PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR MAY 2010 – VOL. 26, No. 5

Obama's Reform: No Cure for What Ails Us

By David U. Himmelstein and Steffie Woolhandler in the *British Medical Journal*, March 30, 2010.

It was a stirring scene: President Obama signing the new health reform law before a cheering crowd, and a beaming vice president whispering in his ear, "This is a big f***ing deal." As doctors who have labored for universal health care, we'd like to join the celebration, but we can't. Morphine has been dispensed for the treatment of cancer — the reform may offer a bit of temporary relief, but it is certainly no cure.

> **Even if the reform works as planned, 23 million people will remain uninsured in 2019.**

The new law will pump additional funds into the currently dysfunctional, market-driven system, pushing up health costs that are already twice those in most other wealthy nations. The Medicaid public insurance program for poor people will expand to cover an additional 16 million poor Americans, while a similar number of uninsured people with higher incomes will be forced to buy private policies. For the "near poor" the government will pay part of these private premiums, channeling $447 billion in taxpayer funds to private insurers over the next decade.

Unfortunately, private insurers win in the marketplace not through efficiency or quality but by maximizing revenues from premiums while minimizing outlays. They pursue this goal by avoiding the sick and forcing doctors and patients to navigate a byzantine payment bureaucracy that currently consumes 31 percent of total health spending. The health reform bill's requirement that uninsured people buy insurers' defective products will fortify these firms financially and politically.

Meanwhile, insurers will exploit loopholes to dodge the law's restrictions on their misbehaviors. For instance, the limit on administrative overheads will predictably elicit accounting gimmickry, for example by relabeling some insurance personnel as "clinical care managers." While insurers are prohibited from "cherry picking" — selectively enrolling healthy, profitable patients — they've circumvented similar prohibitions in the Medicare health maintenance organizations (HMOs). The ban on revoking policies after an individual falls ill similarly replicates existing but ineffective state bans.

Sadly, even if the reform works as planned, 23 million people will remain uninsured in 2019. Meanwhile, the public and other safety net hospitals that uninsured people rely on will have to endure a $36 billion cut in federal government funding.

Moreover, many Americans will be left with coverage so skimpy that a serious illness could lead to financial ruin. At present, illness and medical bills contribute to 62 percent of all bankruptcies, with three-quarters of the medically bankrupt being insured. The reform does little to upgrade this inadequate coverage; it mandates that private policies need cover only 70 percent of expected medical costs. The president has often promised that "if you like your current coverage you can keep it." Yet Americans who now get job-based insurance will be required to keep it — whether they like it or not. And many who receive full coverage from an employer will face a steep tax on their health benefits from 2018.

Soaring costs and rising financial strains seem inevitable, despite claims that the reform will "bend the cost curve." Computer vendors have trumpeted imminent cost savings for half a century (see, for instance, a video made by IBM in the 1960s, available at http://bit.ly/cckdtB). Prevention, though laudable, does not generally reduce costs. Windfalls from prosecuting fraud and abuse have been promised before. The new Medicare advisory board merely tweaks an existing panel. Without an enforcement mechanism, stepping up comparative effectiveness research cannot overcome drug and equipment makers' promotion of profligate care. Existing insurance exchanges where patients can compare and shop among private plans haven't slowed growth in costs for public workers nationally or in California. And the mandated experiments with capitated payment systems are warmed-over versions of

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

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President Nixon's pro-HMO policies and subsequent failed initiatives to fix America's health cost crisis through managed care.

Experience with reforms in Massachusetts in 2006 — the template for the national bill — is instructive. Our state's costs, already the highest of any state, grew by 15 percent in the first two years after reform, twice the national rate. Moreover, capitated physician groups had costs at least as high as those who were paid on a fee-for-service basis. Meanwhile, after initial improvements in the state, access to care has begun to deteriorate, and the state has begun to cut back coverage.

Overall, President Obama's is a conservative bill, drafted in close consultation with the drug and insurance industries.

Overall, President Obama's is a conservative bill, drafted in close consultation with the drug and insurance industries. Its modest salutary provisions — such as an extra $1 billion a year for community health centers and the expansion of Medicaid — mirror measures that have been passed even under Republican regimes. Its central tenet, that the government should force citizens to buy coverage from a for-profit firm, was first proposed by Richard Nixon when faced with the seeming inevitability of national health insurance in 1972. Similarly, Mitt Romney, a favorite of conservatives, embraced the Nixon approach as Massachusetts governor in 2006, a stance he has now abandoned. Democrats, having retreated from their traditional push for national health insurance, freed Republicans to move still further to the right.

Throughout the reform debate we, and the 17,000 others who've joined Physicians for a National Health Program, advocated for a far more thoroughgoing reform: a non-profit, single-payer national health insurance program. We will continue to do so. Our health care system has not been cured or even stabilized. For now, we will continue to practice under a financing system that obstructs good patient care and squanders vast resources on profit and bureaucracy.

Passage of the health reform law was a major political event. But for most doctors and patients it's no "big f***ing deal." ✦

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Available online at: http://www.bmj.com/cgi/content/full/bmj.c1778?ijkey=qLFfFBwLmfvN8vo&keytype=ref

Guide to Avoiding Unnecessary Cesarean Sections in New York State

Nearly a third of cesarean sections in New York state may be performed unnecessarily, and rates of the procedure there are among the highest of states in the country, according to a Public Citizen report released April 21.

Within New York state, rates of C-sections performed vary widely. Public Citizen's report breaks down the data by county and hospital, so patients can see how high C-section rates are for their local hospital in comparison to other local hospitals.

Read the full report at www.citizen.org/hrg1906.

"There is a growing epidemic of C-sections in the United States, where the 2007 national rate of 31.8 percent was the highest it has ever been," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "We estimate that one-third of cesareans are unnecessary, nationally and in New York. These therefore represent unnecessary acts of violence against women. Unnecessary cesareans mean that the health of mothers and their babies are being needlessly jeopardized because mothers go under the knife instead of delivering vaginally."

The estimate that one-third of New York C-sections are unnecessary is based on the fact that the average C-section rate at the 10 New York hospitals with the lowest rate was 20.8 percent, more than one-third lower than the average New York rate for all hospitals.

The New York state hospital with the highest percentage of total C-sections was St. Anthony Community Hospital (Orange County) with 53.5 percent of deliveries by C-section. Auburn Memorial Hospital in Auburn had the lowest percentage of C-sections, with a rate of 16.6 percent.

Among urban hospitals, the lowest rates were at North Central Bronx Hospital, with only 18.5 percent of deliveries done by C-section; St. Barnabas Hospital (Bronx), with 20.7 percent; Maimonides Medical Center (Brooklyn), with 20.9 percent; and New York Downtown Hospital, with 22.3 percent. In contrast, other urban hospitals had very high C-section rates, such as University Hospital of Brooklyn (Brooklyn), with 40.2 percent; New York-Presbyterian at Weill Cornell Medical Center, with 39.2 percent; Lenox Hill Hospital, with 40.1 percent; and Long Island Jewish Medical Center, with 40.3 percent. Six of the eight hospitals in Westchester County also had rates exceeding 39.5 percent.

Public Citizen researchers created a database of 2007 data from hospitals in New York, one of only two states that provide details about all obstetric procedures at the facility level, then analyzed it. The numbers came from the state's 143 hospitals that handle more than 30 births a year. New York has a higher C-section rate (33.7 percent overall, 34 percent in the subset we analyzed) than the country as a whole, with only eight states having higher rates.

Public Citizen's analysis provides the rates of overall and primary C-section (those performed on women who have not had a C-section previously), as well as rates of vaginal births after cesareans (VBACs), by county and hospital. C-section rates in New York vary more than 2.5-fold by county, ranging from a low of 16.6 percent in Cayuga County to a high of 43.1 percent in Westchester County.

Contrary to expectations, the largest hospitals did not have the highest C-section rates, nor was there a consistent relationship between the size of a hospital and its rate of performing C-sections. Rural hospitals had slightly higher overall rates of C-sections than urban hospitals, perhaps because they lack the resources to provide emergency care to handle VBACs.

After several high-profile cases in which women who have had previous C-sections opted to deliver vaginally – and then ruptured their uterus – the American College of Obstetrics and Gynecology revised its guidelines for institutions performing vaginal births after C-sections.

The guidelines now state that hospitals performing VBACs must be "equipped to respond to emergencies with physicians immediately available to provide emergency care." As such, 28 percent of U.S. hospitals did not allow VBACs in 2009, and an additional 21 percent had "de facto" bans on the procedure because their obstetricians would not perform them.

Nationally, the steep rise in C-sections – from 10.4 percent of all deliveries in 1975 to 31.8 percent of all deliveries in 2007 – is a growing concern for those committed to improving the health of mothers and infants. C-sections are being performed now more than ever.

"The model of obstetrical care in this country is all wrong," said Dr. Jacques Moritz, an obstetrician at St. Luke's-Roosevelt, Roosevelt Division. "The model of an overtrained obstetrician attending to a normal birth is all wrong. The proper model is for all low-risk mothers to be managed by a certified midwife with a midwife-friendly obstetrician as back-up. Midwives offer a high-touch versus high-tech approach to delivery."

Added Susannah Donahue-Negbaur, a licensed midwife at the same hospital, "Research shows that low-risk women who use midwives are more likely to have a safe and healthy birth for themselves and their babies, and are less likely to undergo an induction of labor, cesarean or episiotomy than low-risk women who use doctors. The best maternity care is a partnership between

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doctors, midwives and families. If you are pregnant, healthy and low-risk, you are in very good hands with a midwife."

Increasing the number of VBACs is another crucial way to reduce the number of unnecessary C-sections, according to Dr. Howard Minkoff, chief of obstetrics and gynecology at Brooklyn's Maimonides Medical Center, a hospital with a VBAC rate of 30.0 percent, 3.2 times higher than the state average.

"Perhaps the most important step in turning cesarean section rates around is embracing a philosophy that defines a successful hospital stay as the discharge of a healthy mom who delivered a healthy baby vaginally," Minkoff said. "No one would argue that the mode of delivery should trump health considerations of the mother or child, but there are no data demonstrating that ever better health outcomes have been achieved by ever higher operative delivery rates."

To reduce or stabilize C-section rates, Public Citizen recommends that health departments and hospitals require all hospitals to offer the alternative of delivery by a licensed midwife, adopt peer review in all aspects of maternal and fetal care, require all ob/gyns to get a second opinion before deciding on a primary C-section, standardize care right before and after birth, and eliminate financial incentives for performing C-sections (physicians are paid more for performing C-sections, even though they may take less time to perform than vaginal deliveries).

Mothers who want to avoid an unnecessary C-section should talk to their doctor or midwife early about their preferences, use data in the report to find out the rates of C-sections and VBACs in the hospitals they are considering using for their pregnancies, consider using a licensed midwife and use a doula (a woman experienced in childbirth who provides continuous labor support) in conjunction with their doctor.

Variations in Cesareans in New York State

The total number of cesarean deliveries in New York State in 2007 in the subset Public Citizen analyzed was 85,244 (34.0 percent of the 250,780 deliveries for which the method of birth is known in the state that year).

Cesarean rates in New York vary more than 2.5-fold by county, ranging from a low of 16.6 percent for Cayuga County to a high of 43.1 percent for Westchester County. Cayuga has only one hospital performing deliveries and that is a Level 1 hospital without a neonatal intensive care unit (NICU); the rate therefore reflects practices in a single institution. Westchester, however, has eight hospitals, and the rates vary more than twofold among hospitals: from 25.2 percent to 52.7 percent.

Even wider variations are seen among hospitals within the state and within each county.

The 10 hospitals with the lowest overall cesarean rates are:

1. Auburn Memorial Hospital (16.6%)
2. North Central Bronx Hospital (18.5%)
3. Ellis Hospital - McClellan Division (18.7%)
4. Seton Health System - St. Mary's Campus (20.4%)
5. Samaritan Medical Center (20.6%)
6. St. Barnabas Hospital (20.7%)
7. Maimonides Medical Center (20.9%)
8. Good Samaritan Hospital of Suffern (21.2%)
9. Mary Imogene Bassett Hospital (22.3%)
10. New York Downtown Hospital (22.3%)

The weighted average for all deliveries of the 10 hospitals with the lowest overall cesarean rates is 20.8 percent.

The 10 hospitals with the highest overall cesarean rates are:

1. St. Anthony Community Hospital (53.3%)
2. Lawrence Hospital Center (52.7%)
3. Good Samaritan Hospital Medical Center (49.1%)
4. St. Catherine of Siena Hospital (49.0%)
5. Westchester Medical Center (47.5%)
6. St. Charles Hospital (47.3%)
7. Sound Shore Medical Center of Westchester (47.0%)
8. Claxton-Hepburn Medical Center (46.8%)
9. Plainview Hospital (46.7%)
10. St. John's Riverside Hospital - St. John's Division (45.1%)

The weighted average for the 10 hospitals with the highest overall cesarean rates is 48.3 percent.

The 10 hospitals with the lowest overall cesarean rates include rural and urban hospitals and are located in the following counties: Cayuga, Bronx, Schenectady, Rensselaer, Jefferson, Kings (Brooklyn), Rockland, Otsego, and New York.

Similarly, the 10 hospitals with the highest rates include hospitals from rural and urban areas and are located in the following counties: Orange, Westchester, Suffolk, Saint Lawrence, and Nassau.

As indicated above, the average cesarean rate in the 10 hospitals with the highest rates is 48.3 percent. This rate is 2.3 times higher than the average for the 10 hospitals with the lowest rates (20.8 percent).

If the average cesarean rate for all New York hospitals in our subset were 20.8 percent — that is, equal to the average cesarean rate for the 10 hospitals with the lowest rate — only 52,162 women out of the 250,780 who delivered where method of birth was known would have delivered via cesarean section. This means there would have been 33,082 fewer cesareans that year than the 85,244 that actually were done. Thus, more than one-third of the cesarean sections in New York in 2007 may well have been unnecessary.

What Women Can Do to Avoid an Unnecessary Cesarean Section

There are some things a woman can do to avoid an unnecessary cesarean section in New York State.

1. Talk to your doctor or midwife early about your preferences. Do not hesitate to let either know what you want and expect. She/he should hear you out and discuss what is best for you, based on your individual circumstances and those of your baby. If there are any major discrepancies concerning your respective perceptions of risks and benefits, these should be fully aired. If you are not satisfied that you have been provided with complete and accurate information, you should consider finding another provider.

2. Use the data in this report to find the overall, primary and VBAC rates in the hospitals you are considering using for your pregnancy. In addition, it is important to also ask for information specific to the obstetrician(s) or midwife you are considering because there may be considerable variation within hospitals among obstetricians or between obstetricians and midwives. A hospital with a relatively low cesarean rate may have obstetricians with high rates and vice versa.

Fortunately, New Yorkers have a valuable source of information that is not available to women in other states. NYS Public Health Law section 2803 requires that every hospital and birth center provide each prospective maternity patient and the general public an informational leaflet with data on maternity care and insurance coverage. The hospital and birth center must also provide statistics on its maternity-related procedures. These include data on cesarean rates, successful VBACs, midwife-attended births, use of fetal monitoring, use of forceps and analgesia, anesthesia, births delivered vaginally, induced deliveries, use of augmentation of labor and episiotomies, availability of birthing rooms and facilities for rooming-in. This report uses these data to make comparisons not otherwise available to women in New York state.

3. Consider using a certified nurse-midwife or certified midwife. From 1981 to 2006, there was a 5.6-fold increase in the number of midwife-attended births, from 56,000 a year to 311,000 a year in the United States. The percentage of all hospital births attended by midwives rose from 1.53 percent in 1981 to 7.46 percent in 2006, a 4.9-fold increase in the percent of deliveries by midwives.

Of the 143 hospitals listed in this report, 99 have midwives doing deliveries, ranging from 0.1 percent of births at St. Catherine of Siena Hospital and North Shore University Hospital to 79.8 percent of births at North Central Bronx Hospital (See Table 2 to find out if your nearby hospital has midwife deliveries). In New York State in 2007, there were 23,968 midwife-assisted births. Out of a total of 250,780 births that year, the percentage delivered by midwives was 9.6 percent.

In New York State, all midwives must meet certain criteria in order to practice. These are:

- A bachelor's degree (in any subject)
- Midwifery education at a NYS-approved midwifery school
- Demonstrated competency in particular areas related to well-woman care and pharmacology
- Passing the American Midwifery Certification Board (AMCB) examination.

In a study we did surveying national hospital-based midwife deliveries and reviewing the published literature, we found that, in hospitals with both obstetrician and midwife deliveries, the following practices were much more likely to occur with midwife-assisted deliveries than with obstetrician-attended deliveries:

- Oral fluids during labor
- Room to ambulate during labor
- Use of shower, bath, or hot tub
- Encouragement of alternate positions for delivery
- Use of intermittent, not continuous fetal monitoring (less chance of false signals of fetal distress)
- Shorter stay and early (24 hours or less) discharge

These factors contribute to the findings in multiple studies showing that the likelihood of induction, episiotomy, or a cesarean section is generally lower with midwife-attended deliveries than with obstetrician-attended deliveries.

A study involved women with pregnancies that were considered low-risk enough to qualify for a home delivery but all of whom delivered in the hospital. Four hundred eighty-eight of these women had hospital midwife deliveries, and 572 had hospital physician deliveries. The decreased risks in the midwife group included a 42 percent reduction in cesarean sections and a 38 percent decrease in episiotomies. There was also an 81 percent decrease in the use of drugs for resuscitation at birth. The authors concluded that: "A shift toward greater proportions of midwife-attended births in hospitals could result in reduced rates of obstetric interventions, with similar rates of neonatal morbidity."

4. Consider using a doula. If a certified nurse-midwife is not available in the hospital(s) you are considering using, think seriously about using the services of a doula in conjunction with your doctor. A published study evaluated the positive effects of doulas on childbirth. Among 224 women with an uncomplicated pregnancy who took a childbirth education class, half were randomized, after admission for labor, to doulas, who provided close physical proximity, touch, and eye contact with the laboring woman, and teaching, reassurance, and encouragement of the woman and her male partner. The other half of the women served as a control group. "The doula group had a significantly lower cesarean delivery rate than the control group (13.4 percent vs. 25 percent). Among women with induced labor, those supported by a doula had a lower rate of cesarean delivery than those in the control group (12.5 percent vs. 58.8 percent)."

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What Health Departments and Hospitals Can Do to Reduce Unnecessary Cesareans

While the decision-making of the woman and her practitioner may be key at the individual level, there are system-wide interventions that have been found to reduce the prevalence of unnecessary cesarean sections.

1. All hospitals should offer the alternative of licensed-midwife delivery. As discussed in the section on what women can do to avoid unnecessary cesarean sections, this choice for women is currently denied in the 44 hospitals in New York State, including major medical centers in Manhattan, that do not offer nurse-midwife delivery. There is no reason why every hospital, located near the offices of midwives, should not offer this cesarean-sparing alternative.

2. Adopt peer review in all aspects of maternal and fetal care. Physicians should know how they are doing with respect to their colleagues. This includes sharing data on procedures, by type, as well as outcomes. Some hospitals have found that use of comparative outcome data coupled with shared discussion and strong institutional leadership can be an effective tool to curtail practices that are unnecessary as well as costly and potentially harmful. The two elements of this strategy — information and leadership — are necessary to both identify outliers and hold them accountable for their practice styles. As one researcher has stated, "data, in the absence of recognition, praise, public accord and private admonishments are unlikely to actually change physician behaviors. Many such projects have failed because of lack of committed leadership."

3. Require all obstetrician-gynecologists to get a second opinion before deciding on a primary cesarean section. Incorporating this measure as a matter of course not only holds physicians responsible to one another, it also creates a culture of mutual accountability within the institution. This also avoids making a decision on other than clinical grounds. Moreover, the second opinion requirement provides pregnant women additional reassurance that the chosen pathway is the medically correct one. Some hospitals have incorporated such a requirement into their written policies. For example, St. Luke's Roosevelt Hospital Center in New York City states the following in its policy and procedures manual: "Any primary elective C-section requires prior approval by a member of the MFM [Maternal-Fetal Medicine] division" as well as "medical/obstetric justification." Similar approvals also are required for any elective cesarean performed prior to 39 weeks of gestation.

St. Luke's also requires a consultation from a member of the Maternal-Fetal Medicine division prior to any induction of labor before 41 weeks of gestation, with a verbal consultation being followed by written documentation in the patient's chart. These elective early inductions are one source of subsequent unnecessary cesareans.

4. Use "care bundles" to standardize perinatal care. Care bundles are groups of evidence-based interventions that, adopted together, produce better outcomes than those implemented individually. These have been developed by the Institute for Health Care Improvement and cover different aspects of labor and delivery. A group of 44 hospitals in New York State has been implementing a Perinatal Safety Bundle combining three discrete protocols governing elective induction, labor augmentation, and safety climate. The latter is aimed at avoiding the communication breakdowns associated with 85 percent of all adverse events in obstetrics. The protocols include rapid response drills so that all members of the perinatal team know to react to emergent situations. The hospitals share best practices and clinical information through monthly calls and visits.

5. Eliminate financial incentives for performing cesarean sections. As indicated earlier, physicians are paid more for performing cesarean sections, although these often take a much shorter time than a vaginal delivery. This misalignment between compensation and desirable medical practice may act as an incentive for unnecessary cesareans.

Washington State may serve a useful case study of the effect of this approach to reducing the cesarean rate. In 2009, it passed legislation that allows "for the development of patient decision aids to help educate patients, physicians, hospitals, and birth center about the risks and benefits of cesarean delivery." It also adjusted its fee schedule in line with its objectives. After July 1, 2009, the Washington Medicaid program adjusted its system of DRGs (diagnosis-related groups) to pay for uncomplicated cesarean sections as if they were complicated vaginal deliveries. "The new rules adopted will cut Medicaid reimbursements for uncomplicated C-sections from about $3,600 to around $1,000." This attempt at reducing the differential in fees is expected to eliminate the potential financial incentive to perform unnecessary procedures. While it is too early to tell if this will achieve the desired end, the experiment bears watching.

Another way to eliminate the financial "reward" that accompanies cesarean section is to pay physicians other than on a fee-for-service basis. Salaried physicians are paid for their time on the job, rather than for the number of procedures performed. And physicians on capitation are paid for the patients under their care, rather than the services rendered. Both modalities avoid the link between procedures and payment.

6. Adopt the practices of the Indian Health Service (IHS). Some hospitals within this division of the US Public Health Service takes pride in having lower cesarean rates and higher VBAC rates than those of most states. While some of the outcome indicators may be related to the specific characteristics of the population served, IHS facilities "have labor management practices and policies that favor no use of epidural analgesia and increased use of nurse-midwives and family practice physicians."✦

Health, Life Insurers Hold $1.88 Billion in Fast-Food Stocks

Just weeks after the passage of a health bill that will dramatically increase the number of Americans covered by private health insurers, Harvard researchers have detailed the extent to which life and health insurance companies are major investors in the fast-food industry.

Although fast food can be consumed responsibly, research has shown that fast-food consumption is linked to obesity and cardiovascular disease, two leading causes of death, and contributes to the poor health of children. The evidence is so compelling that as part of the new law more than 200,000 fast-food and other chain restaurants will be required to include calorie counts on their menus, including their drive-through menus.

A new article on insurance company holdings, published online in the April 15 *American Journal of Public Health*, shows that U.S., Canadian and European-based insurance firms hold at least $1.88 billion of investments in fast-food companies.

"These data raise questions about the opening of vast new markets for private insurers at public expense, as is poised to happen throughout the United States as a result of the recent health care overhaul," says lead author Dr. Arun Mohan.

Among the largest owners of fast-food stock are U.S.-based Prudential Financial, Northwestern Mutual and Massachusetts Mutual Life Insurance Company, and European-based ING.

U.S.-based Northwestern Mutual and Massachusetts Mutual Life Insurance Company both offer life insurance as well as disability and long-term care insurance. Northwestern Mutual owns $422.2 million of fast-food stock, with $318.1 million of McDonald's. Mass Mutual owns $366.5 million of fast-food stock, including $267.2 in McDonald's.

Holland-based ING, an investment firm that also offers life and disability insurance, has total fast-food holdings of $406.1 million, including $12.3 million in Jack in the Box, $311 million in McDonald's, and $82.1 million in Yum! Brands (owner of Pizza Hut, KFC and Taco Bell) stock.

New Jersey-based Prudential Financial Inc. sells life insurance and long-term disability coverage. With total fast-food holdings of $355.5 million, Prudential Financial owns $197.2 of stock in McDonald's and also has significant stakes in Burger King, Jack-in-the-Box, and Yum! Brands.

The researchers also itemize the fast-food holdings of London-based Prudential Plc, U.K.-based Standard Life, U.S.-based New York Life, Scotland-based Guardian Life, Canada-based Manulife and Canada-based Sun Life. (See table; all data current as of June 11, 2009.)

"Our data illustrate the extent to which the insurance industry seeks to turn a profit above all else," says Dr. Wesley Boyd, senior author of the study. "Safeguarding people's health and well-being take a back seat to making money."

Mohan, Boyd and their co-authors, Drs. Danny McCormick, Steffie Woolhandler and David Himmelstein, all at the Cambridge Health Alliance and Harvard Medical School, culled their data from Icarus, a proprietary database of industrial, banking and insurance companies. Icarus draws upon Securities and Exchange Commission filings and news reports from providers like Dow Jones and Reuters. In addition, the authors obtained market capitalization data from Yahoo! Finance.

The authors write, "The health bill just enacted in Washington will likely expand the reach of the insurance industry. Canada and Britain are also considering further privatization of health insurance. Our article highlights the tension between profit maximization and the public good these countries face in expanding the role of private health insurers. If insurers are to play a greater part in the health care delivery system they ought to be held to a higher standard of corporate responsibility."

Several of these same researchers, all of whom are affiliated with Physicians for a National Health Program, have previously published data about the extent to which the insurance industry is invested in tobacco. They say that because private, for-profit insurers have repeatedly put their own financial gain over the public's health, readers in the United States, Canada and Europe should be wary about insurance firms' participation in care. ✦

By Arun V. Mohan, M.D., M.B.A.; Steffie Woolhandler, M.D., M.P.H.; David U. Himmelstein, M.D.; and J. Wesley Boyd, M.D., Ph.D. in *American Journal of Public Health*, April 15, 2010.

Insurance industry holdings in fast-food companies (in millions of U.S. dollars) as of June 11, 2009

Insurance Company	Jack in the Box	McDonalds	Burger King	Yum! Brands	Wendy's/ Arby's Group	Total
Prudential plc				80.5		80.5
Prudential Financial	34.1	197.2	43.7	80.5		355.5
Mass Mutual	23.1	267.2	58.8	17.4		366.5
New York Life	2.4					2.4
Northwestern Mutual	40.9	318.1		63.2		422.2
Sun Life				26.8		26.8
Standard Life		63.0				63.0
ING	12.3	311.7		82.1		406.1
Manulife		89.1		53.7	3.3	146.1
Guardian Life	7.2				9.5	16.7
MetLife					2.2	2.2
Total	**120.0**	**1,183.3**	**165.5**	**404.2**	**15.0**	**1,888.0**

Product Recalls
March 16, 2010 - April 15, 2010

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

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Botanical Weight Loss Capsules, 350 mg herbal blend, 30 count bottles; Volume of product in commerce unknown; Marketed Without an Approved NDA/ANDA: product contains undeclared Sibutramine. All lots; Young You Corporation.

Slimbionic Capsules, 350 mg of a proprietary herbal blend, packaged in 30 count boxes; Volume of product in commerce unknown; Marketed Without an Approved NDA/ANDA: product contains undeclared Sibutramine. All lots; Young You Corporation.

One Weight Loss Pill, 990 mg of a proprietary herbal blend, packaged in 30 capsule bottles; Volume of product in commerce unknown; Marketed Without an Approved NDA/ANDA: product contains undeclared Sibutramine. All lots; Young You Corporation.

SlimDemand Capsules, with FeiHua formula, 350 mg of a proprietary herbal blend, 30 count bottles; Volume of product in commerce unknown; Marketed Without an Approved NDA/ANDA: product contains undeclared Sibutramine. All lots; Young You Corporation.

Recalls and Field Corrections: Drugs – Class II

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

Demser (Metyrosine) capsules, 250 mg; 100 capsules per bottle; Rx only; NDC: 25010-305-15; UPC 325010305151; Volume of product in commerce: 317 bottles of 100 capsules. Failed USP Dissolution Test Requirements. Samples have failed to meet dissolution specifications. Lot #: 9F661, exp. Date 05/2012; Merck & Company, Inc.

Prednisone Tablets, USP, 1 mg, Rx Only, 100 count (NDC 51991 458 01); 1000 count (NDC 51991 458 10) plastic bottles; Volume of product in commerce: 4,668 bottles. Pharmaceutical failed to meet specification at 18 month stability station. Lot #: 8A064, exp. date 02/2010; Cadista Pharmaceuticals, Inc.

Ranitidine Tablets, USP, 150 mg, 500-count bottle, Rx only, NDC 53746-253-05; Volume of product in commerce: 1,965 bottles. Superpotent (Single Ingredient) Drug: This product is being recalled because of two reports of oversized Ranitidine Tablets. Analysis of a tablet showed 149% of label claim. Lot #: HE14509, exp. date 06/2011; Amneal Pharmaceuticals.

Sucralfate, USP; CAS#54182-58-0, NDC: 055642-0011; Non-Sterile Bulk; Net Weight: 25 KG, Gross Weight: 27.4 KG; For Manufacturing, Processing or Repacking; Volume of product in commerce: 39068.8 KG. Good Manufacturing Practice Deviations: An FDA inspection conducted September 21-25, 2009 observed numerous violations in record keeping practices that are not in accordance with the manufacturer's related SOPs and cGMP requirements, which may cause the final product to be adulterated. Lot #: 20041002, 20041003, 20041004, 20071001, 20071002, 20071003, 20071004, 20071005, 20071006, 20071007, 20071008, 20071009, 20071010; 20071011, 20071012, 20071013, 20071014, 20071015, 20071026, 20071027, 20081001, 20081002, 20081004, 20081005, 20081006, 20081007, 20081008, 20081009, 20081010, 20081011, 20081012, 20081013, 20081014, 20081015, 20081016, 20081017, 20081018, 20081019, 20081020, 20081021, 20081022, 20081023, 20081024; Nanjing Pharmaceutical Factory Co., Ltd.

Yi Shou capsules, 400 mg, (3 x 10-count blister packs) 30 capsules per box; Volume of product in commerce unknown. Marketed Without Approved NDA/ANDA: FDA analysis found that these products contains sibutramine, the active ingredient in an FDA-approved drug indicated for use as an appetite suppressant for weight loss, making it an unapproved new drug. All lots; Healthy Body Forero.

Yi Shou Capsules, 650 mg, Extra Strength, (3 x 10-count blister packs) 30 capsules per box; Volume of product in commerce unknown. Marketed Without Approved NDA/ANDA: FDA analysis found that these products contains sibutramine, the active ingredient in an FDA-approved drug indicated for use as an appetite suppressant for weight loss, making it an unapproved new drug. All lots; Healthy Body Forero.

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 its hotline at (800) 638-2772. The CPSC Web site is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Bicycle Bells. The red paint on the bicycle bells contains excessive lead levels, violating the federal lead paint standard. Do It Best Corp., (877) 326-8954 or www.doitbest.com.

Carolina Function Generator Kits. The yellow lids in the kits contain excessive levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Carolina Biological Supply Co., (877) 316-1848 or function.generator@carolina.com.

Children's Hooded Sweatshirts with Drawstrings. The sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled in the neck and waist drawstrings in upper garments such as sweatshirts and jackets. Haselson International Trading Inc., (800) 217-4478 or www.burlingtoncoatfactory.com.

Children's Snowsuits and Coats. The snowsuits and coats have drawstrings through the hood that can pose a strangulation hazard. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Deux par Deux Minimome Inc., 866-557-2222 or www.DeuxparDeux.com.

DayNa Decker Botanika Candles. The candle flame can unexpectedly flare up and the glass container can crack, posing fire, burn and laceration hazards to consumers. Lumetique Inc., (888) 872-0228 or www.daynadecker.com.

Decorative Wood Chests and Tables. The surface coating paint on the furniture could contain excessive levels of lead in violation of the federal lead paint standard. Hammary Furniture Co., (888) 577-4098 or www.regcen.com/hammaryrecall.

DuraTech Anchor Plate with Damper and DuraChimney II Anchor Plate with Damper. When the consumer attempts to open/close the damper, it can become stuck in its current position. In addition, some of the dampers were assembled backwards and are set to the closed position when the consumer attempts to open the damper. Both pose risk of carbon monoxide poisoning to the consumer. Simpson Dura-Vent Company Inc., (866) 860-7908 or www.duravent.com.

Evenflo Top-of-Stair™ Plus Wood Gates. The slats on the gate can break or detach, posing a fall hazard to children. Evenflo Co. Inc. (800) 233-5921 or safety.evenflo.com.

Flower and Insect Painted Wooden Beads. The paint on the children's wooden beads contains excessive levels of lead, violating the federal lead paint standard. S&S Worldwide Inc., (800) 937-3482 or www.ssww.com/productsafety.

Girls' Hooded Jackets with Drawstrings. The jackets have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Bubblegum USA, (323) 233-9005 or www.bubblegumusa.com.

Girls' Hooded Sweaters with Drawstrings. The hooded sweaters have a drawstring at the neck which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Children's Apparel Network, Ltd., (800) 919-1917.

Glass Water Bottles. The glass beverage bottles can shatter when the consumer is removing or inserting the stopper, posing a laceration hazard to consumers. Crate and Barrel, (800) 451-8217 or www.crateandbarrel.com.

Graco Harmony™ High Chairs. The screws holding the front legs of the high chair can loosen and fall out and/or the plastic bracket on the rear legs can crack causing the high chair to become unstable and tip over unexpectedly. This poses a fall hazard to children. Graco Children's Products Inc., (877) 842-3206 or www.gracobaby.com.

Gund Baby Paperboard Books. The styrofoam used to fill the book binding can detach, posing a choking/aspiration hazard to infants and young children. Gund, (800) 436-3726 or www.gund.com.

Hyland Bicycles and Carbon Bicycle Forks. The bicycle fork can crack or break, posing a fall hazard to the consumer. Civia Cycles, (877) 774-6208 or www.civiacycles.com.

Indoor and Outdoor Extension Cords and Power Strips. The extension cords and power strips have inadequate coating material around the cords and copper conductors that are smaller than required, posing a fire hazard to consumers. Howard Berger Co. Inc., (800) 221-6895 or www.hberger.com.

Jackets and Vests with Moshi Power Systems. Electrical connections in the warming components in the jackets and vest can overheat, posing a burn hazard to consumers. Ardica Technologies, (877) 884-1921 or www.ardica.com.

Jewel Girls' Hooded Sweatshirts with Drawstrings. The sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Liberty Apparel Company, Inc., (212) 768-3030 or www.burlingtoncoatfactory.com.

Konrad and Loft Office Chairs. The chair backs can come loose from the seat base, posing a fall hazard to consumers. Cost Plus Inc., (877) 967-5362 or www.worldmarket.com.

Kuuma IR Stow and Go Grills. If the fuel container is not completely threaded on the regulator during installation, the propane tanks can leak fuel. This poses a fire hazard to consumers. Eastwind Industries Inc., (866) 995-8862 or www.kuumaproducts.com.

Mecca Children's Hooded Jackets with Drawstrings. The jackets have drawstrings through the hood which can pose a strangulation hazard to young children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. 5 Star Apparel LLC, (646) 273-1225 or (646) 273-1228.

Mobile Power Packs. The lithium-ion cells used in the Mobile Power Pack can ignite or explode while charging, posing a fire hazard. This hazard is only present for units that have not been charged. Tumi, (800) 530-0069 or www.Tumi.com.

Niles ZR-6 MultiZone Receivers. A failure in the receiver's internal components can cause connected loudspeakers to overheat and cause a fire, posing a fire hazard to consumers. (800) 667-3991 or www.nilesaudio.com/ZR6Info.

North-Sportif Hooded Jackets and Reversible Vests. The jackets have a drawstring through the hood and the vests have a drawstring through the waist which can pose strangulation and entanglement hazards to young children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings, such as jackets and sweatshirts. North-Sportif Inc., (212) 643-9730 or www.burlingtoncoatfactory.com.

Patio Glow Outdoor Gas Fire Columns. Gas can leak from connections in the column, posing a fire hazard to consumers. Agio International Co., (800) 598-6532 or www.va-cs.com/recall.

PBteen Ottoman Beds. The Ottoman Bed mattresses fail to meet the mandatory federal open flame standard for mattresses, posing a fire hazard. PBteen, (866) 472-3010 or www.pbteen.com.

Posey, Lily, Rose and Daisy Girls' Ski Jackets. The jackets have a drawstring at the waist which can pose an entrapment hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Sport Obermeyer, Ltd., (800)778-5465 or http://www.obermeyer.com.

Remote Control Kits for Electric Fireplaces and Stoves. The plug-in wall unit can overheat, posing a fire and burn hazard to consumers. Dimplex North America, (866) 673-9880 or www.recall.dimplex.com.

Roman Shades and Roll-Up Blinds. Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Roll-Up Blinds - Strangulations can occur if the lifting loop slides off the side of the blind and a child's neck becomes entangled on the free-standing loop or if a child places his/her neck between the lifting loop and the roll-up blind material. Oriental Furniture, (800) 978-2100 or www.orientalfurniture.com.

Six Tier Chrome Shelving Unit. Shelving unit casters can break at the stem causing the unit to collapse or fall, posing an injury hazard. King Long Metal Industrial Company, Ltd., (888) 445-9355 or customerservicegsm@sbcglobal.net.

Superior VFGL Vent-Free Gas Log Sets and VF Vent-Free Fireplaces. The front burners of vent-free gas log set fireplace inserts and the vent-free fireplaces can fail to ignite allowing gas to escape and posing a fire or explosion hazard to consumers. Lennox Hearth Products, (800) 826-8546 or http://www.lennoxhearthproducts.com.

CONSUMER PRODUCTS

TUSA RS-670 Regulators. The first stage balance chamber plug can loosen from the scuba regulator causing a high-pressure leak and creating unstable pressure. This poses a drowning hazard to divers. Tabata USA Inc. (TUSA), (800) 482-2282 or www.tusa.com.

Ventus Ltd™ and Ventus Team™ Bicycle Aerobars. The two rubber hand grips on the aerobars (handle bars) can loosen or slip off during use, posing a fall or injury hazard to the rider. BikeMine, (877) 861-9125 or www.TheNew3t.com/VentusRecall.

Women's Peacoats. The peacoats fail to meet the federal flammability standard for wearing apparel and pose a risk of burn injury. Foria International Inc., (888) 999-6568 or www.foria.com.

Youth and Junior Hockey Sticks, Shafts, and Blades. Paint and decals on the sticks, shafts and blades contain excessive levels of lead, violating the federal lead paint standard. Bauer Hockey Inc., (888) 734-0443 or www.bauer.com.

OUTRAGE from page 12

orientation of authors' expressed views on the rosiglitazone controversy and their financial conflicts of interest with pharmaceutical companies." Specifically, those who had favorable views on the safety of rosiglitazone were more than three times more likely to have a financial conflict of interest with a pharmaceutical company than were those who had unfavorable views. There was a similarly strong association between support for the use of the drug and financial conflict of interest. Conversely, authors who were unfavorable on the issue of rosiglitazone safety were largely free of identifiable conflicts of interest.

The authors of the *BMJ* study ended with a "call to action" to promote greater transparency among readers and writers of the scientific literature. It is a call that Public Citizen has repeatedly sounded, and which is at the core of much of what we do. ✦

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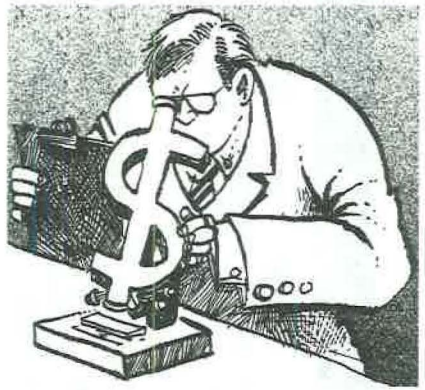
Outrage! The Continuing Saga of Avandia: Paid Cheerleaders for the Drug



The diabetes drug Avandia has become increasingly linked to dubious science and conflicts of interest. The latest chapter in the saga of this drug, also known by its generic name rosiglitazone, concerns the fact that the drug appears to be viewed differently depending on whether or not the beholder has ties to industry. The latest chapter in this unsurprising but still disturbing finding is described in an article published in the *British Medical Journal* in March 2010.

The current controversy is the direct sequel of a debate that took place in 2007, after Steven E. Nissen and Kathy Wolski conducted a meta-analysis of studies on the drug and concluded that rosiglitazone was "associated with a significant risk of myocardial infarction (heart attack) and with an increase in the risk of death from cardiovascular causes that had borderline significance." That conclusion, followed by a subsequent industry-sponsored large study known as the RECORD trial, prompted the publication of a number of articles, many of which were opinion pieces, which weighed in on the merits of rosiglitazone.

These articles were then examined by a team of researchers from the Mayo Clinic, whose objective was to explore a possible link between the authors' financial conflicts of interest and their position on the association of rosiglitazone with an increased risk for heart attack. Two reviewers who did not know the authors' ties then classified the authors' views as being favorable, neutral or unfavorable on the risk of heart attack and on recommendations on the use of the drug. Their views were then matched with whether or not they had ties with the pharmaceutical industry.

The researchers found that disclosure rates for financial conflicts of interest were unexpectedly low, with only 53 percent of the articles having a conflict of interest statement. More important, they concluded that "there was a clear and strong link between the

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