

Health Letter

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Patients' Rights Bills And Other Futile Gestures

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Health care reform is once more at the top of the political agenda, after some six years of neglect in the wake of the failure of the Clinton plan. During those six years, the issue was generally considered one of the third rails of American politics—not to be touched. What is causing the turn-about? There are three reasons. First, after a period of stagnation during the mid-1990s, inflation in health care costs is again sharply on the increase. Second, the number of Americans without any health care insurance at all, or with inadequate coverage, continues to rise. And third—and most important politically—middle-class voters are getting fed up with the abuses of managed care. They are frustrated by shorter hospital stays, restricted choices of doctors, arbitrary denials of coverage, increasing deductibles and copayments, and all the other methods by which the industry resists actually providing services to sick people.

Since the demise of the Clinton plan in 1994, it has been generally agreed that reform of the health care system cannot be full-scale. Conventional wisdom holds that the Clinton attempt failed, in large part, because it was too sweeping. According to this view, reform needs to be incremental to succeed. Thus, what few reforms we have

seen since 1994 have merely nibbled at the edges of the access problem. For example, the Kennedy-Kassebaum statute, which permits employees who leave their jobs to continue their health insurance (if they can afford to pay for it), and the expansion of insurance coverage for children are quite modest in their scope and effects. Similarly, attempts to deal with the abuses of managed care have been piecemeal—for example, legislation to require 24-hour hospital stays after childbirth.

It is in this spirit that a number of "patients' rights" bills are being offered, both in the U.S. Congress and in state legislatures. The proposals differ from one another in some respects, most notably in the population to which they would apply and the extent to which patients would be permitted to sue their managed care companies. However, all have in common efforts to restore to patients and their doctors control over medical decisions—control that has increasingly been assumed by third party payers and managed care plans. For example, the bills pro-

vide for appeals mechanisms when services are denied, for treatment in hospital emergency departments when patients plausibly believe it is warranted, and for decisions about referrals to be made by doctors and patients, not by health plans and employers.

I very much agree with the aims of the patients' rights bills. But I also believe these bills will not achieve their ends. Rather, I am afraid they will have effects opposite from those intended. Patients' rights bills will simply swell the ranks of the uninsured. Why such a perverse effect? The reason is that employers are not required by law to offer any health care benefits at all, and they will not do so if they believe the disadvantages outweigh the advantages. Patients' rights bills will tend to tip that balance. Insofar as they have teeth, they will inevitably increase the costs of managed care companies, which will simply pass their increased costs along to employers. Employers may then decide to drop health care coverage altogether, or to limit it sharply through stratagems such

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Asthma Medications, Wheelchairs and Windshield Washer Fluid are on our list this month. 5

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Bereavement

At least 8 million Americans lose a relative to death each year, and the result, for the survivors, is called bereavement. Medical writer Peggy Eastman has turned her personal tragedy, and her own response to it, into articles which have comforted many others.

"Nothing is more devastating than losing someone close to you, especially a spouse," says Ms. Eastman. Her husband, James Eastman, was a passenger on a small commuter plane which crashed in Maine, killing him, young activist Samantha Smith, and six others. Her first reaction was "violent tears of protest," and she later had nightmares, bouts of depression, and spiritual struggles.

One month after her husband's death, she says, "I set out to research my condition, in a desperate attempt to

understand what was happening to me...I felt it might be the only thing that would help."

Bereavement is defined as "loss through death." The inevitability of death makes bereavement, like pregnancy, a common and natural occurrence which results in changes in both function and behavior. As each person is different, so each death is different, and every bereaved person has some unique reactions, which may depend on the deceased person's age, suddenness of death, and type of death. Each year, death of a spouse results in 800,000 new widows and widowers. Despite the advances of modern medicine, which have reduced childhood mortality, nearly 400,000 persons under age 25 die each year, leaving millions of siblings, parents, and friends in a state of grief. There are at least 27,000 sui-

cides each year in the U.S. Experts feel that the loss of a spouse or the loss of a child are the two most difficult losses to adjust to.

Grief, defined as the behaviors and processes associated with bereavement, usually follows a common course. Grief, sometimes equated with mourning, is normal, and adaptive, allowing the affected person eventually to get on with their own life. Grief may have complications, however, which may require medical attention. Other adverse events, such as a divorce or loss of a limb, may initiate similar grieving patterns.

The Phases Of Grief

Grief is frequently described as occurring in phases, in which one follows another, although some people move back and forth between them.

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as "defined contributions," rather than pay the higher premiums for standard benefits. Workers, for their part, may elect not to accept health care insurance, because of the growing direct costs to them. Thus, patients' rights legislation will very probably increase the number of uninsured and underinsured people. The tougher the regulations, the more likely this outcome. The fundamental problem is that it is impossible to regulate health care in an employment-based system if employers can opt out.

The threat that patients' rights legislation will increase the number of the uninsured and underinsured may not be fully realized in our present economy, when we have nearly full employment and many employers have a strong incentive to offer good benefits to attract workers. However, we need to remember that even in this booming economy, the ranks of the uninsured and underinsured are steadily increasing. Most of the newcomers to these ranks are employed. With a downturn in the job market, bargaining power would probably begin to shift from employees to employers. In that case,

a very large number of employers might be willing to drop or reduce health care benefits, especially if premiums were rapidly increasing.

That is exactly what the managed care industry and many of its allies in Congress argue in opposition to patients' rights bills. I believe they are correct about the probable effects of such bills on the number of the uninsured and underinsured, but they are wrong in concluding that the present managed care insurance system is essentially sound. (The only change the industry advocates from time to time is an expansion of coverage by managed care, but with premiums, of course, set by the private market and subsidized by government.) What we should instead conclude is that the private managed care market has been a miserable failure at delivering health care. It has creamed off ever larger percentages of health care premiums in bloated administrative and marketing costs and profits, it has rewarded health plans that cherry-pick the healthy and avoid the sick, and it has resisted at every turn providing adequate services to those unfortunate enough to need them.

There is no question that patients' rights—and doctors' rights—are essential in any decent health care system. But they cannot be legislated in isolation in a system whose every incentive works against these rights and where the provision of health care insurance is purely voluntary. What needs to be changed is the system itself. Contrary to conventional wisdom, incremental changes, such as patients' rights legislation, will not work. In a competitive private market, they simply provoke reactions that nullify the social objectives of the legislation.

This is not the place to present in detail a plan to overhaul our health care system. But there are three major changes that would address the difficulties in ensuring patients' rights that I have discussed here.

First, employers should get out of the health care business altogether. There is no reason to believe they are good proxies for their workers when it comes to health care decisions. Indeed, they have a clear conflict of interest, since they have a strong incentive to keep premiums as low as possible.

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Second, just as employers are not good proxies for their workers, so investor-owned managed care companies are not good proxies for doctors. They, too, have a conflict of interest. They have obligations to their investors as well as to their enrollees. That the former often take precedence is evident from all the ways in which the industry limits medical services even while maintaining high profits and executive salaries. In my view, there is no place for these businesses in a good health care system.

Finally, health care insurance should

not be optional, as it is in our employment-based system. Just as everyone over the age of 65 is covered by Medicare, so should everyone under that age be covered. In a 1993 editorial in these pages, I called for a universal, single payer system and suggested that we could attain that goal by extending Medicare to all Americans. The need is even greater now. Those who worry that such a reform would increase taxes should remember that we all pay for health care anyway—through our paychecks, deductibles, and copayments, and the prices of goods and services—and that Medicare is far

more efficient than the market-based part of our health care system.

Election year 2000 is the time to look again at our health care system in its entirety, not just in bits and pieces. The insurance industry will once again mount a campaign to prevent that from happening. Harry and Louise will be back, perhaps with aliases. But can they convince the American public once again that government is the bogeyman and that the private sector will take care of their health care needs? I doubt it. We've had six years of hard experience, and we know better.

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The boundaries between the phases may be blurred.

Phase 1

The first phase begins immediately after the loss, and may last up to a few weeks. The survivor experiences shock, numbness, and disbelief. Other common symptoms include crying, sighing, throat tightness, and a sense of unreality. The shock may be more pronounced if the death is sudden and unexpected.

Phase 2

The second phase of grief is characterized by preoccupation with the deceased and a yearning to recover the lost person. The survivor frequently re-examines the past relationship, including disagreements, conflicts, and unresolved anger. Emotions can fluctuate wildly, from intense sadness, to anger, to guilt. Dreams of the deceased may be intense and vivid. Weakness and fatigue are also common. If this phase extends beyond several months and does not progress to further stages, it may signal the need for treatment, as this constitutes "pathological grief."

Pathological grief may refer to several abnormal patterns of grief. Absent grief, delayed grief and distorted grief are three such forms. Distorted grief usually involves persistence of the second stage of grief. This may show itself through compulsive overactivity without a sense of loss, acquisition of the symptoms associated with the deceased, loss of health, social isolation or alienation, or

severe depression. Any of these symptoms may require medical attention, or increased social support. However, cultural norms may differ, and in some cultures a single symptom listed above may not represent a true problem.

Phase 3

Disorganization and despair characterize the third phase, although the end result is that the survivor accepts the permanence and the fact of loss. The survivor ceases attempts to recover the lost person. Sadness persists in this phase, along with feelings of emptiness, and loss of interest in usual activities.

Phase 4

The fourth phase involves resolution and reorganization of behavior. Normal activities resume, and the bereaved person regains interest in usual activities. Some new social contacts are made. Occasional feelings of sadness, emptiness, and crying spells may occur, but less frequently than before, or with less intensity. The result may not be a complete return to previous activities, but is a lessening preoccupation with the deceased. Past events with the deceased person can be recalled with some pleasure.

The distress of grief and mourning was formerly thought to be short-lived, but recent studies have shown that such feelings can persist for many years. In fact, some think that it normally can last a lifetime. This has prompted some to conclude, "You really don't get over it, you get used to it." As noted before,

there is a tremendous amount of individual variation.

The Consequences of Bereavement

It has been a common observation, over many years, that the recently widowed are at increased risk for death. Medical studies of this phenomena have more recent origins. Many studies have looked at the death of a spouse, and according to a 1984 National Academy of Sciences review, "some bereaved persons are at increased risk for illness and even death." Risk factors for death include male gender (widowers) and living alone. Remarriage seems to protect against this effect, but it is not clear if remarriage itself is truly protective, or if those with better support systems tend to remarry and that this protects.

Recent research has shown that the immune system becomes slightly depressed during the grieving process. This may be due to general stress, depression, bereavement itself, or for some other reason. Infections may result from this suppressed immune system, ranging from colds to pneumonia, although this is by no means universal.

Other bereaved persons at increased risk of serious consequences include those who feel a lack of a support system, those in poor health (physical or mental) prior to the death, alcoholics, those with severe financial difficulties, and those under 65. Preventive efforts may avoid some of the serious results of bereavement. Someone with

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many of these risk factors is more likely to need support, counseling, or some other intervention. The suicide of someone especially close also increases risk.

Interventions

As noted, grief is normal and adaptive, and in most cases does not need to be "medicalized" into an illness. However, if help is needed, there are people to turn to.

1. *Support groups*, are where people who have had similar experiences meet and discuss topics of concern. Topics can include social adjustment, research discussions, the grieving process, and how to avoid stumbling blocks.

As noted in a National Institute of Mental Health publication, "Mutual-help groups do not intend to replace physicians, therapists, and other skilled professionals. Rather, the groups function in the belief that many of our physical and mental health needs go beyond the bounds of formal care measures."

2. *Counseling* is another intervention which may help deal with grief. At its simplest, counseling may be support from friends and family, however, health care personnel can provide this service. The basic goal is to facilitate passing through the phases of mourning, by accepting the reality of the loss, dealing with feelings and emotions, and readjusting to the new environment.

3. *Medications* are a controversial part of the bereavement process, particularly because of the risk of delayed or distorted grief. Some people feel that the reason for the widespread use of medications is that physicians find it

easier to write a prescription than to deal with feelings. Some bereaved persons, however, do legitimately need a *short* (7-10 day) course of sleeping pills or tranquilizers. Longer courses of treatment may lead to addiction, or other complications. Research into this area, as recommended by the National Academy of Sciences, is sorely needed.

4. *The hospice movement* has initiated preventive efforts for those with loved ones who have a chronic and fatal disease. They can help prepare for the eventual loss. Their effectiveness is under investigation, because they are so new.

Recommendations

The Institute of Medicine/National Academy of Sciences released a report in 1984 entitled, *Bereavement: Reactions, Consequences, and Care*. They had several conclusions and recommendations for future work in this area, although only some of the actions have been taken so far. Two international conferences on bereavement have been organized in response to the report, and some additional research money has become available, according to Fred Solomon of the Institute of Medicine.

The report recommends:

- Health professionals and institutions have a continuing responsibility to the bereaved.
- Schools should train nurses and physicians to look for warning signs, and should refer people at high risk for pathological grief for counseling.
- The integration of social workers and chaplains into hospital settings,

particularly those involving terminal illness, has improved the care at some medical institutions.

- Increased public education may offer support indirectly to bereaved persons. The report notes that institutional care for the dying, and geographic mobility have left many people unprepared to deal with death. Many people are surprised by the intensity of their emotional reaction to the death of a loved one.

- Further research is needed in several areas, notably the process and outcome of bereavement. The risk factors for death or disease following the death of someone close need to be studied to effectively plan ways to prevent such problems. Health consequences of bereavement in children, in minority groups, and in other cultures, as well as expanded research into the biology and physiology of grieving, were all highlighted as major areas in need of research.

Research into the intervention strategies described above is needed to evaluate their effectiveness and whether they may be broadly applied to the general population. In particular, the panel noted the opportunities available to evaluate the rapidly evolving hospice movement. Finally, they recommended the establishment of a research review committee by the federal National Institute of Mental Health (NIMH) to coordinate bereavement studies of all kinds.

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Product Recalls

May 12—June 7, 2000

DRUGS & DIETARY SUPPLEMENTS

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

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 reasonable 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 website is <http://www.fda.gov>.

Consumers should note the extremely large recalls of generic albuterol, brand name albuterol (Proventil), and brand name beclomethasone (Vanceril, Vancenase) inhalation and nasal aerosols. These drugs, prescribed for the prevention and relief of bronchospasm, asthma and allergy, are being recalled because they may not have any active ingredient. Although the FDA has classified these as Class II recalls, consumers should be aware that since some of the canisters may not have any active ingredient, this could create a life-threatening situation, and as recently as January 1999, the FDA classified a similar recall as Class I. Consumers can view the entire recall notice with all lot numbers and expiration dates on the FDA web site at <http://www.fda.gov/bbs/topics/ENFORCE/ENF00644.html>

Name of Drug or Supplement; Class of Recall; Problem

Albuterol and Proventil Aerosol Inhaler Canisters and refills under Warrick, Martec, Major, Qualitest, Novopharm, Schein, United Research Laboratory labels; Class II; Some canisters may not have active ingredient

Albuterol Sulfate Inhalation Solution, 0.083%, in 3 ml unit dose vials, Rx used for prevention and relief of bronchospasm; Class II; Mislabeling—Exterior carton incorrectly labeled as Ipratropium (vials inside correctly labeled)

Allegra-D Extended-Release Tablets, (Fexofenadine HCL 60 mg and Pseudoephedrine HCL 120 mg), in 100 tablet bottles, Rx; Class III; Incorrect expiration (June 2001 instead of May 2001)

Clindamycin Phosphate Topical Solution, 1%, Rx, packaged in 1-fluid ounce bottles; Class III; One degradant exceeded specification during stability testing

Lot #: Quantity and Distribution; Manufacturer

Numerous codes and lots; 58,936,179 units distributed nationwide, and in Puerto Rico and Canada; Schering Laboratories, Kenilworth, New Jersey

Lot #A9H045 EXP 8/01; 2,340 vials distributed New York, Missouri; Automatic Liquid Packaging, Woodstock, Illinois. Recalled by Alpharma USPD Inc., Baltimore, Maryland

Lot #1017145 EXP 6/01; 12,556 bottles distributed nationwide; Aventis Pharmaceuticals, Inc., Kansas City, Missouri

Lot Numbers 21796 and 22334; 8,239 bottles distributed nationwide; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois

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What You Can Do

Several resources are available for mutual support groups. The national groups listed below may be able to refer people in need to a local group. Larger groups may be listed in the local telephone directory, and names and phone numbers of many more are available from hospitals, and local

health and social-service agencies.

The Compassionate Friends, P.O. Box 3696, Oak Brook, IL 60522-3696, (630) 990-0010

—for parents who have experienced the death of a child

THEOS (They Help Each Other Spiritually), 322 Blvd. of the Allies #105,

Pittsburgh, PA 15222, (412) 471-7779 —for widowed people

The information in this article was compiled by the Institute of Medicine for the National Institute of Mental Health.

Name of Drug or Supplement; Class of Recall; Problem

Lot #: Quantity and Distribution; Manufacturer

Digoxin Tablets, 0.125 mg, unit dose blister packs, Rx for treatment of mild to moderate heart failure, and for control of ventricular response rate; Class II; Tablet thickness failure

Entuss-D Liquid Antitussive (Roberts Pharmaceuticals brand), nasal decongestant, expectorant, 16 fl.oz. Rx Control Schedule III; Class III; Subpotent

Estrostep(r) Fe Tablets, (norethindrone acetate, ethinyl estradiol and ferrous fumarate), in 28 tablet dispensers, Rx oral contraceptive; Class II; Subpotency

Fecosol(r) Elixir Iron Supplement Therapy 44mg, in 16-ounce (473ml) bottles; Class II; Subpotent iron content (stability testing) and crystalline precipitate

Goldline Products: a) Doxycycline Hyclate Capsules, 100 mg, b) Indomethacin Capsules, 50 mg, both in blister packs in boxes of 100; Class II; Mislabeling—Indomethacin Capsules were incorrectly labeled as Doxycycline Hyclate Capsules

Herbal Dietary Supplements in oral dose capsules: a) Diabetes Hypoglucose Capsules, OTC, 70 capsules per bottle; b) Pearl Hypoglycemic Capsules, 60 capsules per bottle; Class I; Misbranding—Product contains undeclared antidiabetic prescription drug glyburide

Lanoxin(r) Tablets (digoxin), 0.125mg, in bottles of 1,000, Rx indicated for treatment of mild to moderate heart failure and for control of ventricular response rate; Class II; Tablet thickness failure

Mintezol(r) Chewable (Thiabendazole) Tablets, 500 mg, in unit dose packages of 36 tablets, Rx for treatment of parasitic infections; Class II; Use of an unapproved binding agent in formulation

NeGram Suspension (Nalidixic Acid Oral Suspension), 250 mg/5mL, in 1 pint bottles, Rx indicated for the treatment of urinary tract infections; Class III; Superpotent

Oxygen Compressed, medical gas in high-pressure cylinders sizes E, D, C and B, Rx for pulmonary use; Class II; Current good manufacturing deviations including lack of odor testing prior to distribution

Oxygen, Rx in E, D, and M-6 Compressed Cylinders; Class II; Current good manufacturing deviations and complaint related to "chlorine-like odor"

Promethazine Syrup Plain, 6.25 mg/5mL in 4 and 16 ounce bottles, Rx for treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic reaction, sedation in both children and adults, and antiemetic therapy in postoperative patients, packaged under the MGP, Major Pharmaceuticals, Qualitest labels; Class II; Subpotency

Promethazine with Codeine Cough Syrup (6.25 mg/5 mL and 10 mg/5 mL), in 4 and 16-fluid ounce (pint) bottles, Rx schedule V narcotic oral liquid for temporary relief of coughs and upper respiratory symptoms associated with allergy or common cold, under labels MGP, Zenith Goldline, Major Pharmaceuticals, Qualitest, URL; Class III; Subpotency of the Promethazine Hydrochloride ingredient

Lot #0547-0003 EXP 1/31/01; 90 blister pack units distributed nationwide; Glaxo Wellcome, Inc., Research Triangle Park, North Carolina. Recalled by Vanguard Labs, Inc., Glasgow, Kentucky

Lot M78280 EXP 12/00; 3,344 bottles distributed in California and New Jersey; Schwarz Pharma Manufacturing, Inc., Seymour, Indiana

Lot Numbers 44808F, 44908F EXP 3/00, and 44708F (Expired 2/00); 29,703 units distributed nationwide; Warner Lambert, Fajardo, Puerto Rico. Recalled by Parke-Davis, Morris Plains, New Jersey

Lot Numbers 9H23A and 9J11A; 10,608 bottles distributed nationwide; SmithKline Beecham Consumer Healthcare, Aiken, South Carolina

Lot Numbers: a) T-1474 EXP 10/01, b) T-1475 EXP 10/01; 970 boxes distributed nationwide; Zenith Goldline Pharmaceuticals, Northvale, New Jersey. Recalled by International Labs, St. Petersburg, Florida

All lot codes; 2,674 bottles distributed nationwide and internationally; Pingchuan International Economic Trade and Tongyi Tang Pharmaceutical, Harbin, China. Recalled by Chinese Angel Health Products, Inc., Blaine, Washington

Lot #9ZP1665 EXP 6/02; Undetermined quantity distributed nationwide; Glaxo Wellcome, Inc., Zebulon, North Carolina

Lot Numbers J800, J8001, J8002, J8003, J8004, J8005 EXP 01/04, J8011, J8012, J8013, J8014, J8016, J8017 EXP 02/04, J8013 EXP 03/04; 24,163 units distributed nationwide and internationally; Merck and Company, West Point, Pennsylvania

1,200 units distributed nationwide, and in Canada; Bayer Corporation, Myerstown, Pennsylvania. Recalled by Sanofi Pharmaceutical, Inc., New York, New York

All lot numbers including all tanks received by customers between 4/97 through 4/7/00; 2,500 cylinders distributed in California; Americair of the East Bay, Vacaville, California

CODE E cylinders coded 0260001 and 0260002, D cylinders coded 0260002, M-6 cylinders coded 0260002; 30 cylinders distributed in Florida; Southern Respiratory, Inc., Naples, Florida

Lot Numbers: 22086A, 22086C, 22086E, 22110 (sublots A,C,E) EXP 04/00 and lot 22227(sublots A,C,E,F,H,K) EXP 06/00; 48,416 bottles distributed nationwide; Morton Grove Pharmaceuticals, Morton Grove, Illinois

Lot Numbers: 22128, 22161, 22238, 22295, 22369, 22500, 22555, 22649A; 231,227 bottles distributed nationwide; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois

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Name of Drug or Supplement; Class of Recall; Problem

Saline Nasal Spray, OTC, in 1.5-ounce white bottles, under labels: Albertson's, Bi-Mart and Health Pride; Class II; Products had discoloration and iron contamination

Spartan(r) Antiseptic Hand Cleaner & Shampoo, OTC, in 800 mL bags, 1 and 5-gallon pails, and 15, 30 and 55-gallon drums; Class II; Product contains unapproved dyes

Sterile and Non-sterile Skin Preparations by Clinipad (also under Afassco brand); Class I, and II; Possibility of bacterial contamination and manufacturer cannot assure sterility; These items were sold as swabsticks, pads and as topical applications separately and as part of first aid kits

Tavist-D(r) Tablets, (Clemastine Fumarate, 1.34 mg/ Phenylpropanolamine HCL 75mg), 8 tablet units, OTC, antihistamine/nasal decongestant; Class II; Low weight tablets

Triamcinolone Acetonide Cream, 0.1%, in 15-gram tubes, Rx; Class III; Mispackaging—Some tubes are incorrectly labeled to contain Gentamicin Sulfate

True Care(tm) Stool Softener with Laxative Softgels, (Docusate Sodium 100 mg/Casanthranol 30 mg), OTC in bottles of 100; Class II; Misbranded—Labeling fails to declare dosage instructions

Vancoril Inhalation Aerosols (beclomethasone dipropionate), Rx for maintenance treatment of asthma and Vancenase Nasal Aerosol, (beclomethasone dipropionate), Rx indicated for relief of symptoms of seasonal or perennial rhinitis; Class II; Some canisters may not have active ingredient

VioNex Antimicrobial Skin Wipe Towelette, (0.5% Parachlorometaxylenol), OTC used to clean skin when soap and water are not available; Class II; Possible microbial contamination

Vira-A(r) Ophthalmic Ointment, 3%, (Vidarabine), in 3.5 gram tubes, Rx; Class II; Leaking tubes at crimp end

Zantac (Ranitidine Tablets), 75 mg, 4 tablet units, OTC acid reducer; Class III; Product fails appearance of specification due to container/packaging deviation

a) **Zilatone Laxative and Digestive Aid Tablets**, (Phenolphthalein 32 mg per tablet), OTC in 50 tablet bottles; Class II; Products contain phenolphthalein which is not generally recognized as safe and effective in over-the-counter stimulant laxatives

Lot #: Quantity and Distribution; Manufacturer

Lot #9M97007; 30,732 units distributed in Indiana, Oklahoma, Oregon, Pennsylvania; Accupac, Inc., Mainland, Pennsylvania. Recalled by Leiner Health Products Inc., Carson, California

Lot Numbers: 0987 through 0993, and all codes prior to "04/03/00" expiration date; 100,800 gallons distributed nationwide; Steiner Company, Inc., Holland, Ohio (packager). Recalled by Spartan Chemical Company, Maumee, Ohio

Numerous codes and lots; Undetermined large quantity distributed nationwide; Clinipad Corporation, Rocky Hill, Connecticut

Lot #306295 EXP 3/02; 345,780 packages distributed in Nebraska, Indiana; Novartis Consumer Health, Inc., Lincoln, Nebraska

Lot #M793 EXP 3/03; 30,000 units distributed nationwide; Thames Pharmacal Company, Inc., Ronkonkoma, New York

Lot Numbers: 5674A, 5765B, and 5834A; 1,584 bottles distributed nationwide; Banner Pharmacaps, High Point, North Carolina. Recalled by Apothecary Products, Inc., Burnsville, Minnesota

Numerous codes and lots; 8,812,838 units distributed nationwide, and in Puerto Rico and Canada; Schering Laboratories, Kenilworth, New Jersey

Lot Numbers: 903193, 911283, 912850, and 913598; 2,481.4 cases (10 units per case) distributed nationwide, and in Puerto Rico and Canada; Clinipad Corporation, Rocky Hill, Connecticut. Recalled by Sybron Dental Specialties, Inc., Orange, California

Lot #5739 EXP 01/02; 38,704 tubes distributed nationwide; Parkedale Pharmaceuticals, Inc., subsidiary of King Pharmaceuticals, Rochester, Michigan

Lot #8ZP1066 EXP 06/01; 10,924 cases distributed nationwide; Glaxo Wellcome, Inc., Zebulon, North Carolina. Recalled by The Consumer Healthcare Division of Warner-Lambert Company, Morris Plains, New Jersey

All lots with expiration dates from EXP OCT 01 to EXP JUN 02 (sold as laxative), all lots with expiration dates prior to EXP OCT 01 (sold as digestive aid); 1,227 units distributed nationwide; Abco Laboratories, Inc., Fairfield, California. Recalled by The Heritage Store, Inc., Virginia Beach, Virginia

M E D I C A L D E V I C E S

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more details. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a device, call 1-800-FDA-1088. The FDA website is <http://www.fda.gov>.

Name of Device; Class of Recall; Problem

Insulin Single Use Syringes, U-100 29 G X 1/2 inch and U-100 Insulin Single Use Syringes, 28 G X 1/2 inch; Class III; Mislabeled volume on outer shelf cartons, device package is correct

Insulin Syringe, B-D 1 ml Safety-Lok 29G 1/2 Ultrafine Needle, Reorder No. 329464; Class II; Product was marked in ml scale instead of insulin units

Power Wheelchairs: a) Power Tiger; b) P7E with dual battery box upgrade only, c) 9M; d) Excel; e) PMC; d) Ranger II; Class II; Wheelchairs may catch fire due to improper wiring harness configuration

Lot #: Quantity and Distribution; Manufacturer

Lot Number 990427 for the 28 gauge X 1 cc product and Lot Number 990426 for the 29 gauge X 1 cc product; 10,000 syringes distributed in New Jersey and Florida; Medcore, Inc., Hialeah, Florida

Lot Numbers 0005853 and 0106646; 10,500 units distributed in Mississippi, Louisiana, Tennessee, Texas, Pennsylvania, Indiana, Minnesota, Ohio, and Michigan; Becton Dickinson, BD Medical Systems, Franklin Lakes, New Jersey

Serial Numbers 93D through 99C; 77,408 units distributed nationwide and internationally; Invacare Corporation, Elyria, Ohio

C O N S U M E R P R O D U C T S

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 (CPSC), call their hotline at 1-800-638-2772. The CPSC website is <http://www.cpsc.gov>.

Name of Product; Problem

AC Adapters for Notebook Computers & Mobile Devices; Adapters can overheat, posing a fire hazard

Baby Hammocks; Hammocks can suddenly become twisted around children's necks and strangle them; 6 ft. long mini-hammocks woven from thin cotton strings

Bug Zapper Toys; Balloon tongue on this toy can detach, posing a choking and aspiration hazard to young children

Bouncer Seats (in-home repair); Removable toy bar that attaches to the seat can suddenly release and cause injuries to babies

Candle Holders; Wooden top of the candle holder can ignite, presenting fire and burn hazards to consumers

Children's Picnic Sets; Paint on the bag contains high levels of lead

Lot #: Quantity and Distribution; Manufacturer

Adapters used with IBM ThinkPad 310 (type 2600) and IBM ThinkPad i Series (type 2611 only) notebook computers, and IBM WorkPad z50 (type 2608 only) companion devices; 220,000 sold nationwide from May 1997 through November 1999; International Business Machines (IBM) Corporation, Armonk, New York (800) 426-3387 www.ibm.com/adapterrecall

The label attached to the end loop reads, "Hangouts"® from Bellartson and "Woven by Hand in MEXICO"; 350 sold by The Hangout Store and its catalogs from January 1990 through September 1999; Hangouts, Boulder, Colorado (800) 205-4916

Frog and Lizard Shapes; 105,000 distributed with children's meals at fast food, drive-in and small franchise restaurants from November 1998 through April 2000; The Promotional Resources Group, Topeka, Kansas (800) 467-4712 info@kidstuffnet.com

Seats sold under the names "Soft Toy Bouncer Seat" or "Comfort Me Bouncer"; 99,000 sold nationwide from October 1997 through April 2000; Kids II, Alpharetta, Georgia (877) 325-7056

Lighthouse-shaped candle holders; 14,000 sold at Rite Aid stores nationwide from January through March 2000; ATICO USA Inc., Ft. Lauderdale, Florida (800) 645-3867 http://www.riteaid.com/company_info/pr/recall_frameset.html

Clear bag reads "AUSTRALIA" in multicolored lettering, "Down Under" in blue lettering, and has an illustration of a koala bear face; 1,200 sold at Mervyn's stores nationwide from April through May 2000; Mervyn's California, Hayward, California (800) MERVYN'S

CONSUMER PRODUCTS, cont.

Name of Product; Problem

Fire Extinguishers; Because of the high-pressure contents of these fire extinguishers, they can explode and expose consumers to flying debris, causing puncture wounds and blast injuries

Grinders; Some grinders were shipped without the side handle, which is used to control and guide the tool

Infant Cargo Skirts; Snaps on the panty of these skirts can detach, posing a choking hazard to young children

Robes; Fabric is not flame resistant, as required by law

Smoke Alarms; May fail to alarm when smoke or fire is present

Sweatshirts; Fail to meet federal mandatory standards for fabric flammability, could ignite easily and present a serious risk of burn injuries

Tweety Rattles and Sandals; Small parts of each product can detach and pose a choking hazard to young children

Windshield Washer Fluid; Bottles, which contain methyl alcohol, are not sealed with child-resistant closures

Wooden Stacking Toys; Wooden peg in the black and white checked base can come off, presenting a choking hazard

Lot #: Quantity and Distribution; Manufacturer

Yellow with "Firestopper" written in orange; 26,000 sold at dollar-type discount stores from January 1999 through February 2000; 99 Cents Only Stores, City of Commerce, California (888) 289-3325

BOSCH Angle Model 1752G7; 920 sold nationwide from February through April 2000; S-B Power Tool Co., Chicago, Illinois (800) 241-3848

100% cotton khaki twill or 100% denim with attached panty sold in sizes 12, 18 and 24 months; 9,500 sold nationwide from January through March 2000; Associated Merchandising Corporation, New York, New York (212) 819-6564

100% cotton terry cloth sold under brand names Aegean, Baby Monarch, b kids, Charter Club, Club Room, and Jr. By Monarch, boys and girls sizes 12 months to 14 and S, M, L and XL; 50,000 sold at Burdines, Goldsmith's, Lazarus, Macy's, Rich's, The Bon Marche and Bloomingdales from July 1995 through January 2000; Federated Department Stores, Cincinnati, Ohio (800) 364-6190

Safe T Alert Model SA-785, Universal models SS-785 and SS-795, USI Electrical model USI-1203; 34,000 sold nationwide from April 1998 through June 1999; Universal Security Instruments Inc., Owings Mills, Maryland (800) 390-4321

FUBU brand long-sleeved pullover, style FB-3855; 5,400 sold nationwide from November 1999 through April 2000; Jordache Ltd., New York, New York (800) 655-3080

Part of the Tweety Bib, Rattle and Spoon Sets and transparent pink plastic sandals with embedded sparkles and a picture of Tweety; 3,800 rattles sold from August 1998 through January 2000 and 1,000 sandals sold from February through April 2000. Both items sold nationwide at Warner Bros. stores nationwide; Warner Bros. Studio Store, Burbank, California (800) 795-9277

1 gallon bottles with twist-off tops; 335,000 sold at Speedway Superamerica stores and other automotive stores in Kentucky, Michigan, Ohio, Pennsylvania and West Virginia from October 1999 through April 2000; Filter Tech Inc., Huntington, West Virginia (800) 834-5832

Stacking King; 9,000 sold nationwide from February 1999 through April 2000; Jack Rabbit Creations Inc., Atlanta, Georgia (888) 376-5225

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approved quickly and beat the competitor drug to the market has intensified. For some drugs, one month earlier to market can mean tens of millions of dollars in additional revenue before the drug is challenged by a generic. Speed and efficiency, from the drug industry's perspective, favor the privatization of human experimentation, moving research away from the academic medical centers where it has traditionally resided. Whereas in 1993, only 20 percent of pharmaceutical company research was done in the private, for-profit research setting, the fraction has gone up 2-1/2 times and by 1998, 50 percent was being done outside of academic medical centers. The number of private practice-based investigators has grown from 3,153 in 1990 to 11,588 in 1995, an increase of almost four-fold.

According to Richard Friedman of Cornell University in the British journal, *The Lancet*, "In the USA, monetary incentives have spawned a whole industry of private physicians who don't necessarily have any experience in research or with protocols in the specialty areas in which they're testing." These private entities "push patients through trial after trial," with little concern for what happens to them afterwards. The result is "stop-gap" medicine for vulnerable patients who can't afford treatment any other way, he says. A recent article in the *New York Times* documents how, with 43 million Americans uninsured, many are forced to turn to a series of research studies to remain treated. This invites exploitation.

The Growth of International Research

Drug companies can increase the likelihood of a drug's success by using exclusion criteria to, as one investigator told the Inspector General's office, "enrich trials with patients who are most likely to benefit." One way to accomplish this is to exclude patients who are currently on medication to treat their condition or even those who have been on medication in the past. Such patients are known in the industry by the double entendre "naive" subjects. These prized subjects are hard

to locate but, according to the Report, can often be found among the uninsured or in foreign countries. Many researchers told the Inspector General's staff that drug companies are increasingly looking abroad for such subjects. One advertisement—in this case, directed toward possible drug industry customers by the world's largest HEC, North Carolina-based Quintiles—with offices all over the world—promised that they can "even help you tap the vast drug-naïve patient populations of China, Korea and other emerging markets."

The Report points out that the number of new foreign investigators in the FDA's database grew from 988 in the 1990-1992 period to 5,380 in the 1996-1998 period. Aside from easier access to drug-naïve patients, the costs for foreign studies are often less than in the United States. Despite this, the FDA only conducted 60 drug investigator inspections abroad in 1998 and, according to the Report, the FDA does not normally inspect foreign Institutional Review Boards (IRBs).

While the Report makes clear that there is increasing internationalization of research, it fails to state that there are ongoing efforts by the research industry to water down the existing international ethics documents to facilitate some of the practices the Report finds troubling. The current version of the Declaration of Helsinki states that, if the patient has a dependent relationship with the investigator, "the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship." (It is noteworthy, as the Report documents, how widely this international ethics document is ignored.) Some have proposed that this language be replaced by the following: "In some cases of this type, it may be preferable if the informed consent were to be obtained by a qualified person who is not engaged in the investigation, independent of the dependent relationship, or both." This is precisely the wrong direction for changes in ethical practice at a time when pressures to recruit are increasing.

Recruitment Method Concerns

The four main categories of findings in the Report which we believe demand action are:

Offering Incentives

Because human experimentation has been transformed to a "business model," this newly emerging "business" of experimenting on people has every imaginable incentive for fast recruitment and fast results. A bonus of \$30,000 after recruiting the first six patients and a bonus of \$6000 per additional patient captures the "competitive enrollment" which, according to the Report, "encourages aggressive recruiting."

Targeting Own Patients

In concordance with a *New York Times* investigation documenting doctors getting paid as much as several thousand dollars per patient to recruit patients from their own practices, the policy of recruitment by physicians of patients from their own practices is further documented in the Report. The vulnerability of a doctor's own patients to be persuaded to become an experimental research subject because of their trust in their doctor, combined with signing bonuses which the doctor pockets for the referral, sets up a toxic situation where some doctors are literally selling their own patients into human experiments. In a gross commercialization of this practice, one large family practice group advertised its "computerized patient data base of 40,000 patients" to HECs and others running clinical trials as one from which "We can actively recruit patients for any study..."

Seeking Additional Patient Bases

In addition to plumbing their own files for potential experimental subjects, some researchers pay "finder's fees" to other doctors who do not even conduct the research: "Occasionally, investigators offer fees to encourage referrals from other physicians or nurses," such as an offer of \$75 to physicians or nurses for each subject referred, according to the Report. The use of patients reached through patient advocacy groups, also described in the

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Report, similarly has the taint of using a relationship of trust to recruit patients who might otherwise not be interested in participation in such experiments.

Advertising and Promotion

The "new industry of patient recruitment firms and research marketing companies" has produced, according to the Report, more advertising for human subjects than in the past. Until public criticism changed this practice, the website DrKOOP.com was using the formerly good name of this medical huckster to recruit patients, for a finder's fee, to the multinational HEC Quintiles.

Erosion of Informed Consent

The Report expresses serious concern about the way the business model of research, as manifested through the practices described above, might erode the essential elements of informed consent.

Information: The Report describes misleading advertisements which blurred the distinction between treatment and research, an excessive focus on monetary or other compensation which can become coercive and the lack of response by drug sponsors to concerns raised by IRBs in the less-than-frequent instances in which the IRBs actually review the advertisements.

Comprehension: The failure to conduct research on or to audit the extent that the patient actually understands the recruitment materials and the informed consent forms is of concern. According to the report, the performance of the physician/investigator in fully informing patients may be compromised by bonuses for more patients recruited and by promises of top authorship on papers emanating from the research tied to recruiting success.

Voluntariness: One medical journal article concerning effective human subject recruitment strategies noted that 'Done correctly, [media] publicity can look like an endorsement by your well-respected newspaper reporter or TV news anchor. It can be an excellent way to generate phone calls needed to fill studies.' This part of the Report

reiterates the concerns about doctors recruiting patients from their own practices and states that 'patients see their doctor as God' because of the trust they place in them.

Successful Models

While the Inspector General's Report makes clear that there is little in the way of guidelines or regulations to prevent the kinds of abuses the Report documents, it does contain a number of examples of innovative approaches that the Report should endorse, rather than merely mention. These fall into the categories of recruitment incentives, the dual physician-investigator role and confidentiality of medical records. Unfortunately, the Report merely identifies four questions that need to be addressed, rather than recommending the answers that the Report's evidence would seem to require and which these models prove is feasible.

Several groups (University of Rochester IRB, Partners HealthCare System) have banned the use of bonus payments designed to encourage patient recruitment, while Partners HealthCare System and the American Medical Association also ban fees for referring patients to other investigators, HECs or drug companies. We strongly endorse these initiatives. We believe that physicians have a right to reasonable reimbursement for any costs incurred or time spent beyond what they would ordinarily expend in the care of the patient, but no more. We agree, in general, with efforts to increase disclosure of potentially conflicting interests to patients. But we are opposed to using disclosure of such interests as a substitute for banning the more egregious of these incentives.

Disclosure has also been the preferred approach (when any approach is put forth) by universities (University of California at Los Angeles, for example) to the problem of the dual physician-investigator role. However, some groups have stated that, at least in some circumstances, the preferred approach is to have a more neutral

intermediary, without the conflict of interest of the investigator approaching the patient. We believe that this approach should be more the norm than the exception. As is almost always the case, the preferred method for resolving potential conflicts of interest is to involve neutral third parties.

Finally, the Report makes clear how little work has been done, particularly by medical associations, in addressing the problem of researchers using databases that include patients cared for by another health care provider to recruit study participants. This is an improper invasion of privacy, and is precluded by some IRBs (Medical College of Ohio, University of California Los Angeles, Partners HealthCare System). All IRBs should follow this model.

In sum, the Report has clearly identified a wide range of relatively new threats to patients in clinical research studies. Furthermore, this burgeoning field is largely unregulated. Even when the IRBs have particular authority, they appear unwilling or unable to exercise their authority. And some of the Report's solutions are to give more authority to IRBs, which the Inspector General's previous reports have already documented are hopelessly overworked. The following are appropriate subjects for regulation: banning finder's fees; banning reimbursement to physicians beyond research-related expenses and time expended; mandatory disclosure to the potential participant of the source and amount of all recruitment fees; and restrictions on the ability of health care providers other than the patient's physician from gaining access to a patient's medical records for the purpose of recruitment. In the absence of regulation, therefore, sponsors will be able to choose the route least protective of patients' rights in their quest to maximize recruitment—the ethical "race to the bottom" of which the Report warns and which has characterized much of globalization to date.

Inspector General's Study on Human Experimentation

Recruiting Human Subjects:

Pressures in Industry-Sponsored Clinical Research

The following are comments filed by Public Citizen's Health Research Group on a report that was released by the Inspector General's Office on June 12.

Somewhat buried in the middle of this highly disturbing report, the authors mention "the transformation of clinical research into a traditional business model." As a result of the shift to this business mind set, the often highly unethical and possibly illegal recruitment practices documented in the Report appear to be increasing rapidly. The rise of separate (from the drug companies themselves) for-profit Human Experimentation Corporations (HECs), a more accurate name for the

more benign-sounding name currently in use—Contract Research Organizations (CROs)—has introduced new techniques for rapidly recruiting patients. When combined with the appallingly inadequate Federal regulation of human experimentation in general, and recruitment practices in particular, and the failure (as usual) of the medical profession to police itself, the risk of abuse of patients increases dramatically.

This Report is the first attempt to thoroughly address the issues involved in the recruitment of patients to clinical trials. Most previous writing has been terribly non-specific; this Report is the best available on current practices in this area. However, as good as the

Report is in description, it remains weak in prescription. We advocate a much stronger set of recommendations than is provided by the Inspector General's Report; in particular, we advocate promulgating strong new regulations based, in part, on models that are being successfully employed in various settings and which are described in the Report.

More drugs are in clinical trials now than even a few years ago. In addition, many therapeutic categories of drugs, such as those for hypertension, are becoming saturated with drugs, leading to increased competition. More human subjects are therefore needed, and the competition to get the drug

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