747 or [www.polarisindustries.com](http://www.polarisindustries.com).

Stuffed Yarn Bunny; about 18,500 sold at discount and dollar stores from Feb 2002-March 2003; Ocean Desert Sales Inc., of Philadelphia, Pa.; (800) 252-1931.

"Maui Ocean Center" Toddler Drinking Cups; 720 sold at the Maui Ocean Center in Wailuku Maui, Hawaii from June 2003-Sept 2004; Charles Products, of Bethesda, Md; (800) 242-7537.

Merona Women's Sidezip "ENA" Style Boots; about 135,000 sold at Target stores nationwide and through Target's Web site from July 2004-Jan 2005; Target Corp., of Minneapolis, Minn.; (800) 440-0680 or [www.target.com](http://www.target.com).

Bernat "Fur Out" yarn; about 730,000 1.75-ounce balls sold by craft stores nationwide and in Canada since April 2004; all colors; Spin Rite LP of Ontario, Canada; (800) 641-5634 or <http://www.bernat.com>.

Kolpin Powersports 50cc and 90cc Youth All Terrain Vehicles (ATVs); about 1,000 90cc units and 39 50cc units sold at Kolpin Powersports' authorized retailers nationwide from Sept-Nov 2004; Kolpin Powersports, Inc. Fox Lake, Wisconsin; 877-9KOLPIN (877-956-5746).

Lands' End Infant and Toddler Squall Parkas, Sport Squalls, Squall Snow Suits and Squall Bibs; about 24,000 sold by Lands' End Catalogue and Web site from Aug-Dec 2004; Lands' End, of Dodgeville, Wis.; (800) 200-6212 or [www.landsend.com](http://www.landsend.com).



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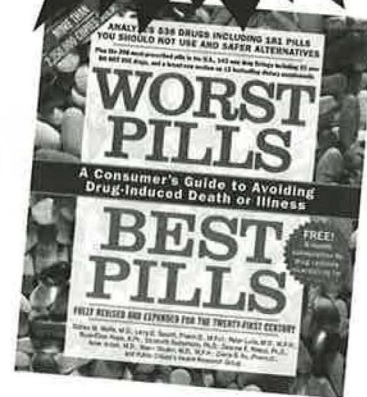
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