

NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES
NEWSLETTER
MAY 31, 2007

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NLARX IN THE NEWS

COLUMBIA LAW CONFERENCE MATERIALS

NLARx Counsel Sean Flynn and Executive Director Sharon Treat, plus many other policy and legal experts were panelists earlier this month at a conference for state Attorneys General sponsored by Columbia Law School on pharmaceutical law and policy. It was a terrific conference with great information on pricing and marketing fraud, state laws and challenges to them, payments to doctors and more. Many excellent materials are now posted on the law school website and I recommend you check out this site. More materials are still to be posted so check back in a few days. Here is the link:

http://www.law.columbia.edu/center_program/ag/Pharma_Conf

NLARX WELCOMES PROVISION IN KOREA-US FTA TO PROTECT MEDICAID PROGRAMS

From 5/25 press release: “The National Legislative Association on Prescription Drug Prices (NLARx) Legislative Working Group on Trade welcomes the release of the negotiated text of the Korea-US Free Trade Agreement, and appreciates the clarification that pharmaceutical provisions of Medicaid and other state drug programs are unaffected by the agreement. Medicaid uses preferred drug lists to steer patients towards the most cost-effective drugs, leading to significant savings. These savings enable cash-strapped states to provide quality care to millions of poor and disabled Americans. Members of the NLARx Legislative Working Group on Trade & Prescription Drugs met several times with US trade negotiators and expressed concerns that language used in the US-Australia Free Trade Agreement could provide a pretext for challenging state administration of Medicaid programs. The Working Group sought specific guarantees that any chapter on pharmaceuticals in a new trade agreement would not threaten their ability to manage drug costs through formularies and preferred drug lists. USTR staff took up this issue and honored the request from states to clarify in the text of the US-Korea Free Trade Agreement a specific exception for Medicaid. “This ‘carve-out’ in the agreement recognizes the central role of states in administering and

paying for Medicaid and other prescription drug programs. It is a victory for states and for consumers, because it will allow states to continue to provide broad citizen access to essential medicines while also managing drug costs," commented Maine State Representative Sharon Treat, a member of the Maine Citizen Trade Policy Commission and Executive Director of NLARx. Working Group co-Chair Senator Meg Burton-Cahill (AZ) thanked USTR for its understanding of state interests. "Although prescription drug pricing remains a big issue at the federal level, states have quietly moved ahead with cost-management approaches of their own. States have shown the way. We appreciate that USTR has recognized the leading role of states, and have moved in the recent US-Korea agreement to safeguard the innovative role played by states. Now, USTR should formalize that understanding for all future agreements, as well," said Senator Burton-Cahill. Trade negotiators produced a text which applies new rules to each Party's "central level of government." The text states that "...Medicaid is a regional level of government health care program in the United States, not a central level of government program."

>>>For more information on other concerns about the Korea agreement, and its details, see comments posted [below](#).

IN THE STATES:

REPORT FROM TEXAS ON PBM LEGISLATION

From Inside Pharmacy, 5/17: "PBMs would have to be more open about their business transactions under new legislation approved by the Texas Senate and waiting for a vote in the Texas House. In addition to requiring greater transparency, the measure also requires PBMs to pass-through full value of discounts from drug manufacturers and give the state full auditing rights if they want to do business with Texas. Those are the new rules included in SB 1834 by Sen. Glen Hegar, R-Katy, which passed the Texas Senate May 1. Rep. Bill Callegari, R-Houston, helped move the bill through the Government Reform Committee in a unanimous vote. It is currently in the Calendars Committee where it is expected to be set for a vote by the full House within the next few days. Hegar noted that PBMs were one of the most influential factors affecting the cost of health care in his statement of intent published by the Senate Research Committee. "PBM mail order and specialty drug offerings have touted significant savings in self-referred information. However, PBMs for the state's benefits have refused to provide needed information to determine whether aggregate savings are being achieved," the statement read. "Studies cited by PBMs do not include the cost data used to calculate results in such studies, and without this information it is impossible to determine whether self-referred mail order and specialty drug offerings are actually saving consumers money." A recent study by The University of Texas Center for Pharmoeconomic Studies raises doubts that mail order saves money over an identical benefit delivered at a retail community pharmacy. The bill affects contracts between PBMs and health plans administered by the Health and Human Services Commission, the Department of State Health Services, the Employee Retirement System of Texas, and the Teacher Retirement System of Texas. Read SB 1834 [here](#)."

MINNESOTA PROJECT

The Prescription Project is featured in this [Minneapolis Star-Tribune editorial](#) praising the steps Minnesota is taking—in partnership with the Project—to get unbiased information into the hands of patients and increase transparency in clinical trial registries and pharmaceutical company payments to doctors.

REPORT FROM MAINE

Several prescription drug bills have been voted favorably out of the Joint Senate/House Health Committee, including LD 4, providing an opt out mechanism for prescribers to protect their personal prescribing data from marketing uses; LD 829, establishing an academic detailing program; LD 1440, banning pop-up ads and other marketing techniques in electronic prescribing software, and LD 807, requiring charging the lower of copay or customary price.

DRUG PRICES

OUTPATIENT SPENDING ON PRESCRIPTION DRUGS INCREASED TO \$191B IN 2004, AHRQ FINDS
http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45102

SOME DOCTORS QUIT INJECTING DRUGS OVER COSTS

(5/25, Avery Johnson, Heather Won Tesoriero, The Wall Street Journal) reports "...Mr. Mattioli's doctor is one of thousands of small practitioners who are getting out of the business of administering drugs for conditions ranging from anemia and cancer to arthritis and infections, forcing hundreds of thousands of

patients to get the drugs elsewhere. It is an unintended consequence of a change in the way Medicare reimburses doctors for a class of drugs that are most often injected or infused.”

<http://www.wsj.com> (Paid Subscription Required)

GOOD NEWS FOR GENERICS:

A report in the May 17 *Boston Globe* said that [increased generic drug use](#) kept the growth rate of prescription drug spending down to 2.8 percent in 2006, even as costs continued to skyrocket among certain therapy classes, such as type-2 diabetes treatments.

INDUSTRY INSIDER: GENERICS DAMPEN SPENDING ON PRESCRIPTION MEDICINES

(5/17, Susan Todd, The Star-Ledger, NJ) reports “...But in its annual drug trend report, Medco, one of the nation’s leading pharmacy benefit managers, said despite the spending increases in diabetes medicines -- as well as a spike for specialty cancer drugs -- overall spending in 2006 increased only modestly, thanks to the growing use of generic medicines and the enactment of new Medicare benefits.”

<http://www.nj.com/business/ledger/index.ssf?/base/business-0/1179377258168410.xml&coll=1>

WHAT DID HE SAY? ELAN CEO: LOWER PRICES

Pharmalot, Posted: 29 May 2007 07:01 AM CDT

“Time to do a double take. Kelly Martin is challenging big pharma to overhaul its business model by offering groundbreaking new treatments at a lower cost, which he says his company is likely to follow for its Alzheimers treatments. “The psychology of the industry is that, if you are first, the price should be high,” Martin tells The Financial Times. “The economic structure is unsustainable. The tension will grow and something has to give.” Referring to Elan’s treatments under development for Alzheimers disease - which are set for launch in about three years - he says there is a commercial advantage to building market share by offering lower-priced drugs over many years. “We would consider using price as one of the parameters for strategically positioning this company for the long term,” he says. “You need low and flexible infrastructure costs, but you can charge less if you continue to innovate.” Please store his remarks somewhere so Elan’s actions can be compared with his words.”

RX PRICES MAKE MINORITIES 'DESPERATE'

Pharmalot, Posted: 24 May 2007 03:16 PM CDT

“The cost of prescription drugs leads many Hispanics and African-Americans to take “desperate measures,” like delaying filling a prescription or skipping doses, according to a recent AARP national study of approximately 2,000 adults 18 years and older. The study also found a high level of support in the Hispanic and African American communities for state legislation to make prescription drugs more affordable. Among the findings: - When asked about their ability to pay for prescription drugs over the next two years, 61 percent of Hispanics and 68 percent of African-Americans expressed concern; - Of those who purchased prescription drugs within the past year, 41 percent of Hispanics and 38 percent of African Americans had a problem paying for them; - More than 87 percent of Hispanics and African-Americans support state legislation to allow the states to do bulk purchasing and pass savings to those without adequate drug coverage; - A big majority - 81 percent of Hispanics and 79 percent of African-Americans, support legislation that would require drugmakers to report their spending on marketing to doctors.” More reading... [AARP press release](#); [AARP report](#).

OVERSIGHT INADEQUACIES IN THE MEDICAID DRUG REBATE PROGRAM RAISE CONCERNS ABOUT THE ACCURACY OF REBATES PAID TO STATES

Excerpt from? “We and others have reported inadequacies in CMS’s oversight of the price information reported by manufacturers under the Medicaid drug rebate program, including a lack of clarity in CMS’s guidance to the manufacturers for calculating prices. We reported in 2005 that CMS conducted only limited checks for errors in manufacturer-reported drug prices and that it did not generally review the methods and underlying assumptions that manufacturers use to determine AMP and best prices.¹⁵ We also noted in that report that OIG found that CMS did not provide clear program guidance for manufacturers to follow when determining those prices—for example, how to treat sales to certain health maintenance organizations (HMO) and PBMs.¹⁶ OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, a lack of manufacturer documentation, or both. Our review also examined the pricing methodologies of several large drug manufacturers and found considerable variation in the methods they used to determine AMP and best price, and some of these differences could have affected the accuracy of these prices and thereby reduced or increased rebates to state Medicaid programs. OIG similarly identified problems with manufacturers’ price determination methods and their reported prices in four reports issued from 1992 to 2001.¹⁷ Recent litigation has highlighted the importance

of the accuracy of prices manufacturers report to CMS and the rebates they pay to states. For example, two drug manufacturers agreed to pay about \$88 million and \$257 million, respectively, to states in 2003 to settle allegations that they failed to include in their best price determinations certain sales to an HMO.¹⁸ For full report go to <http://www.gao.gov/new.items/d07481t.pdf>

HIV TESTING DRAWS \$45 MILLION IN U.S. FUNDS, BOOSTING COMPANIES

Bloomberg, By John Laueran, summary: A plan to screen every American for HIV is set to receive \$45 million in funding next year, government officials said, raising hopes of improved AIDS prevention and boosting the outlook of testing companies. Link:

<http://www.bloomberg.com/apps/news?pid=washingtonstory&sid=a6mnM7Q23B4Q>

BIG PHARMA WATCH

FOLLOWING THE MONEY TRAIL ONLINE

David Pogue, NY Times, May 24, 2007:

"The first step to solving a problem is recognizing that you have one. That's what I keep telling myself, anyway, to avoid becoming depressed by [Maplight.org](http://www.maplight.org). It's a new Web site with a very simple mission: to correlate lawmakers' voting records with the money they've accepted from special-interest groups. All of this is public information. All of it has been available for decades. Other sites, including [OpenSecrets.org](http://www.opensecrets.org), expose who's giving how much to whom. But nobody has ever revealed the relationship between money given and votes cast to quite such a startling effect. If you click the "Video Tour" button on the home page, you'll see a six-minute video that illustrates the point. You find out that on H.R.5684, the U. S.-Oman Free Trade Agreement, special interests in favor of this bill (including pharmaceutical companies and aircraft makers) gave each senator an average of \$244,000. Lobbyists opposed to the bill (such as anti-poverty groups and consumer groups) coughed up only \$38,000 per senator. Surprise! The bill passed. If you click "Timeline of Contributions," you find out that -- surprise again! -- contributions to the lawmakers surged during the six weeks leading up to the vote. On this same page, you can click the name of a particular member of Congress to see how much money that person collected. Another mind-blowing example: from the home page, click "California." Click "Legislators," then click "Fabian Nunez." The resulting page shows you how much this guy has collected from each special-interest group -- \$2.2 million so far -- and there, in black-and-white type, how often he voted their way. Construction unions: 94 percent of the time. Casinos: 95 percent of the time. Law firms: 78 percent of the time. Seems as though if you're an industry lobbyist, giving this fellow money is a pretty good investment. A little time spent clicking through to these California lawmakers' pages reveals a similar pattern in most of them. (A few, on the other hand, appear to be deliciously contrary. Jim Brulte has accepted over \$67,000 from the tobacco industry, but hasn't voted in their favor a single time. Is that even ethical -- I mean, by the standards of this whole sleazy business?) For some reason, Maplight.org doesn't reveal these "percent of the time" figures for United States Congress, only for California. You can easily see how much money each member has taken, but the column that correlates those figures with their voting record is missing. Now, not all bills exhibit the same money-to-outcome relationships. And it's not news that our lawmakers' campaigns accept money from special interests. What this site does, however, is to expose, often embarrassingly, how that money buys votes. I probably sound absurdly naive here. But truth is, I can't quite figure out why these contributions are even legal. Let the various factions explain their points till they're blue in the face, sure -- but to cut checks for millions of dollars? Maplight.org isn't always easy to figure out, and not all of its data is complete. In fact, it's not even evident from the list of bills which ones have already been voted on -- a distinct disappointment, since the juicy patterns don't emerge until the vote is complete. On the other hand, it's painstakingly non-partisan. And it uses very good data; for example, the information on contributions comes from the Center for Responsive Politics (the nonprofit, nonpartisan research group behind OpenSecrets.org), and each special industry's interests (for or against each bill) are taken exclusively from public declarations of support or opposition (Web sites, news articles, Congressional hearings and so on). Spend a few minutes poking around. Check out a couple of the people you voted for. Have a look at how often their votes align with the interests of the lobbyists who helped to get them elected. And be glad Maplight.org makes it so easy to spot those correlations."

DON'T BUY THE HYPE: BIG PHARMA TARGETS WOMEN FOR DRUGS THEY DON'T NEED

By Judy Norsigian, Women's Media Center, Posted on May 25, 2007, Printed on May 26, 2007

<http://www.alternet.org/story/52230/>

"Selling anxiety sells medicine. Drug companies know this and profit by it. But are women benefiting as much as the industry's bottom line? The pharmaceutical industry spent much of its \$4.2 billion direct-to-consumer advertising budget in 2005 on ads targeting healthy upper-income, middle-aged people. A

common underlying message was this: you appear to be healthy, but a deadly heart attack, hip fracture, or other medical catastrophe could occur at any time. Therefore, you should take a prescription drug to prevent such problems. For example, a long-running Merck ad featured an older woman with this message: "See how beautiful 60 can look? See how invisible osteoporosis can be?" and recommended that women ask their doctors about bone density screening. As a result, many women started taking Merck's drug Fosamax, even though the benefit may not outweigh the harm. With such direct-to-consumer ad campaigns, which highlight risk factors and promote screening tests, drug companies move beyond promoting certain pills for treatment of diagnosed conditions to expanding their use in healthy people. And selling prevention through prescription drugs certainly does fill pharmaceutical industry coffers. Healthy people, preferably in early middle age, who can be persuaded to take a drug daily for the rest of their lives, are clearly the industry's most desirable customer base. But as a category, these people who are at low risk of having the problem the drug is meant to treat may still suffer a serious adverse reaction. For example, Fosamax cuts the risk of hip fracture from 2 percent to 1 percent, but that small benefit may not be worth the 1.5 percent risk of suffering an esophageal ulcer. In addition, in a small percentage of women using Fosamax over the long term, the jawbone will start to crumble. And some research now suggests that the type of new bone created by Fosamax is more brittle and more prone to fracturing over time. The over-selling of postmenopausal hormones, supported by the depiction of natural menopause as a hormone deficiency disease, was the forerunner to this type of sales pitch, which now permeates the media. Aging, social anxiety disorder, heartburn, restless leg syndrome, and overactive bladder are all examples of symptoms or normal physiological events that are now presented to consumers as being in need of long-term drug treatment. Prescription drugs used to be advertised mainly in medical journals aimed at health care providers. But since 1997, when the Food and Drug Administration (FDA) loosened the restrictions on direct-to-consumer advertising, pharmaceutical companies have taken their messages directly to the people. They claim these ads are good for consumers because they educate and encourage individuals to be more involved in their medical choices. But whatever the industry's philanthropic motives, the more direct interest is the bottom line. As Marcia Angell, a former editor of the *New England Journal of Medicine*, once put it, "They are no more in the business of educating the public than a beer company is in the business of educating people about alcoholism." Because of direct-to-consumer advertising, more people request prescription drugs from their doctors, and most doctors comply. Most lay people -- and even many physicians -- are not aware that drug ads are not checked by the FDA for accuracy beforehand, and are pulled only after complaints are made and verified. This usually takes about six months, and the drug company is given a grace period of several additional months, by which time most ads would have been changed anyway. A company is rarely required to run a corrective ad, and there is no other penalty for misleading the public. Thus, while the FDA sends hundreds of letters each year requiring drug companies to retract their ads, most people don't hear about them.

Women need to recognize misleading pharmaceutical marketing practices and base drug treatment decisions on scientifically accurate evidence. Be most skeptical of heavily advertised drugs and those that come with coupons. They are the newest, most expensive drugs with the shortest track records of safety. The FDA does not require new drugs to be proven better than competing, often cheaper, drugs already on the market. Though many drugs for chronic conditions like arthritis are taken every day for years, pre-approval trials typically last no more than a few months and long-term safety studies are almost never done. Life-threatening effects may come to light only after the drug is approved and used widely. To reduce unnecessary risk, women should seek independent sources of evidence about medicines, particularly new ones. The [FDA's web site](#) offers extensive information about medicines, herbal supplements, and vitamins, including safety alerts about the latest recalls and warnings for specific drugs. The international nonprofit group [Healthy Skepticism](#) counters misleading drug promotion and maintains a regular "AdWatch" section on its website. Consumers should be cautious when looking for information on other websites. Many are substantially sponsored by pharmaceutical companies. Being skeptical about drug ads and promotions is smart: it can protect both our health and our wallets. Judy Norsigian is the executive director of [Our Bodies Ourselves](#), a nonprofit women's health advocacy organization that also maintains a [daily health blog](#). A co-author of every edition of the book *Our Bodies, Ourselves*, she is also part of the editorial team that has produced *Our Bodies, Ourselves: Menopause* (2006) and *Our Bodies, Ourselves: Pregnancy and Birth* (forthcoming, 2008). © 2007 Independent Media Institute. All rights reserved." View this story online at: <http://www.alternet.org/story/52230/>

BIG PHARMA IS LIKE 'OXYGEN' TO LAWMAKERS

Pharmalot Posted: 29 May 2007 11:56 AM CDT

"Joe Kelley, Lilly's vice president of government affairs, gets philosophical with The Indianapolis Star, which takes a quick look at the drugmaker's new-found willingness to throw money at Democrats, such as

Vermont Senator Pat Leahy, now that they control Congress. For the first four months of this year, Lilly gave slightly more money to congressional Democrats, \$29,500, than to Republicans, \$28,500. Since 1980, at least 65 percent of Lilly's political action committee contributions have gone to Republicans, according to PoliticalMoneyLine, a nonpartisan company that tracks campaign donations. And Lilly is a major donor, making more than \$50,000 in contributions during the 2006 election cycle, the fourth-highest among corporate health-care PACs. "Like it or not," says Kelly (who's pictured to the right, alongside director of government affairs Jay Bonitt), "big pharma is a major part of the oxygen that keeps these guys going." "There are some changes that we made to recognize and be realistic about the fact that you've got a new group that are in town that are running things." You can read the full story [here](#).

HIS NEW LOBBYING JOB LOOKS A LOT LIKE HIS OLD TREASURY ONE

(5/29, A11, Jeffrey H. Birnbaum, The Washington Post) reports "...The Pharmaceutical Research and Manufacturers of America (PhRMA), the industry's trade group, helped launch a new organization, the Partnership to Fight Chronic Disease. The group's executive director is Kenneth E. Thorpe, a health aide in the Clinton administration. PhRMA's Pharmaceutical Industry Labor-Management Association, a group that emphasizes the common interests of drugmakers and unions, has also added several labor-connected Democrats to lobby Congress."

<http://www.washingtonpost.com/wp-dyn/content/article/2007/05/28/AR2007052800936.html>

ELI LILLY FACING MOST CHALLENGES EVER IN WASHINGTON

(5/28, Maureen Groppe, Gannett News Service, USA Today) reports "A Democratic senator who wants to control drug prices through generic competition and re-importation of prescriptions from Canada is not the most likely recipient of campaign contributions from the pharmaceutical industry. But when voters switched congressional majorities from Republican to Democrat, Eli Lilly and Co. followed suit."

http://www.usatoday.com/news/washington/2007-05-28-drug-lobbyists_N.htm

SAFETY & CLINICAL TRIALS

POPULAR DIABETES DRUG LINKED TO INCREASED RISK OF HEART ATTACKS

From The Weekly Reader, The Prescription Project: "...cardiologist and Prescription Project Advisory Board Member Dr. Steve Nissen has pharma and the FDA in the hot seat again with a paper in this week's [New England Journal of Medicine](#) that links a **popular diabetes drug to increased risk of heart attacks**. Nissen, well-known for helping bring to light safety concerns around Vioxx a few years ago, found in a meta-analysis of published clinical trials that people taking Avandia, GlaxoSmithKline's marquee diabetes drug, were at a 43 percent increased risk for myocardial infarction; heart attacks are already one of the major comorbid events associated with type-2 diabetes.

What happened next:

- [GSK responded](#) by saying that Nissen's findings were wrong;
- the [FDA responded](#) by saying the data weren't definitive but that patients should talk to their doctors, then called an advisory committee meeting--ASAP.
- [Congress responded](#) by inviting FDA Commissioner Andrew von Eschenbach to a hearing in early June.
- Investors responded by dropping GSK share-price 7 percent.

There is good coverage in the [Wall Street Journal](#) among other sources. ... Note reports that Nissen's sleuthing was made possible by the **public online clinical trial registry** GSK created as part of the settlement with New York over Paxil—a website Nissen found while Googling, and called "a treasure trove." The formation of mandatory, public and complete clinical trial registries are one of the Prescription Project's major policy goals. [The New York Times](#) looks at how this case may act as a deterrent for drug companies to make disclosure moves similar to GSKs in the future."

HEART RISK SEEN IN DRUG FOR DIABETES

(5/22, Stephanie Saul, The New York Times) reports "An article in a leading medical journal yesterday raised serious safety questions about the widely used diabetes pill Avandia and renewed skepticism about the vigilance of federal drug regulators." <http://www.nytimes.com/2007/05/22/business/22drug.html?hp>

FOR DRUG MAKERS, A DOWNSIDE TO FULL DISCLOSURE

(5/23, Barry Meier, The New York Times) reports "...Whatever the drug's fate, the episode is likely to fuel efforts by some medical experts, including Dr. Nissen, to persuade lawmakers to require makers of drugs

and medical devices to disclose study results publicly. Currently, producers are not required to do so, but Congress is considering legislating a requirement.”

<http://www.nytimes.com/2007/05/23/business/23drug.html?ref=policy>

NEW ENGLAND JOURNAL OF MEDICINE EDITORIAL

Here's the [NEJM editorial](#), which criticizes the FDA for being incapable “of discerning the risk of events as common as coronary disease.” The authors conclude that Avandia [biochemical name rosiglitazone] represents a major failure of the drug-use and drug-approval processes in the United States.”

USA TODAY EDITORIAL: OUR VIEW ON PHARMACEUTICAL SAFETY: LATEST DRUG SCARE SHOWS NEED FOR FDA OVERHAUL

(5/23 USA Today) “...Americans ought to be able to feel secure that the medications they take are thoroughly monitored for safety before and after the drugs hit the market. After all, there's a government agency — the Food and Drug Administration — which does that. Or does it?”

http://blogs.usatoday.com/oped/2007/05/our_view_on_pha.html

OPPOSING VIEW: WE'RE SEEKING MORE DATA; FDA PROTECTS PUBLIC WITH CAREFUL ANALYSIS, NOT SNAP JUDGMENTS.

(5/23, Andrew von Eschenbach, USA Today) “...The American public expects the FDA to be a strong, science-based agency that increases trust through open, clear communication - - and acts based on a full understanding of as much scientific data as possible and not on snap or rash judgments. We strive to achieve the best for public health every day. Andrew von Eschenbach is commissioner of the Food and Drug Administration.” http://blogs.usatoday.com/oped/2007/05/opposing_view_w_1.html

NY TIMES EDITORIAL ON ANEMIA DOSAGE RATES

Prescription Project Weekly Reader: “This week's reader starts with [a Monday editorial the New York Times](#) on last week's story about **anemia drug dosage rates** among cancer patients and the rebates being offered by the drug manufacturers to doctors who prescribe them. The story came out as an FDA advisory panel issued a report warning that the use of these drugs, known as EPOs, may be harmful in the doses commonly being prescribed in the U.S., where a minimum effective dose has not been studied but dosage levels among dialysis patients are twice as high as those in Europe, and three times as high for U.S. cancer patients than for their European counterparts. And here are some **letters** from the Times responding to the above story and the Minnesota psychiatrists story; note the one that ran yesterday from members of the Minnesota Psychiatric Society asking readers to remember pharmaceutical financing's 'important role in advancing research and care across medicine':

<http://www.nytimes.com/2007/05/13/opinion/13doctors.html>

<http://www.nytimes.com/2007/05/12/opinion/12psych.html>;

<http://www.nytimes.com/2007/05/17/opinion/17psych.html>

FDA FAILED TO ACT ON EARLY AVANDIA WARNINGS, PUBLIC CITIZEN SAYS

FDAnews.com, 5/25: “The FDA knew about increased dangers from GlaxoSmithKline's (GSK) Type 2 diabetes drug Avandia nearly five years ago, but failed to make recommended label changes, Public Citizen said. In a 2002 memo, FDA scientists recommended that labels for Avandia and another diabetes drug, Actos (pioglitazone), should be changed to include information on postmarketing reports of heart failure in patients taking the drugs. Although there have now been 803 cases of hospitalization from heart failure related to the drugs, the FDA has not updated the products' warnings, Public Citizen said in a letter to FDA Commissioner Andrew von Eschenbach. The labels lack any mention of the increasing number of postmarketing reports of heart failure, the letter added. “The failure of the FDA to act on the recommendations made almost five years ago by its Division of Drug Risk Evaluation is yet another case in which the conclusions of scientists who are engaged in postmarket drug safety review are not taken seriously enough or addressed soon enough,” Director of Public Citizen's Health Research Group Sidney Wolfe said. The FDA should either ban Avandia and Actos or mandate a black box warning, the agency's highest warning, on the drugs' labeling, Wolfe said. He also called upon the agency to create an independent postmarketing drug safety review division.”

GLAXO COURTS DOCTOR SUPPORT OF AVANDIA

No Plans Currently Set To Run Consumer Ads To Defend Drug's Safety

By JEANNE WHALEN and ANNA WILDE MATHEWS, Wall St. Journal, May 25, 2007; Page B4

“GlaxoSmithKline PLC, under pressure to protect its diabetes drug Avandia, is reaching out to physicians to defend the drug's safety, but isn't currently planning a similar ad campaign for consumers. In meetings with

doctors, Glaxo sales representatives are focusing on data from a large clinical trial called A Diabetes Outcome Progression Trial, or ADOPT. "We are reassuring physicians about the safety data we have, particularly looking at ADOPT," said Alice Hunt, a Glaxo spokeswoman. Monday, the New England Journal of Medicine released an analysis by Cleveland Clinic cardiologist Steven Nissen linking Avandia to a potential risk of heart attacks. Glaxo disagrees with the finding, which it says is contradicted by data the company considers stronger, including ADOPT data. Congressional investigators are examining the Food and Drug Administration's and the company's handling of the drug. Yesterday, Republican Sen. Charles Grassley of Iowa said that the FDA's division of drug-risk evaluation had recommended a tough "black box" warning about heart-attack risk for the label of Avandia, which hasn't been added. He and Senate Finance Committee Chairman Max Baucus, a Montana Democrat, introduced a bill that would grant researchers access to Medicare data on medical treatments. The FDA said that it can't discuss continuing regulatory matters. The agency has said it has conflicting data from different sources about the safety of Avandia, slowing a regulatory decision. In a sign of tension between Capitol Hill and the agency, Reps. John Dingell and Bart Stupak, both Michigan Democrats and leaders of the House Energy and Commerce Committee, complained in a letter that responses to their requests for information from the agency on a range of topics have been "unacceptable." The FDA said it "has been as responsive as possible." Dr. Nissen's analysis led to a sharp drop in Glaxo's stock price, and some analysts have predicted Avandia sales could be cut in half. The Glaxo spokeswoman said the company isn't planning consumer ads defending Avandia, but won't rule them out, either. "At the moment, there is an information vacuum, and GSK may need to step into the void," she said. The ADOPT trial was published in December 2006 in the New England Journal of Medicine. Patients, treated for about four years, showed positive results for Avandia in treating diabetes. The patients taking Avandia had a higher rate of heart attacks than those on glyburide, though, and very slightly more heart attacks than those taking metformin. Glaxo says this difference didn't achieve statistical significance, which means it could be the result of chance. But Dr. Nissen says the ADOPT result helped fuel his concern about Avandia's potential heart risk. Glaxo hasn't advertised Avandia on U.S. television in the past year. Recent ads in consumer magazines and medical journals have touted Avandia's effectiveness. "Every day, I struggle to keep my blood sugar under control. Where can I go from here?" a woman asks in an ad that ran in Better Homes & Gardens last November. Another ad in Woman's Day magazine last October offered patients \$30 off on Avandia if they signed up for an Internet-based program that reminds patients to take their medicine and offers healthy-lifestyle advice. A Glaxo spokeswoman said the company was taking a short break from U.S. Avandia ads when the safety concerns arose, and this break was unrelated to the concerns. In the past, Glaxo played up signs that its drug could hold cardiovascular benefits. A press release in June 2003, headlined "New Studies Suggest Avandia May Provide Certain Cardiovascular Disease Benefits," boasted of the results of studies, including one that showed Avandia might improve markers tied to cardiovascular problems. Glaxo later did its own analysis, which it posted on its clinical-trials Web site, with a finding somewhat similar to Dr. Nissen's. Glaxo says stronger evidence favoring Avandia's safety outweighs it. For a few years, Avandia's label has warned that the drug, like similar treatments, might exacerbate or lead to heart failure, which is different from heart attacks. The warning also noted that when taken with insulin, such drugs may "increase the risk of other cardiovascular adverse events." Last year, the Avandia label warning got new language saying patients with heart failure who took Avandia had a higher risk of cardiovascular events. The Glaxo analysis showing potential heart-attack risk hasn't been placed in the U.S. label.

FDA CAUTIONS RESEARCHERS ON DELEGATION OF STUDY TASKS

FDAnews.com, 5/22: "Clinical investigators should be very careful in delegating clinical trial responsibilities, according to a draft FDA guidance, "Protecting the Rights, Safety and Welfare of Study Subjects — Supervisory Responsibilities of Investigators," which was published in the *Federal Register* May 10. It is advisable for clinical investigators (CIs) to maintain a separate list for each study of appropriately qualified people to whom they have delegated significant trial-related duties, the draft guidance says. This list should describe the delegated tasks, detail the training that the designated individuals have received that qualifies them to perform these jobs and give the study dates. The CI is also responsible for overseeing the work of any staff members who are not directly employed by the site, such as employees of site management organizations. In the past, the FDA has caught unqualified staff members such as medical assistants performing tasks such as screening evaluations, physical examinations, adverse event evaluations, assessments of primary study endpoints and obtaining informed consent. The FDA is accepting public comments on the draft guidance until July 9." The draft guidance can be accessed at:

www.fda.gov/cber/gdlns/studysub.pdf.

GUIDANCE DISCUSSES ENDPOINTS IN CANCER CLINICAL TRIALS

FDAnews.com, 5/24: "Endpoints in cancer clinical trials are the focus of what the FDA says is the first in a series of guidances. It discusses endpoints in studies of drugs to treat patients with existing cancer, not drugs to prevent or decrease the incidence of cancer. For regular approval of a drug, it is critical that the sponsor show direct evidence of clinical benefit or improvement in an established surrogate for clinical benefit, the guidance says. In oncology, survival improvement is considered an appropriate measure of clinical benefit, but sponsors have used other endpoints. Overall survival is the time from randomization until death from any cause. This is considered the most reliable cancer endpoint, and it is usually the preferred endpoint. This is because it is precise, easy to measure and free of measurement bias. Survival improvement should be subjected to a risk-benefit analysis to assess clinical benefit, the guidance says. Overall survival should be evaluated in randomized controlled studies, not historical trials. The guidance recommends consulting the International Conference on Harmonisation guidance "E9 Statistical Principles for Clinical Trials," which is available at www.emea.europa.eu/pdfs/human/ich/036396en.pdf. The FDA guidance is available at www.fda.gov/OHRMS/DOCKETS/98fr/05d-0112-gdl0002.pdf."

LAWMAKERS DEBATE HOW TO ENCOURAGE PEDIATRIC CLINICAL TRIALS

(5/23, Emily Ethridge, Drug Industry Daily) reports "...BPCA gives companies six months of additional marketing exclusivity for a drug in exchange for conducting pediatric studies in response to a request from the FDA. While the six months of exclusivity encourages companies to develop drugs for children, they also block access to generic drugs for consumers, House Subcommittee on Health Chairman Frank Pallone (D-N.J.) said." <http://www.fdanews.com/newsletter?newsletterId=14> (Paid Subscription Required)

WSJ EXAMINES STRATEGIES FOR HELPING PATIENTS ADHERE TO PRESCRIPTION DRUG REGIMENS

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45101

FDA ISSUES WARNING LETTER, DELAYS; FLUMIST APPROVAL FOR MEDIMMUNE

By JENNIFER CORBETT DOOREN, Wall St. Journal, May 29, 2007; Page D2

"WASHINGTON -- The U.S. Food and Drug Administration issued MedImmune Inc. a warning letter for violating the agency's manufacturing rules and held off approving the company's influenza vaccine for use in children younger than age five until the problems are resolved, the company said Friday. MedImmune, based in Gaithersburg, Md., said the FDA found "compliance issues" during a March 2007 annual inspection of plant in the United Kingdom where it makes bulk material for FluMist. MedImmune, which is being acquired by AstraZeneca PLC, is seeking FDA permission to market the vaccine in children as young as age one without asthma or a history of wheezing. FluMist, a nonshot vaccine that's administered through the nose, is currently approved for use in people ages five to 49 years old. MedImmune said it and the FDA agreed to final product labeling for FluMist but final approval hinges on resolving compliance issues at the manufacturing plant. MedImmune didn't disclose the contents of the warning letter but said it would be posted Tuesday on the FDA's Web site. In a statement, the company said it was working with FDA to resolve problems at the manufacturing plant and to be able to release FluMist for the upcoming 2007-2008 influenza season on time. MedImmune said FDA's action won't have an impact on the acquisition of the company by AstraZeneca. Earlier this month, an FDA panel of outside medical experts said FluMist was effective at preventing the flu in children as young as six months old and was safe for use in children ages two and older regardless of wheezing history. The agency has said it had some safety concerns about FluMist in children younger than 24 months of age. The FDA typically follows its panel's advice but is not required to."

DATAMINING

DOCTORS, LEGISLATORS RESIST DRUGMAKERS' PRYING EYES

(5/22, Christopher Lee, The Washington Post) reports "...Many doctors object to drugmakers' common practice of contracting with data-mining companies to track exactly which medicines physicians prescribe and in what quantities -- information marketers and salespeople use to fine-tune their efforts. The industry defends the practice as a way of better educating physicians about new drugs. Now the issue is bubbling up in the political arena."

<http://www.washingtonpost.com/wp-dyn/content/article/2007/05/21/AR2007052101701.html>

COMMENTS OF THE NATIONAL PHYSICIANS ALLIANCE

"We think [data-mining is] a contaminant to the doctor-patient relationship, and it's driving up costs," Jean Silver-Isenstadt told the *Post*. Silver-Isenstadt is the director of the [National Physicians Alliance](http://www.nationalphysiciansalliance.org), a group

that supports ending the sale of prescriber data. And if you have an extra 30 seconds, check out the winner of NPA's [short video](#) contest on data-mining.

NEW AMA PROGRAM USES DATAMINED INFO

[Pharmalot blogger Ed Silverman](#) discusses the AMA's new program, "[Therapeutic Insights](#)," a 'self-assessment tool' that allows doctors to see what other doctors around the country are prescribing through **an online tracking tool**. According to the AMA website, Therapeutic Insights, which docs can get CME credits for, "offers physicians a new opportunity to improve the quality of patient care through a greater understanding of prescribing and treatment information." Conveniently, the tool works by tapping into prescribing data, courtesy of IMS—the very same data which it buys from the AMA every year for \$44 million.

HISTORY OF DATAMINING TACTICS

From The Prescription Project Weekly Reader: "In the current issue of the [Annals of Internal Medicine](#), Brigham and Women's historian of medicine Dr. Jeremy Greene looks to the **history of prescriber-data collection and sales** to shine light on the current policy debate around 'data-mining.' The debate is new, Greene says, but the marketing tactics are far from it, and grew up alongside the post-war pharmaceutical industry. Greene documents how the American Medical Association and willing physicians were pivotal players in the creation of Physician Masterfile, which has evolved into a major revenue source for the AMA, selling to health information organizations for \$44 million every year. Green concludes that physicians will necessarily play a critical role in any remedy sought for a marketing practice that is seen as deleterious and problematic by so many people today.

DOCTORS WANT TO OPT OUT

In the [AIM Editorial](#), Dr. David Grande uses Greene's article as a platform to call on his fellow physicians to go beyond opting out of the Physician Masterfile, and seek legislative and industry-wide curbs on data-mining.

ADVERTISING & MARKETING

DOCTORS PROFITING FROM PRESCRIPTIONS IS WRONG

Concord (NH) Monitor Editorial – May 20, 2007

"To protect the public's health and purse, society needs to inoculate doctors and patients against drug company attempts to infect the decision-making process. This month has seen the conviction of the president, top lawyer and medical director of Purdue Pharma, the Connecticut company that makes the painkiller Oxycontin. The officials pleaded guilty to "misbranding" the drug, The New York Times reported. The misbranding involved lying about how incredibly addictive Oxycontin can be. Another company, Bristol-Meyers Squibb, pleaded guilty to lying about its blood-clotting drug, Plavix. Even more troubling was a Times report that two giant drug companies, Amgen and Johnson & Johnson, were paying cancer doctors, dialysis centers and other health-care providers hundreds of millions of dollars in what could be considered kickbacks for prescribing and administering anemia drugs. Doctors and clinics were typically sold the drugs Procrit, Aranesp and Epogen, which cost Medicare more than any other, for a bit less than they could get reimbursed for them by Medicare and private insurers. The providers had to administer the drugs intravenously or via injection, procedures for which they were also paid, not provide it in pill form. Later, the drug companies gave providers, who had already made one profit on the drug, rebates for a big chunk of the price they had paid for their supply. One group of six doctors, The Times reported, spent \$9 million on the anemia drugs and got \$2.7 million back in rebates. Dosages administered by providers who received rebates were significantly higher, on average, than those prescribed by other physicians. For-profit kidney dialysis centers, for example, gave patients, on average, 16 percent more of one anemia drug than nonprofit dialysis centers, according to a study published in the Journal of the American Medical Association. The federal Food and Drug Administration is investigating charges that the higher dosages shorten the lives of cancer patients and do not improve the survival rate of dialysis patients. The panel advising the FDA on the drugs has voted overwhelmingly for new restrictions on prescribing them and unanimously in favor of new clinical trials. Drug companies say the rebates do not cause physicians to over-medicate their patients to improve profits. Physicians say the same thing; no doctor would admit to purposely doing that. Most doctors do claim that their clinical judgment wouldn't be affected by rebates. They're kidding themselves. Drug companies, hospitals and universities recently began to forbid giving doctors expensive gifts, fancy meals and free vacations. But small gifts, in most cases, are still allowed. Drug-makers have good cause to send their reps out laden with trays of free sandwiches and boxes of pens, pads, clocks and other gifts. The little bribes work. Last year, a former drug representative for two of

the companies now in trouble with authorities told The Times that her employers tracked each doctor's prescription orders. If she brought lunch to an office one week, the drug rep said, she would see the prescription numbers for her product increase the next. Doctors are human. If small gifts can buy their good will, what impact are rebates of hundreds or thousands of dollars having? The medical profession has continued to tighten its ethical guidelines, but that hasn't proven to be enough to protect patients and prevent fraud and abuse. What would help are tougher laws, an aggressive, independent FDA and patients who routinely ask their doctors, "Are you getting paid in cash or sandwiches to prescribe that drug instead of another one?"

ASTRAZENECA'S CUPGATE: DON'T FEED THE PATIENTS

Pharmalot, Posted: 30 May 2007 11:44 AM CDT

"Earlier today, we posted an item about AstraZeneca's MUMS, or Mothers United for Mammograms campaign, which was designed to promote awareness of the test and, of course, promote the drugmaker's cancer meds. As part of the effort, thousands of pink cupcakes were distributed to patients at hospitals, clinics and doctors' offices. One lingering question: [how were the cupcakes treated as an expense?](#) To prompt discussion, we also ran a section of the company's policy toward business expenses, and suggested there may be tax or, perhaps, HIPAA issues. Now, this note comes trickling in...It's written by AstraZeneca's Compliance & Ethics Leader to several district sales manager in the Mid-Atlantic region. And what does she say? Don't give them cupcakes.

From: Paskman, Andrea

Sent: Tuesday, May 01, 2007 4:49 PM

To: Danhoffer, Ronald E; Hardesty, Edward L; Russel, Joseph; Cioll Richard E (ONC DSM); Karcewski, Thomas M; Call, Teresa

Cc: Kelly, Shawn; Hagelbarger, Jeff A

Subject: FW: MUMs Programs

Importance: High

For those who have been asking about the MUMs program: Recently, questions have been raised to both legal and compliance personnel regarding the sales force's ability to distribute patient educational materials for the MUMs programs. During the month of May 2007, the sales force will be permitted to conduct such in-office MUMs programs, however the following provisions apply: 1. Approved patient education materials may be distributed to patients in the office on behalf of, and with the permission of, the HCPs 2. PSS may display patient education materials on a small table in the office waiting room 3. The provision of food, snacks, beverages, and/or flowers to patients is not permitted. The future of the MUMs program and similar in-office programs is currently being evaluated. You will be notified once the evaluation is complete."

EU DISCUSSES DTC MARKETING

From The Prescription Project Weekly Reader: "And across the pond, drug manufacturers make another push for **direct-to-consumer advertising**; the EU currently bans all DTCA, and an earlier attempt to open the airwaves to the good-night-sleep butterflies and allergy fields-of-green failed in 2002. This story in [the Guardian](#) includes an interesting discussion on pharmaceutical companies' alliances—and underwriting—of patient groups."

ANOTHER MED SCHOOL SAYS 'PHARMA STAY AWAY'

Pharmalot, Posted: 28 May 2007 09:15 AM CDT

"Those crazy kids are at it again. Another med school is about to implement a policy to limit drug reps at the urging of some of its students. This time, it's the University of Toledo, which plans to....

- Ban all gifts, including pens and lunches;
- Make sure a faculty member is present while drug rep talks with students;
- Limit companies to giving unrestricted grants, which could be used for lunches;
- Teach students and residents more about dealing with reps and assessing clinical trials;
- Have reps register with the medical center and take a two-hour class on relations with students and residents.

SO DOES UCLA

"You have to constantly be considering what you're doing to make sure everything you do is always in the best interest of your patients," fourth-year student Mary LaSalvia (pictured) tells [The Toledo Blade](#). You have to constantly be considering what you're doing to make sure everything you do is always in the best interest of your patients." ([more...](#))

From The Prescription Project weekly reader: "UCLA went (more) public with its plans to implement a [conflict-of-interest policy](#) at the school of medicine after the American Medical Student Association gave the school a C on its recent [PharmFree Scorecard](#). ... In this [brief blog post](#), Gooznews goes hunting for conflict-of-interest disclosure info in a recent online review of literature on the use of antidepressants during pregnancy—and finds it. The publication: *Women's Health*, a newsletter by the same publishers of NEJM. The reviewer: a Harvard professor who has received speaker fees from multiple antidepressant manufacturers. The disclosure info: very small print."

SURVEY: DTC ADVERTISEMENTS MOTIVATE CONSUMERS TO FIND MORE INFORMATION

FDAnews.com, 5/29: "Direct-to-consumer (DTC) advertisements inspire most consumers to seek out more information, while very few go to their doctors to request a specific medication, a national survey said. While 73 percent of the 1,503 adults surveyed said DTC advertisements helped patients be more involved, 8 percent said they would ask their physicians about a specific medication after seeing a DTC ad. Prevention, Men's Health and Women's Health magazines, along with the FDA's Division of Drug Marketing, Advertising and Communication, have conducted the survey annually for the past 10 years. Sixty-eight percent of consumers said they know a lot about their medical conditions, according to the survey. In addition, 67 percent said they know about the benefits of their prescription medications, and 59 percent said they know about the risks. The survey also found that consumers who said they know a lot about their illnesses and medications were more likely to talk to their physicians about a drug they saw advertised. Three-fourths of the respondents continued to look for information on their medications after a prescription was filled, and 29 percent of those respondents said they took time to watch drug advertisements, the survey noted."

PART D

NEW REPORT ON MOST VULNERABLE UNDER PART D

From Commonwealth Fund: "In a new Commonwealth Fund report, [Improving the Medicare Part D Program for the Most Vulnerable Beneficiaries](#), Georgetown University's Laura Summer and colleagues discuss some of the challenges faced by this group of beneficiaries and make specific recommendations to strengthen Part D. The Medicare prescription drug benefit has improved access to needed medications for millions of Americans. At the same time, an estimated 3.3 million of the 13.2 million beneficiaries eligible for a low-income subsidy to help pay for premiums and medication copayments are not receiving that help. The complexity of Part D poses additional challenges for "dual eligibles"--Medicare beneficiaries who also qualify for Medicaid benefits. Administrators must find better ways, the report finds, to reach out to these beneficiaries, simplify the enrollment process, and provide hands-on assistance in navigating that process."

>>>Coverage and Use of Prescription Drugs in Nursing Homes: Implications for the Medicare Modernization Act, Bruce Stuart, Ph.D., Linda Simoni-Wastila, Ph.D., R.Ph., Fatima Baysac, M.H.S., Thomas Shaffer, M.H.S., Dennis Shea, Ph.D., February 27, 2006, [Read more »](#)

SENATE SPECIAL COMMITTEE ON AGING HOLD PART D MARKETING HEARINGS

testimony from the Medicare Advantage sales and marketing practices hearing on Wednesday, May 16 --- including attachments and other statements submitted for the record---are on the Committee's web site under "United States Senate Special Committee on Aging". Dear Colleague: With the Medicare Part D prescription drug benefit now well into its second year, perhaps the most critical question facing the new program is how some of the frailest, sickest, and most vulnerable beneficiaries are faring.

SALES AGENTS TAKE ADVANTAGE OF SENIORS, A SENATE PANEL IS TOLD.

By STEPHEN NOHLGREN, © 2007 · St. Petersburg Times, May 17, 2007

"Claiming that sales agents are misleading seniors about private Medicare plans, several state insurance commissioners asked Congress on Wednesday for more power to crack down. "Right now I have more authority to deal with pet insurance than I do with seniors in Medicare plans," Oklahoma Commissioner Kim Holland told a hearing of the Senate Special Committee on Aging. Lack of state control has led to "virtual lawlessness in Oklahoma." Georgia has arrested agents for forging signatures and signing up dead people, said insurance regulator Sherry Mowell. Florida officials did not testify but said in interviews that abuse has also been widespread here. "People go to free lunches and sign in and put down their Social Security number and all of a sudden they find themselves switched (into a private plan) and they don't know how it happened," said Ann Whiting, counselor for Florida's SHINE program, which helps seniors with insurance issues. People discover the truth when their regular doctor refuses to treat them or when they can't fill a prescription that is not on the plan's formulary, Whiting said. "We tell them, if they go to a free lunch, do not

to put down their Social Security number," she said. Whiting, one of SHINE's counselors in Pinellas and Pasco counties, said she fielded two or three sales complaints a week during early part of this year. One woman went to a health fair and stopped by a Medicare plan's booth, Whiting said. "The agent said, 'Please sign this. If you don't sign, my boss won't accept that I talked to you.' She didn't read it and she was signing herself up." Particularly vulnerable are poor older and disabled people on Medicaid and Medicare. They have no Part B Medicare premiums, no deductibles and very low co-payments for services -- as long as they stay on traditional Medicare. On many private plans, they can end up paying \$30 every time they see a doctor. Kathryn DeLong helps poor residents of St. Petersburg's Lutheran Apartments navigate Medicare and other social services. "After the whole plan fiasco, I don't let insurance people in the building anymore. They call and ask to make a presentation and I say 'We don't need any more talk about insurance,'" she said. One resident signed up for a new product called "private fee for service," where plans pay doctors and hospitals on a per-visit basis, rather than having an HMO-like network. An agent told the resident "he could see any doctor or go to any hospital and any pharmacy he chose," DeLong said. Unfortunately, many health care providers won't accept those payments. "His bills were not getting paid. He could not get his prescriptions filled, and lo and behold, he found out he could not go to any of his providers." DeLong declined to identify the agents or companies involved. Florida's Office of Insurance Regulation has received 148 complaints about Medicare sales, mostly since late 2006, said investigations chief Barry Lanier. "The most common pattern is people not realizing they are disenrolling" from traditional Medicare, he said. "All it takes is a signature."

With most insurance, states can hold companies responsible for agent conduct. But when Congress rewrote Medicare law three years ago, the federal government got sole authority over how private plans conduct sales. States can sanction agents but not companies. Like state regulators who testified Wednesday, Florida insurance regulators would like more power to regulate companies when sales abuses become a pattern, said senior economist Ray Spudeki. "We don't like the idea of Florida consumers being taken advantage of," Spudeki said. Sen. Herb Kohl, a Wisconsin Democrat who chairs the aging committee, said he would draft legislation to expand state authority. "This is simply unacceptable," he said. Medicare HMOs have been around for decades. Because the government pays private plans up to 19 percent more per person than on traditional Medicare, HMOs often provide extra benefits like eyeglasses and hearing aids. Recently, new types of private plans have complicated Medicare's landscape, including drug plans, PPOs and the new "private fee-for-service" plans. In addition, Medicare now locks people into their choice for most of the year. In the past, people could switch back to traditional Medicare within weeks if a private plan displeased them. That change created a marketplace where agents could earn sizable commissions, because anyone who signed up could be stuck until the end of the year. Abby Block, director of Medicare's Center for Beneficiary Choices, told the senators that "the vast majority" of people are satisfied with their private plans, which now cover one-fifth of the people on Medicare. She acknowledged that sales abuses have occurred, but said the federal government needs to maintain its oversight. Next year, she said, Medicare will require "specific, unambiguous language in all marketing materials" that describe what private plans cover and don't cover. Companies also will have to call everyone who signs up, to make sure they understand their plan and really want it. "We believe very strongly we need to get this under control," Block said. "But I don't want to see the whole program disparaged because of the behavior of some bad apples."

SENATE PANEL HEARS TESTIMONY ON MEDICARE ADVANTAGE MARKETING PRACTICES

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44974

LOW-INCOME MEDICARE BENEFICIARIES ENROLLED IN MORE-COSTLY PRESCRIPTION DRUG PLANS, STUDY FINDS

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44976

USE PATTERNS UNDER PART D

From the Commonwealth Fund: "While the federal government, insurance plans, and others have worked hard to ensure a smooth transition to the Medicare Part D drug benefit, the process has been hindered by a lack of information on how Medicare beneficiaries use drugs and what constitutes effective and efficient utilization. To fill this information gap, researchers at the Peter Lamy Center on Drug Therapy and Aging at the University of Maryland School of Pharmacy have just published a chartbook, with Commonwealth Fund support, that examines patterns of prescription drug utilization among Medicare beneficiaries prior to Part D. Using data from the Medicare Current Beneficiary Survey, Bruce Stuart, Ph.D., and colleagues present drug use patterns for beneficiaries with a selected set of conditions, including hypertension, heart failure, diabetes, and depression. The charts and accompanying text shed light on how Medicare beneficiaries use

prescription drugs and what role those drugs may play for beneficiaries with different conditions and levels of complexity. The research provides a baseline comparison for researchers and policymakers to use in efforts to improve Part D, the Medicare program, and the effectiveness of health care for Medicare beneficiaries. To read the chartbook, please visit: www.pharmacy.umaryland.edu/lamy/Chartbook.html. Or, to order a print copy, please contact Crystal Weaver at the Peter Lamy Center on Drug Therapy and Aging at cweaver@rx.umaryland.edu.

>>>>**Improving the Medicare Part D Program for the Most Vulnerable Beneficiaries**

Laura Summer, M.P.H., Patricia Nemore, J.D., and Jeanne Finberg, J.D. May 24, 2007,

[Read more »](#)

MEDICARE PROPOSES STRONGER PENALTIES

Bloomberg News, May 22 2007

"Medicare, the federal health program for the elderly and disabled, has proposed stronger penalties to prevent fraud and unethical marketing by insurance companies and their agents. The proposals came a week after state regulators asked Congress for power to stop insurance agents from tricking senior citizens into buying health plans that are inappropriate for their needs. The Centers for Medicare and Medicaid Services disclosed the proposal in an e-mail Monday. The proposed rules would require insurance companies that sell Medicare Advantage plans and Medicare prescription drug benefit packages to report potential fraud or misconduct. Medicare also would "streamline" disciplinary procedures to bar an insurer from renewing a contract and to "clarify" the way civil money penalties are imposed, according to the statement. "It is important for CMS to be able to take swift action to safeguard beneficiaries from unlawful or questionable business practices," Acting Administrator Leslie V. Norwalk said in the statement. A final rule is expected this year after a public comment period, the agency said. " Copyright 2007, Hartford Courant

ANALYSIS: PRIVATE MEDICARE UNDER FIRE

By TODD ZWILLICH, WASHINGTON, May 23 (UPI) –

"Democrats appeared one step closer this week to cracking down on private insurance companies that offer a growing number of Medicare plans. Lawmakers are pledging this summer to push legislation that reins in some of the plans, which they say charge the government inflated prices while sometimes using misleading marketing tactics to entice vulnerable seniors into signing up. Supporters of the plans, including the Bush administration, say the plans provide vital extra benefits to many rural and low-income seniors. They warn that cuts threatened by Democrats could undermine healthcare access for millions of seniors participating in the growing program, known as private fee-for-service plans. The plans frequently offer coordinated disease care and disease management services not available with traditional Medicare plans offered by the government. Only about 1.5 million seniors currently use private fee-for-service, mainly in rural areas. But lawmakers have criticized the program because the government pays companies an average of 19 percent more per beneficiary than it pays for traditional Medicare services. In House hearings Tuesday, lawmakers also complained that the plans operate without strict government oversight. Some witnesses told lawmakers that high payment rates and a lack of oversight had led to a kind of "gold rush" by companies. The plans rush to sign seniors, sometimes resorting to misleading information and other illegal marketing tactics to enroll as many as possible. Rep. Fortney "Pete" Stark, D-Calif., chairman of the House Ways and Means Health Subcommittee, warned that private fee-for-service plans could face curbs, most likely in Medicare reform legislation planned for some time this summer. "As we look to improve and protect Medicare, all provider payments must be reviewed and are subject to change. Given what we know about PFFS at this time, they're at the top of my list," he said. Brock Slabach, a board member of the National Rural Health Association, told lawmakers that seniors enrolling in a plan often don't know that physicians are not required by Medicare to accept the plans. "When beneficiaries actually need the services is when they discover the gaps," he said. "Prospective enrollees are being told outright lies," David Lipschutz, staff attorney with California Health Advocates, told the committee. But Bush administration officials defended the plans, saying they offer care coordination services that chronically ill Medicare beneficiaries often cannot get in other plans. PFFS plans also allow beneficiaries to keep their additional benefits even if they move throughout the country, said Leslie Norwalk, administrator of the Centers for Medicare & Medicaid Services. "I think it's important to be cognizant of what those benefits are," she told reporters in a briefing in advance of the House hearings. One day before the hearings, CMS proposed new federal rules forcing insurers to report to the government on their marketing practices. Responding to the new scrutiny of PFFS plans, insurers said the higher government subsidies are key to offering additional benefits. "If Congress cuts ... funding, the (PFFS) product is unlikely to remain a stable product in many areas," said Kathryn Schmidt, vice president of Blue Cross Blue Shield of Michigan. Proposed cuts could come as part of a broader bill cutting Medicare physician payments and increasing

consumer protections under the program's Part D prescription-drug benefit, congressional aides said. Although she also warned against cutting the program, Norwalk suggested PFFS plans and other privately run plans under the "Medicare Advantage" program were likely to face curbs. "I have no doubt that Medicare Advantage is bound to look different after this year," she said." Copyright 2007 by United Press International. All Rights Reserved.

GRAY MATTERS: STATE RUSHES THE ELDERLY TO CHANGE DRUG PLANS

Saul Friedman, Newsday, Family & Relationships, May 26, 2007

"Prescription drug benefits for many of the 355,000 New Yorkers enrolled in the state's Elderly Pharmaceutical Insurance Coverage Program (EPIC) are about to get more complicated and maybe more costly. But don't panic. If things go right, says EPIC, you'll get the same coverage, perhaps for less. That, however is a big if. The change was made by the State Legislature as part of this year's budget, because the state believes it can save money - an estimated \$43 million this year - by shifting much of the cost and burden of providing prescription drug coverage to the federal program. The problem, as we shall see, is that the state is turning over thousands of EPIC's elderly to a program run for and by private insurers. Beginning July 1, at least 114,500 EPIC subscribers not now enrolled in the Medicare Part D plan will be required to join one of the private insurance Part D plans or quit EPIC. And the state intends to transfer these subscribers to a Part D plan on June 8 to meet the Legislature's July 1 start date. Earlier this month subscribers received personalized letters from EPIC explaining the shift and reassuring them that drug coverage will continue. But it gave them little time to consider what to do. If my mail is any indication, the letters came as a complete surprise to many and provoked some panic. The big reason: EPIC director Julie A. Naglieri, who signed the letters, included a list of Part D drug plans from which enrollees could choose, but she told recipients, "If we don't hear from you by June 5, you will be enrolled in the plan" named in the letter. The e-mail I received from Vicki M. was typical of the confusion: "I could not afford a Part D Medicare plan so I took only EPIC as 'creditable coverage' which meant I didn't need to join Part DNow I understand if I want to stay with them I must subscribe to a Medicare drug plan. ... How will this be cheaper for me? " The quick answer is that you will be enrolled in the Part D program named in your letter and whether you choose another plan and remain in EPIC is up to you. There are two types of EPIC plans, which are open to persons 65 or older with incomes of less than \$35,000 if single, and \$50,000 if married. One is the fee plan for lower-income seniors with the yearly fee based on income. The other is the deductible plan for higher-income enrollees, with the deductible amount based on income. Subscribers with EPIC cards pay relatively small co-pays at pharmacies. "Some seniors will not have to join Part D," said state health department spokesman Jeffrey Hammond. The exceptions are deductible plan enrollees who did not meet their deductible in the prior and current coverage year, meaning enrollees who need few drugs; enrollees who are also in Medicare Advantage plans, such as HMOs; and enrollees who risk losing retiree health coverage from a union or former employer by enrolling in a Part D plan. I asked Naglieri why subscribers have been given so little time to choose from more than a dozen Part D plans. "I realize it can be confusing," she said. But, she added, "That is why EPIC has alleviated that burden ... and has selected a plan based on a match of the drugs and pharmacies" they used in the past three months. But this selection doesn't consider that the drug needs of an enrollee may change drastically in the future. "Seniors are being held harmless," Naglieri said, "because EPIC is paying the plan premiums and EPIC will cover out-of-pocket costs - deductibles, co-pays, drugs not covered in the gap - so seniors should not be paying more for their prescription than before, and in most cases should be paying less." She has told skeptics at New York's Medicare Rights Center that the transfer of coverage from EPIC should be "seamless." But EPIC is exchanging a well-working government-run, single-payer benefit for uncontrolled and unsupervised private coverage with competing, profit-driven insurance companies, each of which has different rules, different drug tiers depending on price and different co-pays. Furthermore, Part D plans may and do change their formularies with only a brief notice, and contracts with enrollees may end after a year if the insurer's earnings are below its expectations. Four different letters were sent to EPIC enrollees depending on their status: members in the fee plan; members in the fee plan who qualify for full extra help (no premiums and minimal co-pays); members in the deductible plan; and members in the deductible plan who use few drugs and have not reached their deductible. For fee plan enrollees, said Hammond, EPIC will pay the Part D premium up to \$24.45 a month, the current average. But if the premium is above the average, the Part D enrollee may have to pay the difference. Fees will be waived for seniors on Low Income Subsidies getting extra help. Deductible plan enrollees will pay their own Part D premiums but will receive a credit toward their deductible equal to \$24.45 a month. After you are enrolled in Part D, you're supposed to receive an identification card from the insurer as well as a new EPIC card, both of which should be shown to the pharmacist. If there is any problem, you may call the EPIC help line at 800-332-3742. And let me know." saulfriedman@comcast.net, Copyright 2007 Newsday Inc.

FRAUD ALERT

COURT TO HEAR UPDATE ON PROPOSED DRUG-PRICE CASE AGREEMENT

(5/18, Dinah Wisenberg Brin, Dow Jones News Service) reports "A court plans to hear an update next week on a proposed legal settlement that would trim the price markup on thousands of prescription drugs, potentially setting the stage for the settlement to be finalized, an attorney involved in the case said...Under the settlement, First Databank would cut average wholesale prices for thousands of drugs on its benchmark list by about 4% and eventually stop publishing the average wholesale price."

OPERATORS NOT STANDING BY

From TAF.org: AstraZeneca never got back to a whistleblower's who called the company's internal hotline in November of 2006. After waiting 5 months for a response, the employee sent a letter to the Office of Inspector General (OIG) of HHS, and forwarded copies of the letter to pharmaceutical industry web sites. HHS OIG is now investigating, and so is Capitol Hill. >> [To read more](#)

N.Y. ATTORNEY GENERAL SUBPOENAS AMGEN DATA ON MARKETING PRACTICES

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45104

AMGEN SUBPOENED BY NY

From TAF.org: New York Attorney General Andrew Cuomo has subpoenaed Amgen seeking documents related to the company's sales and marketing activities, medical education, clinical studies, pricing, contracting, licensing and distribution agreements. The subpoena may deal with the sales and promotion of anemia drugs such as Aranesp and Epogen >> [To read more](#)

SCHERING-PLOUGH FACES LAWSUIT FOR FIRING WHISTLEBLOWERS

Pharmalot, Posted: 25 May 2007 03:11 PM CDT

"Four former employees of drugmaker Schering-Plough Corp.'s Argentinian subsidiary can sue over allegations they were fired for complaining about illegal marketing practices, including bribing doctors to boost drug sales, a New Jersey court ruled Friday. The ruling by a three-judge panel of the Appellate Division means the employees, terminated in 2003, can proceed with most of their lawsuit, which had been thrown out by a lower court. The suit names the drugmaker and five execs as defendants, the Associated Press reports. The four longtime employees at Laboratorios Essex S.A. allege they were abruptly terminated after disclosing "widespread unethical and illegal marketing and sales practices." They claim Schering-Plough engaged in "the pervasive and routine bribing of doctors and public officials" to boost sales of cancer and infection-fighting drugs in Argentina. The plaintiffs say they were blacklisted in the industry for having "blown the whistle" on "corrupt acts committed by or with the complicity and approval of the defendants from their Kenilworth, New Jersey, headquarters." Alan Lewis, a New York attorney who reps the three men and one woman suing, says they worked for Schering-Plough for between 10 and 25 years and were in fairly senior positions when they brought to the company's attention what they thought were violations of law. Schering-Plough said in a statement it does not comment on pending litigation or personnel issues. "We vigorously dispute the allegations," the statement said. "This is a preliminary ruling on legal matters which does not reflect any consideration of or judgment on the merits of the case." The appellate court agreed with the original Superior Court ruling on one issue: that the ex-employees' claims they were defamed by Schering-Plough and prevented from getting other jobs in the pharmaceutical industry in Argentina shouldn't be heard in New Jersey. However, the appellate panel overruled the trial court and ruled the plaintiff's whistleblower claims should be heard, and in New Jersey. Besides alleging they were wrongly terminated for discussing the marketing practices, the defendants allege they were coerced into signing settlement agreements the day they were fired, with the threat they would otherwise receive no severance pay. The drugmaker has been paying hefty fines to settle numerous ills: In January, Schering-Plough agreed to pay \$435 million to settle allegations it lied to the government about drug prices and illegally promoted two drugs for the treatment of cancers for which they were not approved. In 2004, Schering-Plough agreed to pay \$346 million to resolve charges it paid a big health insurer a kickback to protect the market for its one-time blockbuster allergy drug, Claritin. And in 2002, the company agreed to pay the federal government a then-record fine of \$500 million and to resolve repeated quality control violations dating to 1998 at four manufacturing plants." Source: [The Associated Press](#)

CONGRESSIONAL ACTION

HOUSE SUBCOMMITTEE EXPECTS PDUFA HEARINGS IN MID-JUNE

(5/29, Emily Ethridge, Drug Industry Daily) reports "...Other changes to the House's PDUFA bill are unknown because the legislation is 'a work in progress,' House Energy and Commerce Committee spokeswoman Jodi Seth told DID. However, the subcommittee spokeswoman noted the subcommittee would 'presumably avoid anything that would slow the bill down.'"

<http://www.fdanews.com/newsletter?newsletterId=14> (Paid Subscription Required)

SAFETY FRAMES GENERICS DEBATE

(5/27, Stephen Pounds, Palm Beach Post) reports "...The Access to Life-Saving Medicine Act is scheduled for debate in Congress in mid-June. It aims to bring lower-cost treatments to more patients by setting guidelines for the Food and Drug Administration to review and approve biogenerics. The bill going before the Senate Committee on Health, Education, Labor and Pensions pits pharmaceutical and biotechnology giants against the generics industry and its supporters, including Consumers Union, AARP and large employers such as General Motors Corp. and Ford Motor Co."

http://www.palmbeachpost.com/business/content/business/epaper/2007/05/27/a1f_biogenerics_0527.html

COALITION OF MODERATE DEMOCRATS BACKS INSLEE APPROACH TO 'FOLLOW-ON BIOLOGICS'

(5/23 Biologic Drug Report, FL) reports "The leadership of The New Democrat Coalition, 60 moderate Democratic members of the House of Representatives, on May 23rd announced they were supporting Rep. Jay Inslee's approach to creating a pathway for FDA approval for 'follow-on biologics' rather than the bill sponsored by Rep. Henry Waxman." <http://www.biologicdrugreport.com/News/news-052307.htm>

OTHER COUNTRIES

STEALTH LOBBYING: DRUGMAKERS BEHIND PUSH FOR CANADA TO PAY FOR AIDS DRUGS

Pharmalot, Posted: 28 May 2007 09:52 AM CDT

"Louise Binder is HIV-positive, and also suffers from Tin Ear Syndrome. Binder, you see, is chairwoman of a coalition that fights for drug-policy reform in Canada. And during a recent visit to Ottawa, the nation's capital, she urged Parliament to rewrite rules governing prescription drugs that would increase the access patients have to new, expensive meds and require the government to foot the bill. One thing she didn't mention during her visit - her association, the Best Medicines Coalition, receives 100 per cent of its funding from Canada's drugmakers, which stand to profit most from a governmental decision to approve new and expensive meds for use and coverage in Canada. Critics say such groups are conflicted and behaving badly by not properly disclosing the links. "Here they are representing exactly the same positions as big pharma," Steve Fletcher, a conservative MP and parliamentary secretary to the health minister, tells [The Financial Post](#). "If they disclosed that at the onset, that would've been much better than disclosing it once they were asked." During her recent visit to Parliament, Fletcher asked Binder pointed questions about her group's funding and potential conflict of interest. She told the health committee her group receives half its funding from Health Canada, and half from the drug industry, but couldn't name which companies provided money, adding that some comes from Canada's drug industry trade group. In an interview with the Post, Binder argued she isn't a parrot and relies on industry funding because the government doesn't provide any. Yet she acknowledged the group actually receives 100 per cent of its \$250,000 operating budget from the pharmaceutical industry. Although it received half its funding from Health Canada last year, it was an anomaly, in the form of a grant for a research project. Fletcher called that omission "disgusting." Click [here](#) for the full article."

SASKATCHEWAN CUTS DRUG COSTS FOR SENIORS

From Suddenly Senior: "Seniors in this province will pay no more than \$15 per prescription for drugs listed under the Saskatchewan Formulary. That is the guarantee of the Government of Saskatchewan's new multi-million dollar enhancement to the Seniors' Drug Plan. "My government is providing the most significant expansion of health services for seniors in a generation," Premier Lorne Calvert said. "We recognize the important role seniors play in Saskatchewan and it is vital that we help make sure their healthcare is affordable at a time when prescription drug costs are quickly and constantly increasing." Under the Seniors' Drug Plan, all Saskatchewan residents 65 years of age and older are eligible. Seniors will be automatically covered based on Health Registration Card information; no application is required. "It is clear that seniors, on average, rely more on prescription drugs than non-seniors," Health Minister Len

Taylor said. "With 115,000 seniors saving an average of \$400 per year, we think this program will play a role in building a better future for Saskatchewan families." The program goes into effect July 1 at a cost of \$35.7 million in 2007. The annual cost of the Seniors' Drug Plan is estimated at \$53.1 million. "We have heard from seniors who say that the rising cost of prescription drugs is having a direct impact on the quality of their life," Minister Responsible for Seniors Graham Addley said. "The new Seniors' Drug Plan recognizes the important contributions that seniors have made in our province and ensures that cost is not a barrier to seniors accessing prescription drugs. Low-income seniors receiving the Guaranteed Income Supplement, Saskatchewan Income Plan or Special Support coverage who currently pay less than \$15 per prescription will continue to do so. Palliative care patients and those covered by Saskatchewan Aids to Independent Living (SAIL) will continue to receive Saskatchewan Formulary drugs at no cost."

DRUG MAKERS FINANCE NURSES FOR U.K. DOCTORS

(5/30, By Jeanne Whalen, The Wall Street Journal) reports "...Britain's state-financed health-care system prides itself on providing care for all. But the system's funding pinch is causing some doctors' offices to rely on financial support from the pharmaceutical industry...The work is part of what the industry calls "disease-management programs," which the companies say improve care for people with illnesses like diabetes, asthma or heart disease...The U.S. runs industry-sponsored disease-management programs, too, but most often targeted at patients on Medicaid or Medicare. The biggest programs to date have been financed by Pfizer Inc., which has a subsidiary called Pfizer Health Solutions to manage the projects." <http://online.wsj.com/home/us> (Paid Subscription Required)

THAILAND TO KEN ADELMAN: WATCH YOUR MOUTH

Pharmalot, Posted: 27 May 2007 09:27 PM CDT

"The Thai government is going after Adelman's lobbying group. The country's [Government Pharmaceutical Organization](#) plans to file a \$30 million lawsuit against Adelmans' USA for Innovation for defaming its reputation and its AIDS drug through newspaper advertisements. The GPO's board unanimously agreed to also pursue the case in the civil court after filing a criminal charge against USA for Innovation last week, board chairman Vichai Chokewiwat tells [The Bangkok Post](#). USA for Innovation early this month paid for a [full-page ad](#) in three Thai newspapers, claiming the organization's GPO-VIR AIDS med has a very high resistance rate. The ad appeared shortly after the Public Health Ministry issued compulsory licences for Merck's Efavirenz and Abbott's Kaletra. Adelman's lobbying group has been aggressively criticizing Bangkok in recent weeks. Last month, USA for Innovation issued press releases urging the White House and Congress to get tough with Thailand. [Adelman](#) is a current member of the Defense Policy Board, which advises the US Defense Secretary. He's also a senior counselor at Edelman Public Relations, whose clients include Abbott Labs, which intensified the row with Thailand by threatening to withhold new meds from the country after a compulsory license was issued for Kaletra. As part of his campaign, Adelman created a web site - [Thaimyths.org](#) - and posted a [video on his web site](#) in which he accuses the Thai government of censorship. Adelman, however, is very selective when it comes to his audiences - he hasn't returned phone messages left to discuss his lobbying group."

TRADE ISSUES & IMPORTATION

PRESCRIPTION DRUG SALES TO U.S. RESIDENTS FROM CANADIAN PHARMACIES HAVE DECREASED BY HALF SINCE 2004, GROUP SAYS

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45179

BRAND-NAME DRUG INDUSTRY ALARMED AT IPR PRECEDENT OF FTA TEMPLATE

(5/25 FDA Week) reports "The brand-name pharmaceutical drug industry is arguing that the intellectual property rights provisions in a bipartisan compromise for handling free trade agreements scales back protections for brand-name drugs and could set a much lower standard for IPR protection in developing country markets." <http://www.insidehealthpolicy.com> (Paid Subscription Required)

NEW YORKER ARTICLE

An opinion piece from the [Financial Page](#) in last week's *New Yorker* explores the **bounds of American free trade** when IP restrictions are part of the package.

ANALYSIS OF KOREA-US TRADE AGREEMENT

For more information on the Korea-US Agreement, see comments posted by Sean Flynn and Mike Palmedo, Program on Information Justice and Intellectual Property, AU, Washington College of Law, May 25, 2007: http://www.bilaterals.org/article.php3?id_article=8424

KOREAN TRADE AGREEMENT: THREAT TO PUBLIC HEALTH

Analysis provided May 30, 2007, Ellen R. Shaffer, PhD MPH, Co-Director, Center for Policy Analysis on Trade and Health (CPATH):

"The U.S.-Korea Free Trade Agreement (KORUS) continues the practice of corporate hijacking global trade negotiations to the benefit of transnational drug and tobacco companies, and at the expense of people's health. It threatens core protections for public health, long under fire from NAFTA's notorious Chapter 11. Despite mounting calls for democratic participation in trade policies relevant to public health, labor and the environment, the U.S. Trade Representative failed to involve its own advisory committees, members of Congress, and the public in negotiating key provisions of KORUS. The agreement would:

- Affect reimbursement rates for hospital drugs covered by Medicare and drugs provided in community clinics in the U.S.
- Raise drug prices in Korea. Many Koreans already cannot afford life-saving drugs, and the national health program's budget is strained.
- Reverse recent tobacco controls in Korea, where 67% of men smoke and cancer is the leading cause of death.
- Subject water and sanitation services to privatization and deregulation in the U.S. and Korea.
- Strengthen NAFTA-style corporate rights that encourage frivolous trade challenges against public health protections, at a cost of millions of dollars to taxpayers.

"Public health, Congress and the public at large have a right to a voice on these critical trade policies before the ink is dry," according to Dr. Ellen R. Shaffer, Co-Director of the Center for Policy Analysis on Trade and Health (CPATH). Instead, the US Trade Representative and the Bush Administration have championed a corporate agenda which fails America and endangers our future health. CPATH's "Public Health Report Card on KORUS," online at www.cpath.org, details how KORUS undermines Public Health Objectives for Global Trade:

1. Access to affordable medicines
2. Tobacco control
3. Democratic participation by public health and transparency in trade policy
4. Protect vital human services such as health care, water supply and sanitation
5. National, regional and local government sovereignty to protect population health
6. Sustainable economic development
7. Alcohol beverage control

HPV VACCINE

ARIZONA, NEVADA TAKE ACTIONS ON HPV VACCINE

Kff.org, 5/25, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45128

Arizona: The Senate last week approved a budget bill that includes language that would prohibit the state from requiring HPV vaccines for middle-school age girls, the [Arizona Republic](#) reports. According to the *Republic*, supporters of the language have said that they do not trust state health officials to make the right decision about whether to mandate HPV vaccination and that the vaccine could cause girls to become promiscuous. State health officials have said that the language is unnecessary and that they are not considering mandating the vaccine. Health officials added that they would like the option to consider mandating the vaccine in the future and that the Senate is setting a potentially harmful precedent in approving such language. Sen. Amanda Aguirre (D) unsuccessfully attempted to remove the language from the bill. According to the *Republic*, the Senate and House still must agree on the budget proposal before it moves to Gov. Janet Napolitano (D), who has said she will sign the Senate measure. According to Jody Hatz of the [National Conference of State Legislatures](#), no other state has attempted to prohibit mandating the vaccine (Crawford, *Arizona Republic*, 5/17).

Nevada: The Assembly Commerce and Labor Committee last week approved a bill ([SB 409](#)) that would require most insurance companies in the state to cover HPV vaccines for girls and women ages nine to 26, the [Las Vegas Review-Journal](#) reports. The measure was approved after Assembly Speaker Barbara Buckley (D) made a motion to combine it with a separate bill ([SB 113](#)) that mandates coverage for prostate screenings, according to the *Review-Journal*. The combined legislation restores a provision, which had

been removed in the Senate after objections from local governments, that would require self-funded health plans to cover the vaccine. According to the *Review-Journal*, the prostate-screening bill already included a mandate that self-funded plans cover screening, and some lawmakers questioned why such plans would not also be required to cover HPV vaccination. The bill now moves to the full Assembly. Funding for HPV vaccines has been included in budgets for the state's Medicaid and SCHIP programs, the *Review-Journal* reports (Whaley, *Las Vegas Review-Journal*, 5/17).

CONNECTICUT LEGISLATION DIES: "STATES STEP BACK FROM VACCINE'S PROMISE; CERVICAL CANCER SHOTS VICTIM OF WARINESS"

By HILARY WALDMAN, (Hartford CT) Courant Staff Writer, May 20 2007:

"For a brief moment this past winter, a new vaccine that can prevent most new cases of cervical cancer seemed like one of those motherhood-and-apple-pie issues for state governments. Lawmakers jumped on the bandwagon quickly, with 25 states - including Connecticut - proposing laws that would require the shots for girls as young as 11 or 12. But as legislative sessions wind down this spring, only Virginia has passed such a mandate. Here, and in most other places, the efforts to make it a requirement for middle school enrollment appear to be dead - at least for now. The lack of support has very little to do with the vaccine's efficacy. Studies show that a three-shot series of the Gardasil vaccine can prevent infection from strains of the HPV, or human papillomavirus, that cause 70 percent of cervical cancers in women who have not yet become sexually active. Instead, a confluence of factors - all influential in so many aspects of the national health care debate - weighed in to help quash efforts to make the vaccine a legal requirement. First, suspicion was touched off in January when the pharmaceutical company Merck & Co. launched an expensive and aggressive advertising campaign and bankrolled lobbying efforts pushing state legislatures to require its HPV vaccine, Gardasil, for young girls entering middle school. The vaccine had been approved by the U.S. Food and Drug Administration only six months earlier. Many saw the drugmaker's hard sell as too much, too soon - particularly in a country already stung by deaths associated with drugs such as Vioxx, which were FDA-approved and then yanked from the market. Combine national wariness with a vaccine that costs more than any other in U.S. history; skimpy or non-existent insurance payments to doctors; and concern from social conservatives that a vaccine to prevent a sexually transmitted disease might promote promiscuity, and efforts to mandate the HPV vaccine ended up on the legislative back burner. On top of all that, while cervical cancer remains a serious disease, it is not a public health crisis in the United States. Regular pap tests can detect pre-cancerous cell changes that can be treated before they become deadly. About 3,700 women die of cervical cancer in the United States each year - compared with more than 40,000 deaths from breast cancer - although the number is much higher in the developing world.

"I think a lot of it was a lot of issues and a lot of factors happening at the same time," said Alina Salganicoff, vice president and director of Women's Health Policy for the non-partisan Kaiser Family Foundation. "Everybody ran out of the gate really fast and everybody said, 'Whoa, let's slow down here.'" At a public hearing in Hartford this winter that set the groundwork for the ultimate legislative defeat, a broad cross-section of physicians, public health officials and women's advocates agreed that a vaccine to fight the deadly cancer is a laudable goal. But it was the cautionary words of experts such as James Hadler, head of the Connecticut Department of Public Health's infectious disease section, that sealed the mandate's fate. "Some vaccines have been shown to have unanticipated side effects when they go into wide use during the first year," Hadler told members of the Connecticut legislature's public health committee in February. He suggested that lawmakers wait at least two years to ensure that the vaccine is safe and that there is enough to go around before they consider requiring it. That was among the arguments that convinced state Sen. Mary Ann Handley, D-Manchester, co-chairman of the public health committee, to back off a vaccine mandate this year. "Conversations with constituents and public health people suggested that maybe that euphoria should be restrained," Handley said. The editor of the *Journal of the American Medical Association* concurs. "Years from now, when additional data and experience better inform clinicians and policy makers about the risks and benefits, states might consider requiring the HPV vaccination as a condition of school entry," wrote Catherine D. DeAngelis, editor of *JAMA* and co-author of an editorial published in the journal this month. By then it is also possible that at least one other drugmaker, GlaxoSmithKline, will have won approval for a competing vaccine, which might drive down the cost. For now, the vaccination is approved for young women from 9 to 26 years old and is available at most physicians' offices, although there have been insurance-coverage problems. "People are excited and feeling very positive about the possibility of preventing cervical cancer," said Salganicoff of the Kaiser Family Foundation. "But we're not ready to move so quickly on this." The death of most cervical cancer vaccine legislation - including Connecticut's, which was never voted out of the public health committee - does not mean that HPV will not someday join measles, mumps and rubella on the list of vaccines required for schoolchildren. It is likely that the discussion of a school requirement will come back. In fact, about the

same time bills that would require the vaccine for girls were dying on most state capital vines, evidence was mounting that the vaccine may benefit boys as well. Last week, a newly published study linked the HPV virus to certain types of throat cancer among people infected through oral sex. The incidence of oral cancer has not dropped in the United States, despite a decline in the major risk factor, smoking, leading researchers to suspect that HPV might be a culprit. "It makes it absolutely clear that oral HPV infection is a risk factor," said Maura L. Gillison, an assistant professor of oncology and epidemiology at Johns Hopkins in Baltimore, who led the study published May 10 in the New England Journal of Medicine." Contact Hilary Waldman at hwaldman@courant.com. Copyright 2007, Hartford Courant

BIOTECH

BIG PHARMA BLURRING THE LINES WITH BIG BIOTECH NOVARTIS, ABBOTT, WYETH, BRISTOL HEDGING THEIR BETS WITH BIOTECH DRUGS; LESS VULNERABILITY TO GENERICS.

(5/29, Aaron Smith, CNNMoney.com) reports "...Biotech drugs, which are made out of living cell cultures, instead of the simple molecules used to create traditional pharmaceuticals, are an attractive investment for Big Pharma for two reasons: the industry is fast-growing, and generic competitors can't touch it." <http://money.cnn.com/2007/05/25/news/companies/biotech/>

ANALYSTS SEE DRUGMAKER DEALS; LOSS OF PATENT PROTECTIONS DRIVES GROWTH IN TAKEOVERS

(5/28, Angela Cullen, Bloomberg News, Chicago Sun-Times) reports "Pharmaceutical companies, who lost patent protection on drugs with \$23 billion in sales last year, are likely to increase acquisitions in an effort to limit generic competition, Standard & Poor's analysts predicted." http://www.philly.com/philly/business/20070526_increase_in_drug-firm_mergers_predicted.html

GENERICS & PATENT LAW

INSURERS PROMOTE USE OF GENERIC ANTICHOLESTEROL DRUGS

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45103

US SOLICITOR GENERAL TO SUPREME COURT: DON'T REVIEW PATENT PAYOFF CASE

(5/23, Ed Silverman, Pharmed) reports "...Solicitor General Paul Clement advises the Supreme Court that an appeal to review a closely watched reverse settlement case should be denied, because it's not 'an attractive vehicle,' he writes in his brief. At issue is a lawsuit challenging a \$21 million deal in which Barr Pharmaceuticals agreed to delay marketing a generic version of AstraZeneca's widely prescribed Tamoxifen breast cancer treatment." http://pharmed.com/2007/05/us_solicitor_general_to_suprem.php

DRUG WARS AT THE BIG-BOX STORES, HUGE RETAILERS LIKE WAL-MART AND TARGET ARE CUTTING PRICES FOR SELECTED PRESCRIPTION GENERICS. HOW LONG CAN THEY KEEP IT UP?

(5/24, Pallavi Gogoi, Business Week) reports "...The simple \$4 price has certainly brought transparency to the retail drug arena. Until recently, when a drug's patent expired, pharmacies would charge as much as they liked for the generic version. While it would be far cheaper than the brand-name version, many pharmacies would mark up prices dramatically."

http://www.businessweek.com/bwdaily/dnflash/content/may2007/db20070524_804592.htm?chan=top+news_top+news+index_businessweek+exclusives

DISTRICT COURT EXPLAINS DISMISSAL OF MERCK V. APOTEX FOSAMAX SUIT

(5/23, Aaron Barkoff, Orange Book Blog) reports "Last month (as we reported then), the U.S. District Court for the District of Delaware granted Merck's motion to dismiss the patent suit Merck filed against Apotex concerning generic Fosamax. The court indicated at the time that an opinion would 'follow at the court's earliest convenience.' On Monday, the court issued the promised opinion."

<http://www.orangebookblog.com/>

PFIZER TO APPEAL NORWAY COURT RULING ON LIPITOR

(5/29 Crain's New York Business) reports "(AP) Pfizer Inc., the world's largest drug maker, said Tuesday it will appeal to Norway's supreme court to fight for the legitimacy of patents covering its cholesterol drug Lipitor...The announcement comes after Indian generic drug maker Ranbaxy won an appeal from the Borgarting Court in Oslo, Norway, that overturned a decision on a patent protecting atorvastatin calcium, the active ingredient in Lipitor..."This is a most important decision for Ranbaxy as it completely validates

our position in relation to the atorvastatin patents," said Jay Deshmukh, Ranbaxy's global intellectual property head, in a statement...Pfizer stresses that the rulings do not bear on Lipitor patent fights in other countries, including the United States..."

<http://www.nybusiness.com/apps/pbcs.dll/article?AID=/20070529/FREE/70529005>

ONE FINAL LOOK AT THE OLD MYLAN

(5/29, By Brian Lawler, The Motley Fool) reports "...Two weeks ago drugmaker Mylan Laboratories stunned the generics industry by gobbling up the generics business of German pharma Merck KGaA for nearly \$7 billion despite it being one-and-a-half times the size of Mylan...As with any company, the future is more important than the past and Mylan's future, even sans Merck, is solid in terms of upcoming new generic product launches. It has 62 abbreviated New Drug Applications (aNDA) pending FDA approval. More importantly, it is the first to file and could receive six months of generic drug marketing exclusivity on 14 of these aNDAs, a key factor in profitability for generic drugmakers..."

<http://www.fool.com/investing/general/2007/05/29/one-final-look-at-the-old-mylan.aspx>

ANALYSIS: PHARMA SWIMMING AGAINST IP TIDE?

(5/23, Olga Pierce, UPI) reports "In an effort to head off a potential worldwide flood of so-called compulsory drug licenses -- where foreign countries skirt intellectual-property laws and make generic versions of a patented drug -- the head of the U.S. pharmaceutical manufacturers' trade group met with Thai officials this week, but activists say those efforts might not prove successful."

http://www.upi.com/Health_Business/Analysis/2007/05/23/analysis_pharma_swimming_against_ip_tide/8748/

PATENT LAW CHANGE TO AFFECT N.J.

(5/27, George E. Jordan, The Star-Ledger) reports "A Supreme Court ruling that turned on the definition of a single word is quietly rocking the pharmaceutical industry...Nowhere will the effect of the ruling be felt more than in New Jersey, home to some of the world's biggest drugmakers, which depend on patents to protect their enormous investments in research and development."

<http://www.nj.com/business/ledger/index.ssf?/base/business-0/1180240143218120.xml&coll=1>

STATE POLICIES COULD CURB UPTAKE OF FOLLOW-ON BIOLOGICS, MEDCO SAYS

(5/21, Christopher Hollis, Drug Industry Daily) reports "...At the state level, pharmacy boards could implement policies regulating the interchange or substitution for follow-on proteins, Medco said. For example, Medco told DID that Florida currently limits substitutions for drugs with a narrow therapeutic index and similar regulations could apply to follow-on proteins."

<http://www.fdanews.com/newsletter?newsletterId=14> (Paid Subscription Required)

FTC MAY SET PARAMETERS OF ACCEPTABLE BRAND/GENERIC REVERSE SETTLEMENT

(5/21 The Pink Sheet) reports "While the Federal Trade Commission is continuing its battle against reverse settlements, the agency concedes that not all deals are anticompetitive - and it would like to delineate which ones are acceptable." <http://www.thepinksheet.com> (Paid Subscription Required)

"INGENIOUS" SIDE DEALS TO REVERSE SETTLEMENT SPOTTED BY FTC

(5/21 The Pink Sheet) reports "Brand-name and generic drug companies have come up with a strategy to try to get around the Federal Trade Commission's opposition to reverse settlements- they are tacking various side deals onto the agreements." <http://www.thepinksheet.com> (Paid Subscription Required)

PTO SAYS PATENT DAMAGES SHOULD BE LEFT TO COURTS. NOT CONGRESS

(5/21 The Pink Sheet) reports "...The legislation, H.R. 1908, would limit damage awards for patent infringement to the value of the patented item. Currently, courts can assess damages and reasonable royalties on the basis of the entire value of the product of which the patented item is a part...The Bush administration weighed in on the debate, opposing change to the status quo. 'The amount of a reasonable royalty should turn on the facts of each particular case,' Department of Commerce General Counsel John Sullivan, writing on behalf of the Patent and Trademark Office..." <http://www.thepinksheet.com> (Paid Subscription Required)

TEVA ORDERED TO HALT GENERIC LOTREL DESPITE FDA'S OK

(5/20 Reuters News) reports "Israel-based Teva Pharmaceutical Industries said on Sunday it had received final U.S. Food and Drug Administration approval to sell a generic version of Novartis's drug Lotrel.

However Teva, the world's largest generic drugmaker, said in a statement that a U.S. court had then granted an emergency request made by the Swiss-based firm Novartis for Teva to halt shipments of the drug that treats high blood pressure on the grounds of patent infringement."

<http://www.reuters.com/article/health-SP/idUSL2010245520070521>

PHRMA TAKES AIM AT THAILAND FOR PRODUCTION OF GENERICS, HINTS THAT IT WILL PUSH FOR SANCTIONS

(5/23, Ian Swanson, The Hill) reports "Drug companies are making a concerted effort to increase pressure on Thailand and other developing countries to honor U.S. drug patents. The Pharmaceutical Research and Manufacturers Association (PhRMA) is alarmed by Thailand's decision to authorize the production of generic versions of two AIDS drugs that are still under U.S. company patents, as well as one cardiovascular drug."

<http://thehill.com/business--lobby/phrma-takes-aim-at-thailand-for-production-of-generics-hints-that-it-will-push-for-sanctions-2007-05-23.html>

ONWARD & UPWARD WITH THE ARTS

MICHAEL MOORE'S HEALTH INDUSTRY DOCUMENTARY 'SICKO' DEBUTS

[May 21, 2007, kff.org] " The *Wall Street Journal* on Friday examined how supporters of documentary film maker Michael Moore's next film about the health care industry "hope that the new movie will stir up emotions and help generate the kind of buzz that made his last movie ... a topic of national debate and an unprecedented blockbuster in the documentary genre." Moore has said that the film, called "SiCKO," "will expose the health care industry's greed and control over America's political processes." Producer Harvey Weinstein said that the film "will ignite the country once and for all to deal with health care." According to the *Journal*, Moore "has largely kept a lid on the contents of the movie," but "[r]umors started circulating" after nurses unions and health care experts saw the film. The *Journal* reports, "Picking a fight with the opposition is a key component of Mr. Moore's typical marketing plan," and drug companies already have "started taking the bait." When Moore started working on the documentary, some drug companies sent warnings to employees not to speak with him. [The Pharmaceutical Research and Manufacturers of America](#) already has prepared a statement in response to the film, though no one at the organization has seen it. PhRMA Vice President Ken Johnson said, "No one should be surprised that Michael Moore is making baseless accusations designed to drum up publicity for his movie." He added that "SiCKO" was not on his organization's "top 10 list of concerns." [America's Health Insurance Plans](#) spokesperson Mohit Ghose said his organization will respond to the movie once officials view it but added that AHIP already is focusing on improving health care access and affordability. The film debuted over the weekend at the Cannes Film Festival and will open in U.S. theaters on June 29 (Marr, *Wall Street Journal*, 5/18)."

FOR MICHAEL MOORE, CONTROVERSY IS MARKETING

By MERISSA MARR, Wall St. Journal, May 18, 2007; Page B1

"Filmmaker Michael Moore says on his Web site that his new documentary, "SiCKO," "will expose the health-care industry's greed and control over America's political processes." Controversy has become a key ingredient of marketing Mr. Moore's work, and the backers of "SiCKO" hope that the new movie will stir up emotions and help generate the kind of buzz that made his last movie, "Fahrenheit 9/11," both a topic of national debate and an unprecedented blockbuster in the documentary genre. "Fahrenheit 9/11" had a budget of \$6 million and grossed more than \$100 million in the U.S. alone. Mr. Moore's formula is simple: Pick a divisive topic and goad opponents into a public debate before the movie opens. The question is whether his new film's subject material -- health care and insurance -- will deliver the kind of heat that he generated for "Fahrenheit 9/11," a movie about the Bush administration's actions before and after the Sept. 11th attacks. "SiCKO" makes its debut at the Cannes Film Festival this weekend and opens in U.S. theaters June 29. Movie producer Harvey Weinstein, who has worked on Mr. Moore's previous movies and whose company is financing, marketing and co-distributing this one, predicts his new release "will ignite the country once and for all to deal with health care." Unlike "Fahrenheit 9/11," he says the movie will appeal to both ends of the political spectrum, though it may be difficult for Mr. Moore to win backing from conservatives he has previously lambasted. Mr. Moore's critics -- like Canadian documentarians Debbie Melnyk and Rick Caine, who recently released a movie that slammed his style -- say that he understands the appeal of a good brawl. "Michael knows the entertainment quotient trumps all," says Ms. Melnyk. "Fahrenheit 9/11" had a lucky break early on when Walt Disney Co. refused to distribute it, a point Mr. Moore and company used to generate enormous amounts of free publicity for the film. To help build buzz for "SiCKO," Mr. Weinstein brought back the "Fahrenheit 9/11" team, including political consultant Chris Lehane. Mr. Lehane is perhaps best known as an ex-adviser to Bill Clinton; he helped the former president

navigate such crises as Whitewater and Monica Lewinsky. As was the case with "Fahrenheit 9/11," the team is overlaying its traditional marketing campaign with an aggressive online outreach, including postings and chat on progressive sites like Daily Kos and screenings for bloggers. But this time it's a broader push, including conservative sites. Says Mr. Lehane: "The film has the potential to appeal to a broader audience because it is not red state versus blue state, but the little guy versus powerful corporations and a broken political system."

In a classic move to heighten the suspense of the project, Mr. Moore has largely kept a lid on the contents of the movie. Still, the drug companies have already started taking the bait. When Mr. Moore was just beginning the documentary, some of them sent out warnings to employees not to speak to the baseball-capped documentarian. Rumors started circling in the industry after the filmmakers showed the movie to key groups such as the nurses' union and leading health-care experts. The producers of "The Passion of the Christ" employed a similar tactic by screening their movie in advance of the opening for religious groups and stoking interest among Christians. The "SiCKO" team also plans to cross-market premieres of the film with organizations with an interest in the subject. They declined to name the groups. The trade group Pharmaceutical Research and Manufacturers of America (PhRMA), has already prepared a press release that it is sending out when asked for comment on the movie, even though no one at PhRMA has seen it yet. In the press release, the group says Mr. Moore has a track record for sensationalism and will not make a documentary that is "balanced, thoughtful and well-researched." The sensitivity is perhaps understandable, given that the drug companies are still licking their wounds from the 2005 drama "The Constant Gardener," a fictional film which portrayed pharmaceutical firms in an unflattering light. The trade group America's Health Insurance Plans (AHIP) hired William Morris several years ago to help improve their image in Hollywood. Picking a fight with the opposition is a key component of Mr. Moore's typical marketing plan. Depending on the response of the industry, the "SiCKO" marketers have created various tactics to fire back. That may include gimmicks such as placing logos of HMOs on tombstones in newspaper ads, according to people familiar with the situation. Mr. Weinstein acknowledges that a shrill response from the film's targets would play right into their hands. "If they want the movie to succeed, they should fire away," he says. Adds Mr. Lehane: "If someone throws a \$1,000 bill at our feet, of course we'll bend down and pick it up." He noted though that health-industry companies are likely to rely on groups they fund and political allies to respond. Ken Johnson, senior vice president for PhRMA responded: "No one should be surprised that Michael Moore is making baseless accusations designed to drum up publicity for his movie." He added that Mr. Moore's movie was not on their "top ten list of concerns." AHIP spokesman Mohit Ghose says they will respond to the movie once they've seen it, but they are already focused on improving quality access to health care and affordability. Mr. Moore has mined other sensitivities. Details of a trip to Cuba to film part of the movie have been much discussed in the press in recent weeks. Mr. Moore took a group of 9/11 first-responders suffering from respiratory problems to Cuba, where they received treatment. That provoked accusations that he used the workers as pawns. The U.S. government also piled in, saying it had launched an investigation into whether Mr. Moore violated a travel ban by filming in Cuba. Shortly after receiving a letter from the U.S. Treasury Department, Mr. Moore posted a response on his Web site. People involved in the movie say the Cuba scenario has been misreported. Mr. Moore's team declined requests to clarify the details. Mr. Lehane would only say: "People will be very surprised and provoked about the motivations for the trip to Cuba and what transpired on the ground." Mr. Moore uses his Web site to publicize daily reaction to his movie, including the latest stories on the "controversy." Recent headlines include a news agency story about how Mr. Moore is hiding the copy of his movie from U.S. authorities ahead of the Cannes screening. This week, it also featured a section on former Sen. Fred Thompson, a possible presidential candidate, who jumped into the debate by criticizing Mr. Moore for going to Cuba. Mr. Moore responded by scolding the Republican from Tennessee, citing a report about his fondness for Cuban cigars and inviting him to debate the subject of health care. In a video response, Mr. Thompson, cigar in hand, declined to meet Mr. Moore and said he should think about a mental hospital, which he claimed was where Cuba locked up one documentary maker." --Sarah Rubenstein contributed to this article Data Update

RESEARCH TIPS

Statehealthfacts.org has recently added new and updated data on Health Coverage & Uninsured, Medicaid & SCHIP, Women's Health, HIV/AIDS, and Demographics & the Economy. You can also view a list of all recent updates at <http://cme.kff.org/Key=12611.CW9.C.C.FB5rHD>.

Health Coverage & Uninsured

>> Health Insurance Status

Statehealthfacts.org has updated more than 50 health coverage topics to reflect a recent correction made by the U.S. Census Bureau to the March 2005 and 2006 Current Population Surveys. Health coverage data for key populations - the nonelderly, adults, children, and people living in poverty – have all been updated. <http://cme.kff.org/Key=12611.CW9.D.C.DtRBcF>

Medicaid & SCHIP

>> SCHIP Enrollment

Updated data on monthly SCHIP enrollment for June 2006 compiled by Health Management Associates from state enrollment reports for the Kaiser Commission on Medicaid and the Uninsured are now available for all states and the nation. Data are also available for the Change in Enrollment from June 2005 to June 2006 and for SCHIP Program Type by state. <http://cme.kff.org/Key=12611.CW9.F.C.Dxj7LR>

Women's Health

>> Preventive Health

Updated data from the Centers for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance System (BRFSS) Survey Data are now available for mammogram rates in women 40 and older, 50 and older, and by race/ethnicity for 2006. Data are also available for Pap smear rates in women 18 and older and by race/ethnicity for 2006. Additionally, data are available for colorectal cancer screening rates in women for 2006, cholesterol screening rate among women in 2005, and percent of women visiting dentists or dental clinics in 2006. <http://cme.kff.org/Key=12611.CW9.G.C.DyS5nk>

>> Women's Health Status

Updated data also from the CDC's BRFSS survey are now available for the percent of women with high blood pressure and the percent of women with arthritis in 2005 for all states and the nation. <http://cme.kff.org/Key=12611.CW9.H.C.FNFIIP>

HIV/AIDS

>> HIV Testing and Reporting Policies

State-by-state requirements for HIV Anonymous/Confidential Testing and HIV Name Reporting from the CDC have been updated to May 2007. <http://cme.kff.org/Key=12611.CW9.M.C.F35zZQ>

Demographics and the Economy

>> Unemployment Rate

The latest unemployment rates for March 2007 from the U.S. Bureau of Labor Statistics have been added and are now available for all states and the nation. <http://cme.kff.org/Key=12611.CW9.N.C.FZ5tdC>

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