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HERE 'S THE STORY...

BY CHRISTIANA HERR

The muckraking journalists at the turn of the 20th century exposed the horrors of the food industry. Upton Sinclair's book, *The Jungle*, was intended to promote socialism, but instead made the public aware of the disgusting secrets of the meatpacking industry. After over a hundred proposed bills were denied, President Wilson finally signed the Food and Drugs Act in 1906. The act was first administered by the Bureau of Chemistry and prohibited adding any ingredients that would substitute for the food, be a health hazard, hide flaws and damage, or that were disgusting and unsanitary. Ingredients such as alcohol, cocaine, and heroine were required to be included in the labeling. In 1907, Wilson created the Board of Food and Drug Inspection to help enforce the act.

Although the Act of 1906 did improve food quality, there was much more that needed to be accomplished. Banbar, which was supposed to cure diabetes, and Wihide Exhaler, which was promised to cure tuberculosis, were some of the false cures that were being marketed that were not forbidden by law. Lash-Lure was a dye that blinded many women. Radithor, a tonic that caused slow and painful deaths, and Elixir Sulfanilamide, a drug that contained antifreeze and killed over a hundred people, caused people to become aware



that something needed to be done. The Food, Drug, and Cosmetic Act was signed into law in 1938 after people began pushing for changes in the old law. This new act allowed the FDA to make quality standards for foods, prohibited false therapeutic claims for drugs, and allowed the government to regulate cosmetics, inspect factories, control advertising, and regulate medical devices.

Later on, the Drug Abuse Control Amendments of 1965 gave the FDA increased control over amphetamines, barbiturates, hallucinogens, and other dangerous drugs. By the 1960's over half of the food products had to meet certain qualifications and the FDA developed lists of what could and couldn't be added to foods. The nutrition label was also enforced and foods were required to state if they were imitations. In the seventies, the FDA became part of the Public Health Service and was given several more responsibilities. Today, the FDA is working hard to insure safe food, cosmetics, and medical drugs and devices and making decisions on such things as whether they should allow products from cloned animals. The FDA plays a vital part in making sure that Americans receive only the best when it comes to food, makeup, and medicine. All Americans should be thankful for this organization that protects their health and well being. ●

Inside the FDA's CFSAN

BY LISA FONG

Almost everything you have consumed today has been thoroughly checked by the FDA's Center for Food Safety and Applied Nutrition (CFSAN). 80 percent of all goods consumed in the United States—the entire food supply except for meat, poultry, and some egg products—is checked by CFSAN. It is responsible for the safety of food and color additives, proper labeling of foods, health claims, the safety of dietary supplements, infant formulas, and medical foods, and the development of sound international food standards. This immense organization does so much good for consumers by trying to prevent and cure sickness and diseases. Many people should be gratified to have an organization that genuinely cares for their health.

Center for Drug Evaluation and Research (CDER) is the largest of FDA's five centers, with a staff of about 1,800. It has responsibility for both prescription and over-the-counter drugs. Besides evaluating new drugs, CDER also promotes the public health by regulating the manufacture, labeling and advertising of drug products. The center's job is to seek to market a drug to test it and submit evidence that it's safe and effective. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the sponsor's new drug application containing the data and proposed labeling to make sure it's safe for



consumers to use. With the numerous amount of staff members, the FDA is reliable to thoroughly examine and investigate food and drugs well. They would want to be certain that their results are accurate and organized. Consumers can depend on the FDA for safe and reliable products.

The FDA is not only accountable for the safety of food and drugs, but also for the safety and proper labeling of cosmetics which is the responsibility of the Office of Cosmetics and Colors (OCAC). Millions of men and women who use lotion, hair dyes and hairspray bottles, nail products, sunscreens, eye products, and tanning products, and who wear contact lens, and tattoos, count on the OCAC to produce secure cosmetic products. Most of the time, cosmetics do not harm the skin and hair. However, there are incidences of allergic reactions and skin irritations.

Without the FDA to study new drugs and devices in clinical trials, the development of new health-care products would plummet. There won't be a secure knowledge that the food and drugs people consume are not dangerous. Without a law requiring companies to attach warning and nutrition labels on their products, people would not know the ingredients and harmful effects that may take place when the products are consumed. New diseases, illnesses, and deaths would take place if the FDA did not take charge. Each and every person is affected by the FDA. ●

DOUBLE TROUBLE

BY CHRISTIANA HERR



Is it healthy to eat meat from cloned animals? The Food and Drug Administration with the aid of the National Research Council has begun to research this new idea and so far there has been no evidence that meat or milk derived healthy cloned farm animals is harmful, but this doesn't mean that they will allow it. The FDA hasn't yet researched what society thinks about this issue, but they have been encouraged to do so. It will be at least a year before the FDA comes to their decision on this subject, but meanwhile the farmers have voluntarily agreed not to sell anything products from cloned animals.

The FDA is continuing to research whether cloned animals are healthy themselves if products from cloned animals have the same nutritional value as those from non-cloned animals. Although cloned

animals should be no different than normal animals, the technology to clone them is not yet advanced enough to always prevent birth defects. When cloned animals do not have birth defects, they are almost indistinguishable from non-cloned animals.

If the FDA cannot find anything harmful about products from cloned animals, they may not have the authority to stop the sale of cloned products. The way consumers respond to the idea of cloned products will have the most influence on whether scientists want to invest more money in cloning animals. Even if the FDA declares the products are safe, cloned animal products may not end up being sold if they are not bought. However, the FDA may not require companies to identify cloned products so that the public will not know the difference and cloned products will be successful.

There have been several criticisms of the FDA's research that found nothing wrong with

cloned products. The Consumer Federation of America and the Veterinary Medicine Advisory Committee are among those who doubt that the subject has been researched well. Because the first cloned mammal, the sheep named Dolly, was cloned less than 10 years ago, there hasn't been enough time for more than a couple hundred cattle to be made. Only the healthy cloned cattle have been studied because the deformed ones will never be allowed to be made into food. The research group only performed medical tests on the cloned animals, and did not study their meat. It is not likely, however, that we would be eating cloned meat anytime soon because each cloned animal costs at least \$20,000, but we might be eating their milk products and their offspring in the near future. Besides, since there is no benefit from cloned animal products, why bother? ●



ARE CELL PHONES REALLY SAFE?

BY JASON POPE



WITH THE GROWING POPULARITY OF cell phones, people are now questioning the long term affects of cell phone usage. Cell phones emit a small amount of RF (radiofrequency energy). RF energy can be very dangerous in large amounts and it is present in many devices in the home like, cordless phones, microwaves, cell phones, and wireless networks. The FDA is in charge of ensuring that these devices don't threaten the safety and health of consumers. They have set up limits of RF exposure called SAR (specific absorption rate) which is the amount of RF energy every pound of tissue can be exposed to in one year. The limits in the US are markedly smaller than European countries.

FDA and FCC say "The available scientific evidence does not show that any health problems are associated with using wireless phones. There is no proof, however, that wireless phones are absolutely safe." There have been many conflicting findings. Some scientists have discovered that cell phone usage increases the risk for cancer, tumors, and brain damage while some have actually reported benefits.

Three years ago, the Stewart Report (available at www.iegmp.org.uk) concluded that there was no evidence linking mobile phones to ill health, but that we should be cautious in our use of them until further research has been completed.

However, the latest reports claim that prolonged use of mobile phone handsets destroys cells in areas of the brain important for memory, movement and learning, and that this could cause premature onset of illnesses linked to ageing.

Yet another report in a series of worrisome, but inconclusive, studies suggests that cell phone use may cause neuron damage. Just two hours of exposure to radio signals from cell phones caused cells in three areas of rats' brains to die.

The three affected areas were the cortex, which plays a role in high-level mental function; the hippocampus, which is important in learning; and the basal ganglia, which plays a role in the experience of sensation.

Researchers say that the study doesn't conclusively demonstrate that cell phone use is harmful to humans, but they do recommend that people use hands-free devices to keep their



cell phones as far from their brains as possible.

The scientists added in their report that the rise in the use of cell phones is a "huge biological experiment."

A technology research group in Amsterdam released the results of a study that sought to determine the health risks of exposure to 3G (3rd generation) mobile base stations. So far, the group is emphasizing its negative findings: that 3G may cause headaches and nausea. However, the same study revealed that 3G signal exposure may also improve memory and response reflexes.

Officials in Finland say that the increasing use of mobile phones has helped to curb the nation's suicide rate.

One scientist told FDA Consumer magazine that he believes there is no risk of cancer even for a person speaking hours a day on a cell phone. "Go right ahead," he said, "but please, please, please don't use it while driving. That is dangerous." ●

RECOMMENDATIONS

A solid answer to the question of whether cell phones are safe won't be known for years. If you are concerned, you can follow these precautions:

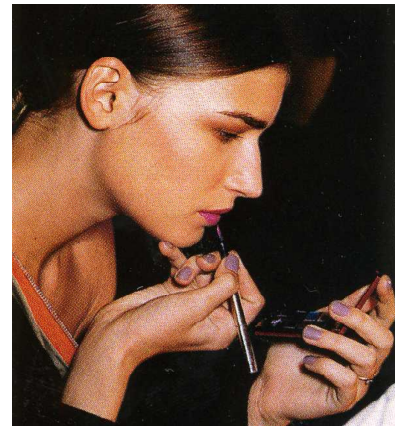
- * Use a headset. It can keep the phone's antenna away from your head and body. But it's not necessary to buy shields that claim to reduce exposure. Such products generally don't work as advertised, say the FDA and FCC.
- * Limit use by children and teens. Encourage them to wear a headset or to send text messages (that keeps the phone away from the head).
- * Use the phone prudently. Do you, for example, really need to order that pizza while standing on a street corner?

Are There Any Risks in Using Cosmetics?

BY LISA FONG

Many consumers question the safety of makeup, lipsticks, foundations, and hair and nail products, yet a majority of them use cosmetic products to enhance the attractiveness of their face, hands, or hair. Can Cosmetics be harmful to the skin? Are shiny hair, glossy lips, and flawless-looking skin worth any risk at all?

Most people would agree that they have little concern about the dangers of cosmetics. After all, these products have been tested and used for decades without serious cause for



the product and find out what ingredient caused the reaction or irritation to stay away from other products with the same ingredient. If the consumer has an acute allergic reaction, he/she should see a doctor immediately.

The FD&C Act requires the cosmetic labels to state the name and place of business of the manufacturer, packer or distributor; an accurate statement of the quantity of contents; and any appropriate directions for safe use and/or warning



concern. One would think that the high rates of cosmetics sold and used would prove that even small injuries from makeup doesn't prevent consumers from buying it.

Fortunately, severe injury from using cosmetics is rare and doesn't happen often. Even reports of the most serious problems, eye infections from contaminated mascara wands, have stopped since January 1989. Most cosmetic complaints are either allergic reactions or skin irritations, which the FDA can't do much about. The consumer should avoid

statements. This law helps consumers better select safe cosmetics.

Even though it is the individual's responsibility to evade products that give him or her allergic reactions or irritation, the person should still report any problems he or she encounters with cosmetics. If the FDA sees many complaints for one product, the agency has reason for concern. ●

WATCH OUT FOR THOSE TRANS...

BY CHRISTIANA HERR

Starting January 1, 2006, it is required that all food labels and some dietary supplements contain trans fat on the nutrition label. It has been scientifically proven that trans fatty acids produce cholesterol and lead to CHD (Coronary Heart Disease), a leading cause in death. The FDA has required saturated fats and dietary cholesterol to be on the Nutrition Facts since 1993 and now they are requiring that trans fatty acids be posted as well. This new addition to the label will hopefully help thousands of Americans that are trying to prevent CHD and those that simply want to be healthy.

How is trans fat different from other fat? Trans fat is made when hydrogen is added to the fat chain in a process called hydrogenation. Trans fatty acids are called trans because the hydrogen atoms end up on opposite sides of the carbon chain. The new configuration of atoms makes it more difficult for the fat to be broken down by the body. When fat is not easily broken down, it begins to clog up the blood vessels and this may lead to a stroke, a heart attack, or even death.

The only people that could possibly be opposed to this law are managers of food companies who now have to print new labels and whose food is high in trans fatty acid. However, they do have until 2006 to do so which would give them time to use up their old labels, make new ones, and possibly alter the contents of their products to reduce the trans fatty acids. It is expected that many companies will make their products slightly more healthy. Those who enjoy eating unhealthy products have no right to complain about the new law because they can choose not to read the label. This law is a true blessing for those who need to watch their diet and hopefully will help prolong lives. ●

NUTRITION

**NEW
NUTRITION
LABEL TO GO
INTO EFFECT
ON JANUARY 1.**

Healthy Tips

Check the Nutrition Facts panel and choose foods lower in saturated fat, *trans* fat, and cholesterol.

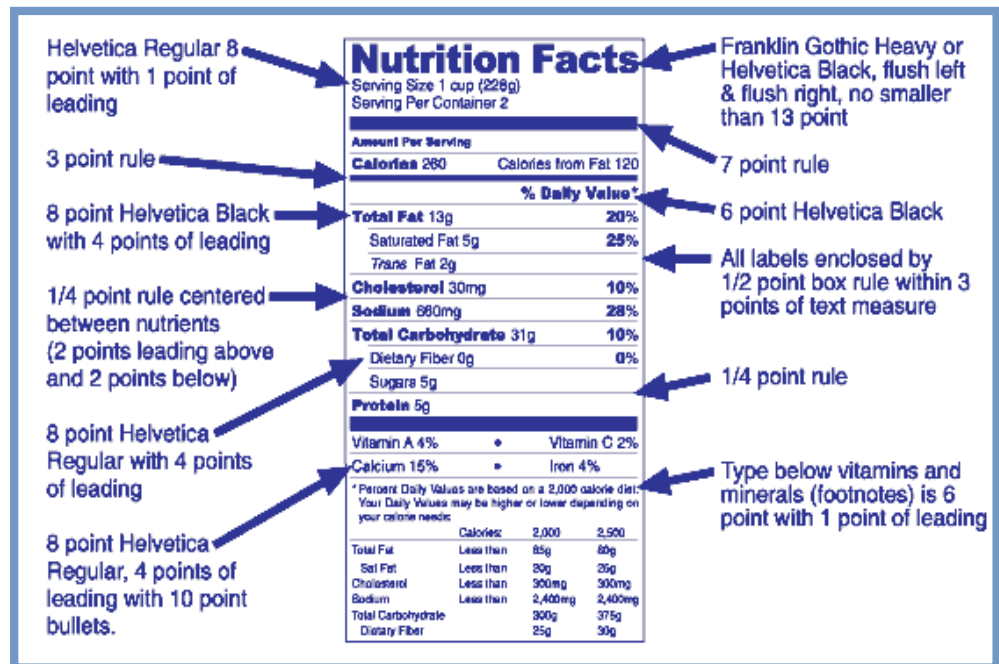
Compare the percent of the daily value (%DV) and stay away from foods that are over 20%. The trans fat does not yet have a (%DV).

Instead of saturated and *trans* fats, choose monounsaturated and polyunsaturated fats. Nuts and fish contain good fats.

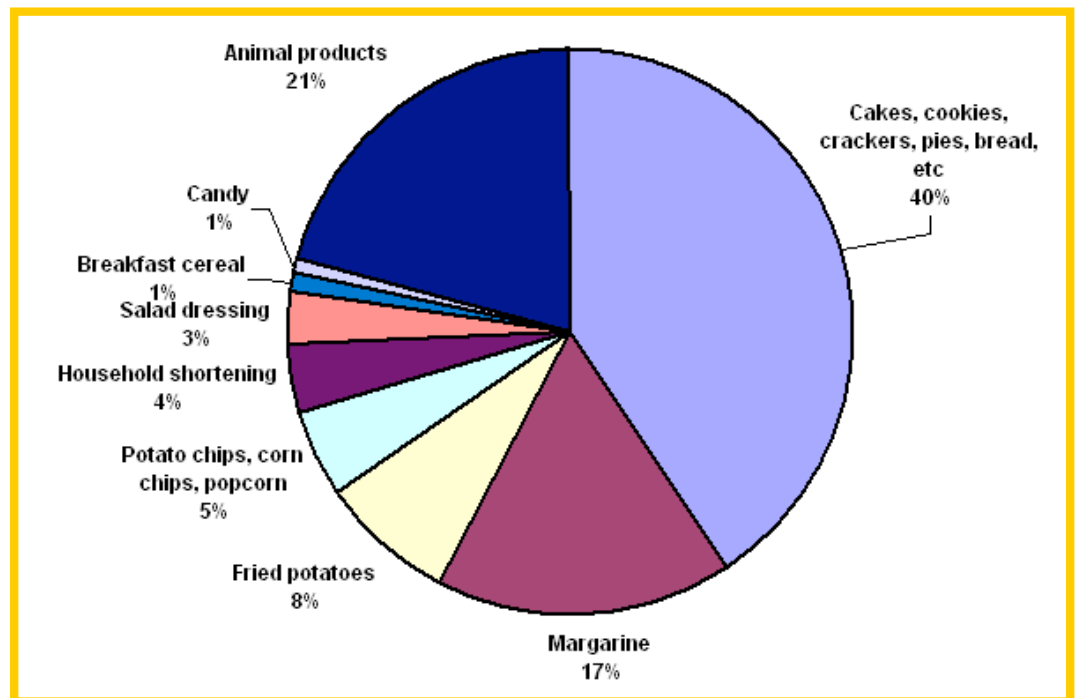
Choose vegetable oils and soft margarines instead of the alternatives which are high in saturated fat, *trans* fat, and cholesterol.

When you eat out, ask what type of fats are being used in your meal.

Remember that fats have 9 calories per gram whereas proteins and carbohydrates only have 4. ●



MAJOR SOURCES OF TRANS FATTY ACIDS



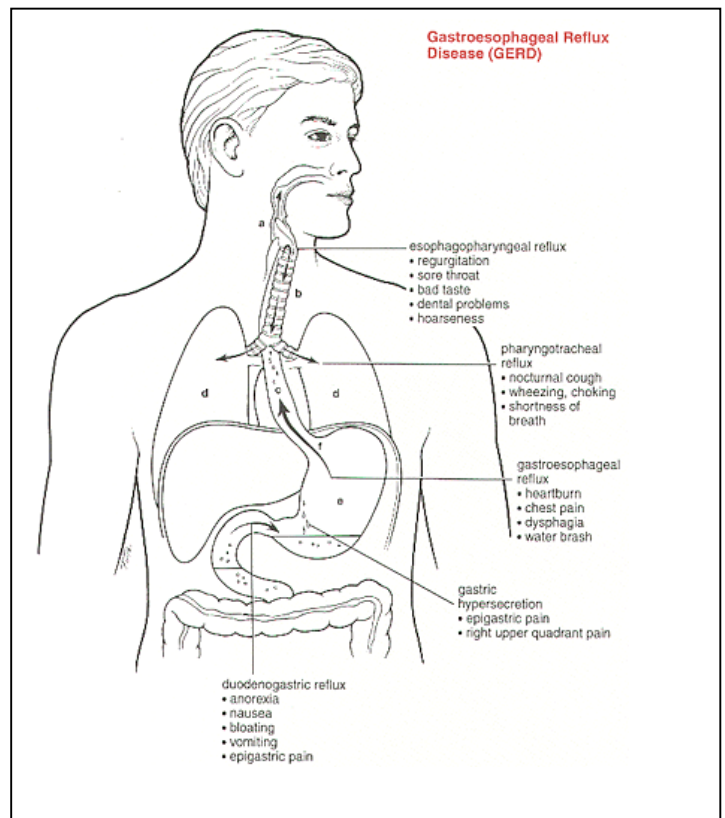


GERT

BY JASON POPE

Gastroesophageal reflux disease, or GERD, causes frequent heartburn and more than 60 million Americans have GERD and about 25 million of them have daily symptoms. A permanent implant, called Enteryx, that can free patients from the bondage of taking daily medications to fight acid

reflux disease, was developed and now has been approved by the FDA. The implant is a liquid solution containing a solvent that solidifies into a sponge-like material in the muscular valve between the esophagus and stomach. The purpose is to reinforce the valve preventing stomach acid from flowing in to the throat and causing heartburn. The FDA said that the device has been found to help reduce or eliminate the need for medications, and to improve the symptoms of GERD. In a 12-month study of 85 patients, about two-thirds were able to discontinue use of medications known as proton pump inhibitors, and 9 percent could reduce the dose by at least half, the FDA said. Seventy-two percent said their symptoms improved when compared with taking no medications prior to the implant. Some names of Proton pump inhibitors are AstraZeneca, Prilosec, Nexium, and Prevacid. The FDA approved Enteryx for use in patients who have GERD symptoms and who require and respond to proton pump inhibitors. This implant may be the answer to many of GERD patients prayers. ●



NEW DRUG FOR PROSTATE CANCER APPROVED

BY LISA FONG

A deadly disease, prostate cancer takes the lives of about 30,000 men every year, and 200,000 new cases are diagnosed each year. These high numbers give worry and concern to many men and their families. Fortunately, Plenaxis was approved Nov. 23, 2003, by the FDA for advanced prostate cancer to treat patients who have no alternative therapy. Designated for men with advanced prostate cancer who cannot take other hormone therapies and who have refused surgical castration, the drug will be marketed under a voluntary risk management program. One would think that plenaxis could be given to any man. However, it is restricted to those patients with advanced, indicative prostate cancer and who do not have other treatment



options because of this increased risk of serious allergic reactions.

How does this miraculous drug work?

Plenaxis lowers the male hormone testosterone, a significant factor involved in prostate cancer growth. Patients could avoid surgery by going through at least twelve weeks of treatment. Because surgery is risky, one would think that treatment is the better alternative of the two.

The process of administering Plenaxis is an injection in the muscles of the buttocks every two weeks for the first month, followed by once every four weeks afterward. Doctors perform blood tests every



two months to make sure Plenaxis is working by keeping the level of testosterone low. The most common side effects of Plenaxis are sleep disturbances, pain, constipation, and hot flashes. It is probably worth going through these side effects in order to kill the cancer. One would rather endure the pain than to possibly die from the cancer.

It is remarkable what a tiny pill or shot of fluid can do for the human body. It can exterminate a virus, prevent sickness, or restrain an ailment. By just knowing that there is a treatment to a deadly disease gives patients hope to be cured. People are so fortunate and blessed to have a profusion of drugs that can cure the most fatal diseases. ●

A LOOK INTO THE FUTURE...

BY LISA FONG



Each year, the FDA focuses on several different topics to help better educate the public about the agency's concerns about drugs and food. This year, the agency will be focusing on 1) risk management, 2) improving health through better information, 3) improving patient safety, 4) protecting America from Terrorism and 5) more effective regulation through a better workforce.

"The agency is also in the midst of campaigns to teach the public about Trans Fat, Using Labels to make better food choices, making better decision about menopausal hormones, weight management, diabetes, and reporting of adverse reactions and problems products through Medwatch and CAERS," says Laurel Eu, a

Public Affairs Specialist for the Los Angeles District of the U.S. Food and Drug Administration.

Regulating a broad spectrum of products, the FDA will soon have to take up a significant responsibility of approving new medications for the most unusual treatments to enter the market. The branch of the FDA who will approve these medications is the Center for Biologics Evaluation and Research (CBER). CBER regulates biological products for disease prevention and treatment that are more complex than chemically synthesized pharmaceuticals.

The biomolecular treatments include cellular replacement therapies, animal organ transplants, and cellular and tissue transplants, in which stem cell therapy is used to restore damaged tissue.

Additional intricate and exciting areas of biomedical research are human gene therapy which is designed to alleviate human diseases by transferring normal versions of genes into the affected cells, and xenotransplantation, in which organs, tissues, or cells from animals such as pigs are transplanted into patients.

CBER's scientists are also prepared to evaluate the safety and effectiveness of new vaccines and new vaccine technologies against diseases such as AIDS, malaria, TB, and chronic illnesses. Once approved, these new vaccines will be in great demand with the public because of the rising percentage in the number of people with these diseases. Hopefully before long, CBER will look over and approve the drugs and treatments and release it to the public. ●



OPINION

Concerning the article, “A Look into the Future...,” I applaud the FDA for including “improving health through better information” in this year’s focus. I am glad that they are going to teach the public about Trans Fats that are harmful to the body and consumers to watch their weight and what they eat. However, if an overweight person is comfortable with his or her weight, he or she shouldn’t be pressed to lose weight or change their eating habits. An organization can only do so much to help people improve their health.

More consumers would be influenced by the FDA’s involvement with their physical condition than by their friends and family because the FDA has infinitely more insight and

authority over the effects of food and drugs. I am so thankful that the USA has this organization to watch over the health of the American people. –Lisa Fong

I don’t believe cell phones are really a threat. They have been in use for over 15 years and have only become “safer” in those years, due to regulations. There has been no concrete evidence that links cell phone usage to any disease or illness. Since, there is no link to any problems people should use their cell phones with caution. Use hands-free devices, and try not to use your phone in unnecessary situations. Cell phones are a threat in that they are a distraction to drivers.

–Jason Pope

Regarding the article “Double Trouble,” I am pleased that the FDA plans to do more research on whether they will allow food

products from cloned animals to be sold. Personally, I don’t have a problem with eating cloned food, but I know that there are people who don’t understand that cloned may be just as nutritious as regular food. The FDA should require that cloned products be labeled as such. There has been much money poured into making clones, and I don’t understand the point other than to accomplish a great scientific feat. Even if products from cloned animals are just as good as normal products, they still are not better and are far more expensive. It would be best if scientists diverted their efforts and their funding elsewhere. – Christiana Herr

After researching about the FDA we conclude that it has truly made a positive impact on the health of Americans and will continue to do so. – All editors

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In case you haven't heard ... (Brief Article)
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YAKKETY YAK. (wireless phones and health risks research) Dan O'Shea.
5. *Wireless Week*, May 15, 2003 v9 i11 p18(1)
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