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Regulation of Tattoo Ink Production and the Tattoo Business in the US

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Abstract

The production of tattoo ink and pigments in the US is unregulated. There are no guidelines or standards issued by national agencies. However, the practice of tattooing is regulated at the state and local levels but varies widely. Adverse events are addressed when a problem is reported.

One out of five adults (21%) in the US today has a tattoo. This amounts to over 50 million people, and the number is increasing. The fact that the art of tattooing is associated with health risks is undeniable and openly acknowledged by the US Food and Drug Administration (FDA) [1]. Therefore, due to the large number of people at risk for adverse reactions from tattooing procedures and the deposition of pigment into the body, meaningful regulation of tattoo ink production and the tattoo industry in the US is crucial.

The structure of the legal system in the US differs from that in Europe. The country's Constitution grants specific powers to the national or 'federal' government. The 10th Amendment to the US Constitution states that 'powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States, respectively, or to the people'. Therefore, the individual states have the power to regulate everything else. As laws governing the tattoo artistry are not outlined in the US Constitution, rules relating to this field are controlled independently by each of the 50 states. The result is that different rules apply in different states, with the extent of regulation varying widely. Some jurisdictions have stringent laws in place, whereas others have very minimal requirements (table 1). Within the states, at the local level, agencies such as a city or county board of health have the power to enact and enforce laws.

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Table 1. A comparison of selected tattoo regulations between the 50 states

State	Educational standards for artists for infection control	Disclosure of potential risks to consumers	Standards for sterile technique	Tattoo artists required to wear gloves	Hepatitis B vaccine offered to tattoo artists	Artist health screening, including for hepatitis B, required	Artists required to report adverse events
Alabama	Y	Y	Y	Y	Y	N	Y
Alaska	Y	Y	N	N	N	N	N
Arizona	N	N	N	N	N	N	N
Arkansas	Y	N	Y	Y	N	Y	Y
California	Y	Y	Y	Y	Y	N	N
Colorado	Y	Y	Y	Y	Y	N	N
Connecticut	Y	N	N	N	N	N	N
Delaware	Y	Y	Y	Y	Y	N	N
Florida	Y	N	Y	Y	N	N	N
Georgia	N	N	Y	Y	Y	N	N
Hawaii	Y	N	Y	N	N	N	N
Idaho	N	N	N	N	N	N	N
Illinois	Y	Y	Y	Y	N	N	Y
Indiana	Y	N	Y	Y	Y	N	N
Iowa	Y	N	Y	Y	N	N	N
Kansas	Y	Y	Y	Y	N	N	N
Kentucky	N	Y	Y	Y	N	N	N
Louisiana	Y	Y	Y	Y	Y	N	N
Maine	Y	N	Y	Y	N	N	Y
Maryland	N	N	Y	Y	Y	N	N
Massachusetts	Y	Y	Y	Y	Y	N	Y
Michigan	Y	N	Y	Y	Y	N	N
Minnesota	Y	N	Y	Y	N	N	Y
Mississippi	Y	Y	Y	Y	N	N	N
Missouri	Y	Y	Y	Y	N	N	N
Montana	Y	Y	Y	Y	Y	N	N
Nebraska	Y	N	Y	Y	N	N	N
Nevada	Y	N	N	Y	N	N	Y
New Hampshire	Y	N	Y	N	N	N	N
New Jersey	Y	Y	Y	Y	Y	N	Y
New Mexico	Y	N	N	N	Y	N	N
New York	Y	N	N	N	N	N	N
North Carolina	N	N	Y	Y	N	N	N
North Dakota	Y	Y	Y	Y	Y	Y	Y
Ohio	N	Y	Y	Y	N	N	N
Oklahoma	Y	Y	Y	Y	Y	Y	Y
Oregon	Y	N	N	N	N	N	N
Pennsylvania	Y	Y	Y	Y	Y	Y	N
Rhode Island	Y	N	Y	Y	Y	N	N
South Carolina	Y	Y	Y	Y	Y	N	Y
South Dakota	N	N	Y	Y	N	N	Y
Tennessee	Y	N	Y	Y	Y	N	N
Texas	Y	N	Y	Y	N	N	Y
Utah	N	N	N	N	N	N	N
Vermont	Y	N	N	N	N	N	N
Virginia	N	N	Y	N	N	N	N

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Table 1. Continued

State	Educational standards for artists for infection control	Disclosure of potential risks to consumers	Standards for sterile technique	Tattoo artists required to wear gloves	Hepatitis B vaccine offered to tattoo artists	Artist health screening, including for hepatitis B, required	Artists required to report adverse events
Washington	Y	N	Y	Y	N	N	N
West Virginia	N	Y	Y	Y	N	N	N
Wisconsin	N	Y	Y	Y	N	Y	N
Wyoming	N	N	N	N	N	N	N

Y = Yes; N = no.
Data obtained from http://www.cdc.gov/niosh/topics/body_art/stateRegs.html, accessed September 30, 2014.

Engaging in tattoo artistry is not a risk-free process for either the tattoo artist or the tattooee. Gaps in the regulatory system create the potential for widespread harm. Pathogen contamination of tattoo materials to be injected into the skin can occur during ink production as well as during the tattooing process. During the tattooing process, bacteria can be introduced through a nonsterile needle, the tattoo artist not wearing gloves, or the tattoo artist or the tattooee carrying and passing on a blood-borne disease through failure to use proper aseptic techniques. The composite parts of the pigments may include carcinogens and allergens. The deposition of these into the body is another source of risk. An area of particular concern with any needle-using activity is the transmission of human immunodeficiency virus and hepatitis, as these infections can have devastating potential sequelae. In order to ensure safety, each step requires oversight.

Another agency regulating and overseeing disease control within the US is the Occupational Safety and Health Administration, a federal agency within the US Department of Labor. This federal department outlines safety and health standards for employees in contact with toxic and hazardous substances. These include standards for handling contaminated materials, planning exposure control, washing hands, disposing of sharps, wearing gloves, and offering hepatitis B vaccination for employees. Within these regulations, hepatitis B vaccination is not compulsory, and employers need only make hepatitis B vaccinations available to employees who have had an occupational exposure such as a needle stick injury. However, some workplaces are exempt from these regulations. These include independent contractors and other self-employed individuals, and therefore, it is likely that many tattoo facilities are excluded from these rules. Local governments and municipalities have the power to enact and enforce such regulations but are not obliged to do so.

The FDA has the power to regulate the production of the ink and pigments used in intradermal tattoos, yet it has chosen not to due to 'competing health priorities and a lack of evidence of safety problems specifically associated with these pigments' (FDA website: Tattoos and Permanent Makeup: Fact Sheet). Tattoo inks have been classified as cosmetics and are not regulated before going to market. This is in contrast to other 'colors', such as colors in food and drugs for ingestion and colors in cosmetics for external placement on the skin, which the FDA does regulate. As the pigments used in tattoo inks are color additives, they could be subject to premarket approval under the Federal Food, Drug, and Cosmetic Act. The FDA's goal is to encourage consumers as well as

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tattoo and permanent make-up artists to take precautions and to urge potentially infected clients to seek medical care. Adverse event reporting is important in order for the FDA to be able to investigate and take action. The FDA posts warnings to consumers about adverse events and recalls. These are publicly available to enable both consumers and tattoo artists to take steps in order to help to decrease the likelihood of further problems.

Instead of carrying out premarket approval of tattoo inks, the FDA reacts to adverse events to prevent further consumer injury or illness. The FDA investigates incidents that are reported and takes action as appropriate [1]. An example of the FDA responding to such an event occurred following an outbreak of *Mycobacterium chelonae* skin infections in Monroe County, New York, in 2011, which led to a voluntary recall of the contaminated ink. There were also cases in Washington, Iowa, and Colorado that were unrelated to the New York cases. The contaminated ink in those cases was identified, and there were voluntary recalls involving multiple ink manufacturers. This emergency response was a joint effort between the FDA and the Centers for Disease Control and Prevention. As with the FDA, the Centers for Disease Control and Prevention are reactive, not proactive, and only act in response to outbreaks of infections related to tattooing. No agency is taking precautionary measures to prevent the occurrence of such crises.

Interestingly, the FDA has carved out a medical exception to its solely reactive role in the tattoo business. Tattooing devices, which were developed for tattooing radiotherapy targets on the skin of radiation oncology patients, have been approved by the FDA. They are described as tools to 'to permanently mark the central axis or field borders of any radiation fields used to treat a patient'. These were approved under the 'medicinal device category' as FDA class 1 exempt devices, and therefore, one could argue that the ink within was also approved. In fact, the tattoo pigment used within these devices may be regular ink sold for use in fountain pens. This FDA safety 'guarantee' is reassuring to both physicians and patients. It appears as though these devices or a similar device could be developed or approved for cosmetic use. Today, many pigments used in tattoo inks are industrial-grade colors suitable for printers' ink or automobile paint. The FDA could theoretically develop an administrative code to create standards and criteria for tattoo ink in order to prevent distribution of contaminated inks or inks containing known allergenic components.

The risk of immediate introduction of infection with tattooing is undeniable. Another area of concern is the long-term safety of intradermal pigment. The implications of this have not been thoroughly investigated. Recently, tattoo inks that contain azo and polycyclic pigments are becoming more widely used. Not one of these products has been adequately studied to determine whether it is safe for use in humans. At the FDA's Arkansas-based National Center for Toxicological Research, investigations are being performed into the chemical composition of some tattoo inks and their metabolism in the human body, in addition to other studies to clarify their safety [2]. Tattoo pigments can drain from the skin and move deeper into the body through the lymphatic system, a collection of fluid-carrying vessels in the body that filter out disease-causing organisms. The long-term effects of this have not yet been established.

In conclusion, the production of tattoo ink and pigments in the US is an unregulated industry. There are no guidelines or standards issued by federal agencies. Furthermore, there is no screening of tattoo pigments prior to placement on the market for permanent introduction into the body. Adverse events such as infections are addressed only once a problem is reported.

For the physical act of tattooing, regulation is controlled at the state and local levels. The degree to which this is regulated differs widely by location. Regulations sufficient to safeguard the

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health and safety of consumers in tattoo parlors are dependent on the local jurisdictions across the US. Interestingly, probably due to a cultural moral preference, regulations regarding the age at which a minor may get a tattoo, who must give consent and be present at such a time, and what records must be kept do exist in a meaningful form in virtually every state.

At the federal level, the FDA is prepared to react quickly when there is a crisis. Recently, the FDA discovered and forced a recall of a do-it-yourself tattoo kit being sold online in which the ink was contaminated with multiple bacteria, thus stopping a potentially large-scale outbreak of infection in the US. However, tattoo inks, pigments, and do-it-yourself at-home tattoo kits are still readily available online, and due to the fact that the FDA has to rely on reporting of adverse incidents by consumers in order to act, the timely reporting of such incidents to this agency is the only way that consumers can be protected and protect others. Despite the lack of regulation and the large numbers of Americans who get tattoos annually in this growing industry, the fact is that getting a tattoo remains reasonably safe, with a very low reported occurrence of adverse events.

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