PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Health Care Reform in the United States: Arguments for a Single Payer System

Last month in Health Letter, *Public Citizen reported on a series of community meetings that tapped into public opinion on key issues in health care. The results of those meetings showed that many Americans are in favor of a single payer system. Here,* Health Letter *examines the reasons for supporting a single payer system.*

Creating a universal health entitlement scheme for all Americans is an idea that has been seriously debated since 1912, when the American Association for Labor Legislation established a Committee on Social Insurance. The rationale for this was both technological and social. Medical advances and changes in the content and organization of health care increased the cost of services, and it made sense to spread the financial risks of ill health over a larger number of people. The Social Security movement was therefore committed to safeguarding individuals against both loss of earnings and unexpected health expenditures.

While the concept was widely discussed over the course of 6 years, it did not succeed. But the need for universal health care did not go away and the topic gained prominence during the administrations of Franklin D. Roosevelt, Harry S. Truman, Richard Nixon, and, more recently, Bill Clinton. In each case, the debate produced more sound than light, and all legislative attempts ended in failure. But the issue has not gone away, and it was more recently revived when the *Citizens' Health Working Group* was appointed by the Comptroller General of the United States. The group was charged with engaging the population at large to find out "the services they want covered, the health coverage they want, and how they are willing to pay for coverage." The group has now issued a report and Interim Recommendations and called for comments on its preliminary findings and proposals. Public Citizen's Health Research Group therefore took this opportunity to reiterate its position in support of a universal single payer system.

The rationale for single payer has become increasingly compelling right now, when U.S. businesses are feeling the pinch of rising health care costs, the number of uninsured continues to rise, the nation is losing its comparative advantage in world markets, hospitals are eager to shed the burden of their "bad debt and charity" pool, and consumers are increasingly baffled by an array of insurers who offer confusion in the guise of "choice."

The arguments in favor of having a single payer are summarized below. These reasons are in addition to the most overwhelming reason, namely that such a system is the only way we can realistically afford to end the dangerous, embarrassing, and worsening situation wherein about 45 million people in this country lack health insurance and tens of millions more are seriously underinsured.

Single Payer is good for business. Publicly financed but privately run health care for all would cost employers far less in taxes than their current costs for insurance. With universal coverage, employers would no longer have to pay for medical care as part of the compensation package offered to

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workers. And with health care outlays expected to increase between 14 percent and 18 percent between now and 2010, employers can expect no relief from the already unsustainable situation they are facing at present. A survey of senior-level executives in Detroit found that 75 percent consider employee health insurance "unaffordable," while the remaining 25 percent consider it "very unaffordable."

If the situation is untenable for individual employers, it is even worse for the economy as a whole. Increases in health care costs are a drag on economic growth: they thwart job growth, suppress increases for current workers, weaken the viability of pension funds, and depress the quality of jobs. Rising health care costs are also causing budgetary problems for federal and state governments, which are currently paying over 50 percent of the U.S. health care bill.

Universal health coverage would also have a salutary effect on labor-management relations. Many, if not most, strikes in the past five years have involved conflicts over health benefits. Universal coverage would defuse this contentious issue, provide benefits independent of employment status, and allow business greater flexibility in whom to hire.

Single Payer will enhance the comparative position of the US in the global market. President Bush has repeatedly said that the United States is not reluctant to compete in the international market as long as there is an even playing field. At present, the lack of universal health insurance places the U.S. at a disadvantage vis-à-vis other countries. Companies such as General Motors that have factories in both the United States and other countries have learned this lesson well; for example, in 2003 the costs of manufacturing a midsize car in Canada were $1,400 less than that of manufacturing the identical car in the United States, primarily because of much higher health costs in this country.

Single Payer builds on existing experience. Those who fear that single payer is new and foreign, and therefore untested, need to be reminded that Medicare is, in essence, a single payer system. For those who are eligible, Medicare is universal and identical, not means-tested, and administered by the government, which acts as a single payer for hospital and outpatient physician services. Because it did not have to sift and sort the population or cope with a layer of insurers, the roll-out of Medicare in 1966 was amazingly smooth. Practically overnight — and without computers — the program covered services provided by 6,600 hospitals, 250,000 physicians, 1,300 home health agencies, and hundreds of nursing homes. By the end of its first year, Medicare had enrolled more than 90 percent of eligible Americans, a feat that cemented its popularity and redeemed President Johnson's faith in the efficacy of government.

In contrast, Part D of Medicare, which departed from the single payer model and introduced private insurers, encountered the wrath of consumers who were unable to maneuver the complicated choices required to obtain prescription drug benefits.

Single Payer has significantly lower administrative costs. Studies by both the Congressional Budget Office and the General Accounting Office (GAO) have repeatedly shown that single payer universal health care would save significant dollars in administrative costs. As early as 1991, the GAO concluded that if the universal coverage and single payer features of the Canadian system had been applied in the United States that year, the total savings (then estimated at $66.9 billion) "would have been more than enough to finance insurance coverage for the millions of American who are currently uninsured." More recently, estimates published in the *International Journal of Health Services* conclude that "streamlining administrative overhead to Canadian levels would save approximately $286 billion in 2002, $6,940 for each of the 41.2 million Americans who were uninsured as of 2001. This is substantially more than would be needed to provide full insurance coverage." At present, the U.S. spends 50 percent to 100 percent more on administration than countries with single payer systems.

Single Payer facilitates quality control. Having a single payer system would create for the United States a comprehensive, accurate, and timely national database on health service utilization and health outcomes. This would provide information on gaps and disparities or duplication of care, thereby serving as valuable intelligence for decision-making and resource allocation. At present, the closest analogy to this is the Veterans Health Administration (VHA), which has been highly successful in containing costs while providing excellent care. According to *New York Times* contributor Paul Krugman, the key to its success is that it is a universal, integrated system:

> Because it covers all veterans, the system doesn't need to employ legions of administrative staff to check patients' coverage and demand payment from their insurance companies. Because it's integrated, providing all forms of medical care, it has been able to take the lead in electronic record-keeping and other innovations that reduce costs, ensure effective treatment and help prevent medical errors.

Single Payer gives the government greater leverage to control costs. A single payer would be able to take advantage of economies of scale and exert greater leverage in bargaining with providers, thereby controlling costs. Recent experiences with both the VHA system and Medicare Part D indicate the difference exerting such leverage can make. The Department of Veterans Affairs uses its power as a major purchaser to negotiate prices with pharmaceutical makers. But when the legislation leading to the drug prescription plan (better known as Medicare Part D) was passed, Congress explicitly barred negotiating prices with drug makers. The results of this are now becoming evident: at present, the VA is paying 46 percent less for the most popular brand-name drugs than the average prices posted by the

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The Changing Dynamics Of C-Sections In The United States

Part 1

Here, Health Letter *examines the social, technological, and medical trends that have led to an increased rate of women undergoing cesarean sections. This article is the first in a two-part series. Next month, we will look at a more specific study outlining the phenomenon of so-called "cesarean delivery on maternal request".*

Cesarean sections are the most frequently-performed surgery in the United States: more than 1.1 million procedures were carried out in 2004, the most recent year for which data are available. Although lowering the c-section rate has been a national goal for the past 25 years, both the goal and its formulation have been modified to reflect new data and standards. Questions over the rising cesarean trend in the 1980s led to a goal of lowering c-sections to no more than 15 percent as part of the *Healthy People Year 2000* objectives.

When the goals were subsequently assessed and updated for 2010, the focus of the objective was changed from all women giving birth to *low-risk* women. A "low-risk" woman was defined as one with a full-term (at least 37 completed weeks of gestation), singleton (not a multiple pregnancy), with vertex fetal presentation (head facing in a downward position in the birth canal). Separate objectives were established for low-risk women giving birth for the first time, and for low-risk women who had had a prior cesarean birth. The current objectives are

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Medicare plans for the same drugs. Because Part D increased the effective demand for drugs without controlling costs, prescription drug prices have risen sharply: during the first quarter of 2006, prices for brand-name pharmaceuticals "jumped 3.9 percent, four times the general inflation rate ... and the largest quarterly price increase in six years."

If this trend is allowed to continue unchecked, it could jeopardize the fiscal viability of the Medicare drug program and seriously undermine whatever political and public support it now has. In addition, this could have significant repercussions on the program as a whole. In the words of economist Stephen W. Schondelmeyer, who specializes in drug industry issues, "Higher drug prices may lead to higher premiums next year, which may discourage enrollees from joining or staying in the program, and fewer enrollees could drive premiums even higher."

Single Payer promotes greater accountability to the public. One of the key features of the US health care system is its fragmentation. When every player is responsible for only part of the care of part of the population part of the time, there is no overall accountability for how the system functions as whole. Consumers are therefore left wondering who is in charge, and to whom they can appeal when their knowledge is incomplete or their care is inadequate.

The most recent report to Congress of the Medicare Advisory Commission recognizes this: "...perverse payment system incentives, lack of information, and fragmented delivery systems are barriers for full accountability."

The creation of a single payer would provide an opportunity for creating a system run by a public trust. Benefits and payments would be decided by the insurer which would be under the control of a diverse board representing consumers, providers, business and government.

Single Payer fosters transparency in coverage decisions. Ironically, single payer plans have been criticized for "making all sorts of unbearable trade-offs explicit government policy, rather than obscuring them in complexities." In fact, we see making tradeoffs explicit as a virtue. Given finite resources, it may not be possible to cover every single treatment, device or pharmaceutical a patient may require or desire. Priorities must be set, and the criteria for these should be transparent and consistently applied.

The practice of "obscuring trade-offs" is irresponsible and demeaning to the American public. Medical care decisions are too important and affect everyone too directly to be made surreptitiously. Moreover, forcing policy-makers to make decisions concerning what to cover will ensure their confronting issues of safety, efficacy, and value-for-money that are often circumvented or overlooked. Trade-offs that are transparent to health care consumers will therefore be in the public's interest.

In sum, the reasons for supporting single payer are practical as well as based on values of openness and social responsibility. We therefore urge the Citizens' Health Care Working Group to adopt the creation of a single payer as an essential pillar, without which the guiding principles included in the Group's *Interim Recommendations* will not be fulfilled. We also exhort our readers to send their statement or comments in support of single payer to the Citizens Health Care Working Group by September 1, 2006 in any of three ways:

- online at www.CitizensHealthCare.gov;
- by e-mail to citizenshealth@ahrq.gov; or
- by mail to:
  Citizens' Health Care Working Group Attn:
  Interim Recommendations
  7201 Wisconsin Ave., Rm. 575
  Bethesda, MD 20814 ■

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described in the chart that accompanies this article.

The changes in objectives reflect a focus on women who are more likely candidates for vaginal births, as well as new concerns over the rising incidence in surgery when there are no medical indications to justify it.

Healthy People 2000 objectives regarding cesarean delivery

	1998 Data	2003 Data	2010 Target
	Percentage of live births		
Women giving birth for the 1st time	18	24	15
Women who had a prior cesarean birth	72	89	63

Trends in cesarean sections

Over the past 15 years, trends in cesarean rates have undergone significant changes. Total cesarean sections in the United States decreased from 22.7 percent of all live births in 1990 to 20.7 percent in 1996. After that date, the trend reversed itself, increasing steadily to reach a high of 27.6 percent in 2003, the most recent year for which data are available. The data for low-risk women giving birth for the first time reflected the overall trend: after declining from 21.0 percent to 17.8 percent between 1990 and 1997, the rate rose to 23.6 percent between 1997 and 2003.

Women who have already had a cesarean delivery have one of two alternatives for subsequent delivery: they can have a repeat cesarean, or a vaginal birth after cesarean (VBAC). The VBAC rate rose overall from 19.9 percent to 28.3 percent between 1990 and 1996, after which it decreased precipitously to 10.6 percent in 2003. Among low-risk mothers, the slope of decrease was equally steep: VBACs decreased by 63 percent, falling from 30.2 percent to 11.3 percent during the same period. As a result of these trends, 31.1 percent of all cesarean deliveries in 2003 were to low-risk women having a repeat cesarean.

As trends have diverged from the established health objectives, researchers have focused on identifying the reasons for the change, especially for the shift that occurred in 1996-97. The debate centers not only on the appropriate level for c-sections, but also on how to achieve it. Because the increase in the cesarean rate has been steady and widespread, affecting women of all ages and ethnic groups, a recent CDC report concludes that "the criteria or indications for cesarean delivery in the United States have changed." There are multiple reasons for these changes; these involve not only women and their physicians, but the entire health care system as well.

Patient-related factors

While these may not be the determining factors, changes in the risk profile of patients provide a partial explanation for the increase in the overall rate of c-sections. Data on births show an increase in the numbers and proportions of older women giving birth: in 2003, the birth rate for women 40 to 44 years increased to 8.7 births per 1000 women, the highest rate reported since 1969. Obesity and diabetes have been other risk factors that have been on the rise: the rate for diabetes among women giving birth rose nearly 40 percent between 1990 and 2003. Finally, the greater use of fertility-enhancing therapies and the consequent rise in multiple pregnancies have also increased the number of women likely to deliver by c-section.

In addition to changes in the population itself, there has been some documentation, however inadequate, that more women are electing to undergo a c-section. In the absence of a medical indication, some of these "elective C-sections" are presumed to reflect a desire for a scheduled delivery. The trend towards elective primary cesarean delivery has been associated with higher income and/or better educated women who are popularly described as being "too posh to push."

Although effective as a tabloid headline, this phrase is inaccurate as well as gratuitously demeaning to women. Women who opt for a c-section most often do so not to avoid labor or for the sake of convenience, but because they fear the risks of vaginal childbirth more than those of undergoing a cesarean section. In addition, most of the risks of C-section affect the mother, while some of those of vaginal birth affect the child. A woman may accept a higher risk to herself in the expectation of increasing the probability of a healthy baby.

Women facing delivery may therefore face conflicting odds, or a complicated constellation of burdens and benefits. Moreover, some of the effects are immediate and others are more long-term; the final decision therefore involves weighing consequences with varying time horizons. Because people weigh present and future events differently, the same set of "facts" may be interpreted in differing ways by different persons. This adds to the complexity of the decision-making process, and provides greater leeway for conflicting views.

Physician-related factors

The rise in 'patient choice' cesareans has coincided with changes in the risk-benefit balance in both c-sections and VBACs. Both procedures carry risks and involve making trade-offs based on health issues as well as on personal and idiosyncratic factors. A cesarean section is a major surgery and carries a number of risks, including reactions to anesthesia, bleeding, infection, and urinary tract injury. In addition, the procedure has a longer recovery time and requires a longer hospital stay; it therefore costs 2.3 times as much as a vaginal delivery. For the child, the risks of c-sections include bodily injury and respiratory problems.

For the mother, undergoing a c-section may have implications for subsequent deliveries and for her future health in general: women who have c-sections are three times as

likely to have complications during subsequent childbirths by surgical delivery and eight times more likely to get a hysterectomy than those who deliver vaginally. A national study carried out in 1996 also found that, after adjusting for maternal age, women who had c-sections were 1.8 times more likely to be hospitalized within two months of delivery than women who had had a spontaneous vaginal delivery.

A meta-analysis of studies looking at cesarean delivery and placenta previa (the attachment of the placenta such that it obstructs the cervix) found that women with one prior delivery were at a 2.6 times greater risk for development of placenta previa in a subsequent delivery. A study based on maternity records in Scotland found that operative vaginal deliveries (using forceps and vacuum extraction) and all cesarean deliveries were associated with longer interpregnancy intervals.

A Finnish study found that problems subsequent to cesarean delivery were not explained entirely by indications for a cesarean: after adjusting for the indication and other factors, the researchers found that more complications and poorer infant outcomes were found at later births when the first or second birth was by c-section than after first spontaneous vaginal delivery.

Vaginal childbirth can cause pelvic floor disorders, in which the bladder and other internal organs drop down into the vagina. Some complications of this include urinary and fecal incontinence, and loss of feeling in the vagina. While rare, these risks are serious enough to weigh into any decision on childbirth.

Because lowering the c-section rate is partly dependent on increasing the incidence of VBAC, this modality has been the focus of several studies. One of the most comprehensive and often-quoted studies looked at maternal and perinatal outcomes associated with trial of labor after prior cesarean delivery. This cohort study of more than 33,000 women found hypoxic-ischemic encephalopathy (brain damage resulting from a lack of blood or oxygen to the brain) in 12 infants born at term whose mothers underwent a trial of labor, compared with no cases among infants whose mothers underwent elective repeat cesarean section. This finding was considered important enough to cause obstetricians to rethink what they counsel their patients, and has been seen as a representing a turning point affecting practice standards in the United States.

For the physician, the decision to perform a c-section is most often based on what is best for the woman and her newborn. C-sections are usually indicated when a woman is carrying more than one fetus and when the fetus is too large to pass through the woman's pelvis. Physicians may also decide to perform cesareans on women with HIV, an active outbreak of herpes, heart disease, or health problems that may interfere with vaginal childbirth. The latter, some of which may appear or become obvious only during the delivery itself, include problems with the placenta, umbilical cord, positioning of the fetus, or fetal distress.

Whereas it was once standard for any woman having had a c-section to undergo surgical delivery for subsequent childbirths, vaginal birth after a previous cesarean birth has been found to be viable and safe in most cases. A recent large-scale study found that women who have had several previous cesarean deliveries before attempting vaginal delivery are not at greater risk for uterine rupture than women who have had a single prior operation. Clinical practice guidelines in obstetrics therefore suggest that women having had an earlier transverse, low-segment c-section be offered a trial of labor together with a full discussion of maternal and perinatal risks and benefits.

Nevertheless, prior data regarding potential risks to the fetus, combined with the fact that many physicians who were trained under the "once a cesarean, always a cesarean" standard may be reluctant to perform VBACS, have decreased reliance on this modality. The most recent national data reveal that, once a woman has a cesarean, there is an almost 90 percent chance that subsequent deliveries will also be by cesarean.

Because women receive most of their medical information from their physicians, physician values and practices are likely to inform their choices. Moreover, the locus of control is ultimately in medical hands, especially at the time of delivery. As Tonya Jamois, the president of the advocacy organization International Cesarean Awareness Network has stated, "It is difficult to be Rosa Parks when your contractions are two minutes apart." Doctors' opinions concerning c-sections are therefore highly influential, if not determinant, in delivery practices. Even when they are trying to be non-directive and just give "the facts, Ma'am," how they frame the options and describe the alternatives facing the patient often influences the final decision.

The medico-legal environment

Changes in the medical and legal environment reflect and refract the changes mentioned above. As giving birth has become more technology-intensive, health professionals have more tools to detect more potential problems, and to intervene earlier in order to avert them. Technology tends to diffuse quickly, often before issues of safety and efficacy have been resolved. (This was the case with electronic fetal monitoring 30 years ago, and similar processes may be occurring with other devices.)

At the same time, cesarean sections have become safer over time. The risks of anesthesia have decreased, physicians are better able to gauge accurately the size and gestation of the fetus, and women are more closely monitored during pregnancy. The expanding set of tools available to assess fetal status means that problems that may have resolved themselves in the course of the pregnancy are now highlighted and acted upon; indeed, failure to act may be grounds for legal action.

Whatever their commitment to patients, physicians are not devoid of self-interest. Some increases in litigation accompanied by disproportionate rises in malpractice insurance premiums have prompted the adoption of practices to "protect" physicians from

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Product Recalls

June 20, 2006 — July 18, 2006

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.

CLASS I Recalls

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

NeutraGard 0.05 % Anticavity Treatment Rinse, 0.05 % Neutral Sodium Fluoride; Microbial Contamination — Pseudomonas aeruginosa and Burkholderia cepacia. All lot numbers ending in 06, 07, 08, 09 or 10, Pascal Co., Inc.

NeutraGard Plus Anticavity Treatment Rinse, 0.02 % Neutral Sodium Fluoride; Microbial Contamination — Pseudomonas aeruginosa and Burkholderia cepacia. All lot numbers ending in 06, 07, 08, 09 or 10, Pascal Co., Inc.

NeutraGard 0.05 % Anticavity Treatment Rinse, 0.05 % Neutral Sodium Fluoride; Microbial Contamination — Pseudomonas aeruginosa and Burkholderia cepacia. All lot numbers ending in 06, 07, 08, 09 or 10, Pascal Co., Inc.

NeutraGard Plus Anticavity Treatment Rinse, 0.02 % Neutral Sodium Fluoride; Microbial Contamination — Pseudomonas aeruginosa and Burkholderia cepacia. All lot numbers ending in 06, 07, 08, 09 or 10, Pascal Co., Inc.

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legal action. So-called defensive medicine, the extent of which has been greatly exaggerated, has tended to become encoded in medical standards. Whether subtle and hidden or blatant and overt, these practices may be at odds with good medicine. Many elements of defensive medicine are merely cover-ups for tests and surgery that will actually yield more income for the physician. However, at key decision points, the essential question may become "How will this stand up in court?" rather than "What is best for the patient?" The result is that doctors would rather err on the side of doing something — in this case a cesarean delivery — even when the wiser option may be to refrain from further or more aggressive treatment.

Malpractice settlements have tended to 'punish' conservative treatment and further fueled the practice of surgical intervention. For example, $112 million was awarded to a New York couple who claimed that the physicians who had attended her delivery had failed to act quickly on signs of fetal distress. Other cases that have linked fetal distress or prolonged labor to cerebral palsy have also received significant awards. In contrast, a woman who suffered complications of an unwanted cesarean delivery and spent one year in the hospital was awarded $1.5 million.

It is not surprising that Dr. Bruce Flamm, who repeatedly sounded the alarm when cesarean sections began to rise twenty years ago, has described the current situation as a "perfect storm of medical, legal, and personal choice issues." Indeed, the confluence of several phenomena has created an exceptionally strong trend that may be difficult to slow down or reverse. It is against this backdrop that a recent NIH conference on cesarean sections must be evaluated.

Last March, the National Institute of Child Health and Human Development and the Office of Medical Applications of Research convened a State-of-the-Science Conference to assess the available evidence concerning the trend and incidence of cesarean delivery over time in the United States and other countries. The findings and recommendations of this will be the subject of an article in the September issue of *Health Letter*. ■

DRUGS AND DIETARY SUPPLEMENTS

CLASS II Recalls

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

Amantadine HCl, USP, 100 mg, Soft Gelatin Capsules; Failed USP Content Uniformity Requirements. Lot numbers: 25101150, 25030655 and 25101146, Banner Pharmacaps, Inc.

Budesonide 2.0 mg, 5 mL unit dose, Black Vials Only; Subpotent. All lot numbers, Computerx Pharmacy, Inc.

Extra Strength Pain Relief PM (acetaminophen 500mg and diphenhydramine HCl 25mg); Presence of Foreign Particles; acrylic mirror. Lot 5ME0438, Perrigo Company.

FIRST AID brand EXTRA STRENGTH NON-ASPIRIN, Acetaminophen 500 mg. Lot number 03M847, exp. date 12/2006, Generic Pharmaceutical Services, Inc.

Glyburide and Metformin Hydrochloride tablets, 2.5 mg/500 mg; Failed specification for one impurity. Lot 133750, exp. date 04/2006, IVAX Pharmaceuticals, Inc.

Glyburide and Metformin Hydrochloride tablets, 5 mg/500 mg; Failed specification for one impurity. Lot 133749, exp. date 05/2006, IVAX Pharmaceuticals, Inc.

Metformin Hydrochloride ER, 500 mg TAB; Mispacked; outer carton labeled as Metformin Hydrochloride ER may actually contain Thiothixene 5 mg Tablets. Lot K40834D30, exp. date 07/31/2007, Heartland Repack Services LLC.

Midrin Capsules (Isometheptene Mucate 65 mg, Dichloralphenazone 100 mg and Acetaminophen 325 mg); Adulterated Presence of Foreign Tablets; the bottles may contain foreign tablets of the NSAID oxyprozin. Lot 50968B, exp. date 07/2007, Caraco Pharmaceutical Laboratories, Ltd.

Mobic (meloxicam), 15 mg. tablets; Oversized tablets. Lot 651237 (exp. date 12/2008), 651296 (exp. date 02/2009), Boehringer Ingelheim Roxane Inc.

Thiothixene Capsules, 5 mg, Mislabeled; Outer carton is labeled as Thiothixene 5 mg Capsules but actually contains blister packs of Metformin Hydrochloride ER 500 mg Tablets. Lot K39006B30, exp. date 09/30/2007, Heartland Repack Services LLC.

Ultram ER Tablet, (Tramadol Hydrochloride) Extended Release Tablet, 200 mg; Dissolution failure due to a tablet coating defect caused by the tablet printer. Lot Number: 06A081P, exp. date: 12/2007, Ortho-McNeil Pharmaceutical Inc.

Ultram ER Tablets, (Tramadol Hydrochloride) Extended Release Tablets 300mg; Dissolution failure due to a tablet coating defect caused by the tablet printer. Lot Number/Expiration Date: Note: All lots Expire 12/2007: Lot Numbers: 06A066P; 06A067P; 06A068P; 06A094P; 06A111P; 06A097P; 06B012P; 06B013P; 06B023P; 06B024P; 06B025P; 06B031P; 06B002P; 06B056P; 06B059P; 06B067P; 06B072P, Ortho-McNeil Pharmaceutical Inc.

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; Manufacturer and Contact Information

Arm Saws. Cracking of the plastic motor housing of Ryobi Radial Arm Saws can cause the blade assembly to fall during operation, posing a risk of laceration to the operator or bystanders. The detachment may occur unexpectedly and without warning. Ryobi Motor Products Corp., (800) 525-2579 or www.ryobi.com.

Bicycle Headsets. The headsets mount to bicycle frames and fasten to the front fork assembly. A protruding component of the headset can contact the steering tube of the front fork assembly, score or scratch the steering tube, and weaken the structural integrity of the front fork. The front fork could break, causing the handlebars to separate from the bicycle during use and result in a crash. M2Racer LLC, (415) 738-8186 or headset@m2racer.com.

Name of Product: Problem: Manufacturer and Contact Information

Candles. The Cement Candles can unexpectedly flare, posing a fire hazard to consumers. Home Fragrance Holdings Inc., (800) 245-4595 or www.pier1.com.

Computer Storage Devices. The recalled JumpDrives® FireFly and Secure II products could overheat, posing a risk of burns to consumers and property damage. Lexar Media Inc., (800) 248-2798 or www.lexar.com.

Crossbows. The triggers on Fred Bear F-Series and Outfitter Compound Crossbows could fire when the safety mechanism is moved from "safe" to "fire" position without pulling the trigger. Bystanders could be unintentionally hit by an arrow fired by these bows. Bear Archery, (800) 467-1397 or safetyinfo@escaladesports.com.

Electronic Toy Guitars. The Toy Guitars can break into small parts, posing a choking hazard to young children. Sino Trading Group, LLC, (713) 789-9996 or alisaxia8@yahoo.com.

Heat & Glo Indoor/Outdoor Gas Fireplaces. Temperatures in the framing header area above Heat & Glo Twilight II and IIB Gas Fireplaces can get too high, posing a fire hazard. Heat & Glo, (800) 215-5152 or www.heatnglo.com.

Humidifiers. Water from the Warm Mist CareFree® Humidifier can leak into the unit's electrical compartment posing a fire hazard. Hunter Fan Co., (866) 818-7609 or www.hunterfan.com.

Lawn Tractors. The fuel line on these lawn tractors can separate from the fuel tank outlet. If this occurs, fuel will spill out, posing a fire hazard. Husqvarna Outdoor Products Inc., (866) 284-8872 or www.husqvarna.com. Consumers with Craftsman-brand tractors should call (800) 659-5917. Consumers with Poulan Pro, Poulan, Weed Eater, Southern States or Murray brand tractors should call toll-free at (866) 284-8872.

Mountain Bicycles. The steel brake boss of Felt Mountain Bicycles can detach from the frame, causing the rider to lose control and fall. Felt Bicycles, (866) 433-5887 or www.feltracing.com.

Office Chairs. The legs and backs of Mainstays Associate Office Chairs can break, and the chairs can easily tip over, posing a fall hazard to consumers. Wal-Mart Stores Inc., (800) 925-6278 or www.walmartstores.com.

Paloma Rattles. Seams on the Paloma Rattles can open during use, releasing small round beads. The beads can pose an aspiration hazard to young children. The breakage also can create ragged edges on the ring, posing a laceration hazard. Cunill Orferbres for Tiffany and Company, (800) 464-5000.

Porter-Cable Cordless Nailer. The Porter-Cable Cordless Brad Nailer can eject a nail while the switch is in the "off" position if the trigger is pulled and it is placed on a surface. This can pose a serious injury to consumers or bystanders. Porter-Cable, (800) 940-3126 or www.Porter-cable.com.

Quick-Release Device. The Shimano Quick Release Device's quick release skewers can unexpectedly fail or break when locked in position. When this happens the rider could lose control and fall. Shimano Inc., (800) 353-4719 or bike.shimano.com.

Terrain Vehicles. The operator of Bombardier Model Year 2006 Outlander 650 and 800 ATVs and Can-AM Model Year 2007 Outlander 650 ATVs could ride with their foot engaging the rear brake without noticing. This can cause the rear brake to overheat and possibly ignite, posing a risk of serious injury or death. Bombardier Recreational Products, (888) 864-2002 or www.brp.com.

Toy Vehicles. The plastic wheels on the vehicles in the IQ Baby Pillow Soft Activity Blocks, IQ Baby Travelin' Train Blocks, IQ Baby Vroom Vroom Vehicles and Discovery Channel Vroom Vroom Vehicles can detach, posing a choking hazard to young children. Small World Toys, (800) 421-4153 or recall@smallworldtoys.com.

Wood Burning Fireplaces. Due to insufficient insulation or a missing weld, some Sequoia Wood Burning Fireplaces could pose a fire hazard. CFM Corp., (866) 757-6649 or www.cfmcorp.com.

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Beliefs about the Free Market

There are three beliefs commonly associated with the "free market." The first is that human beings are creatures of limitless but insatiable needs, wants, and discomforts. The second is that the free market is a place where these needs might be satisfied through the exercise of free choice. The last of these beliefs is that the surest avenue to innovation in all industries is unfettered competition in the market.

Insatiable needs. The anthropologist Marshall Sahlins theorizes that the belief in unlimited wants is unique in the West, and stems from the Christian notion of "fallen man" as sufferer. This results, says Sahlins, in a peculiar idea of the person "as an imperfect creature of need and desire, whose whole earthly existence can be reduced to the pursuit of bodily pleasure and the avoidance of pain". A historical and philosophical examination of professional marketing shows that an assumption of boundless needs and wants is also at the heart of marketing theory. In this sense, marketing can be regarded as the institutionalization of this view of human nature. The marketer's challenge is to translate those limitless needs into profits.

Sahlins also points out that "in the world's richest societies, the subjective experience of lack increases in proportion to the objective output of wealth". In other words, the richer we get, the more we want. One explanation of this paradox lies in the way marketing activities are instrumental in getting us to think more about what we lack. Marketers and advertisers project and reflect back to us our discontent with the status quo. Americans are said to spend, on average, three years of their lives watching television advertisements, and the effect is that they are conditioned to want more and more. According to the advertisements, the viewer's personal anxieties and dissatisfactions are best addressed by consumption. This same message lies at the heart of much pharmaceutical advertising.

Lifestyle choices. In a consumer society, when individuals make choices toward the satisfaction of their needs and wants, they experience this as constructing their own individuality and identity. This special consumer identity is what people refer to when they use the word lifestyle, though they may not realize the consumerist implications of the word. Marketing claims to provide a solution to the problem of unlimited needs and wants, while simultaneously enhancing free choice and the construction of lifestyle. In pharmaceuticals specifically, "lifestyle drug" marketing techniques were honed in the 1980s and 1990s for cosmetic and sexual enhancements. These techniques have been broadened to include other areas of medicine. The campaigns used to market cosmetic and sexual enhancements were focused on expanding perceived need for these products, and in this respect were a simple extension of customary marketing conduct that had existed for over half a century. The crossover to curative medicine occurred with psychotropic drugs, which have a very wide range of active properties, thus granting the marketer latitude in reinterpreting their value back to the consumer. For example, one class of antidepressants, the specific serotonin reuptake inhibitors, is marketed for eight distinct psychiatric conditions, ranging from social anxiety disorder to obsessive-compulsive disorder to premenstrual dysphoric disorder. And "lifestyle marketing" has now extended to the promotion of many of the blockbuster "maintenance drugs" intended for daily, lifelong consumption, such as drugs for allergies, insomnia, and acid reflux.

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As a result of this sequence of events, industry opened the treatment of the inside of the body — the final frontier — to the same logic that governs all other marketing. Whether, in the antidepressant market, the "distribution channel captain," as marketers refer to the predominant competitor, ends up sailing the serotonin reuptake channel (the serotonin reuptake inhibitors) or the norepinephrine reuptake channel (the challenger, serotonin-norepinephrine reuptake inhibitors) may yet be determined by marketing rather than by medical jockeying.

Competition among drug companies yields innovation. It is an article of faith among free market devotees that breakthroughs spring not from paternalistic expert systems such as medicine but from industrial competition. As long as firms are committed to producing medications to treat diseases — as they are classified by medical science — this argument has some authority. But once a firm becomes principally driven by marketing-the case for most companies in most industries since the 1980s-then innovation comes to mean an elaboration of meaningless differences among a field of comparable "me too" products. "If marketing is seminally about anything," said Theodore Levitt, one of the towering figures of marketing and former editor of the *Harvard Business Review*, "it is about achieving customer-getting distinction by differentiating what you do and how you operate". More harmfully, expanding and altering the consumer's perception of disease is just as effective, and evidently a lot easier, than finding new cures.

From Patients to Medical Consumers

Since, in a consumer society, we see

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ourselves as individuals and as free agents when we exercise consumer choice, it is not difficult for pharmaceutical companies and other privatized health-care deliverers to convince us that it is empowering to think of ourselves not as patients but as consumers. This conversion from patient to consumer also paves the way for the erosion of the doctor's role as expert. A startling report of this was described in a recent *New York Times* article: "For a sizable group of people in their 20's and 30's, deciding on their own what drugs to take-in particular, stimulants, antidepressants and other psychiatric medications-is becoming the norm. Confident of their abilities and often skeptical of psychiatrist's expertise, they choose to rely on their own research and each other's experience in treating problems like depression....A medical degree, in their view, is useful but not essential". This phenomenon, the article suggested, is "driven by familiarity" with the drugs. The emergence of this potentially dangerous situation demonstrates an unchecked expansion of the drug industry into an already accepted mode of thought-that "every minor mood fluctuation," as the article reported, can and should be remedied.

Promoting consumer familiarity with drugs is one example of the very broad influence of the pharmaceutical industry. This influence extends to clinical trial administration, research publication, regulatory lobbying, physician and patient education, drug pricing, advertising and point-of-use promotion, pharmacy distribution, drug compliance, and the legal and ethical norms by which company practices themselves are to be evaluated. Actors traditionally found outside the "distribution channel" of the market are now incorporated into it as active proponents of exchange. Physicians, academic opinion leaders, patient advocacy groups and other grassroots movements, nongovernmental organizations, public health bodies, and even ethics overseers, through one means or another, have one by one been enlisted as vehicles in the distribution chain. The inclusion of patients in the distribution chain fundamentally changes their role from recipients of medical care to active consumers of the latest pharmaceuticals, a role which surely helps to support industry profits.

Ethical Justification for Marketing

Because illness is one of the most tangible forms of suffering, the pharmaceutical industry, more than other industries, can link its marketing activities to ethical objectives. The result is a marriage of the profit seeking scheme in which disease is regarded as "an opportunity" to the ethical view that mankind's health hangs in the balance. Marketers and consumers in the West to some extent share a common vision of needs and the terms of their satisfaction. This apparent complicity helps even the most aggressive marketers trust that they are performing a public service. Pharmaceutical company managers that I speak to signal this when they characterize their engagement with the public as "doing good while doing well."

These managers also see nothing wrong with integrating doctors, patients, and other players into the drug distribution channel. On the contrary, they say, this is state-of-the-art management, making it professionally principled and tactically astute. Marketers also regard the incorporation of consumers into the channel as ethical because then people's needs can best be determined and satisfied, conferring upon them the power of self-determination through choice.

But this choice is an illusion. For in our pursuit of a near-utopian promise of perfect health, we have, without realizing it, given corporate marketers free reign to take control of the true instruments of our freedom: objectivity in science, ethics and fairness in health care, and the privilege to endow medicine with the autonomy to fulfill its oath to work for the benefit of the sick. ■

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Pharmaceutical Marketing and the Invention of the Medical Consumer

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It is often said that leading drug companies now spend more on marketing than on research and development. While such contemporary pharmaceutical marketing practices are sometimes believed to be a modern phenomenon, they are in fact a direct continuation of 19th-century patent medicine advertising. "Nostrum-mongers," as the novelist Henry James dubbed them, are noted in the history of advertising as having been the leading spenders on, and foremost originators of, advertising technique. Nostrum sellers pioneered print advertising, use of trademarks and distinctive packaging, "pull" or demand stimulation strategies, and even the design and commissioning of medical almanacs that functioned as vehicles for promotion of disease awareness. Henry James's psychologist brother, William James, was so exasperated by "the medical advertisement abomination" that in 1894 he declared that "the authors of these advertisements should be treated as public enemies and have no mercy shown". There is no doubt that drug company discoveries have profoundly improved upon our capacity to treat illness. But pharmaceutical marketing is more closely aligned with consumer marketing in other industries than with medicine, for which the consequences are not trivial. Once we view pharmaceutical industry activities in this light, we can disentangle industry's influence on contemporary medicine. Because we believe that we owe corporations our wealth and well-being, we tend not to question corporations' fundamental practices, and they become invisible to us. What follows is an attempt to demystify some of the assumptions at work in the "culture of marketing," toward the goal of explaining contemporary disease mongering.

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