

FDA approves Seroquel for treatment of bipolar disorder

AstraZeneca announced that the U.S. Food and Drug Administration (FDA) has approved SEROQUEL® (quetiapine fumarate tablets) for the maintenance treatment of patients with bipolar I disorder, as adjunct therapy to lithium or divalproex.

"This new indication for SEROQUEL marks an important milestone in the treatment of bipolar I disorder because it provides patients with another option over the long-term. In fact, despite the number of currently available treatments, many patients with bipolar I disorder do not receive effective therapy and

some 20 to 30 percent of patients continue to display residual mood symptoms of bipolar I disorder," said Mark Scott, Executive Director, Clinical Development, SEROQUEL. "The studies showed that SEROQUEL, with lithium or divalproex, can provide clinicians with a safe and effective long-term treatment option that reduced the risk of relapse of both manic and depressive mood events in bipolar I disorder."

Source: AstraZeneca.com



Adam W. Hamm
Insurance Commissioner

Welcome to the *RxConnector* newsletter!

Dear friends,

This newsletter is designed to keep you up-to-date about the Prescription Connection for North Dakota program and to keep you in the know about the various prescription assistance programs that are available.

From time to time, we may also include other items of interest related to Medicare and the State Health Insurance Counseling (SHIC) program.

As always, thank you so much for all that you do for the Prescription Connection program. Without your help, our work would be that much harder. Your efforts are valued and appreciated.

If you have items of interest that you think should be included in this newsletter, we would love to hear about them. Please contact Sharon St. Aubin at sstaubin@nd.gov or call her at 1.888.575.6611.



Adam W. Hamm
Insurance Commissioner

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Prescription Assistance Program updates

Salix Pharmaceuticals has a new PAP application and has added two new medications: OsmoPrep Tablets and Moviprop Oral Solution.

The address and application for **Allergan PAP** have changed, and Combigan Ophthalmic Solution and Sanctura XR 60 mg tablets have been added.

For **Astra Zeneca's AZ and Me Program** for the uninsured, the following medications have been added: Faslodex, Symbicort Inhaler, Arimidex, and Merrem. The **AZ and Me Program** for those with Medicare D has added Symbicort Inhalers.

The **Adderall XR PAP** ended June 30, 2008. No new patients have been or will be enrolled.

Together RX Access has added several meds to their PAP: Axid, Baraclude, Cytomel, Cytotec, InnoPran XL, Lovaza, and Reyataz.

TEVA has added epirubicin and paclitaxel to its PAP, but those medicines are not listed on their current application.

Source: Patient Advocate News

Brand-name prescription drug companies reached deals with generic manufacturers to delay sale of generics

Brand-name prescription drug makers in fiscal year 2007 reached 14 agreements with generic drug makers to delay market entry of generic medications, according to a report released on Wednesday by the Federal Trade Commission, *Reuters* reports (Bartz, *Reuters*, 5/23). Drug makers are required to report such deals to FTC under the 2003 Medicare law (Rugaber, *AP/Bergen Record*, 5/26). The report did not name which drugs were affected by the deals.

According to the report, there were 33 deals made between brand-name and generic drug makers in 2007, and 14 of the agreements resolved patent litigation on more than 13 brand-name drugs. In all 14 of the deals, the generic drug maker received some kind of compensation to delay market entry of a generic version of a drug. In 11 of the agreements, the brand-name drug maker agreed not to sell its own generic version when its patents expired, and in three deals, there was a side agreement on an unrelated issue that was to the generic drug maker's advantage (*Reuters*, 5/23). The report found that the number of agreements blocking new generics in FY 2007 was the same as in FY 2006. There were three such deals in FY 2005.

FTC has said that so-called "pay-for-delay" settlements harm consumers. The commission has sued to block some of the deals but "has had limited success," according to the *AP/Bergen Record*. FTC also supports legislation that would ban such deals (*AP/Bergen Record*, 5/26). According to *Reuters*, "Neither the Senate bill to ban the deals nor its companion in the [House] has made much headway because of opposition from pharmaceutical companies

and makers of generic medicines." Democratic presidential candidate Sen. Barack Obama (Ill.) is among 10 co-sponsors of the Senate bill.

FTC Commissioner John Leibowitz said, "What [the report] shows is that this problem is persistent," adding, "It's becoming the new way to do business. It means that consumers in need of affordable drugs are going to get generics later, not sooner" (*Reuters*, 5/23).

However, pharmaceutical companies and some generic drug makers say that the agreements can reduce costly litigation and that some of the deals still allow generic manufacturers to introduce generic drugs before their patents expire (*AP/Bergen Record*, 5/26).

Source: Kaiser Daily Health Policy Report



Google offers online medical records service

Google Inc. made available to the public a free service that allows customers to manage their medical records online and get health information, the Mountain View Internet company said Monday.

Google Health (www.google.com/health) allows users to create an electronic health profile that stores their

medical information and get relevant health information. The service also gives people the option of sharing their records with doctors and other providers.

Source: San Francisco Chronicle

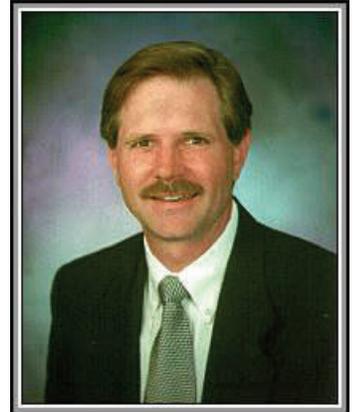
ND receives federal approval to expand SCHIP

Gov. John Hoeven announced that the federal Centers for Medicare and Medicaid Services has approved North Dakota's request to expand eligibility for the Healthy Steps State Children's Health Insurance Program (SCHIP).

The North Dakota Department of Human Services submitted an SCHIP State Plan amendment to CMS in March 2008. The agency typically approves State Plan changes on an individual basis. Governor Hoeven has worked with HHS Secretary Mike Leavett and other federal officials to secure their approval.

The higher eligibility level will allow uninsured children living in families with net incomes of up to

150 percent of the federal poverty to qualify. This is about \$31,800 per year for a family of four. North Dakota families can deduct child care expenses, standard payroll taxes, court ordered and paid child support, among other things. Under some circumstances, families could qualify at up to 200 percent of gross income.



Source: North Dakota Governor's office

Walgreens agrees to pay \$35M settlement

Walgreens has agreed to pay \$35 million to settle allegations that the company improperly switched the form of generic medications prescribed to Medicaid beneficiaries to receive higher reimbursements from the

program, the *Hartford Courant* reports (Levick, *Hartford Courant*, 6/5).

Source: Kaiser Daily Health Policy Report

FAST FACT

In 2007, generic drug manufacturers lowered or did not change the list price for almost all of the 185 generic drugs used most commonly by people with Medicare, according to AARP Public Policy Institute ("Rx Watchdog Report: Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries 2003 to 2007," AARP Public Policy Institute, May 2008).

On the other hand, manufacturers increased the list

price for the 220 brand-name drugs used most commonly by people with Medicare, by 7.4 percent on average, a significantly higher price hike than the rate of inflation ("Rx Watchdog Report: Trends in Prices of Prescription Drugs Used by Medicare Beneficiaries" AARP Public Policy Institute, March 2008).

Source: AARP

Case flash

Coverage of screening and diagnostic mammograms

Ms. C has Original Medicare Parts A and B. At a recent doctor's appointment, Ms. C's doctor told her about some of the preventive services that Medicare covers, including an annual screening mammogram for women over 40. Ms. C scheduled an appointment for a screening mammogram. Medicare Part B paid 80 percent for the procedure, and Ms. C only had to pay the 20 percent coinsurance.

When the test results came back, the doctor said that there were some abnormalities and that it was medically necessary for Ms. C to have another mammogram to investigate. The next month, Ms. C went back for the second mammogram. The results from that mammogram and some additional tests indicated that she had early-stage breast cancer. Ms. C paid the 20 percent coinsurance for the second mammogram.

A few months later, she received her Medicare Summary Notice (MSN) in the mail, which stated that Medicare denied payment for the second mammogram because she had "exceeded the limit" for coverage of mammography services. Ms. C called her doctor and found out that the doctor's office had never received payment from Medicare for the second mammogram.

Ms. C called the Medicare Rights Center to ask a hotline counselor why Medicare would not pay for a second mammogram. The counselor said that Medicare should pay for both tests. He suggested that perhaps the claim for the second mammogram was submitted as a screening mammogram rather than as a diagnostic mammogram. Diagnostic services are procedures that your doctor uses to diagnose a condition for which you show symptoms. The counselor explained that Medicare only covers a screening mammogram once a year, but that Medicare will cover a diagnostic mammogram as frequently as needed.

The counselor then suggested that Ms. C call the medical billing department of her doctor's office to make sure that the claim was coded as a diagnostic service, and ask that the office resubmit the claim to Medicare. When Ms. C called her doctor's office, she found out that, in fact, there had been a coding error. The doctor's office resubmitted the claim to Medicare, with the correct coding for a diagnostic procedure, and Medicare paid for the mammogram.

Source: Medicare Watch

Drug safety during pregnancy and breastfeeding



Women and their doctors may soon have better information about the safety of drugs taken during pregnancy and breastfeeding.

Women need much better guidance, says Sandra Kweder, deputy director of the agency's office of new drugs. Women take an average of three to five medications during pregnancy. More than 90 percent of nursing mothers take medication during the first week after delivery.

Because half of the nation's six million annual pregnancies are unplanned, many women take medications before they realize they're pregnant, Kweder says.

Source: USA Today

The Food and Drug Administration on Wednesday proposed replacing a 30-year-old system for classifying drugs in favor of labels that provide far more detailed information about a medication's risks and benefits.

Contaminated nipple cream

The Food and Drug Administration (FDA) is warning people not to use or buy Mommy's Bliss Nipple Cream because the product contains potentially harmful ingredients that may cause respiratory problems or vomiting and diarrhea in infants.

Marketed by MOM Enterprises Inc. in San Rafael, Calif., the product is promoted to nursing mothers to help soothe and heal dry or cracked nipples. The product labeling specifically states that there is no need for mothers to remove the cream prior to nursing. However, FDA is alerting the public because of the potential harm this product could have on nursing

infants. To date, no injuries to infants have been reported to FDA.

Potentially harmful ingredients

The two potentially harmful ingredients in Mommy's Bliss Nipple Cream are *chlorphenesin* and *phenoxyethanol*, which may interact with one another to further increase the risk of slow or shallow breathing (respiratory depression) in nursing infants.

Source: FDA

CMS announces \$15M funding increase for counseling

CMS officials on Friday announced that the agency this year will increase funding by \$15 million to a total of \$50 million to organizations that advise Medicare beneficiaries on prescription drug and health plan choices, *CQ HealthBeat* reports.

State Health Insurance Assistance Programs—informally known as SHIPs, which fund community-based organizations that aid seniors in reviewing Medicare options and answering questions—will use additional funds to help Medicare beneficiaries who are unable to use the Internet to get information and answers to questions.

Other CMS announcements

Agency officials also announced efforts to better inform hospice patients about their rights. On June 5, CMS officials announced a regulation that specifies that hospice patients have the right to choose care to minimize their suffering rather than continue to try to cure their diseases. In addition, hospice patients have

the right to help design their treatment plans, to refuse treatment and to select their own physicians.

CMS officials also announced that the agency will update public information on cancer drugs covered by Medicare. CMS is recognizing a new reference tool while eliminating another to help beneficiaries determine which drugs are covered for chemotherapy under Medicare Part B. The agency will recognize the National Comprehensive Cancer Network Drugs and Biologics Compendium and eliminate the out-of-date American Medical Association Drug Evaluations compendium, according to *CQ HealthBeat*.

CMS Administrator Kerry Weems said, "We use these compendia to ensure that Medicare beneficiaries can be assured that the Medicare (claims payers) and their physicians have the most up-to-date drug information and the best available treatment options" (*CQ HealthBeat*, 6/9).

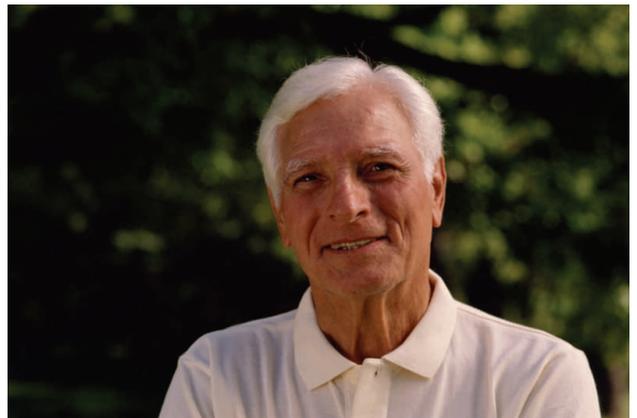
Source: Kaiser Daily Health Policy Report

US life expectancy hits 78 years

U.S. life expectancy has reached 78 years, a record high driven by declines in all but one of the major causes of death, the government reported Wednesday.

Despite the good news, the USA ranks 29th in life expectancy among the United Nations' member nations. Tops is Andorra, which has an average life expectancy of 83, followed closely by Japan, Sweden, Australia and Switzerland.

Source: USA Today



Albuterol inhalers: time to transition

Albuterol is a quick-relief medication that's used to open up the airways so that it's easier to breathe. The medication is used by people with certain airway diseases, such as asthma and chronic obstructive pulmonary disease (COPD), a group of lung diseases that includes chronic bronchitis and emphysema.

One method of delivering albuterol is the metered dose inhaler, a hand-held device that delivers a specific amount of medication directly into the lungs. Traditionally, inhalers have contained chlorofluorocarbons (CFCs), a type of propellant that helps the albuterol reach the lungs. But inhalers with CFCs are being phased out because they are harmful to the environment.

Here are facts you should know about switching from your CFC-propelled albuterol inhaler to inhalers that contain propellants called hydrofluoroalkanes (HFAs).

CFCs DEplete THE Ozone Layer.

CFCs deplete ozone high up in the stratosphere—the part of the earth's atmosphere that protects us from the sun's harmful ultraviolet radiation. In the stratosphere, the ozone layer serves as a shield that absorbs ultraviolet radiation and keeps it from reaching the earth's surface. CFCs are among the substances that damage the ozone layer. This leads to higher levels of ultraviolet B radiation, which has negative effects, including increases in skin cancers and cataracts. Under an international agreement, the United States, along with almost all countries of the world, agreed to phase out CFCs and other ozone-depleting substances.

CFC-Propelled Albuterol Inhalers Will No Longer Be Available After Dec. 31, 2008.

In accordance with an FDA Final Rule and under the authority of the Clean Air Act of the U.S. Environmental Protection Agency, no CFC-propelled albuterol inhalers can be produced, marketed, or sold in the United States after Dec. 31, 2008. Manufacturers have been increasing production of HFA-propelled albuterol inhalers so that sufficient supplies exist to replace the CFC-containing inhalers. If you haven't done so already, you should talk with your health care professional about switching to an HFA-propelled albuterol inhaler.

Albuterol Inhalers Containing

HFAs Deliver the Same Medicine, But There Are Some Differences. The HFA-propelled albuterol inhalers are still convenient and have been shown to be safe and effective in studies with patients. But you may find that the spray from an HFA inhaler tastes and feels different than the spray from the CFC-propelled albuterol inhalers. The spray from an HFA inhaler may feel less forceful, but this does not mean that the medication is not working.

Cleaning and Priming Your HFA Inhaler Are Especially Important.

Cleaning and priming helps prevent medication build-up and blockages, and ensures that the inhaler works properly. Priming an inhaler involves shaking it well and then releasing test sprays into the air. Be sure to hold the inhaler away from your face so that you don't get medication in your eyes. Each inhaler has specific instructions for cleaning and priming that you should follow. Refer to the patient information that accompanies the product.

Four Alternative HFA-Propelled Inhalers Are Approved by FDA.

There are four products available that can be used to replace your CFC-propelled albuterol inhaler:

- Proair HFA Inhalation Aerosol (Ivax Corp.)
- Proventil HFA Inhalation Aerosol (Schering-Plough)
- Ventolin HFA Inhalation Aerosol (GlaxoSmithKline)
- Xopenex HFA Inhalation Aerosol (Sepracor)

While they have all been shown to be effective, there are some differences between the products. You may need to talk with your health care professional and try different inhalers to find the product that is right for you.

For More Information

Metered Dose Inhalers (MDIs)

www.fda.gov/cder/mdi/default.htm

FDA Safety Update: Asthma Medications

www.fda.gov/consumer/updates/asthmameds051308.html

FDA's web page on Eliminating Ozone-depleting Substances from Metered-Dose Inhalers

www.fda.gov/cder/mdi/albuterol.htm

Source: FDA

Medicare Part D patients may apply for selected medications through patient assistance programs

AMGEN: Sensipar and Enbrel only
ASTELLAS PHARMA: Prograf only
EISAI: Aricept only
ELI LILLY: Zyprexa, Forteo and Humatrope only through Lilly Medicare Answers
GENZYME: Renagel only through Renagel Part D PAP
LIGAND: Only if drugs are not in patient's Part D Plan
ORTHO-BIOTECH: Only if drugs are not in patient's Part D plan
SHIRE: Fosrenol, only if drug is not in patient's Part D plan
TAP: Prevacid only
VALEANT: only if drugs are not in patient's Part D plan; Part D enrollees ineligible for Infergen PAP

All Medicare patients may apply for prescription assistance programs with the following companies:

ABBOTT
ALCON (Part D enrollees must submit a hardship letter)
ALLERGAN
ASTRAZENECA – Part D enrollees use AZ Medicines & Me
BISTOL MYER SQUIBB

BERLEX/BETA SERON FND. (Cannot be LIS eligible)
CELGENE
CHIRON/TOBI- Part D enrollees may be eligible for product or co-pay assistance
DIGESTIVE CARE
EYTECH
GILEAD
GLAXOSMITHKLINE-Part D enrollees use GSK Access program
JOHNSON & JOHNSON
KOS
MERCK
MERCK/SCHERING PLOUGH
NABI (Cannot be LIS eligible)
NOVARTIS
PFIZER (Some medications may not be available to Part D enrollees)
PROCTER & GAMBLE (Cannot be LIS eligible)
SANOFI-AVENTIS (Appeal process for Medicare enrolled, financially-needy patients who have a life threatening condition confirmed by physician)
SCHERING-PLOUGH
TAKEDA
WYETH (Part D enrollees must submit a hardship letter or LIS denial letter)

Warning for Regranex—cream for leg and foot ulcers

On June 6, 2008, the Food and Drug Administration (FDA) announced that a boxed warning has been added to the label of Regranex Gel 0.01% (becaplermin). The warning addresses the increased risk of cancer death in patients who use three or more tubes of the product.

Regranex is a topical cream for treating leg and foot ulcers that are not healing in patients with diabetes. A boxed warning on a drug's label calls attention to serious or life-threatening risks.

WHAT IS THE BASIS FOR THE REVISED LABEL?

A study compared cancer incidence and cancer death among 1,622 patients exposed to Regranex to 2,809 otherwise similar patients who were not exposed to the product. Although the study showed no overall increase in cancer incidence among the patients exposed to Regranex, there was a five-fold increased risk of cancer death in the group exposed to three or

more tubes of the product.

WHAT IS FDA ADVISING IN REGARD TO REGRANEX?

In announcing this label change, FDA cautions health care professionals to carefully weigh the risks and benefits of treating patients with Regranex. The product is not recommended for patients with known malignancies (cancerous tumors). FDA urges health care professionals to promptly report serious and unexpected adverse reactions associated with Regranex to FDA's MedWatch reporting program. MedWatch reports may be submitted the following ways: online at www.fda.gov/medwatch/report.htm by returning the postage-paid FDA form 3500 (available in PDF format at www.fda.gov/medwatch/getforms.htm) to 5600 Fishers Lane, Rockville, MD 20852-9787; by faxing the form to 1-800-FDA-0178; or by phone at 1-800-332-1088.

Source: FDA

Beware of online cancer fraud

While health fraud is a cruel form of greed, fraud involving cancer treatments can be particularly heartless—especially because fraudulent information can travel around the Web in an instant.

"Anyone who suffers from cancer, or knows someone who does, understands the fear and desperation that can set in," says Gary Coody, R.Ph., the National Health Fraud Coordinator and a Consumer Safety Officer with the Food and Drug Administration's (FDA) Office of Regulatory Affairs. "There can be a great temptation to jump at anything that appears to offer a chance for a cure."

Medicinal products and devices intended to treat cancer must gain FDA approval before they are marketed. The agency's review process helps ensure that these products are safe and effective.

Nevertheless, it's always possible to find someone or some company hawking bogus cancer "treatments." Such "treatments" come in many forms, including pills, tonics, and creams. "They're frequently offered as natural treatments and 'dietary supplements,'" says Coody. Many of these fraudulent cancer products even appear completely harmless, but may cause indirect harm by delaying or interfering with proven, beneficial treatments.

"Advertisements and other promotional materials touting bogus cancer 'cures' have probably been around as long as the printing press," says Coody. "However, the Internet has compounded the problem by providing the peddlers of these often dangerous products a whole new outlet."

UNPROVEN 'REMEDIES,' FALSE PROMISES

Coody cites black salves as one of the fake cancer "remedies" that indeed have proven to be harmful. "Although it is illegal to market these salves as a cancer treatment, they are readily available online," he says.

The salves are sold with false promises that they will cure cancer by "drawing out" the disease from beneath the skin. "However, there is no scientific evidence that black salves are effective," says Janet Woodcock,

Director of FDA's Center for Drug Evaluation and Research (CDER). "Even worse, black salves can cause direct harm to the patient."

The corrosive, oily salves "essentially burn off layers of the skin and surrounding normal tissue," says Woodcock. "This is not a simple, painless process. There are documented cases of these salves destroying large parts of people's skin and underlying tissue, leaving terrible scars."

Another unproven "remedy" that has been hawked for decades is an herbal regimen known as the Hoxsey Cancer Treatment. "FDA has taken regulatory and enforcement action against this discredited course of therapy beginning in the 1950s," says Coody.

"There is no scientific evidence that it has any value to treat cancer," he adds. "Yet consumers can go online right now and find all sorts of false claims that Hoxsey treatment is effective against the disease."

RED FLAGS

Coody says that firms engaged in cancer treatment or prevention fraud often use exaggerated and bogus claims to promote these products. He adds that consumers should recognize the following phrases as red flags:

- "Treats all forms of cancer"
- "Skin cancers disappear"
- "Shrinks malignant tumors"
- "Non-toxic"
- "Doesn't make you sick"
- "Avoid painful surgery, radiotherapy, chemotherapy or other conventional treatments"
- "Treat Non Melanoma Skin Cancers easily and safely"

"Unproven claims are also found in unverified testimonials, research results, or even in product and website names," says Coody. He offers important points that consumers seeking cancer treatments should keep in mind:

- Always consult with your health care professional before starting a new treatment or adding one to existing therapies. "Some products may interact with your medicines or keep them from working the way they are supposed to," says Coody.

continued ...

- Understand the difference between fraudulent drug products and what FDA calls "investigational drugs." Investigational drugs undergo clinical testing to determine if they are safe and effective for their intended uses. Fraudulent products, on the other hand, are unapproved and typically have never been clinically tested or reviewed by FDA for safety and effectiveness. Marketing them is a violation of federal law.

"There are legal ways for patients to access investigational drugs," says Coody. "The most common way is by taking part in clinical trials. But patients can also receive investigational drugs outside of clinical trials in some cases." For more details on this, visit www.fda.gov/oashi/speedaccess.html.

AGENCIES TAKE ACTION

FDA and the U.S. Federal Trade Commission (FTC), in collaboration with other North American government agencies, have announced a new initiative to prevent these deceptive products from reaching consumers. Coody says that as part of the joint campaign, FDA and FTC have sent approximately 135 warning letters and two advisory letters to firms that market these products online.

The initiative originated not only from consumer complaints, he says, but also from a Web surf for fraudulent cancer products by FDA and members of the Mexico-United States-Canada Health fraud

Social Security officials call for numbers to be removed

Social Security Administration officials have requested that CMS take immediate action to issue beneficiaries new membership cards that do not include their Social Security numbers to address concerns regarding identity theft, the *New York Times* reports.

Medical identity theft is the fastest-growing form of identity theft, according to Byron Hollis, director of the antifraud department at the Blue Cross and Blue Shield Association. Most private insurers have removed Social Security numbers from their membership cards because many states forbid the inclusion of such information, the *Times* reports. SSA cannot prohibit CMS from including Social Security numbers on Medicare cards, but Congress could, according to the *Times*.

Clay Johnson, deputy director of the White House

working group (MUCH).

SIGNS OF HEALTH FRAUD

All consumers seeking information about any health product or medical treatment should be familiar with the following signs of health fraud:

- Statements that the product is a quick and effective cure-all or a diagnostic tool for a wide variety of ailments.
- Suggestions that a product can treat or cure serious or incurable diseases.
- Claims such as "scientific breakthrough," "miraculous cure," "secret ingredient" and "ancient remedy."
- Impressive-sounding terms, such as "hunger stimulation point" and "thermogenesis" for a weight loss product.
- Claims that the product is safe because it is "natural."
- Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results.
- Claims of limited availability and advance payment requirements.
- Promises of no-risk, money-back guarantees. Promises of an "easy" fix for problems like excess weight, hair loss or impotency.

Source: FDA

Office of Management and Budget, in a May 2007 memo to the heads of federal departments and agencies, wrote that CMS should develop plans to "eliminate the unnecessary collection and use of Social Security numbers within 18 months."

However, CMS Chief Operating Officer Charlene Frizzera said issuing new cards would be a "huge undertaking" and would require three years to plan the change and eight more years to completely reissue cards. She said that beneficiaries would be alarmed if the government began issuing new cards or changing individual identification numbers. "We don't want to scare them," she said. Medicare officials estimate that issuing new identification numbers would require \$500 million in computer changes.

Source: Kaiser Daily Health Policy Report