

s the popularity of tattoos continues to grow, so does the concern about potential risks. Some risks, such as the spread of infections through the use of unsterilized needles, have long been known. But what isn't clear is the safety of tattoo inks.

- 1. No tattoo ink pigments have been FDA approved.
- 2. Tattoo removal is time consuming, costly, and doesn't always work.
- 3. Don't use do-it-yourself tattoo removal products.
- 4. Consult your health care provider, not a tattoo parlor, about tattoo removal.
- 5. Don't avoid an MRI if you need one.

Photo by Madoka Yamakawa for FDA

Permanent tattoos are made by using needles to inject colored ink below the skin's surface. Permanent make-up is considered a permanent tattoo that mimics the results of cosmetic products such as an eyebrow pencil, lip liner, eyeliner, or blush.

While state and local authorities oversee the practice of tattooing, ink and ink colorings (pigments) used in tattoos are subject to FDA regulation as cosmetics and color additives. However, because of other public health priorities and a previous lack of evidence of safety concerns, FDA has not traditionally regulated tattoo

inks or the pigments used in them.

FDA has received reports of bad reactions to tattoo inks right after tattooing or even years later. Some people report itchy or inflamed skin around their tattoos in the summer when they've been out in the sun. Recent reports associated with permanent make-up inks have prompted FDA to study tattoo ink safety.

"Our hope is to get a better understanding of the body's response to tattoos and their impact on human health, and to identify products at greatest risk," says Linda Katz, M.D., M.P.H., Director of FDA's Office of Cosmetics and Colors in the Center for Food Safety and Applied Nutrition.

# What are the Risks?

- **Infection** Dirty needles can pass infections, like hepatitis and HIV, from one person to another.
- Allergies Allergies to various ink pigments in both permanent temporary tattoos have been reported and can cause problems.
- **Scarring** Unwanted scar tissue may form when getting or removing a tattoo.
- Granulomas These small knots or bumps may form around

- material that the body perceives as foreign, such as particles of tattoo pigment.
- MRI complications People may have swelling or burning in the tattoo when they have magnetic resonance imaging (MRI). This happens rarely and does not last long.

# Tattoo Ink Research

In a laboratory within FDA's Arkansas-based National Center for Toxicological Research (NCTR), research chemist Paul Howard, Ph.D., and his team are investigating tattoo inks to find out

- the chemical composition of the inks and how they break down (metabolize) in the body;
- the short-term and long-term safety of pigments used in tattoo inks;
- how the body responds to the interaction of light with the inks.

"There have been no systematic studies of the safety of tattoo inks," says Howard, "so we are trying to ask—and answer—some fundamental questions." For example, some tattoos fade over time or fade when they are exposed to sunlight. And laser light is used to remove tattoos. "We want to know what happens to the ink," says Howard. "Where does the pigment go?"

NCTR researchers are exploring several possibilities:

• The body cells may digest and destroy the ink, just as they rid the body of bacteria and other foreign matter as a defense against infection. NCTR studies show that a common pigment used in yellow tattoo inks, Pigment Yellow 74, may be broken down by enzymes, or metabolized. "Just like the body metabolizes and excretes other substances, the body may metabolize small amounts of the tattoo pigment to make it more water soluble, and out it goes," says Howard.

- Sunlight may cause the ink to break down so it is less visible. NCTR researchers have found that Pigment Yellow 74 decomposes in sunlight, breaking down into components that are colorless. The pigment components may still be there, says Howard, and we don't know if these are potentially toxic.
- The skin cells containing the ink may be killed by sunlight or laser light and ink breakdown products may disperse through the body.

Research has also shown that some pigment migrates from the tattoo site to the body's lymph nodes, says Howard. Lymph nodes are part of the lymphatic system, a collection of fluid-carrying vessels in the body that filter out disease-causing organisms. Whether the migration of tattoo ink has health consequences or not is still unknown. NCTR is doing further research to answer this and other questions about the safety of tattoo inks.

# Tattoo Tips for Consumers

- FDA has not approved any tattoo pigments for injection into the skin. This applies to all tattoo pigments, including those used for ultravioloet (UV) and glow-in-the dark tattoos. Many pigments used in tattoo inks are industrial-grade colors suitable for printers' ink or automobile paint.
- The use of henna in temporary tattoos has not been approved by FDA. Henna is approved only for use as a hair dye.

### PERMANENCE \_

• Consider tattoos permanent. Removal is time-consuming, costly, and doesn't always work. The most common method of tattoo removal is by laser treatment, which delivers short flashes of light at very high intensities to the skin to break down the tattoo ink. FDA allows

- several types of lasers to be marketed for tattoo removal. Some color inks are harder to remove than others. Many repeat visits every several weeks may be required to remove a tattoo, and it may never be entirely gone.
- Do not buy or order online do-ityourself tattoo removal products.
  These acid-based products are not FDA-approved and can cause bad skin reactions.
- Consult your health care provider—not a tattoo parlor—if you want a tattoo removed. The American Society for Laser Medicine and Surgery (http://www.aslms.org/index.shtml) can help you find a doctor experienced in tattoo removal.

# DON'T AVOID AN MRI \_

• If you need to have an MRI done, don't avoid it. Inform the radiologist or technician that you have a tattoo so appropriate precautions can be taken.

This article appears on FDA's Consumer Updates page (www.fda. gov/ForConsumers/ConsumerUpdates), which features the latest on all FDA-regulated products.

# For More Information

Protect Your Health Joint FDA/WebMD resource www.webmd.com/fda

Tattoos and Permanent Makeup http://www.fda.gov/Cosmetics/ ProductandIngredientSafety/ ProductInformation/ucm108530.htm