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Health Letter

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Unhealthy Partnership: How Massachusetts and Its Managed Care Contractor Shortchange Troubled Children

This article was written by former Health Research Group staffer, Joshua Sharfstein, M.D. who is now a pediatrician and fellow in general pediatrics at the Boston University School of Medicine. It is excerpted with permission from The American Prospect.

Fourteen years old and sullen, he came to the hospital on a Sunday afternoon for evaluation of longstanding abdominal pain. A first-year pediatric intern, I thought of incredible diagnoses: An intermittent twisting of the bowel? A rare parasite? When the preliminary tests came back negative, I told my patient the good news. He just cried, looked away, and held his stomach.

The next morning, a senior pediatrician remarked that abdominal pain is often the only obvious manifestation of depression in children. Returning to the patient's room, I elicited from him a story of loneliness, anger at his siblings, and unwillingness to confide in his parents. Then I drew in a slow breath and ventured that some people do not find life to be worth living. Doctor, he replied, at night I stand in the kitchen with a knife to my neck and pray for the courage to kill myself.

The next couple of hours passed quickly. I consulted with the primary-care pediatrician and explained the situation to my patient's family. After a quick phone call from the psychiatry service to the insurance company, the patient was approved for treatment in a psychiatric hospital.

While I've changed some identifying details of the story for confidentiality, this part can't be altered: It was the closest I came to saving a life in my first year of training. I imagined that referring troubled children to the mental health care system for timely and effective treatment would continue to be an important part of my job as a pediatrician.

But it was not to be. Over the next three years, I observed from a front-row seat as mental health services for children in Massachusetts deteriorated. During my first night shifts in the Emergency Department, I often heard psychiatrists argue with managed care reviewers over approval for inpatient stays. Over time, the next step—finding an available bed in a psychiatric hospital in New England—became the bigger hurdle.

Eventually my experiences with suicidal or out-of-control children passed through the looking glass. I wasn't sending patients to the mental health system for care; the mental health system was sending children

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with acute psychiatric emergencies to me. About once a day, pediatric residents admitted a child to "board" on the pediatric unit of the hospital until a bed in a psychiatric facility—any psychiatric facility—became available.

I fantasized that somewhere in Massachusetts, corrupt officials had absconded with money intended for troubled children. What I discovered is far more shocking. The Massachusetts Behavioral Health Partnership—the state's largest mental health insurance company and the outfit responsible for managing mental health care benefits for tens of thousands of children on Medicaid—has met all of its contractual obligations. What's more, the state pays the plan, known as the "Partnership," millions of dollars each year in performance bonuses. Policy experts and state officials have called it a national model. Starting in October 2000, the largest HMO in the state, the not-for-profit Harvard Pilgrim Health Care, began to contract with the Partnership to provide mental health benefits, leaving the for-profit company with approximately 70 percent of the market for children's services in Massachusetts.

In New Mexico, Medicaid officials have just pulled the plug on a for-profit managed care experiment after recent audits showed 83 percent of patients in one plan were inappropriately treated. In Tennessee and Arizona, recent studies have shown that half of all children with serious mental illness had not received any services in the past six months. When a for-profit contractor nearly destroyed emergency crisis services across the state, furious state legislators in Montana canceled a contract after two of five years. Arkansas lawmakers waited just six weeks to back out. Connecticut sued its for-profit contractor for what the state's attorney general described as a "purposeful and systematic" scheme to deny necessary care and eventually settled for $4 million.

Massachusetts' experience, by contrast, has led some observers to give for-profit managed mental health care a second chance. But how can a mental health plan be so highly regarded even as the service system for children crumbles around it? The answer becomes obvious only with the realization that the plan's purpose was never to ensure access to care for children in need. Indeed, its true function has been to maintain the appearance of success. The company has earned every penny of its more than $200 million Medicaid contract by contributing to the illusion that the system is reasonably intact, allowing the state to dodge pressure for more difficult but necessary reform.

The Partnership illustrates what's really missing in public policy for children with mental illness: not more crafty language for managed care contracts, but a political commitment to ensuring basic access to care.

The Partnership

This story began on July 1, 1996, when the Partnership started to manage mental health benefits for nearly 400,000 Massachusetts Medicaid recipients. Although its name suggests a special relationship between the company and the state, this "partnership" was a joint venture of two of the nation's largest for-profit behavioral health care firms, the Connecticut-based Value Behavioral Health Inc. and the Virginia-based FHC/Options Inc.

Massachusetts officials were eager for the Partnership to prove that for-profit managed mental health care could actually work. Under the terms of the Partnership contract, Massachusetts paid the company a set fee per child and then limited to $2 million the amount of profit it could make by underspending the budget for services. The contract also allowed for $4 million in bonuses for meeting administrative targets and performance standards.

These incentives largely centered on the nuts and bolts of administrative efficiency. During the first year of the contract, the Partnership earned the maximum of $4 million in bonuses. In subsequent years, the incentives were expanded, mostly to include training for providers and state officials and funding for patient surveys and groups. The Partnership continued to excel at hitting these targets, earning $5 million out of a possible $6.7 million in fiscal year 1998.

Yet nothing in the contract held the Partnership accountable for basic access to mental health care for all enrolled children. While the Partnership kept processing claims on time, the demand for inpatient hospitalization was steadily rising, with emergency departments seeing more and more acute referrals**.** Several area inpatient psychiatric units for children folded. Most significantly, openings for troubled adolescents in residential settings such as halfway houses overseen by the state's Department of Social Services dried up, leaving dozens of children in state custody stranded inside psychiatric hospitals, ready for discharge but with no place to go. From July 1998 to June 1999, according to records I obtained under the state's Freedom of Information Act, these children spent a collective total of 8,194 unnecessary days in locked wards.

Suicidal and violent children who needed to get into inpatient psychiatric facilities were put on indefinite hold. Some became boarders in pediatric hospitals; others languished for days in community emergency departments; a few waited in jail. Martha Grace, chief justice of the Massachusetts Juvenile Court, told *The Boston Globe* that judges occasionally had to send troubled children into locked detention simply to protect them while they awaited psychiatric hospitalization. "To put a mentally ill child in a delinquent or criminal population is not good for either population," Grace said. "Now they're being punished for being ill."

This collapse of care for troubled children, however, did not interfere with the Partnership's stellar record of meeting its performance targets. In 1999, the company stood to earn another $400,000 bonus by holding two optional trainings on child and adolescent issues for Partnership providers and state employees. Even in July 2000, as the mental health care system's collapse hit the front page of the *Boston Globe*, an internal Partnership's memo boasted in boldface that "All FY

2000 Performance Standards on track for success."

A Catch-22

Given the multitude of other performance standards, why can't Massachusetts just hold the Partnership responsible for basic access to care? Partnership CEO Richard Sheola says that such a step would be patently unfair. His reasoning: The Partnership has no control over what's really broken with the mental health care system for children.

This claim enables a for-profit company to escape responsibility for children in distress. But it has elements of truth. Massachusetts state agencies, by leaving dozens of children inappropriately stuck in psychiatric hospitals, are largely responsible for the bed crunch that has forced children to languish in pediatric units, community emergency departments, and jails. The state's troubles started in the late 1980s as private insurance practically abandoned seriously mentally ill children. Nationally, from 1988 to 1997, employer spending on mental health services fell by 54 percent in constant dollars. As private managed care plans reduced their benefits, families increasingly turned to the state government for assistance. But state spending in Massachusetts and elsewhere did not match the need.

The most recent data indicate that children in the care of state agencies spent more than 20,811 unnecessary days in psychiatric hospitals from July 1999 to June 2000—the equivalent of 57 years of wasted time. Similarly, while the Partnership has not particularly improved community mental health services, the state's support of key elements of the outpatient system has been sorely lacking. At last count, 2,497 children were waiting for case managers from the Department of Mental Health.

It's a catch-22. The state cannot hold the Partnership fully responsible for basic access to care without first doing a better job itself. But that's exactly what the state government wants to avoid. A real commitment to the mental health needs of children would involve guaranteeing community placements and case management services for all troubled children who need them, backing support teams for families with troubled children, and dedicating additional spending for recruitment and training of new mental health providers. Pilot programs such as the Mental Health Services Program for Youth have successfully reduced foster care rates and improved care for even the most vulnerable children by combining resources from the mental health, education, and criminal justice budgets and creating accountable community based treatment teams. *[See sidebar.]*

But such an investment statewide would be costly up front. Led by tax-cut-obsessed Republican Governor Paul

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Sidebar: A Better Model

The recent Surgeon General's report *Mental Health* concludes that there are inherent limits to what for-profit health plans like the Massachusetts Behavioral Health Partnership can do to assist children in the public sector: "Management of only the Medicaid portion of a complex funding system that includes Medicaid, mental health, special education, child welfare, and juvenile justice not only creates . . . cost shifting. . . . [It] also underestimates the need to manage the funds spent by all agencies."

Some pilot programs around the country are trying a different approach; one such effort began in Cambridge and Somerville, Massachusetts, in March 1998. Combining funds from Medicaid with those from the child welfare system, the education system, and the juvenile justice system, the Massachusetts Mental Health Services Program for Youth (MHSPY) offers comprehensive services to 30 children with "persistent symptoms of serious emotional disturbance" who are at high risk of being placed into foster care.

Dr. Katherine Grimes, a psychiatrist and medical director of the program, says that the key to MHSPY is accountability. Her frequent two questions to project staff are "Hello? Is the kid any better?"

Grimes assigns each child a case manager who obtains all medical records, meets extensively with the child, family, and teachers, and applies resources creatively to support effective care. A rotating system of call allows enrollees 24-hour access to case managers. If a parent has problems attending key psychiatric appointments, a case manager may negotiate a solution with his or her employer or even provide transportation. According to the final grant report, the program makes generous use of respite care "to help young people and their families 'take a break' from each other, preventing the need for longer-term placements."

A preliminary analysis of MHSPY has found that children in the program experienced substantially fewer psychiatric symptoms, inappropriate behaviors, and school problems in the year after enrollment. Compared to the prior year, the number of days spent in the psychiatric hospital, residential care, and foster care dropped by about two-thirds.

Grimes believes that the MHSPY model, which is run out of the not-for-profit Neighborhood Health Plan, can be replicated in communities across the country. As she imagines a better system, severely troubled children would qualify for a case manager in their own communities; others would have their care coordinated by primary care pediatricians with around-the-clock backup from psychiatrists.

Surprisingly, MHSPY's costs are about 20 percent lower than anticipated. Grimes even argues that the program does not cost more than what state agencies are already each paying for narrowly focused and less effective interventions. The real challenge, she says, is not finding additional resources. It is mustering the political resolve to transform the way the mental health care system works for children.

Bad Policy, Worse Medicine

The authors are Dr. Sidney Wolfe, Dr. Philip J. Landrigan of the Mount Sinai School of Medicine and Dr. Godfrey P. Oakley, Jr. of Atlanta, Georgia.

On January 6, 2000, the Food and Drug Administration (FDA) issued a new rule that defined morning sickness and leg edema during pregnancy as "conditions" rather than "diseases." At first glance, this appears a trivial distinction. Contained within it, though, are the seeds for pediatric disaster.

What Is Wrong with the FDA Rule?

To understand the potential for catastrophe embodied in the FDA rule, it is necessary to understand the special interest provisions that are contained within the Dietary Supplement Health Education Act, the major federal statute governing food supplements. This law, enacted by Congress in 1994, creates a loophole in the food and drug laws by classifying as "dietary supplements" products that claim to affect the structure or function of the body, but that do not claim to cure or treat disease. This is a narrow but critical difference, and it has been massively exploited by the "dietary supplements" industry. This loophole allows drug-containing products to enter the market without having to go through the New Drug Application process and without being subject to either Good Manufacturing Practice regulations or quality control requirements. Classifying medications as "dietary supplements" rather than as "drugs" also exempts them from the requirement that they be proven, through controlled clinical studies, to be safe and effective. Numerous products that would otherwise be considered over-the-counter medications fall within the scope of this definition. The *New England Journal of Medicine* has declared that the labeling of these products "has risen to an art form of double-speak." The peril of this situation is significant, as some "dietary supplements" have been shown to contain potent toxins, including lead, arsenic, and digitalis.

Whether a product is subject to the strict controls applicable to "drugs" or to the lax regulation of "dietary supplements" depends in large part, under the 1994 law, on whether the manufacturer claims the product is intended to treat "disease" (drug) or whether it is intended merely to "affect the structure or function of the body" (supplement). The prob-

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Cellucci, Massachusetts politicians are unlikely to target significant new resources to help such a politically unempowered group. Beyond funding, the political obstacles to reforming the mental health care system are daunting. These would include battles to create new residential homes across the state and to break down the walls between several entrenched bureaucracies. Massachusetts is not alone in failing to tackle these problems: Advocates have recently sued New York and Maine on behalf of emotionally disturbed children who do not receive adequate care, and more than a dozen states have recently reported crises in access to children's mental health services.

Massachusetts, however, has uniquely been able to minimize political embarrassment by hiring a managed care plan, holding it responsible for a limited array of "performance standards," and declaring it a success. "If something is happening in a social system over time, it's been designed in," says managed care expert James Sabin. One could conclude, he adds, that Massachusetts' mental health care system "appears to be designed to keep spending level . . . at the cost of not doing anything for kids."

The Future

To avoid Massachusetts' problems, other state governments will have to do more than tinker with the contract language in their deals with managed care plans. They'll have to treat children's mental health as a continuum including insurance for psychiatric services, residential care, school support, social services, and the criminal justice system. They'll have to foot the bill for comprehensive community-based services. And they'll have to demand and monitor basic access to inpatient and outpatient care as well as actual improvement in the lives of troubled children. It remains to be seen whether for-profit plans can play anything more than a limited role (such as efficiently paying hospitals and providers) in such a system.

Even the best managed care plan is only as strong as the political commitment to troubled children that supports it. Legislatures must establish measurable goals for the system and hold agencies responsible for meeting them. Through its oversight of the Medicaid program, Congress can do the same. Virtually all state Medicaid plans have federal waivers to allow managed care for mental health services; Congress should pressure the Department of Health and Human Services to require basic data on access to care before approving renewals. The recent denial of a waiver in New Mexico is a good first step.

From my vantage point, Massachusetts is hardly a model for the future of public mental health services. I am concerned, however, that the Partnership and similar companies will make offers that other state governments cannot refuse. The Partnership's parent organization, called ValueOptions, now manages mental health benefits for 900 companies, as well as 4.8 million people in the public sector. It's a promising market. Even in the face of public desire to help troubled children, governments will always be looking for partners who can help avoid politically daunting but necessary change.

Let the 'Non-Governments' Beware: Multinational Organizations Are Out to Co-opt You and Your Tactics

We all know that December 1999 in Seattle was a memorable time and place for non-governmental organizations (NGOs). In direct response to their successes in Microsoft's home town, the events aroused intense concern in the business community. Why and how were the NGOs so successful? How can corporations "win" when dealing with NGOs? At Public Citizen, our policy has always been to accept no money from either corporations or government, and here's the reason why:

The business community has been quite successful in dulling and even obliterating the purpose of many NGOs by dangling before them the gold rings of prestige and money. Board memberships on corporate bodies, funding of research projects, easy access to policy makers, funding of meetings, retreats and web sites—all of these are in the subtle and seemingly helpful arsenal of savvy corporations. These and other even blunter approaches have been accepted by many environmental and educational groups and disease-specific groups, among others. As anyone with a limited budget and hopes of reform can understand, the temptation to accept "assistance" is difficult to resist when an offer seems benign and aboveboard and the perceived need is great.

Strategy One, a unit of Edelman Public Relations Worldwide (Edelman), initiated an inquiry on behalf of corporate clients aimed at understanding NGOs. It conducted a survey of 500 opinion makers here and abroad that provides a detailed analysis of the perceived effectiveness of NGOs, and at the same time provides the basis of

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lem, therefore, with listing complications of pregnancy as "conditions" rather than "diseases" is that this relaxed definition permits the manufacturers of dietary supplements to evade the strict federal regulations that control the approval and manufacture of drugs.

The FDA's decisions to 1) permit over-the-counter medications to be termed "dietary supplements" and 2) reclassify complications of pregnancy as "conditions" indicate that the agency was prepared to allow dietary supplement manufacturers to market their products to pregnant women for relief of complications of pregnancy, without regard to whether those products had been proven safe and effective for women or safe for their fetuses.

The FDA knows from experience that fetal exposure to teratogens and other toxic materials can have devastating consequences. Indeed, in one of its proudest moments, the FDA refused to permit the registration of thalidomide for use in the United States. Marketed to pregnant women in other nations as a cure for morning sickness, thalidomide caused 15,000 infants worldwide to be born with deformed limbs—phocomelia—as a consequence of in utero exposure to the drug. The FDA's January 2000 ruling ignored that history and threatened to place enormous risks on pregnant women and their infants.

What About The Future?

The short-term news is good. On February 9, 2000, after several days of negative news reports, the FDA backed down on the food supplement rule. The agency announced that it is reconsidering that portion of the rule that would have allowed dietary supplement manufacturers to market products specifically for use in pregnancy.

At a hearing held on March 30, 2000, it was proposed that the FDA require any dietary supplement promoted to pregnant women meet the full federal standards for efficacy and safety that apply to drugs. This seems most reasonable. Indeed, even if the FDA cannot require this level of safety and efficacy under present law, manufacturers would be wise to hold themselves voluntarily to such a standard. To do otherwise is to risk grave liability.

For the long-term, the threat of lax regulation continues, and continuing vigilance will be essential. Dietary supplements are still available to anyone, including pregnant women and children, to treat everything from colds to sleeplessness, fatigue, depression and memory loss. Pediatricians need to understand the potential hazards of these products. They need to know that dietary supplements may contain toxic ingredients, that quality control may be poor, and that safety and efficacy may not have been proven. They need to see for themselves what products are being sold in drugstores, groceries, ethnic stores, and "health foods" stores, and what extravagant claims are being made about them. Equipped with this information, pediatricians will be better able to advise their patients about the use of these products. They will be empowered to contact the Commissioner of Food and Drugs to call for careful scrutiny of the products marketed to their patients. They will be educated to demand that Congress amend the ill-considered provisions of the Dietary Health Supplement Education Act.

Postscript

We do not intend these comments to discourage women of reproductive age from consuming vitamin supplements with folic acid. The dietary supplement synthetic folic acid has been proven in randomized controlled trials to prevent spina bifida. As recommended by the U.S. Public Health Service, the Institute of Medicine, and the American Academy of Pediatrics, pediatricians should encourage all women of reproductive age to consume each day a multivitamin or a serving of a cold breakfast cereal with 400 μg of synthetic folic acid.

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a strategy to counter the NGO challenge. From the NGOs' point of view, the survey provides a window into how corporations are reacting to the NGO "threat" and offers some cautions about the mechanisms of corporate co-opting of NGO goals and strategies.

The first of the survey's major findings is that NGOs are trusted to "do the right thing" 2 to 1 as compared with government, media, or corporations. Secondly, NGOs ranked significantly higher as sources of believable information on such issues as human rights, environment and health than did media outlets or companies in all the countries surveyed (U.S., United Kingdom, Australia, France and Germany) (see table below). Furthermore, 64 percent of the opinion leaders surveyed said they believed that NGOs' influence had increased significantly over the past 10 years.

	Human Rights		Health		Environment	
	NGO	Corporation	NGO	Corporation	NGO	Corporation
USA	59%	4%	54%	7%	55%	6%

Edelman recently held a conference in Washington DC, largely for business executives but with a few large and powerful NGOs and some government representatives present, the purpose of which was to address the problem of public confidence. The meeting was chaired by Michael Deaver, Ronald Reagan's deputy chief of staff in the White House in the 1980s. The meeting was aimed at educating corporate executives on how to improve their companies' image in the public eye by adopting media techniques and working with NGOs. The obvious was never mentioned: actually reforming business so that it *was* more trustworthy rather than be simply *seen* that way—or, to borrow the state motto of North Carolina, *Esse quam videre* (To be rather than to seem).

Thomas ("Mac") McLarty, former chief of staff to President Clinton and now a member of Edelman's international advisory board, and Robert Hormats, vice-chairman of the Wall Street house of Goldman Sachs, agreed on the importance of proactive, sustained dialogue with NGOs. They argued that in addition to improving businesses' image, such dialogue can assist corporations by alerting business to issues of future importance.

Tony Long, director of the World Wildlife Office for European Policy (known in the U.S. as the World Wildlife Fund and elsewhere as the Worldwide Fund for Nature) noted that NGOs can spot societal trends as well as provide a global perspective on issues. His organization is now part of the largest collection of environmental organizations, called the Green G8, which meets regularly with the environmental commissioner and the director general of the European Union. Green G8 is also talking formally to poverty, child protection and human rights groups. In addition, a global NGO movement is emerging that uses information technology to keep abreast of such activities worldwide.

Steven Lombardo, director of the Edelman Strategy One survey, and others at the meeting, advised corporations to adopt NGO techniques to improve their public face. NGOs effectively use the media to disseminate information about their issues, thereby gaining public trust. The message from these speakers was that corporations should also use this channel in a manner to show that their activities benefit the consumer and that the success of their business has a positive effect on consumers' daily life.

Ann McLaughlin, currently CEO of the Aspen Institute, a non-profit organization that sponsors seminars and policy programs on global issues for business, government and educational leaders, emphasized the need to include the values of the work force in dealing with NGOs. In order to be successful, she said, corporations and their leaders must have the trust and loyalty of their employees, and one way to get this is to project an image reflecting employees' personal values (which are often NGO values) in employer-employee relationships. An example: American Airlines and other companies include Earthshare, an environmental United Way, as a possible payroll deduction.

The need for transparency in dealing with NGOs was emphasized throughout the meeting—but what is "transparency"? Does it mean opening up corporate records to disclose actual environmental and labor policies? Or is it just a spin-word—a term used only for public relations? Whatever it is, Goldman Sachs' Robert Hormats noted that the Internet has increased the need for transparency, which has been used very effectively by NGOs. Corporations should learn from them, he advised.

Barbara Shaler, the AFL-CIO director of the American Center for International Labor Solidarity Programs, agreed that there is a critical need for cooperation between NGOs and business. But she questioned whether the two groups really see eye-to-eye on the effects of globalization, arguing that NGOs are by definition anti-corporate as long as corporations oppose environmental, health and labor standards in the global market. Tony Long of the World Wildlife network pointed out that free-market principles are incapable of valuing and accounting for the root causes of environmental damage and growing social inequalities, two major issues in the NGO communities. Other speakers did not discuss these issues.

Horst Teltschik, a former board member of the Bavarian Motor Works that makes BMW cars, and a former German government official, presented a different viewpoint. He said that the German Green Party's experience shows that in time NGO movements can be co-opted into the government itself, and if given responsibility will become "reasonable" and more ready for compromise. In addition, he and Long mentioned that business relationships have been established between NGOs and business. In Germany there has been a long-standing disagreement between NGOs and the automobile industry including BMW, but this dissension has lessened through BMW's research on traffic problems, recycling cars, reduction of fuel consumption and emissions, and alternative energy (including cooperation with the Greens on hydrogen). There are, of course, two ways of looking at this:

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Product Recalls

December 8, 2000—January 10, 2001

DRUGS & DIETARY SUPPLEMENTS

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and 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 web site is *www.fda.gov*.

Class I Recall

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Etodolac Capsules (Lodine Capsules), 300 mg, in 100-unit bottles, Rx used for arthritis and pain management; Cross contamination with Acebutolol Hydrochloride, a beta-blocker drug	Lot #9991052 EXP 7/02; Approximately 935 bottles were distributed nationwide; Wyeth-Ayerst Company, Guayama, Puerto Rico. Wyeth-Ayerst Laboratories, Philadelphia, Pennsylvania

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one, that both parties benefit from the collaboration; the other, that the Green Party was compromised in the process. While cooperation as an aim is commendable and may aid in solving one environmental issue, we believe it is important that NGOs remain independent in pursuit of the common good.

The conference ended with a discussion that also suggests a need for vigilance by NGOs. The "bottom line"—the vital importance of profitability to corporations—was agreed on, but at the same time a need for constant, open, proactive cooperation with NGOs was stressed. Corporations were advised to adopt other proactive tactics with NGOs, by assisting the process of cooperation by bringing in NGO people to their management teams. They were urged to pay attention to younger members of their organizations, who are usually more inquisitive and willing to raise more questions, and who may be more sympathetic than their elders to NGO concepts. To a bystander this raises the issue of whether such a trend is favorable to NGOs or actually an attempt to neutralize their effectiveness—a question that must be carefully followed.

The need to recognize the importance of NGOs was an obvious "call to arms" to the corporations represented at the Washington meeting. Later, this concept was reinforced by Robert Edelman, president and CEO of Edelman PR Worldwide, in a statement that as a result of increasing distrust in the motives of corporations and governments, NGOs will grow in importance, where the public is concerned, in cases like "Mad Cow" disease, for instance.

A not-so-subtly hidden agenda came clear in the meeting's basic message to business—placate NGOs by making them part of the "old boy" network. Jonathan Wootliff, managing director of Edelman's global NGO practice, cited as examples Home Depot's alliance with the Forest Stewardship Council and the Chiquita partnership with the Rainforest Alliance. In both instances, the companies have ostensibly adapted their business practices to cooperate with their partner NGOs. What adaptations were made by the NGOs, if any, were not reported.

All this needs to be put in the context of Nobel Prize-winning economist Milton Friedman's warning to corporations about their behavior: "Few trends could so thoroughly undermine the very foundations of our free society as the acceptance by corporate officials of a social responsibility other than to make as much money for their stockholders as possible."

The bottom line: *Caveat NGOs*!

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Collyrium Eye Wash, (Boric Acid) in 4-fluid ounce (118 mL) bottles, OTC aqueous ophthalmic solution indicated for cleansing the eye, under Wyeth and Bausch & Lomb labels; Class II; Phenol contamination	Wyeth Ayerst lots 3981543, 3982156, 3982217 EXP 6/01, Bausch & Lomb lots 3982224 EXP 7/01, 3982225 EXP 8/01, 3982226 EXP 9/01, 3991526, 3991172 EXP 1/02, 3991269 EXP 4/02, 3990414 EXP 7/02; 704,424 bottles distributed nationwide; Wyeth-Ayerst Pharmaceuticals, Inc., Rouses Point, New York (contract manufacturer). Recalled by Bausch & Lomb, Inc., Rochester, New York
Ibuprofen Tablets, 400 mg, in blister packs 10 x 10 tablets, Rx oral nonsteroidal anti-inflammatory agent; Class III; Dissolution failure (three month stability)	Lot #21392 EXP 12/01; 5,809 cartons were distributed nationwide; BASF Corporation, Shreveport, Louisiana. Recalled by Watson Pharmaceutical, Inc., (formerly Schein Pharmaceutical, Inc.), Florham Park, New Jersey
Phenazopyridine Hydrochloride Tablets, 100 mg, in 100-count bottles, Rx for urinary irritation; Class II; Dissolution failure	Lot #046060; 16,987 units distributed in Alabama; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina
Premarin Tablets, 2.5 mg (Conjugated Estrogen Tablets), in 100-count bottles, Class III; Dissolution failure	Lot numbers R9K00522, R9K00522A EXP 08/01 and R9K00608, R9K00608A EXP 09/01; 5,086 100-tablet bottles distributed nationwide and in Puerto Rico; Ayerst Laboratories, Division of Wyeth-Ayerst Pharmaceuticals, Inc., Rouses Point, New York; and Wyeth Pharmaceuticals Company, Guayama, Puerto Rico. Recalled by Bergen Brunswig Corporation, Orange, California
Premarin Conjugated, 0.625 mg, 1.25mg, 2.5mg in 100 & 1,000 count bottles; Class III; Manufacturer failed to meet USP dissolution specifications for Conjugated Estrogen	Lot #9990086 EXP 9/02 and EXP 12/03, Lot #999029U and Lot #9990585W EXP 11/03, Lot #9980299 EXP 11/02, Lot #9980874 EXP 2/03, Lot #9990175 EXP 10/03; 108,394 bottles distributed nationwide and in Puerto Rico; Wyeth-Pharmaceuticals Co., Guayama, Puerto Rico. Recalled by National Pharmpak Svcs, Incorporated, Zanesville, Ohio
Pseudoephedrine HCL Tablets, 30 mg, in 24, 32, 48, 96, and 384-count bottles, OTC Suphedrine under the labels: Finast, Super G, Stop & Shop, Family Pharmacy, Medallion, Your 1st Choice for Value, Brooks, DeMoulas Market Basket, Discount Drug Mart Food Fail, DR duane reade, Family Dollar, Fred's, GU, Kinney Brand, Snyder, Medic Drug, MS Pharmaceutical, Smart Choice, Equate; Class III; Failure to validate manufacturing process (sequence of addition of components)	Numerous lot numbers; 8,139,867 bottles distributed nationwide; Leiner Health Products, Inc., Wilson, North Carolina and Carson, California
Skin Guardian, in 2-ounce aerosol cans, OTC topical skin protectant; Class III; Product is an unapproved new drug	Any code shipped after 6/28/00; 2,640 units distributed in Oklahoma; Unique Laboratories, Inc., Chatsworth, Georgia
Suphedrine Cold & Allergy Tablets (Pseudoephedrine HCl 60 mg & Chlorpheniramine Maleate 4 mg), in 24-tablet units, OTC; Class III; Failure to manufacture as per validated method—(reduced blend time and excessive ingredient amount)	Lot #0032996; 1,147,392 tablets distributed in Arkansas; Leiner Health Products, Wilson, North Carolina and Carson, California
Synthroid Tablets (Levothyroxine sodium tablets) 112 mcg (0.112mg) and 200 mcg (0.2mg); Class II; Mispackaging	Lot numbers #00045501 and #00045517, physician samples; 30,474 boxes of four cards distributed in unknown area; Knoll Pharmaceuticals, Jayuya, Puerto Rico. Recalled by Knoll Pharmaceutical Company, Mount Olive, New Jersey

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Tegretol (carbamazepine), 200 mg, in 100 and 1,000 unit bottles, Rx anticonvulsant; Class II; Dissolution failure	Lot Numbers: 128B1120 EXP 6/02, 156B3063 and 158B3063 EXP 10/02, 170D4247 EXP 1/03, 121B9991 EXP 4/02, 137B1238 EXP 6/02, 144B1825 EXP 8/02, 150B2289 EXP 1/02, 155B2289 EXP 10/02, and 1T237018 EXP 9/01; 172,586 bottles distributed nationwide; Novartis Pharmaceutical Corporation, Suffern, New York
Triaminic Vapor Patch Menthol Scent, Cough Suppressant, (Camphor 4.7%/Menthol 2.6%) in boxes of six patches, OTC for the treatment of cough; Class III; Pouch seal failures (opening along top, sides and/or bottom)	Lot Numbers: LE505342 EXP 6/02, LE505483 EXP 6/02, LE505503 EXP 7/02, LE505536 EXP 7/02, LE505588 EXP 7/02, LE505680 EXP 8/02; 223,416 cartons distributed nationwide; Lectec Corporation, Minnetonka, Minnesota. Recalled by Novartis Consumer Health, Inc., Summit, New Jersey
Triple Sulfa Vaginal Cream (Sulfathiazole/Sulfacetamide/Sulfabenzamide), in 2.75-ounce tube, Rx under Alpharma label; Class III; Subpotency of sulfacetamide at 12 month stability testing	Lot #L908034 EXP 2/01; 37,265 units distributed nationwide and in Puerto Rico and Canada; Alpharma USPD, Inc., Lincolnton, North Carolina

MEDICAL DEVICES

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 information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call 1-800-FDA-1088. The FDA web site is *http://www.fda.gov*.

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
FastTake Compact Blood Glucose Monitoring System, used to quantitatively measure glucose (sugar) levels in whole blood taken during home care use, under trade names: One Touch FastTake Compact Blood Glucose Monitoring System (in the U.S. and Canada); PocketScan Compact Blood Glucose Monitoring System (in the United Kingdom); EuroFlash Compact Blood Glucose Monitoring System (in Europe); SmartScan Compact Blood Glucose Monitoring System (in Asia, Middle East, Africa, Europe); Class II; The meter may display a "y" character instead of a number in the test result	All meters with serial numbers starting with K, L, M and N; 846,874 meters were distributed nationwide; Inverness Medical, Inc., Waltham, Massachusetts. Recalled by LifeScan, Inc., Milpitas, California

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 1-800-638-2772. The CPSC web site is *http://www.cpsc.gov*.

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Bath Toys; Size, texture, shape and easy compressibility of the fish toy make it possible for an infant to compress the toy and place it in his or her mouth. If the toy reaches the back of the mouth and expands, it may block the child's airway	Scoop Pour 'N Squirt and Bath Time Pals; 370,000 sold nationwide from February 1999 to December 2000; Sassy, Inc. Kentwood, Michigan (800) 764-8323 www.sassybaby.com/safetynotice.html
Battery Chargers; Charger can fail to automatically shut off after battery is fully charged, which can cause the battery to burst, and pose fire, burn and electrical shock hazards to consumers	Chargers used with cordless power tools DEWALT (DW9107, DW9108) and Black & Decker Industry & Construction™ (97015, 97016); 1.7 million sold nationwide from May 1996 through August 2000; DEWALT® Industrial Tool Co., Baltimore, Maryland (866) 543-3401 www.dewalt.com

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Boots (toddler); The toggle, a small plastic ball attached to the laces, can detach, posing a choking hazard to young children	Boys' and girls' styles sold in sizes 6 through 10; 38,000 sold at discount department stores from September through December 1999; BBC International, Boca Raton, Florida (800) 632-4450
Busy Poppin' Pals Toys (Expansion of earlier recall); Small springs inside toys can break loose, posing a choking and laceration hazard to young children	Model 5446 Sesame Street; 170,000 sold nationwide from November 1994 through 1996; Playskool, Pawtucket, Rhode Island (877) 518-9743
Educational Pull Toys (Recall to repair); The toy has a red plastic connector on the pull string designed to separate under tension. Plastic pieces can detach from the string when the connector is pulled apart and could pose a choking hazard to young children	"Alphabet Pal" green caterpillar musical pull toy; 500,000 sold nationwide from June 1999 through November 2000; LeapFrog, division of Knowledge Kids Enterprises Inc., Emeryville, California (877) 477-6641 www.leapfrog.com
Lawn and Garden Tractors; Hood latch on these tractors can damage fuel tank and cause fuel to leak when the hood is raised and lowered, presenting a fire and explosion hazard	Year 2000 models with 42, 46 or 50 inch mower decks, 16 to 25 horsepower engines and a foot pedal speed control—red and gray two tone in color; 9,700 sold nationwide from November 1999 through December 2000; White Outdoor Products Co. (subsidiary of MTD Products Inc.), Cleveland, Ohio (888) 848-6038
Propane Gas (Recall to inspect); Propane may not have contained enough odorant to allow consumers to smell leaking gas, presenting a fire, explosion or thermal burn hazard to consumers	Cenex Harvest States Cooperatives (CHS), Inver Grove Heights, Minnesota is voluntarily coordinating the testing of propane gas delivered to dealers since June 1, 2000 in Idaho, Montana, Oregon, Washington and Wyoming. Call (800) 635-3998 for more information
Scooters; Front of the folding mechanism, where steering column meets the base of the scooter, can create a pinch-point. Fingers can be injured while folding or unfolding the scooter	Excite Super Speeder II and Viper models; 80,000 sold at Rite Aid stores nationwide from August through December 2000; Excite Ltd., Hong Kong (888) 571-3731
Strollers; Lock mechanisms found on both sides of stroller can break and create a pinch-point hazard. Young children can be injured when their fingers, arms or hands are pinched between parts of the locking mechanism	Kolcraft Ranger and Ranger Quattro model numbers 46720 and 46721; 25,500 sold nationwide from January through November 2000; Kolcraft Enterprises Inc., Chicago, Illinois (800)757-4770

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and requires details. It apparently doesn't matter whether those claims were ever paid.

For the Public Citizen officer who would have to sign this form, answering most of the questions would be easy: "I have no idea, because only our insurance carriers have all that data, and I don't think they would give it to us even if we asked." But more important from our perspective, we don't think that any employer should have access to that kind of highly private information because it could be used, legally or not, to the disadvantage of the employee who is forced to provide it.

Therefore, we at Public Citizen decided as a matter of policy that, even if we could get the information, we would not ask for it since it is really none of our business, even though it may directly affect the cost of our health insurance program, which *is* our business. Indeed, as we subsequently learned, although some carriers did not insist that we fill out this kind of form before quoting us a price, almost all of them had a policy such as that reflected in the form's last line: "Rates contingent upon review and acceptance of medical information."

In the end, we kept the same carriers, albeit with a few changes and a price increase that was less than we had originally been told. In all likelihood, the small increase was because our carriers already had the answers to the questions on the form, as well as much more information about our employees and their dependents, from which they were able to decide how likely they were to make a profit at a given level of premiums. We felt good because we had not cooperated with the massive invasions of privacy that these forms demanded, but that was only because our cooperation was not needed.

The whole episode was particularly distressing because Public Citizen is a well-known consumer advocacy organization that might be expected to resist this kind of personal interrogation. Surely insurance companies are at least as invasive when dealing with other employers, who may be less concerned about protecting the medi-

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cal records of their employees.

This episode clearly illustrates how the business of medical insurance in America works today. The theory behind group health insurance is that it is supposed to spread risks and costs so that the healthy subsidize the sick. That is a fair trade-off since most of us at one time or another will need some sort of expensive medical treatment. The use of these forms, however, makes clear that insurance companies are doing their best not to sell insurance, but to sell prepaid services to people who are unlikely to need much medical treatment or, at worst, who will only need fairly predictable and inexpensive services. As a result, these companies are no longer in the business of *spreading risk* , but of *avoiding* risk.

If this trend continues, it will become even more difficult for anyone to obtain reasonably priced, moderately comprehensive health coverage. Even if insurance companies were prohibited from asking for such private information, before they signed up a group, there is nothing to stop them from "dumping" a group afterwards if its medical costs go too high. Indeed, health insurers already are dumping patients if, after too many of them actually need medical care, they are deemed "unprofitable" as a group. That's what happened to 100,000 people in North Carolina, South Carolina and Georgia who subscribed to Mid-South Health Plan, a subsidiary of Trigon, a large managed care company. Trigon announced in October 1999 that, because of "an unexpected increase in medical costs," it would close Mid-South. Trigon says it gave its former customers six months to find other coverage; but for any of those, whose illnesses made them unprofitable in the first place, this was probably quite difficult.

As the old saying goes, "there ought to be a law," but passing one that will work is easier said than done. Congress has already tried to deal with a narrow aspect of the problem of refusing insurance to people with preexisting conditions, but the experiment has been largely unsuccessful. In 1996, in response to complaints that insurance companies were refusing to insure people who had potentially expensive conditions (such as AIDS, but also including pregnancy), Congress enacted a law that prevents outright discrimination by providers of group health insurance. The law also forbids charging higher rates for the sick than for the healthy. But the law expressly *allows* the insurer to raise the rates of the group as a whole. This doesn't end the discrimination, it simply shifts the cost to a somewhat larger group—but not the entire community, let alone the entire population of a state or region. And for individuals who are not part of a group, the law assures that they can purchase medical insurance, but gives them no protection against having to pay outrageous amounts for it.

Another option for Congress would be to establish a whole regime to control health care prices—which would include new rules and regulations for insurance companies, hospitals, doctors, and companies that sell products and services to them. If it did, of course, there would have to be a significant, costly government enforcement and regulatory program to see that companies complied, not to mention the internal costs for each company to be sure that it doesn't violate these inevitably complex laws. If such a system were put in place, we could pretend that the free market was still at work, but it would be unlike any free market ever seen in this country. Moreover, there is no guarantee that the new laws would do anything more than eliminate the very worst abuses, while insurance companies would still find a way to serve mainly the well and the well-off.

Of course, if we had a system under which there was no shopping around for insurance coverage, and in which the health care providers treated whoever came in the door and were paid accordingly, the problem of group dumping would disappear.

There is such a system, found in almost all developed countries, in one form or another. It's called national health insurance. But the gods of conventional wisdom in this country have removed it from the list of options for discussion. However, if you believe that group dumping—and other similar flaws in our current system—should not be allowed to continue, don't be so quick to dismiss a single payer system, like Medicare, unless you have something else that will do the job as well.

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Managing Editor ..... *Phyllis McCarthy*

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None Of Your Business

This article was written by Alan B. Morrison, director of the Public Citizen Litigation Group and Dr. Sidney M. Wolfe, director of the Public Citizen Health Research Group and Health Letter *Editor and was run in the* Washington Post *Outlook section on January 7.*

A not-so-funny thing happened when our employer, Public Citizen, began to investigate whether to renew its existing health insurance policies or shift to other carriers. We asked our insurance broker to obtain bids from our current plans (an HMO and Blue Cross) and from others that might be interested in a group with about 90 employees.

What disturbed us were not so much the prices—we're used to annual sticker shock—but the questionnaires that we received from several of the new bidders. They wanted to know more than how many employees we had, how many dependents, and of what ages; they required detailed personal medical histories on everyone who would be covered.

Here's the opening salvo of one questionnaire: "Please answer the following questions to the best of your knowledge. How many of your employees or dependents are pregnant? Give due dates and explain any complications." The next item asks how many covered persons are "disabled," without distinguishing which of the term's several legal and medical definitions it means. It goes on to ask whether anyone has been hospitalized within the past 12 months "or expects to be hospitalized in the next 12 months." Unsurprisingly for a group our size, the answer is yes; so we are then asked to "state reason(s) for hospitalization," with several lines left to fill in the details.

Those questions are intrusive enough, but it gets worse. Question 4 asks the employer to go back 36 months and find out whether anyone has been diagnosed with any of 14 categories of ailments. Along with such diseases as cancer and diabetes, the insurance company wants to know about highly personal matters such as alcohol/drug abuse, infertility, immune system disorders (such as AIDS) and any psychological diseases or disorders. Again, these are not just yes or no questions; employers are asked to provide information about when each diagnosis was made, what the prognosis is, and what treatment the patient is receiving. And to be sure that nothing has been missed, the last question asks whether anyone has "incurred medical claims in excess of $5,000 over the last 12 months"

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