INFOTECH

Getting under Your Skin

REGULATORY QUESTIONS ABOUT IMPLANTABLE CHIPS PERSIST **BY DAVID APPELL**

When identification microchips were implanted in members of the Jacobs family on the *Today* show last May, George Orwell's surveillance society seemed to be another step closer. But confusion over the chip's medical status and even safety, among other stumbling blocks, has left many wondering if the era of the embedded human ID really is at hand.

For several months, Applied Digital Solutions (ADS) in Palm Beach, Fla., has been offering an integrated chip, called the VeriChip, that is about the size of a grain of rice and is injected beneath the dermal layers. Operating just like those in millions of pets, the chip returns a radio-frequency signal from a wand passed over it. The chip can serve as basic identification or possibly link to a database containing the user's medical records. ADS is also planning a chip with broadcasting capabilities—a kind of human "lojack" system that could signal the bearer's GPS coordinates, perhaps serving as a victim beacon in a kidnapping.

As of mid-November 2002, 11 people in the U.S. and several people overseas had been "chipped," says ADS president Scott R. Silverman. But the company ran into problems after the VeriChip's May rollout. Because ADS had said the chip data could be transmitted to an "FDA compliant" site, the Food and Drug Administration insisted on taking a closer look. (Adding to ADS's woes, stockholders filed class action lawsuits alleging that ADS had falsely claimed that some Florida-area hospitals were equipped with scanning devices. And the company's stock price, which rose by almost 400 percent last April and May, tanked last summer and was delisted from the Nasdaq.)

On October 22, 2002, the FDA somewhat surpris-

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FAST FACTS: CHIPS, ANYONE?

Some features of Applied Digital Solutions's VeriChip:

- **12 millimeters long by 2.1 millimeters wide**
- **Encased in glass**
- **Special polyethylene sheath bonds to skin**
- **Cost of being "chipped": $200**
- **Expected lifetime: 20 years**

ingly announced that the VeriChip would not be considered an FDA-regulated device if it were used for "security, financial, and personal identification/safety applications." But it is a regulated medical device "when marketed to provide information to assist in the diagnosis or treatment of injury or illness." The FDA's Office of Compliance is now studying what will be required in the latter case.

Many question the FDA's decision not to regulate the implant fully, because some research suggests that it is not completely safe in animals. A 1990 study in the journal *Toxicologic Pathology* by Ghanta N. Rao and Jennifer Edmondson of the National Institute of Environmental Health Sciences in Research Triangle Park, N.C., reported that a subcutaneous tissue reaction occurred in mice implanted with a glass-sealed microchip device (not unlike the VeriChip). No problems were seen in the 140 mice studied after 24 months, except in those mice that had a genetic mutation in their *p53* gene. In that case, if the device was kept in too long, "these mice develop subcutaneous tumors called fibrosarcomas," Rao says.

HOLD STILL: Like millions of other pets before it, a Labrador mix has a tracking device implanted under its skin. Humans are getting chipped as well.

In humans, the corresponding *p53* mutation causes Li-Fraumeni syndrome, a rare disorder that predisposes patients to a wide variety of cancers. Rao sees reason for caution: "More evaluation may be necessary before they are used in humans."

Implanted microchips may not be so stable under the skin either, according to a 1999 paper in the *Veterinary Record* by Jans Jansen and his colleagues at the University of Nijmegen in the Netherlands. Jansen found that in just 16 weeks chips inserted in shoulder locations of 15 beagles had moved, a few by as much as 11 centimeters. (Transponders implanted in the dogs' heads, however, hardly moved at all.) An inflammatory response is also a risk, Jansen observes, similar to what is sometimes seen with other devices implanted in humans. "I'm not claiming it's not safe," he says, "but you have to be completely sure it will not damage patients in the end."

ADS insists that the implanted chips are safe. The bulk of that evidence "obviously lies with the animal application," Silverman remarks. Other research, such as that reported in 1991 by the Sandoz Research Institute in East Hanover, N.J., found no adverse reactions in rats, although the rodents were observed for only a year. Still, more than 25 million dogs, cats, racehorses and other animals have been chipped without reports of significant problems. Silverman also points out that "no side effects or ramifications whatsoever" have come to those people who received chips in May, including himself and other company executives.

Since the FDA's partial ruling, ADS has signed up distributors in Latin America, Europe and China and has four hospitals in Florida testing the scanners now. Silverman says that the firm has received inquiries from "several hundred people" interested in getting chipped. The procedure can take place at a doctor's office or in ADS's "Chipmobile"; it was scheduled to begin this past December.

The VeriChip faces other hurdles as well. Unless a substantial fraction of the population is chipped, hospitals may not bother installing scanning devices; if that's the case, what good is being chipped? And, of course, the chip introduces the potential for unsolicited surveillance and various privacy violations, a possibility that makes many people's skin crawl, even without a chip under it.

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SILICON STITCHING

Uses for implantable devices may go far beyond those envisioned for the VeriChip. British engineers are experimenting with a "tooth phone," a chip implanted in a tooth. Futurist Ian D. Pearson of BTexact Technologies in Adastral Park, England, foresees circuitry tattooed into the skin. Such "active skin" would display television pictures, serve as cosmetics, provide a virtual-reality interface without data gloves or goggles, or even—in the ultimate in cyber-isolation—deliver orgasms by e-mail.

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