

Daniel Kass Deputy Commissioner Environmental Health 125 Worth Street New York, NY 10013 212 788-4646 tel 212 788-2159 fax NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE Thomas Farley, MD, MPH *Commissioner*

April 30, 2013

0972954 WESTLEY WOOD

Dear Licensed Tattoo Artist,

Re: Infections associated with the use of non-sterile water for dilution of tattoo ink

I am writing to inform you of additional steps you should take to avoid tattooassociated skin infections. Recently, at least two New York City residents developed skin infections with unusual and difficult to treat bacteria after receiving tattoos with ink diluted using non-sterile water. Non-sterile water includes tap, bottled, filtered, or distilled water. In these two cases, the artists used tap water. Similar cases from diluted ink have occurred elsewhere, as documented by the Centers for Disease Control and Prevention, the US Food and Drug Administration, and other health departments. To prevent additional cases, all tattoo artists must use sterile water when diluting ink.

Sterile water is readily available for purchase at most drug stores. Once a sterile bottle has been opened and used, it should no longer be considered sterile. Discard open bottles of sterile water after a single use. Though using sterile water to dilute tattoo inks will help prevent infections from occurring, it is also critical that all other infection control tattoo practices be followed. This information will be added to the 3-hour Infection Control Course and Infection Control Examination that is required for new tattoo licenses and renewals. The current infection control manual is available online at http://www.nyc.gov/html/doh/downloads/pdf/hany/tattoo-manual.pdf

As a reminder, you are required to give the customer written instructions on how to care for the tattoo. Should the customer notice any signs of infection (e.g., pus, redness, swelling), advise the customer to seek medical attention immediately. Both the customer and the tattoo artist should report the infection to the Health Department by calling 311. Thank you for your cooperation.

Daniel E. Kass, MSPH Deputy Commissioner

Additional information:

FDA: <u>http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm316357.htm</u> CDC: MMWR: Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States, 2011–2012. August 24, 2012 / 61(33);653-656. Available at: <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6133a3.htm.</u> Re: NYC Dept. of HHM, Environmental Health Daniel Kass, Deputy Commissioner Letter of April 30, 2013

No Response

Dear Deputy Commissioner Daniel E. Kass, MSPH,

Re: "Infections associated with the use of non-sterile water for dilution of tattoo ink."

I would like to comment on the wording of the letter announcing the new rule: "all tattoo artists must use sterile water when diluting ink."

The new rule would mandate the abandonment of using distilled water and the ink manufacturers' diluents. Both have proven to be safe by decades of use, effective, available, and the tattoo industry's ordinary choice, and at a reasonable cost.

The two NYC skin infections (attributed to NYC tap water) and the "cluster of cases" reported by the CDC as Nontuberculous Mycobacterial Skin Infections caused by "tap water", are not caused by the larger category, "non-sterile water". Looking at the argument, the conclusion is false:

Tap water has been shown to cause infection. (True) Tap water is (a type of) non-sterile water (diluent). (True) Therefore, non-sterile diluents have been shown to cause infection. (False)

First, distilled water, a type of non-sterile water has a long record of safe usage. Secondly, the non-sterile diluents that are used to make non-sterile inks are sold separately by the manufacturers. The new rule would eliminate these two proven-safe-by-decades-of-use-products.

Arguing that a higher standard or superior or safer product would be better violates the principle of good rule making, which is, a properly written standard (ASTM) specifies the essential characteristics of acceptable products. Any proper standard-making rule affecting health would allow any diluent that has proven itself over time, and by use, to be safe and effective. Safe usage trumps all arguments in public health. Such products must not be discarded without significant and important improvement to public health. Distilled water and manufacturer's mixing solutions are proven safe products by decades of use. A proper rule might prohibit the use of a harmful product, such as NYC or Arizona "tap water" for diluting tattoo inks

Important to consider is that tattoo inks are not sterile.

To repeat: the wording of the new rule would exclude manufacturers' diluents, the very diluents (non-sterile) used to make non-sterile ink.

Secondly, Distilled water has proven itself to be safe and effective by decades of use and should not be discarded without evidence of harm or significant improvements promoting a safe and healthy populace.

Bouncing new rules off an industry-accepted expert in tattoo issues such as myself, might contribute to a deeper understanding of industry practices and rationale. I request a review of the wording of the new rule so as not to exclude distilled water and manufacturers' diluents.



NYC Dept. of Health and Mental Hygiene Commissioner Thomas Farley, MD, MPH 125 Worth St New York, N.Y. 10013

Dear Commissioner:

Re: New rule: "...tattoo artists must use sterile water when diluting ink."

I previously wrote to you and Deputy Commissioner Daniel Kass requesting a review of the wording of the new rule: tattoo artists must use sterile water when diluting ink. (copy of letter attached) The reasons for the review were presented.

Today I am stepping up my request by writing, not as a licensed tattoo artist, but in my role as tattoo supplier to the tattoo community for more than 25 years, a trusted source of knowledge, experience and help. The new rule is having unintended results.

1) "Sterile" Water is an FDA term, a sterile product or device, and as such is available only by prescription. It is not over-the-counter. (See attached photo of a product).

2) There are different kinds of "sterile" water, for intravenous use, for inhalation and injection. We would need guidance.

3) Is it true that N.Y. City water caused "skin infections with unusual and difficult to treat bacteria" when applied to a wound? Are New Yorkers with surface wounds and the immunocomprimised being advised to avoid N.Y. City water?

I request again, an expeditious review of the issues presented in my letter (attached), for a correction to the existing new rule, and ask for a reply.

Respectfully submitted,

Westley Wood, Pres. Unimax Supply Co Inc, (1989) 269 Canal St, New York, N.Y. 10013 Unimax West, (2010) Arlington, Texas 76011 Daniel Kass, Deputy Commissioner Extern 125 Worth St New York, N.Y. 10013 August 2, 2013

Dear Deputy Commissioner Kass:

Re: April 30, 2013 new rule: "All tattoo artists must use sterile water when diluting ink."

After two attempts to open a dialogue without success, a petition effort is now under way to call this "well-intentioned-but-incorrect" rule to the attention of all NYC tattooists. The petition effort is going well.

A letter was sent to you and Commissioner Farley, MD. in June and a month later another was sent to open a dialogue. The letters explained some of the reasons why the new April 30, 2013 rule was, first of all, impossible to comply with, too broad, unjustified by the actual evidence, syllogistically false, did not follow principles of good rule-making, and a misreading in the CDC report (a report with no similarity to artists' diluting ink) supposedly concluding that it was the lack of using sterile water that caused infections!

When tattooing was being legalized in 1996-1997, during the tenure of Acting Deputy Commissioner, Dr. Benjamin Mojica, I served on the committee representing the NYC tattoo community. At that time Dr. Mojica testified that since there hadn't been any public health problems from tattooing in 40 years he opposed changing the rules because it would divert taxpayer resources from efforts that would actually benefit public health. It was up to him to change the rule then, it is up to you to change this new rule now.

This third and final letter asks you to rescind the new April 30, 2013 rule without further to-do.

Respectfully submitted,

Westley Wood, NYC Licensed Tattoo Artist



Attachments cc to Commissioner Farley, MD, MPH Michael Cardozo, NYC Legal Counsel



NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE Thomas Farley, MD, MPH *Commissioner*

August 6, 2013

Daniel Kass Deputy Commissioner Environmental Health 125 Worth Street New York, NY 10013 212 788-4646 tel 212 788-2159 fax

Westley Wood Unimax Supply Co Inc. 269 Canal Street New York, NY 10013

Dear Mr. Wood:

I write in response to your letters of June 17, 2013 and April 30, 2013. In the most recent letter, you make three points, which I address below:

- "Sterile' Water is an FDA term And as such is available only by prescription." We recently visited drug stores in several areas of the cities and found sterile water for sale without a prescription. It is generally sold in large volumes without a prescription. While the quantity is excessive for the amount necessary for diluting ink on a given day, that is not justification for not purchasing and using it. I note that several tattoo supply outlets make sterile water available in smaller quantities without prescription, among them <u>http://www.tatooneedles.us</u> and your own supply company, Unimax, for \$0.99 each in 3.07 oz containers (<u>http://store.unimaxshop.com/sterile-water-c373.aspx</u>, accessed 8/6/2013).
- 2. *"there are different kinds of 'sterile' water..."* Any non-saline water that is sterile is acceptable for use.
- 3. "Is it true that N.Y. City water caused 'skin infections with unusual and difficult to treat bacteria' when applied to a wound? Are New Yorkers with surface wounds and the immunocompromised being advised to avoid N.Y. City water?" You imply that we have called into question the safety of New York City's public water supply. New York City's drinking water meets or exceeds all federal and state standards for potability. This means that New York City public water is safe for consumption. It is not safe for injection."

Your earlier letter suggests that distilled water is an acceptable dilutant. We disagree. Distilled water does not meet sterility standards, and may be distilled and bottled under non-sterile conditions. There no scientific basis to conclude that it would sufficiently address the risks of bacterial or mycobacterial contamination determined to be the source of infections in the cases we cite. Our letter addressed the use of water as a dilutant. There may be additional manufactured dilutants that are equivalent to inks, but we do not prohibit their use. Westley Wood August 6, 2013 Page 2

New York City is hardly alone in drawing attention to the risks associated with the use of non-sterile water as a tattoo ink dilutant. On August 23, 2012, the FDA issued an alert to tattoo artists, ink and pigment manufacturers and public health officials that the use of sterile water to dilute inks helps to ensure that bacteria are not introduced during the dilution process (unboiled tap, bottled, distilled and filtered water are not sterile and should not be used to dilute inks). <u>http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm316357.htm#2</u>, accessed 8/6/2013). While we have not undertaken a comprehensive review of state and location regulations, a quick search uncovered several neighboring jurisdictions that limit water used in the dilution of tattoo inks to sterile water. See, for example, Section 25-3301(7.7) of the Fargo Municipal Code, and in our area, the Ocean County New Jersey Health Department and Article XIII(§11(d)) of the Chemung and Chautauqua Counties in New York State. Counties and States across the United States have alerted body art practitioners to observe the FDA recommendation to only use sterile water for the dilution of inks.

New York City stands by its letter to licensed body artists and strongly recommends that they only use sterile water when diluting inks with water.

Sincerely, Daniel E. Kass, MSPH **Deputy Commissioner**

c: Thomas A. Farley, MD, MPH, Commissioner