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CONSUMER NEWS

by Charles R. Whitt

FDA approves over-the-counter test system for "drugs of abuse"

The Federal Food and Drug Administration ("FDA") approved the first non-prescription test system for drugs of abuse. The test detects the presence of marijuana, PCP, amphetamines, cocaine, heroin, codeine and morphine in urine. The product is marketed as Dr. Brown's Home Drug Testing System, and is made by Personal Health and Hygiene Inc., of Silver Spring, Maryland. It will be available in drug stores, pharmacies and other places where over-the-counter products are sold.

"It is crucial for parents to talk openly with their children about the dangers of drug abuse," said U.S. Department of Health and Human Services Secretary Donna E. Shalala. "Parents also need access to the best medical information and drug-abuse counseling services. The approval of this test gives parents another option to consider to help ensure that their children remain drug-free."

The product consists of three components: (1) a kit for urine collection, storage and mailing; (2) a laboratory testing service; and (3) a results and referral service. The collection kit contains a paper cup for collecting urine

and two plastic tubes with screw-on lids into which the urine is poured for storage and shipping. The tubes are placed in a plastic pouch which is inserted into a bubble bag for mailing to a designated laboratory. Each kit has an identification number which is placed on the urine specimen, making it possible to obtain results anonymously. The kit also contains directions for use and for obtaining and interpreting results.

The designated laboratory is certified by the Substance Abuse and Mental Health Services Administration, the College of American Pathologists, and the Health Care Financing Administration. The lab evaluates the urine sample for possible tampering and then analyzes it for drugs of abuse. The screening tests used are cleared by the FDA. The lab then performs confirmation tests to minimize false positive reports and sends the results via computer to the company's results center. Results are available one to three days after the lab receives the sample.

To obtain their results, users call an 800 telephone number which is operated seven days a week and identify themselves by the identification number

Pizzeria Uno restaurant chain settles FTC charges

The operators of Pizzeria Uno, a nationwide restaurant chain, agreed to settle Federal Trade Commission ("FTC") allegations that their advertising of their thin crust pizzas as "low fat" was false and misleading. In settling the charges, the chain agreed not to misrepresent the existence or amount of fat or any other nutrient or substance in their pizzas or other food products

containing a baked crust. This was the FTC's first enforcement of an action involving nutrient content claims made by a restaurant chain.

"Millions of consumers are conscientious about the fat content of their food," said Jodie Bernstein, Director of the FTC's Bureau of Consumer Protection. "Whether selecting low fat foods at the grocery store or restaurants," she

said, "consumers expect nutrient content claims made for products to be true."

The FTC alleged that the Boston, Massachusetts-based Uno Restaurant Corporation and its subsidiaries, Pizzeria Uno Corporation and Uno Restaurant, Inc., promoted their "Thinzettas" line of thin crust pizzas in television commercials and print advertisements as "low fat." The ads

attached to the urine sample and instruction booklet. A "Personal Health and Hygiene" informs the user of the results by and gives information about the meaning of the test result and the potential for false positive and false negative results. If necessary, or upon request, the phone representative offers referrals for drug abuse counseling and medical assistance.

A positive result indicates that a drug of abuse tested for existed in sufficient quantity for detection in the urine. The FDA and the manufacturer recommend that test users who receive a positive test result, have questions about their results, or believe their results are inaccurate should consult a physician for further evaluation. Although standard laboratory testing is highly accurate in detecting drugs of abuse in urine, certain medicines and, in rare cases, certain foods may produce false positive test results, according to the U.S. Department of Health and Human Services. In rare cases, it is also possible that technical or procedural errors in the laboratory or other factors could interfere with test results. A negative result means that either the substances tested for are not present or that the quantity

is insufficient to be detected. Lapse of time following drug use or exposure is another factor that may cause a false negative test result.

The FDA based its approval of this product on several factors, including a review of scientific issues involved in the test system; sample stability; collection tube adequacy; effectiveness of labeling along with the availability of health representatives for conveying the meaning of test results and the limits of the procedure; and laboratory credentials and procedures to ensure accurate and reliable test results.

The marketing requirements for the home test systems are under review by the FDA and an interim policy is in effect for such tests. Under this interim policy, home tests for drugs of abuse may be marketed without FDA clearance if three criteria are met: (1) the laboratory conducting the testing uses FDA-cleared tests; (2) the laboratory is certified by the Substance Abuse and Mental Health Services Administration; and (3) the product has accurate labeling.

of misleading "low fat" thin crust pizza ads

included statements such as "great tasting low fat thin crust pizzas," and "[t]ry our ...8 new Lowfat Thin Crust Pizzas." According to the complaint, six of the pizzas in the line exceeded acceptable limits for low fat claims, with some pizzas contained up to 36 grams of fat per serving. The complaint also alleged that the claim these pizzas are low in fat was false and misleading.

To settle the FTC charges, Pizzeria Uno agreed to a consent order that prohibits misrepresenting the existence or amount of fat or any other nutrient or substance in any of its pizzas or "baked crust" food products. The settlement does not prohibit the restaurant chain from making representations that are specifically allowed by the Food and Drug Administration's food labeling

regulations. The consent agreement is for settlement purposes only and does not constitute an admission of a violation of any law; however, the FTC's final consent order carries the force of law regarding future actions, and each violation could result in a civil penalty of \$11,000.

Judge rules Medicare members are shortchanged

In what is being touted as a major victory for consumers, a federal judge in Tucson, Arizona ruled that Medicare beneficiaries who belong to health maintenance organizations (“HMOs”) are being “short-changed” on their rights to appeal certain grievances and are entitled to immediate hearings whenever they are denied medical services. The ruling potentially impacts more than four million people age 65 and over who currently belong to Medicare HMOs. The case, *Grijalva v. Shalala*, 946 F. Supp. 747 (D. Arizona 1996), was brought on behalf of Gregoria Grijalva, an Arizona woman, against the U.S. Department of Health and Human Services (“HHS”), which oversees Medicare.

In his decision, Judge Alfredo Marguez set forth minimum standards that HMOs must meet in notifying members of their appeal rights and in holding grievance hearings. He also called for a corrective-action plan to be drafted by attorneys for several dozen Medicare HMO members, who in 1993 filed a nationwide class-action suit alleging that the federal government did not respond to patients’ grievances in a timely manner. Each year, approximately 3,000 Medicare HMO members ask for federal review of coverage disputes, involving issues such as unapproved emergency-room visits, specialist referrals, and nursing home stays. Health plan officials contend that the number is a tiny percentage of the total

Warning labels now required on iron-containing drugs and supplements

The Federal Food & Drug Administration (“FDA”) recently set rules protecting children from accidental poisoning from iron-containing drugs and dietary supplements. Such products must now bear a warning label statement. In addition, products containing 30 milligrams or more iron per unit must be packaged as individual doses that limit the number of pills or capsules a child can consume. Despite present child-resistant packaging efforts, accidental iron overdosing is a leading cause of poisoning deaths in children under six years old. Since 1986, according to the FDA, over 110,000 incidents of children ingesting iron have been reported and 35 children have died.

Packages containing iron or iron salts for use as dietary iron supple-

ments or for therapeutic purposes must now display the following statement “in a prominent and conspicuous place set off by surroundings lines”:

‘WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.’

Most of the serious injuries have occurred with products containing more than 30 milligrams of iron per dosage unit, including most prenatal iron products, which are likely to be found in households with young

children. The FDA determined that requiring individually-dose packaging would limit the number of capsules or tablets a child could consume if the child accidentally gained access to the product. In 1978, the U.S. Consumer Product Safety Commission adopted regulations requiring iron-containing products with more than 250 milligrams of total iron per container be packaged in child resistant containers. However, in some reported poisoning cases, young children were left unattended with uncapped containers. The FDA, public health officials and industry groups hope the combination of the additional safety measures and increased public awareness will reduce the incidence and severity of pediatric child poisoning.

by HMOs on complaints

Medicare HMO membership because few members actually present serious complaints. The patients' attorneys assert that the complaint rates are artificially low because many members find the full grievance process too daunting or confusing to pursue.

In his ruling, Judge Marquez criticized the existing appeals procedure for Medicare HMOs, declaring that they "fail to secure minimum due process for beneficiaries" and that cases existed where health-plan members had to "guess at what evidence to submit for reconsideration of the claim." The HHS unsuccessfully sought to dismiss the suit, arguing that the Department was not responsible for the actions of HMOs which contract with

the federal government to care for Medicare patients. Judge Marquez, in rejecting the Government's argument, said that when HMOs denied services to Medicare patients their decisions amounted to government action; therefore, beneficiaries could not be denied without due process of law. Hence, at a minimum, a full notice of adverse decisions and a meaningful opportunity to challenge the denial of care is required. HHS declined to indicate whether it would appeal the ruling. It is possible that both parties may try to negotiate a set of guidelines for Medicare HMO members to appeal coverage disputes more quickly and efficiently.

Consumer Protection Safety Commission announces voluntary refund of Cabbage Patch Kids and recall of Maytag gas dryers

The U.S. Consumer Product Safety Commission ("CPSC"), in cooperation with Mattel, Inc. and Maytag Corporation, will withdraw a potentially hazardous toy from the market and recall thousands of malfunctioning older gas dryers. Both products were recently the target of consumer complaints alleging injuries and property damage associated with the products. The CPSC protects the public from the unreasonable risk of injury or death from 15,000 types of consumer products under the agency's jurisdiction.

In response to concerns related to its Cabbage Patch Kids Snacktime Kids dolls, Mattel Inc., working with the CPSC, voluntarily announced a refund program for all dolls purchased since Mattel introduced the toy in the fall of 1996. Mattel will offer consumers a full cash refund of \$40 and simultaneously withdraw the product from all retail shelves across the United States. Mattel will also discontinue all distribution of the Snacktime

Kids dolls. The company's action follows reports of people getting their hair and fingers caught in the mouths of the dolls; however, neither Mattel's nor the CPSC's testing of the doll identified any serious safety hazards associated with the product. As of January 1997, approximately 500,000 Cabbage Patch Kids Snacktime Kids dolls had been sold.

Additionally, Maytag Appliances, a business unit of Maytag Corporation of Newton, Iowa, agreed to inspect and repair up to 73,000 older gas dryers produced under the brands Magic Chef, Admiral, Crosley, Norge, and Signature. An electrical switch in the gas dryer can malfunction, resulting in the dryers overheating which poses a potential fire hazard. The recall does not include Maytag brand dryers. Maytag has received over 30 reports of dryer fires possibly caused by the switch malfunction. The company is inspecting and repairing the products at no charge to consumers.

FTC and FCC issue rules for 900 number services

The Federal Trade Commission (“FTC”) and the Federal Communications Commission (“FCC”) recently enacted rules protecting consumers against fraud and misleading advertising by 900 number services. The “900 Number Rule” is the general term used to describe a range of new guidelines setting forth minimum standards for marketing and advertising 900 number services. At a minimum, advertising for all 900 number services must now include how much the call will cost, what customers will get for their money, and what will happen should a billing dispute arise.

All print, radio, and television advertisements for 900 number services must include:

- (1) the total cost of the call if there is a flat fee;
- (2) if the call is charged by the minute, the per-minute rate, along with any initial minimum charge. If the length of the program is known in advance, the ad must also state the total cost of the complete program;
- (3) the range of fees if there are different rates for different options; and
- (4) the cost of any other 900 number to which the consumer may be transferred and any other fees the service might charge.

This information cannot be hidden in small print and the cost of the call must appear next to the 900 number in a print size at least half the size of that number. In a television ad, an audio cost disclosure must also be made. When dialing a 900 number costs more than \$2.00, the rules mandate that customers hear a free, introductory message or “preamble.” The preamble must briefly describe the service, the name of the company providing the service, and the cost of the call. The message must also state that anyone under age 18 needs parental permission to complete the call. Once this information is provided, consumers must be given three seconds to hang up without incurring a charge. The 900 Number Rule does not apply if customers have a pre-existing contractual agreement with an information service. If a prior contract exists, calls to the service —

and resulting bills — will not be subject to the Rule’s requirements. Credit card calls are also excluded. However, bills for such calls would be covered by the dispute resolution procedures of the Fair Credit Billing Act.

Billing Errors and Disputes

The 900 Number Rule also provides procedures for resolving billing disputes. For each 900 call made, the customer’s billing statement should include the date, time, and, for services that have per-minute rates, the length of the call. These charges must appear separate from local and long distance charges. A billing statement must also include a local or toll-free number for customers who have questions about pay-per-call charges. Under FCC regulations, the phone company cannot disconnect regular local or long-distance service if a customer does not pay a 900 number charge. However, the phone company can block the customer from making future calls to 900 numbers if legitimate 900 number charges are not paid. If an error appears on a bill, the customer’s statement is required to inform the person who to call or write to dispute the charge. In most cases, it will be the local or long-distance telephone company, but it can be the 900 number company or an independent firm that provides billing services for that company.

In addition, if a billing error is disputed, a 900 number service cannot charge the customer to investigate or respond to a billing dispute. No one can try to collect a disputed charge — or report it to a credit bureau — until the company handling the dispute either has corrected the error or explained its reason for not doing so. Companies that do not comply with these rules lose their right to collect up to \$50 of each disputed charge. In addition, consumers are also granted rights under the Fair Debt Collection Practices Act.

Sweepstakes and Federal Programs

The Rule also covers 900 number services that promote sweepstakes or offer information about government programs. For example, some services offer

to protect consumers

the chance to enter a sweepstakes and win a prize simply by dialing a 900 number and, in some cases, entering a code. The Rule requires ads for sweepstakes to state the odds of winning or how odds will be calculated.

Furthermore, the ad or preamble must say whether there is a way to enter the sweepstakes free of charge, how to enter, or how to get that information. Consumers should not have to call — and incur a charge — to enter. This provision does not apply to contests where a customer must demonstrate a skill, such as answering a question correctly.

Other 900 numbers provide information about federal programs even though they are not affiliated with a government agency. Such numbers could mislead some consumers; under the new rules, the ad and preamble must state that such services are not authorized, endorsed, or approved by a federal agency.

Children

The Rule essentially prohibits companies from promoting 900 numbers to young children. Some companies have promoted 900 numbers encouraging children to pick up the phone to talk to a cartoon character. The FTC's 900 Number Rule, prohibits companies from advertising or offering pay-per-call services to children under age 12 unless the services are truly educational in nature. Ads are directed to people under age 18 must state that parental permission is required to make the call. The preambles for all 900 number services must contain that statement.

Tool Free and Collect Calls

For toll free numbers, the Rule generally prohibits:

- (1) using 800, 888, or other toll-free numbers for pay-per-call services, unless there is a pre-existing agreement with the company or the person charges the call to a credit card;
- (2) connecting a party directly from an 800, 888, or other toll-free number to a 900 number; and
- (3) calling back collect if the customer dialed an

800, 888, or other toll-free number.

Under FCC regulations, pay-per-call services cannot make collect calls to customers if the charge would be more than — or in addition to — the regular long distance charge for the call. Services that do not impose this additional charge can call collect. However, a person cannot be charged for the call unless he or she clearly indicates that they will accept the charge.

Tips for Avoiding 900 Number Problems

To help protect yourself from scams involving 900 number services:

- (1) Deal only with reputable companies. Some companies or organizations sponsor 900 number services for opinion surveys, information, entertainment or other services. Before calling a 900 number, understand the cost of the call and the nature of the information or service.
- (2) Think twice before calling a 900 number for a “free” gift. Television ads, postcards and telemarketers may urge consumers to call a 900 number to get a “free” prize. However, the customer pays for the so-called free gift by making the 900 number call. The provider of the service usually makes money on a per-minute basis. Also, remember there is a charge for a 900 number call. Companies typically pay for most 800, 888, or other toll-free number calls.
- (3) Talk with children. Make sure that children understand they should not call 900 numbers without a parent's or an adult's permission. The phone company can block 900 number calls from a person's telephone and the FCC requires local phone companies to make blocking available — where technically feasible — for a “reasonable” fee. However, any subscriber with a new number can request free blocking within 60 days after service begins.