save, rather than cost, money.[5] And residents of states that do not expand will still be paying federal taxes to cover the expansion in states that do expand.

Given the clear language of the Court's decision, the July 10 letter permits states to decide whether to accept funding to support the Medicaid expansion for newly eligible adults as a group or to reject it and with it hundreds of billions of dollars in much-needed federal assistance. But some states may press the administration to interpret the expansion as a simple state option, allowing them to cover some portion of the expansion group and not others. This approach has no support in the law and would invite states to leave the most vulnerable members of the expansion group — adults without children — exposed to the worst sort of discriminatory exclusion. The administration may be pressured to enter into negotiations with each state, using its waiver authority. The ACA specifically amended the Medicaid waiver process to ensure that it was used for genuine research, not political horse trading. One can only hope that the states will come to their senses and we all will be spared the spectacle of federal and state governments struggling over the lives and health of the poorest among us.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From Washington and Lee University School of Law, Lexington, VA (T.S.J.); and the Department of Health Policy, George Washington University School of Public Health and Health Services, Washington, DC (S.R.).

This article was published on July 25, 2012, at NEJM.org.

1. National Federation of Independent Business v. Sebelius, U.S., 2012 WL 2427810 (June 28, 2012).
2. 42 U.S.C. § 1304.
3. States of Florida, et al., v. United States. Petition for a writ of certiorari (http://acalitigation.wikispaces.com/file/view/States+cert+petition+%2809.29.11%29.pdf).
4. Letter from Kathleen Sebelius, Secretary of Health and Human Services. July 10, 2012 (http://www.scribd.com/doc/99753526/Secretary-Sebelius-Letter-to-the-Governors-071012).
5. Buettgens M, Dorn S. Carroll C. States would spend at least $90 billion less with the ACA than without it from 2014 to 2019. Washington, DC: Urban Institute, 2011.

DOI: 10.1056/NEJMp1208219

Tattoo Ink–Related Infections — Awareness, Diagnosis, Reporting, and Prevention

Pamela M. LeBlanc, M.P.H., Katherine A. Hollinger, D.V.M., M.P.H., and Karl C. Klontz, M.D., M.P.H.

Related article, p. 1020

Tattoos have become increasingly popular in recent years. In the United States, the estimated percentage of adults with one or more tattoos increased from 14% in 2008 to 21% in 2012.[1] The process of tattooing exposes the recipient to risks of infections with various pathogens, some of which are serious and difficult to treat. Historically, the control of tattoo-associated dermatologic infections has focused on ensuring safe tattooing practices and preventing contamination of ink at the tattoo parlors — a regulatory task overseen by state and local authorities.[2] In recent months, however, reported outbreaks of nontuberculous mycobacterial infections associated with contaminated tattoo ink have raised questions about the adequacy of prevention efforts implemented at the tattoo-parlor level alone. The Food and Drug Administration (FDA) is reaching out to health care providers, public health officials, consumers, and the tattoo industry to improve awareness, diagnosis, and reporting (through the MedWatch program) in order to develop more effective measures for tattoo ink–related public health problems.

In late January 2012, the FDA was notified, through MedWatch adverse-event reports,[3] of a cluster of patients in New York who had contracted nontuberculous mycobacterial infections manifested by red papules on the gray-colored areas of recently acquired tattoos (see photo and the article by Kennedy and colleagues in this issue of the *Journal*, pages 1020–1024). The FDA collaborated with local and state health departments and the Centers for Disease Control and Prevention to investigate the outbreak. Efforts to identify additional cases nationwide revealed that there were other outbreaks of tattoo ink–related nontuberculous mycobacterial infection that were associated with multiple brands of ink, occurred in other states, and involved multiple species of mycobacteria (e.g., chelonae, fortuitum, and abscessus).

Previously published reports of

Papules Associated with Tattoo Ink–Related Nontuberculous Mycobacterial Infection.
Photo by Matthew J. Mahlberg, M.D., Dermatology Associates of Colorado, Englewood, courtesy of Sarah Jackson, M.P.H., Colorado Department of Public Health and Environment.

tattoo-related nontuberculous mycobacterial infections suggested that tap water or distilled water used to dilute inks at tattoo parlors was a likely source of contamination.[4] Findings from the recent outbreak investigations, however, suggested that the inks were contaminated before distribution. During the response to the New York outbreak, the outbreak strain of mycobacteria was isolated from an unopened ink container. Thus, contamination could have occurred at various points in the ink-production process — for instance, from unsanitary manufacturing processes or the use of contaminated ingredients such as water, glycerin, or pigments.

Under the Federal Food, Drug, and Cosmetic Act, tattoo inks are considered to be cosmetics,[5] whereas the pigments used in the inks are color additives that require premarketing approval. This law requires that cosmetics and their ingredients not be adulterated or misbranded, which means, among other things, that they cannot contain poisonous or deleterious substances or unapproved color additives, be manufactured or held in unsanitary conditions, or be falsely labeled. Furthermore, cosmetic manufacturers are supposed to ensure the safety of a product before marketing it.

However, the FDA does not have the authority to require premarketing submission of safety data from manufacturers, distributors, or marketers of cosmetic products, with the exception of most color additives (dyes, pigments, or other substances used to impart color). The FDA does have the authority to take other actions to protect the public health. For example, the agency can conduct investigations, request that a manufacturer recall violative products, and issue advisory letters. The agency can also request that the Department of Justice conduct seizures, enjoin a firm or person from manufacturing or distributing products, or file criminal charges against a firm or responsible persons on behalf of the FDA.

Several features of nontuberculous mycobacteria make it particularly important to increase awareness about these types of tattoo ink–related infections. Nontuberculous mycobacterial infections may be difficult to diagnose and treat. Commonly reported symptoms of such infections associated with tattoo ink include lesions consisting of red papules solely in areas where the contaminated ink has been applied. Symptoms can be difficult to recognize, since other conditions (e.g., allergic reactions) may present with similar findings. Recovery of mycobacteria may be challenging, often requiring a skin biopsy, and special culture mediums may be required for diagnosis. Depending on the medium used, it can take up to 6 weeks to identify the organism. Because of these diagnostic challenges, infections may initially be misdiagnosed and patients may receive ineffective treatments. Antibiotic choices are limited by the susceptibility profile of the organism, and prolonged treatment may be necessary to clear the infection. Moreover, complications such as coinfection with pathogens such as methicillin-resistant *Staphylococcus aureus* may pose a further challenge to a patient's full recovery. Many of the persons affected by the recent tattoo-associated outbreaks of mycobacterial infection who received medical treatment were given macrolide therapy, to which they had a favorable response. Health care providers need to be aware of the symptoms associated with nontuberculous mycobacterial infections from tattoo ink, the challenges involved in diagnosing and treating them, and their own essential role in reporting such cases to MedWatch.

Even if a person receives a tattoo at a tattoo parlor that maintains the highest standards of

hygienic practice, there remains a risk of infection from the use of contaminated ink. People who get tattoos must be made aware of this risk and should seek medical attention if lesions consisting of red papules or a diffuse macular rash develop at the tattoo site. Consumers should patronize artists who use sanitary tattooing practices and who can confirm that their inks have undergone a process that eliminates harmful microbial contaminants.

In light of the recent tattoo ink–related outbreaks of nontuberculous mycobacterial infection, the FDA is committed to pursuing educational and outreach efforts to health care providers, public health officials, consumers, and the tattoo industry. Our messages seek to raise awareness, improve diagnosis, and encourage adverse-event reporting, with the intent of preventing future infections. The FDA encourages health care providers, public health officials, consumers, and tattoo artists to use MedWatch to report to the FDA any tattoo-related infections and any other adverse events related to tattooing.[3] The agency will continue to collaborate with other public health partners in investigating reported adverse events, identifying root causes, and taking the actions necessary to prevent future illnesses.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD.

This article was published on August 22, 2012, at NEJM.org.

1. Braverman S. One in five U.S. adults now has a tattoo. New York: Harris Interactive, 2012 (http://www.harrisinteractive.com/vault/Harris%20Poll%2022%20-Tattoos_2.23.12.pdf).
2. Armstrong ML. Tattooing, body piercing, and permanent cosmetics: a historical and current view of state regulations, with continuing concerns. J Environ Health 2005;67:38-43.
3. Food and Drug Administration. Reporting serious problems to FDA. 2012 (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm).
4. Drage LA, Ecker PM, Orenstein R, Phillips PK, Edson RS. An outbreak of *Mycobacterium chelonae* infections in tattoos. J Am Acad Dermatol 2010;62:501-6.
5. Food and Drug Administration. Cosmetics: tattoos and permanent makeup. 2010 (http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm108530.htm).

DOI: 10.1056/NEJMp1206063

There Is More to Life Than Death

Pamela Hartzband, M.D., and Jerome Groopman, M.D.

Physicians and patients alike crave certainty. We all want to know that we're making the best decisions about our health. But how do we know what's best? The value of screening tests such as mammograms, prostate-specific antigen (PSA) measurements, colonoscopies, electrocardiograms, and routine physical examinations has recently been called into question. Expert groups have made sweeping recommendations regarding such testing that will significantly affect medical practice.

Numbers and formulas convey a sense of certainty and seem to provide a scientific and rational basis for making medical decisions. Classic medical decision analysis, widely used by expert groups, is based on the work of Daniel Bernoulli, an 18th-century mathematician who devised a formula to determine the "best" choice.[1] When an outcome is uncertain and the choice involves risk, this "best" choice is the option with the "highest expected utility." To find that number, you multiply the probability of a given outcome by the utility, or impact, of that outcome: (probability of outcome) × (utility of outcome) = expected utility. In economics, the probability of a future outcome might refer to the likelihood of selling a certain number of products. The utility is generally calculated in monetary terms — the effect on the bottom line. This formula has been imported into medicine, where decisions invariably involve risk and uncertainty. In clinical decision analysis, the outcome that is generally measured is death. This outcome fits neatly into the Bernoulli formula. Death is readily determined, easily quantified, concrete.

For example, the U.S. Preventive Services Task Force (USPSTF) based its recent recommendation against routine PSA screening largely on the U.S. Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial that showed no difference in mortality between a PSA-screened group and a control group. This expert panel concluded that the harm from treatment of prostate cancer that was diagnosed through PSA testing outweighed any benefit. The chairperson presented the result of the panel's analysis