PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Vermont's Pharmaceutical Laws Move Toward Fuller Disclosure

Vermont can take pride in its health achievements. When states are ranked in terms of four groups of health determinants personal behaviors, the community environment, health policies, and clinical care Vermont ranked #1 in 2007, the most recent year for which the data are available. The state's achievements include a low prevalence of obesity, a high rate of high school graduation, low rates of violent crime and infectious disease, a low proportion of children in poverty, low uninsurance, high immunization coverage, strong prenatal care, a high ratio of primary physicians-to-population, and a low rate of preventable hospitalizations. These translate into favorable health outcomes: few days of poor health (mental and physical), low infant mortality, and a low rate of premature death.

When the state pioneered in passing a Pharmaceutical Marketing Disclosure Law in 2002, there was much interest in the information provided and how it would affect marketing to health care providers. The law required pharmaceutical manufacturers to disclose payments made to doctors, hospitals, universities, and others that prescribe or dispense pharmaceuticals. These payments include consulting and speakers' fees, travel expenses, gifts, and other payments proffered by the companies in exchange for marketing their products.

In 2007, when Public Citizen examined the data for 2002-2004, it found that 61 percent of payments were not released to the public. The reason? The enacted legislation had a sizeable loophole which exempted pharmaceutical companies from disclosing payments that could be construed as "trade secrets." Moreover, Public Citizen found that the information was difficult to get and that 75 percent of the publicly disclosed information did not allow data users to identify the recipient. Public Citizen obtained the information required for its assessment only after protracted negotiations with Vermont's Office of the Attorney General and a Freedom of Information Act request.

The most recent report from the state Attorney General, published in April 2009, reveals that in fiscal year 2007-2009 78 manufacturers spent $2,935,248 on 2,280 Vermont providers to market pharmaceutical products. The top five spenders accounted for 52 percent of all expenditures. Similarly, a majority of all payments went to a small fraction of providers: 60 percent of total payments went to 4.3 percent of all providers. As a group, psychiatrists received the largest share of payments, totaling nearly half a million dollars. But this was skewed by the fact that one psychiatrist received more than $112,000, the most spent on any one person that year. Additionally, 25 providers received more than $20,000 each in cash or benefits, and 10 received more than $50,000 each.

When the data are broken down by drug, 70 percent was spent on the top 13 percent of all drugs marketed. The greatest marketing costs were spent on drugs aimed at treating attention-deficit/hyperactivity disorder (ADHD). Expenditures for the next seven top-ranked drugs covered only three indications: depression, Alzheimer's, and diabetes.

Despite the state's attempt at transparency, the data became

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What is Comparative Effectiveness Research, and Why is it Being Badmouthed?

For all the talk of U.S. being at the forefront of medical research, we do not know if many of the tools we use in health care — drugs, devices, screening and treatment protocols — actually work and therefore can not calculate whether their benefits outweigh their risks. Nor do we know if they constitute the best treatment for specific patients, or under particular conditions. Collectively, much of the care we get is duplicative, ineffectual or harmful. At the same time, many tried-and-tested preventive and therapeutic strategies are woefully underused. Indeed, in a study published in 2003, researchers looking at a sample of U.S. adults found that Americans receive appropriate care only 55 percent of the time.

Our health care system leaves many people out and lags in terms of favorable health outcomes.

More recently, concern over health care costs has led many scholars to question whether or not we are getting a good return on our investment. The question is particularly pertinent because the U.S. ranks #1 — overall and per capita — in what it spends on health care among developed nations, but our health care system leaves many people out and lags in terms of favorable health outcomes.

Given the need to enhance value in our health care systems, many experts and policy-makers support the creation of a center for comparative effectiveness research (CER) in the U.S. The center would study the effectiveness of different treatments for the same illness, gathering solid evidence to document what works for whom, and at what cost. At present, Britain, France, Australia and Germany are at the forefront of this type of research, using their findings to make decisions concerning what treatments to promote and what services to cover.

The American Recovery and Reinvestment Act of 2009 allocated $1.1 billion to support CER within the U.S. Department of Health and Human Services and created a Federal Council to coordinate the CER efforts. The goal is to increase the knowledge base to help health care providers decide what treatments are the most likely to benefit their patients. But because some opponents of the idea have visions of apparatchiks with checklists hovering over practitioners or denying payment for care, the legislation precludes the Council itself from enacting clinical guidelines and from making coverage and reimbursement decisions.

CER is not altogether new to the U.S. Between 1972 and 1995 the U.S. Congress had an Office of Technology Assessment whose mission was to provide objective analysis of the scientific and technical issues of the late 20th century, including the beneficial and adverse effects of emerging technology. Although the agency's scope went beyond health and health care, it provided evidence on a variety of devices and treatments, from AIDS prevention to wheelchairs. Since the agency's demise, however, this task has been only carried out only partially and sporadically.

At present, the Agency for Healthcare Research and Quality (AHRQ) has a limited mandate to conduct research on the effectiveness and appropriateness of various health services, including prescription drugs. The agency contracts with 13 Evidence-based Practice Centers affiliated with universities and private organizations to synthesize existing knowledge. The agency also generates new research by working with other health care organizations that have large databases at their command. Current efforts in CER have also been supplemented by private sector efforts. For example, Blue Cross and Blue Shield operate a Technology Evaluation Center that reviews existing clinical evidence to assess the appropriateness and efficacy of certain procedures, drugs, or devices. Similarly, other health plans also evaluate evidence to provide a basis for their drug formularies and the devices and procedures they cover.

The need and rationale for CER has prompted broad-based interest in systematizing and expanding this effort, making sure that the knowledge gained reaches practitioners and is available to patients. This would ensure that more health care decisions are based on evidence rather than hunches, and that ineffective, potentially harmful, costly treatments are avoided. CER has therefore been endorsed by the Institute of Medicine, the Medicare Payment Advisory Commission, America's Health Insurance Plans, and the American Medical Association, among others.

But at the same time, CER has earned the wrath of some who want to perpetrate the idea that the comparative effectiveness research is the 'entering wedge' for government to dictate medical practice and decide who gets what service. CER has therefore become a boogeyman. Opponents have used scare tactics against it, brandishing a number of allegations concerning what it is and what it will do. Let us examine some of these:

Myth #1: *CER will insert government into the patient-doctor relationship.* This was the same argument that was

used to delay or obstruct third-party payments by insurers many years ago. Then, it assumed that it was the exchange of money for care that defined patient interaction. Now, the argument is equally specious. Having more evidence of what works for whom in no way interferes with the relationship between physician and patient. Indeed, it can promote a more egalitarian relationship, facilitate communication on the risks and benefits of different treatment options and, most importantly, improve patient outcomes.

Myth #2: *CER is driven primarily by a desire for cost control.* While it may very well be — and should be — that CER will lead to the discontinuation of practices that are not effective and can even be harmful, there is no assurance that this will save money. Indeed, because CER can also identify beneficial treatments that are now underused, it may result in certain services being made available more widely or more intensively. Moreover, there is no assurance that, in comparing two very different types of treatment, the least expensive one will prove to be the more effective one. CER is aimed primarily at providing evidence, giving decision-makers — both providers and patients — a firmer ground on which to base their decisions. Any savings resulting from this will be strictly a bonus.

Myth #3: *CER will restrict choice.* Much of the current gamut of choices involves practices of dubious value. In addition, "choice" often entails a process of trial-and-error that is costly in terms of both suffering and money. CER will broaden some options for care and restrict others. Its aim, however, is to build evidence that will allow physicians and other health providers to identify which treatments are most likely to benefit their patients. As ethicists Ruth Faden and Jonathan Moreno have succinctly expressed it, "an uninformed choice is like no choice at all."

Myth #4: *CER is a way to ration care.* This argument plays on people's fears that some treatments may not be available as a result of CER. That may indeed be the case if there is evidence that some treatments serve no useful purpose, are inferior to other options, or are downright harmful. But the deliberate separation of the proposed CER Council from clinical guidelines and reimbursement decisions protects against this possibility.

Additionally, this argument assumes that care is not being rationed at present, which is not the case. Services are rationed by price: if you cannot afford to pay for a given service or your insurance does not cover it, you face definite barriers to care.

Myth #5: *CER will focus on majority populations, neglecting the fact that treatments can affect different groups in different ways.* Another way of expressing the same "rationing" idea is the statement that "CER promotes 'one-size-fits-all' health care." Some groups are therefore worried that effectiveness will be judged on average results across the entire population rather than on effects on particular individuals. This is something that is already occurring. As Alan M. Garber and Sean R. Tunis have recently stated, "...with too few appropriately designed studies, physicians, patients, and families have often had little guidance about which patients were most likely to benefit from a clinical strategy." This concern can be addressed in the design of the research strategies employed to assess different treatments. The 'comparative' part of the research should therefore refer not only to different treatments but also to a variety of populations, which should be included in sufficient numbers to warrant reliable conclusions.

As with most other health-related research, the findings of comparative effectiveness research will be contested, argued about, and fought over. CER, like most policy issues, will have winners and losers. It is therefore not surprising that that the topic has been described as a "medical minefield." But, as ethicists Faden and Moreno point out, "Choosing blindly is an empty right; choosing with evidence respects patients' rights and enhances quality. This is a case in which good ethics demands good facts." ◆

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increasingly incomplete over time. Whereas in 2002-2004 some 61 percent of the payments were cloaked under the label of "trade secrets," the most recent report showed that fully 83 percent of the most recently reported payments fell under that rubric and were therefore shielded from public scrutiny. As a result, the pharmaceutical companies showed a decline of 30 percent in marketing expenditures over the past five years.

In order to plug this loophole and provide consumers with more complete and specific information, in May 2009 the Vermont legislature enacted a bill which eliminates the "trade secret" cover. The bill also allows Vermonters to know how much, if any, individual doctors are receiving in cash payments from which manufacturers and for what drugs. The legislation, which had the support of the Vermont Medical Society and the Vermont Public Interest Research Group, also bans most gifts to doctors and other health care professionals. Still allowed are free drug samples, an exemption which many legislators fought to the keep and which assured the legislation's passing by a vote of 137 to 4.

Through this act, Vermont has overtaken Massachusetts and Minnesota as the state with the most comprehensive legislation regarding the disclosure of gifts and payments to prescribers. The state has therefore secured its status as a leader in the health field, allowing consumers to know who is getting how much for what purpose. ◆

Introduction to Comparative Health Systems

As the debate on health reform intensifies, many people wonder what policy wonks are actually talking about when they discuss the possible options. The discussion is often framed in terms of alternatives, with possibilities for combining features of different proposals. At the heart of the choice is the matter of payment, which conditions many other aspects of the plan.

Public Citizen's Health Research Group has long favored a single-payer plan. Our advocacy on its behalf is rooted on our belief in uniform coverage for all based on the principle of social solidarity and that we cannot afford to waste the $400 billion a year of extra administrative cost imposed by the existence of multiple private health insurers. We consider health care as a social good, a right which should be made available to everyone based on need rather than ability to pay.

The table that follows summarizes the implications of the choice between single payer and multiple payers, pointing out the implications of what the ultimate decision will mean in terms of values, eligibility, administrative efficiency, cost controls, and delivery of care, among other aspects. ◆

Aspect	Universal Coverage Under Public Single Payer Plan	Universal Coverage Based on Multiple Payers (Insurance companies)
Eligibility	Everyone in the U.S. is covered.	Everyone is eligible, but each individual must enroll in a specific plan or be subsidized to enroll in a plan.
Basic value underlying plan	Health care is a social good and a right.	Health care is a commodity, purchasable on the market.
Scope of Services	Broad array of services	Depending on individual plan and premium paid, although the state can regulate coverage and mandate a uniform service package
Control of Costs	Single payer can exert leverage with all providers, negotiating from position of strength. Economies of scale can reduce costs. Lack of profits and marketing expenses will lower overhead, thereby reducing administrative costs. See also Rationing.	Companies exert control over costs by avoiding higher risk patients, pegging price to risk, instituting cost-sharing (deductibles, co-payments), and denying unprofitable services. If state mandates a uniform package and no profits, insurers benefit only from selling supplementary coverage.
Risk-Pooling	Entire population is part of a single risk pool; younger, healthier members of the pool offset those who are older and sicker. Exclusion for pre-existing illness is not allowed.	Each insurer attempts to attract lower risk patients; premiums may vary accordingly. Insurers protect themselves by raising prices to avoid higher risks. State may mandate 'guaranteed issue' (accepting all applicants, regardless of risk), uniformity in premiums, or adjust for differences in relative risks. Regulation is needed to correction for these market failures. These methods to prevent or compensate for adverse section require much data and are expensive to operate.
Administrative Costs	With no profits, no need for marketing, a single package of services, and much less complex and contested billing, administrative costs are kept to a minimum.	The sifting and sorting of enrollees, together with marketing expenses and a varied and complicated billing apparatus siphons off a significant portion of revenues from actual health care.

Aspect	Universal Coverage Under Public Single Payer Plan	Universal Coverage Based on Multiple Payers (Insurance companies)
Choice	Consumers would have choice of any provider. Few physicians and hospitals would 'opt out' without incurring major loss of income.	Choice would depend on arrangement between purchaser and provider; choice may be among plans rather than between or among health care providers.
Service delivery system	Single payer could exert leverage to correct current fragmentation and raise quality of care.	No built-in goad to change the present lack of continuity and coherence in care
Provider payment	Public sector could innovate ways of paying providers, as it has with Medicare. Could bundle services and provide alternatives to fee-for-service care, which is inherently inflationary. Price discrimination would be avoided.	Subject to multiple discrete negotiations: insurers pay different fees to different providers for same service; providers bill different insurers different fees for the same service. Price discrimination is rampant.
Access to Care	State can adopt incentives to deploy resources according to need, and to provide adequate access to primary care.	Subject to market forces. If you live in poor community, you are likely to have limited providers to choose from. Some adjustment between supply and demand will take place over time.
Focus on preventive care	Plan would have an incentive to foster prevention because it would reap the savings later.	Limited incentives to foster prevention because patients change plans. Emphasis is on the short-term.
Rationing	Based on need, and on cost-effectiveness of different treatments.	Based on price and ability to pay: those who cannot afford a service are unable to acquire it.
Utilization Control	Large-scale database would flag trends and identify outliers. Data would indicate patterns of consumption, overuse, service gaps, and relations between treatments and diseases they might cause.	Achieved by denying services. No uniform data-collection system.

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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Editor.....*Sidney M. Wolfe, MD*
Managing Editor.....*Kate Resnevic*
Contributor.....*Annette B. Ramìrez de Arellano, DrPH*

Proofreader..... *Kate Resnevic*

Acting Public Citizen President Sidney M. Wolfe, MD

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Product Recalls

April 22, 2009 - May 12 , 2009

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. 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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – CLASS II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Calan, verapamil hydrochloride tablets, 80 mg, 100 tablet bottles, Rx only; NDC 0025-1851-31, 9,445 bottles; Product does not meet dissolution specifications on stability. Lot #: C061194, exp. date: 12/2010; Pfizer, Inc.

On May 6, 2009, the Food and Drug Administration released a Class II Drug recall of a number of products manufactured by KV Pharmaceutical Co. Westport of Saint Louis, MO. These products are being recalled because they were not made in conformance with Good Manufacturing Practices. The amount of affected products is not known. If your drug is on the list, contact your pharmacy to see if it is one of the affected lots.

Dextroamphetamine Sulfate Tablets, USP, 5 mg and 10 mg., CII, packaged in 100 count bottles, Rx Only;

Hydromorphone Hydrochloride Tablets, USP, CII, 2 mg, 4 mg and 8 mg, packaged in 100 count bottles (NDC 58177-620-04) and 100 count blister cartons, Rx Only;

Isosorbide Mononitrate Extended-Release Tablets, 30 mg, 60 mg and 120 mg packaged in 100 count bottles, 500 count bottles, and 100 count cartons unit-dose blisters, Rx Only;

Metoprolol Succinate Extended-release Tablets, USP, 25 mg, 50 mg, 100 mg and 200 mg packaged in 100 count bottles, 1,000 count bottles and 100 count unit-dose cartons, Rx Only;

Morphine Sulfate Extended-release Tablets, 15 mg, 30 mg, 60 mg, 100 mg and 200 mg CII packaged in 100 count bottles, Rx Only;

Morphine Sulfate Immediate-Release Oral Tablets, 15 mg and 30 mg CII, packaged in 100 count bottles, Rx Only;

Propafenone HCl Tablets 150 mg, 225 mg and 300 mg, packaged in 100 count bottles (NDC 58177-331-04) and 100 count unit dose cartons, Rx Only;

Benazepril Hydrochloride Cl Tablets 5 mg, 10 mg, 20 mg and 40 mg packaged in 100 count bottles, Rx;

Benazepril Hydrochloride Tablets, packaged in 100-count bottles. (NDC 58177-342-04) and 500-count bottles, Rx;

Benzonatate Capsules 100 mg, 200 mg, packaged in 100-count bottles, 100-count unit dose cartons, and 500-count bottles, Rx;

10 ptBromfenex, Brompheniramine Maleate/Pseudoephedrine HCl, Extended-Release Capsules, 12 mg/120 mg and 6 mg/60 mg, packaged in 100-count bottles, Rx;

10 ptBuspirone HCl Tablets, USP, 5 mg, 10 mg and 15 mg packaged in 100 count bottles and 500-count bottles, Rx;

10 ptCodeine Phosphate and Guaifenesin Tablets, CIII, 10 mg/300 mg, packaged in 100 count bottles, Rx;

10 ptDiltiazem HCl Extended-release Capsules (Once-a-Day Dosage) 120 mg, 180 mg, 240 mg, 300 mg, 360 mg and 420 mg, packaged in 30 count bottles and 90 count bottles, Rx;

Disopyramide Phosphate Extended-release Capsules, USP, 150 mg, packaged in 100 count bottles, Rx;

10 ptDoxazosin Mesylate Tablets, 1 mg, 2 mg 4 mg, 8 mg, packaged in 100 count bottles and 500 count bottles, Rx;

EtheDent Chewable Tablets 0.25 mg F, (From 0.55 mg sodium fluoride), Sodium Fluoride Chewable Tablets, Vanilla Flavored, packaged in 120 count bottles, RX, NDC 58177-432-40, Recall # D-302-2009;

EtheDent Chewable Tablets 0.5 mg F, (From 1.1 mg sodium fluoride) Sodium Fluoride Chewable Tablets, Grape Flavored, packaged in 120 count bottles and 1,000 count bottles, Rx;

EtheDent Chewable Tablets 1 mg, F (From 2.2 mg. sodium fluoride), Sodium Fluoride Chewable Tablets, Cherry Flavored, packaged in 120 count bottles and 1,000 count bottles, Rx;

EthexDerm BPW-5, Benzoyl Peroxide Topical Wash 5%, 10%, packaged in 8 oz. tubes, Rx;

ETHEZYME 650 Papain-Urea Debriding Ointment, each gram contains Papain, USP (6.5 x 10 5 USP units of activity) and 100 mg Urea, USP, packaged in 1 oz tubes, Rx;

ETHEZYME 830 Papain-Urea Debriding Ointment, each gram contains Papain, USP (8.3 x 10 5 USP units of activity) and 100 mg Urea, USP, packaged in 1 oz (30 gm) tubes, Rx;

Ethezyme Papain-Urea Debriding Ointment, each gram contains Papain (1.1 x 10 6 USP units of activity) and 100 mg Urea, packaged in 1 oz tubes, Rx;

ETH-Oxydose (oxycodone hydrochloride) Oral Concentrate Solution, CII, 20 mg/1 mL, packaged in 1 fl oz bottles, and 30/1 mL InveAmp ampoules, Rx;

Guaifenex DM, Guaifenesin/Dextromethorphan HBr Extended-Release Tablets, 600 mg/30 mg, packaged in 100 count bottles, Rx;

Guaifenex GP, Guaifenesin/Pseudoephedrine HCl Extended-release Tablets, 1200 mg/120 mg, 600 mg/60 mg, 600 mg/120 mg and 800 mg/80 mg, packaged in 100 count bottles, Rx;

Guaifenex PSE 80, Guaifenesin/Pseudoephedrine HCl Extended-Release Tablets, packaged in 100 count bottles, Rx;

Guaifenex PSE 85, Guaifenesin/Pseudoephedrine HCl Extended-Release Tablets, 795 mg/85 mg, packaged in 100 count bottles, Rx;

Hista-Vent DA Extended-Release Tablets, Chlorpheniramine Maleate/Phenylephrine Hydrochloride/Methscopolamine Nitrate, 8 mg/20 mg/2.5 mg, packaged in 100 count bottles, Rx;

Hista-Vent PSE Tablets, Pseudoephedrine HCl, Chlorpheniramine Maleate/Methscopolamine Nitrate, 120 mg/8 mg/2.5 mg, packaged in 100 count bottles, Rx;

Histinex HC Syrup, CIII, containing in each 5 mL: 2.5 mg Hydrocodone bitartrate, 5.0 mg Phenylephrine hydrochloride, and 2.0 mg Chlorpheniramine maleate, packaged in 16 fl oz bottles and 32 fl oz bottles, Rx;

Histinex PV Liquid, containing in each 5 mL: 2.5 mg Hydrocodone Bitartrate, 30 mg Pseudoephedrine Hydrochloride, and 2.0 mg Chlorpheniramine Maleate, packaged in 16 fl oz bottles, Rx;

Hydrocodone Bitartrate & Acetaminophen Oral Solution, 7.5 mg/500 mg per 15 mL, packaged in 16 fl oz bottles, Rx;

Hydrocodone Bitartrate/Guaifenesin Liquid, CIII, containing in each 5 mL: 5 mg Hydrocodone Bitartrate and 100 mg Guaifenesin, packaged in 16 fl oz bottles, Rx;

Hydrocortisone and Iodoquinol Cream 1%, packaged in 1 oz tubes, Rx;

Hydroquinone 4% Cream Skin Bleaching Cream, packaged in 1 oz tubes, Rx;

Hydroquinone 4% Cream with Sunscreens Skin Bleaching Cream, packaged in 1 oz tubes, Rx;

Hydro-Tussin CBX Syrup, containing 2 mg/5 mL Carbinoxamine Maleate and 25 mg/5 mL Pseudoephedrine Hydrochloride, packaged in 16 fl oz;

Hydro-Tussin DHC Syrup, CIII, containing 7.5 mg/5 mL Dihydrocodeine Bitartrate, 2 mg/5 mL Chlorpheniramine Maleate, and 15 mg/5 mL Pseudoephedrine Hydrochloride, packaged in 16 fl oz bottles, Rx;

Hydro-Tussin DM Liquid, containing 200 mg/5 mL Guaifenesin, and 20 mg/5 mL Dextromethorphan hydrobromide, packaged in 16 fl oz bottles, Rx;

Hydro-Tussin EXP Syrup, CIII, containing 7.5 mg/5 mL Dihydrocodeine bitartrate, 15 mg/5 mL Pseudoephedrine Hydrochloride, and 100 mg/5 mL Guaifenesin, packaged in 16 fl oz bottles, Rx;

Hydro-Tussin HC Syrup, CIII, containing 3 mg/5 mL Hydrocodone bitartrate, 2 mg/5 mL Chlorpheniramine maleate, and 15 mg/5 mL Pseudoephedrine hydrochloride, packaged in 16 fl oz bottles, Rx;

Hydro-Tussin HD Syrup, CIII, containing 100 mg/5 mL Guaifenesin, 30 mg/5 mL Pseudoephedrine hydrochloride and 2.5 mg/5 mL Hydrocodone bitartrate, packaged in 16 fl oz bottles, Rx;

Hydro-Tussin XP Syrup, CIII, containing 3 mg/5 mL Hydrocodone bitartrate, 15 mg/5 mL Pseudoephedrine hydrochloride, and 100 mg/5 mL Guaifenesin, packaged in 16 fl oz bottles, Rx;

Hyoscyamine Orally Disintegrating Tablets 0.125 mg, packaged in 100 count bottles, Rx;

Hyoscyamine Sublingual Tablets, USP 0.125 mg, packaged in 100 count bottles, Rx;

Hyoscyamine Sulfate Extended-Release Capsules 0.375 mg, packaged in 100 count bottles, Rx;

Hyoscyamine Sulfate Extended-Release Tablets 0.375 mg, packaged in 100 count bottles, Rx;

Hyoscyamine Sulfate Oral Tablets 0.125 mg, packaged in 100 count bottles, Rx;

Potassium Chloride Extended-Release Tablets, USP, 1500 mg (20 mEq), packaged in 100 count bottles, 500 tablet bottles, and 1000 tablet bottles, Rx only;

Meperidine HCl and Promethazine HCl Capsules, 50 mg /25 mg, 100 count bottles;

Morphine Sulfate Concentrated Oral Solution 20 mg/1 mL, packaged in 1/2 fl oz (15 mL) bottles; packaged in 1 fl oz (30 mL) bottles; packaged in 4 fl oz (120 mL) bottles; and packaged in 8 fl oz (240 mL) bottles;

Morphine Sulfate InveAmp immediate-release CONCENTRATED oral solution 5 mg/0.25 mL, NDC 58177-888-80, packaged as follows: Unit dose package of 30 InveAmp" ampoules (each ampoule contains 0.25 mL);

Morphine Sulfate InveAmp 20 mg/1 mL immediate-release CONCENTRATED oral solution, packaged as follows: Unit dose package of 30 InveAmp" ampoules (each ampoule contains 1 mL);

NitroQuick (nitroglycerin) Sublingual Tablets, USP 0.3 mg, 0.4 mg and 0.6 mg, packaged in 100 tablet bottles, Rx only;

Nystatin Topical Powder, USP, (100,000 USP units per gram) 15, 30 and 60grams per bottle, Rx Only;

Ondansetron Orally Disintegrating Tablets, 4 mg and 8 mg, packaged in 3 - 10 tablet blister pack boxes (30 tablets), Rx only;

Oxycodone Hydrochloride Immediate-Release Capsules, USP, 5 mg, CII, 100 count bottle and 10 - 10 Unit Dose packs per box, Rx only;

Oxycodone Hydrochloride Tablets, USP, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg, CII, packaged in 100 tablet bottles and 10 -10 tablet blister packs, Rx only;

Pangestyme CN10 (pancrelipase, USP) delayed release capsules, packaged in 100 count bottles, Rx only;

Pangestyme CN20 (pancrelipase, USP) delayed release capsules, packaged in 100 count bottles, Rx only;

Pangestyme EC 100 (pancrelipase, USP) delayed release capsules, packaged in 100 count bottles, Rx only;

Pangestyme EC 250 (pancrelipase, USP) delayed release capsules, packaged in 250 count bottles, Rx only;

Pangestyme MT16 (pancrelipase, USP) delayed release capsules, packaged in 100 count bottles, Rx only;

Pangestyme UL12 (pancrelipase, USP) delayed release capsules, packaged in 100 count bottles, Rx only;

Pangestyme UL18 (pancrelipase, USP), packaged in 100 count bottles, Rx only;

Pangestyme UL20 (pancrelipase, USP), packaged in 100 count bottles, NDC 58177-050-04, Rx Only, Recall # D-364-2009;

PhenaVent (Guaifenesin/Phenylephrine HCl), Extended-release Capsules, 400 mg/15 mg, packaged in 30 count bottles. Rx only;

PhenaVent D (Guaifenesin/Phenylephrine Hydrochloride), Extended-release Tablets, 1200 mg/40 mg, packaged in 100 count bottles, Rx only;

PhenaVent LA, phenylephrine extended-release/guaifenesin capsule, 30 mg/400 mg, packaged in 30 count bottles, Rx only;

PhenaVent PED (Guaifenesin/Phenylephrine Hydrochloride), Extended-release Capsules, 200 mg/7.5 mg, packaged in 100 count bottles, Rx only;

Plaretase 8000 (pancrelipase USP), packaged in 100 tablet bottles and 500 tablet bottles, Rx only;

Potassium Chloride Extended-Release Capsules, USP, 8 mEq (600 mg), 10 mEq (750 mg), 20 mEq (1500 mg), packaged in 100 count bottles and 500 count bottles, Rx only;

PrednisoLONE Sodium Phosphate Oral Solution, 15 mg/5 mL, packaged in 8 fl oz bottle, Rx only;

PrednisoLONE Syrup, USP, 5 mg/5 mL, packaged in 120 mL bottles, Rx only;

PrednisoLONE Syrup, USP, 15 mg/5 mL, packaged in 8 fl oz (240 mL) bottles and 16 fl oz (480 mL) bottles, Rx only;

Pseudovent 400 (Pseudoephedrine HCl (extended-release)/ Guaifenesin), Capsules, 120 mg/400 mg, 250 mg/120 mg and 300 mg/60 mg, packaged in 100 count bottles, Rx only;

Tri-Vent DM Syrup, Dextromethorphan HBr 15 mg, Pseudoephedrine Hydrochloride 40 mg, Guaifenesin 100 mg, packaged in 16 fl oz (480 mL) bottles, Rx only;

Tri-Vent DPC Syrup, Dextromethorphan HBr 15 mg, Phenylephrine Hydrochloride 6 mg, Chlorpheniramine Maleate 2 mg, packaged in 16 fl oz (480 mL) bottles, Rx only;

Tri-Vent HC Liquid, CIII, Hydrocodone Bitartrate 5 mg, Pseudoephedrine Hydrochloride 30 mg, Carbinoxamine Maleate 2 mg, packaged in 16 fl oz (473 mL) bottles, Rx Only;

Colgate Luride (Sodium Fluoride), 0.25 mg F and 0.5 mg F Lozi-Tabs, Vanilla Flavor, packaged in 120 count bottles, Rx Only;

Advanced NatalCare, Prenatal Vitamins, 90 tablet bottles, Rx only;

Advanced-RF NatalCare, Prenatal Vitamins, 90 tablet bottles, Rx Only;

Anemagen Caplets, (contains Elemental Iron-as Sumalate/Succinic Acid/Vitamin C/Vitamin B12/Desiccated Stomach Substance), 90 count bottles, Rx only;

nemagen Forte Caplets with Folic Acid, (contains Elemental Iron- as Sumalate/Ferrous Fumarate/Succinic Acid/Vitamin C/Folic Acid, USP/Vitamin B12), 90 caplet bottles, Rx only;

Cal-Nate, Prenatal Multivitamin/Multimineral with Dual Iron and Calcium Citrate, 90 tablet bottles, Rx only;

CareNatal DHA Tablets, Prenatal Multivitamin/Multimineral Tablets and Omega-3 Fatty Acid, 30 tablets and 30 soft gelatin capsules, (packaged in a box with 5 unit dose blister cards of 6 tablets and 5 unit dose blister cards of 6 soft gelatin capsules), Rx only;

ComBgen Tablets, Folic Acid 2.2 mg, Vitamin B6 25 mg, Vitamin B12 500 mcg, packaged in 100 count bottles, Rx only;

CombiRx Tablets, packaged in 30 count bottles, Rx only;

Conison Capsules, Hematinic Concentrate with Intrinsic Factor, packaged in 60 count bottles;

Fe-Tinic 150 Forte Capsules, packaged in 90 capsule bottles, Rx Only;

NataCaps, Prenatal Multivitamin/Mineral Capsules, packaged in 100 count bottles, Rx Only;

NatalCare Gloss Tabs, Prenatal Vitamins, packaged in 90 tablet bottles, Rx Only;

NatalCare PIC, Prenatal Multivitamin/Mineral Tablets with Polysaccharide-Iron Complex, packaged in 100 count bottles, Rx Only;

NatalCare PIC Forte, Prenatal Multivitamin/Mineral Tablets with Polysaccharide-Iron Complex, packaged in 100 count bottles, Rx Only;

NatalCare Plus Tablets, Prenatal Multivitamin/Mineral Tablets, packaged in 100 count bottles, Rx only;

NatalCare Rx, Prenatal Multivitamin/Mineral Tablets with Beta Carotene, packaged in 200 count bottles, Rx Only;

NatalCare Three, Prenatal Vitamins, packaged in 100 tablet bottles, Rx only;

NataTab FA, Prenatal Vitamin and Mineral Tablets with Folic Acid, packaged in 100 count bottles, Rx Only;

NataTab Rx, Vitamins and Minerals with Folic Acid, packaged in 90 tablet bottles, Rx Only;

NutriNate Chewable, Chewable Prenatal Multivitamin Tablet with Iron, packaged in 90 tablet bottles, Rx only;

Nutrispire, Vitamins and Minerals With Folic Acid, packaged in 90 tablet bottles, Rx only;

Prenatal MR 90 Fe, Prenatal Multivitamin/Mineral Tablets with Micro-Release Iron, packaged in 100 count bottles Rx only;

Prenatal MTR with Selenium, Prenatal Multivitamin/Mineral Tablets, packaged in 100 count bottles, Rx only;

Prenatal Rx 1 (one tablet daily), Prenatal Multivitamin/Mineral Tablets, a) packaged in 100 count bottles and b) 10 x 10 unit dose blister packs, Rx Only;

Prenatal Z Advanced Formula, Prenatal Multivitamin/Mineral Tablets, packaged in 100 count bottles, Rx Only; Ultra NatalCare, Prenatal;

Multivitamin/Multimineral Oral Tablets, packaged in 100 count bottles, Rx only.

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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product: Problem: Recall Information

Abalone and Venetian Carnevale Necklace Craft Kits. The lobster clasps in both craft kits contain high levels of lead. The Abalone Necklace's pendant also contains high levels of lead. Lead can be toxic if ingested by young children and can cause adverse health effects. Action Products International Inc., (800) 772-2846 or www.APII.com.

babyGap Children's Coats. The coats have toggle fasteners that could break and detach from the coat, posing a choking hazard to young children. Gap Inc., (888) 747-3704 or www.gap.com.

Children's Hooded Jackets. The jackets have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Jason Evans Assoc. LLC, (888) 683-0063.

2008 model year Dahon and REI Novara Folding Bicycles. The hinge on the handlepost can crack, posing a fall hazard. Dahon California Inc., (800) 442-3511 or www.dahon.com.

DayNa Decker 16 ounce Botanika Candles. The glass can break during use, posing a fire hazard. Lumetique Inc., (888) 872-0228 or www.daynadecker.com.

Dinosaur Play Sets. The surface paint on the monkey figure contains excessive levels of lead, violating the federal lead paint standard. DND Imports, (818) 815-1791.

Erwin Beanie and Poseidon Beanie Children's Knitted Hats. The eyeballs on the Erwin Beanie and the octopus legs on the Poseidon Beanie can come loose, posing a potential choking hazard. Ambler Mountain Works, (888) 267-6968 or email returns@amblermw.com.

Fricon Upright Freezers. The controller of the freezer is incompatible with the unit and can overheat and melt the relay, posing a fire hazard. Unilever, dba Good Humor Breyers United States, (800) 800-7900, x3828.

Full Length Women's Chenille Robes. Some robes fail to meet federal flammability requirements and present a risk of serious burns to consumers if they are exposed to an open flame. Blair LLC, (877) 392-7095 or www.blair.com/recall.

Jardine Cribs. The wooden crib slats can break, creating a gap, which can pose an entrapment and strangulation hazard to infants and toddlers. Jardine Enterprises, (800) 646-4106 or www.jardinecribrecall.com/.

Leg Curl Machines. A consumer's hand can become caught between the cylindrical counter weight and the frame of the fitness machine, posing a crushing hazard that can result in lacerations and finger amputation. Paramount Fitness Corp., (888) 825-8905 or www.paramountfitness.com.

"Majestic 360" Floor Cleaners. The recalled cleaners' wiring can overheat, causing electrical arcing and melting. This poses a burn hazard to consumers. HMI Industries Inc., (800) 566-5606 or www.Filterqueen.com.

Off-Road Motorcycles. The front fork inner tube on the off-road motorcycles can crack and separate from the fork axle, posing a risk of injury or death to the operator. KTM North America Inc., (888) 985-6090 or www.ktmnorthamerica.com.

Playground Equipment. The handrails and posts on the playground contain high levels of lead paint. Lead can be toxic if ingested by young children and can cause adverse health effects. Floteks, (800) 727-8180 or www.sportsplayinc.com.

Popcorn Machines. The heating element of the popcorn machine's warming deck can remain on after being switched off. This poses a burn hazard to users. DTX International (d/b/a Great American Popcorn Co.), (800) 665-0728 or www.greatamericanpopcorn.com.

Pumpkin Patch Hooded Girls' Raincoats. The raincoats have a drawstring through the hood which poses a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Pumpkin Patch LLC, 1-866-898-0344 or www.pumpkinpatchusa.com.

Special and Narita Hair Dryers. The hair dryers are not equipped with an immersion protection device to prevent electrocution if the hair dryer falls into water. Immersion protection devices, which prevent electrocution, are required by industry standards for all electric hand-held hair dryers. Universalink International Trading Inc., (866) 997-6768 or sales@naritausa.com.

Toaster Oven/Broilers. Electrical connections in the toaster oven/broilers can become loose, posing electrical shock and burn hazards. Haier America Trading L.L.C., (866) 927-4810 or www.haieramerica.com.

Torcofix/Torcoflex and Mountz Torque Wrenches. The internal spring mechanism on the wrench can fail or break, allowing bolts or screws to break or become unscrewed, posing a risk of injury to the user or bystander. Mountz Inc., (866) 367-5526 or www.klanngedore.com.

Under Armour Athletic Cups. The cups can break if hit, posing a risk of serious injury hazard to athletes. Under Armour Inc, (888) 823-0343 or www.underarmour.com/productsafety.

Wagner Paint Sprayers. The on-off switch can be dislodged from the casing, resulting in exposure of electrical connections. This can pose an shock hazard to the consumer. Wagner Spray Tech Corp., (888) 925-6244 or www.wagnerspraytech.com.

OUTRAGE from page 12

commitment to reduce "overuse and underused of health care by aligning quality and efficiency incentives." As initially reported, the pledge sought to shave 1.5 percent off the growth rate in health care spending, thereby reducing health expenditures by $2 trillion over the next decade.

How will this be accomplished? The prescription is purposefully vague, although some of the strategies include reducing administrative costs, lowering hospitalization rates, improved management of chronic diseases, emphasizing prevention, and adopting health information technologies. These voluntary "concessions" are not very different from measures that have been talked about for years, with or without universal coverage. They therefore raise the following questions:

1. If there is consensus on the desirability and feasibility of adopting them, why aren't these measures already in place as requirements?

2. If these companies can stay in business while instituting these changes, why have they not espoused them until know?

3. Are the projected 'savings' another way of giving us an estimate of the inefficiencies and price-gouging that have prevailed up to now?

It would be delusional to take these actions at face value. Indeed, as this is written, there has been a marked escalation in the vagueness of the original promises. Various industries have stated that they are not committing to anything specific in terms of actions or savings. What first appeared to be a "goodwill gesture" and even a "peace offering" now seems more like another public relations gimmick that will do little to change a broken health system that costs too much and excludes too many. ◆

OUTRAGE OF THE MONTH

A Coalition of the Scared

As health reform becomes more of a political process and less of a slogan, different groups are establishing their positions. In what can best be described as a pre-emptive strike, six stakeholders in the medical-industrial complex are positioning themselves to ensure their survival and protect their bottom line. They are also working to re-invent themselves as consumer advocates and protectors of the public trust.

Some of them are worried that, it they do not modify how they do business, they will be excluded from a national health plan altogether. The health insurance companies, for example, fear that they would be marginalized under a single-payer system. Similarly, the lobbying groups for drugs and devices are concerned that increased regulation and greater reliance on evidence-based medicine will significantly reduce the scope of their products and hence their market. For its part, the American Hospital Association is fearful of controls on reimbursement that can reduce its billings. And physicians are always wary of changes that impinge on their "usual and customary" practices and fees.

These players have joined a major union, the Service Employees International Union, to pledge a

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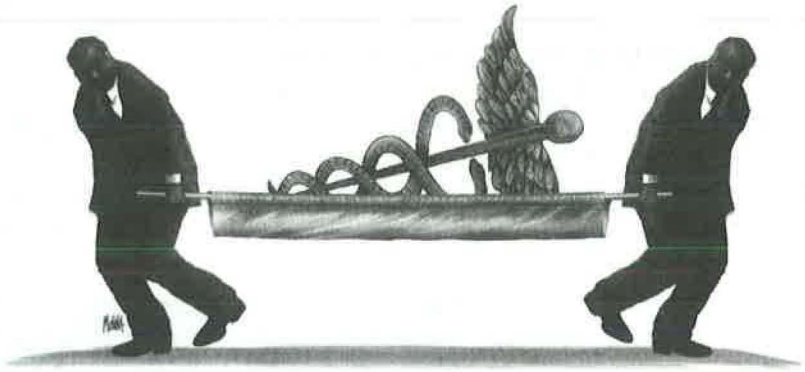

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