

FDA Consumer Antimicrobial Handwash Proposed Rule: What Does It Mean and Does It Impact Healthcare or Not?

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Foreword

The following whitepaper is designed for healthcare professionals responsible for selecting hand hygiene products in a facility. It is intended to be an objective review of both sides of the discussion regarding antimicrobial soaps for consumer use and why the Proposed Rule has been issued. This topic is relevant for this audience because, as consumers, it is possible that staff may bring concerns to your attention. This informational communication is meant to arm you with background information and to help you bring context to the discussion, should your staff be misinformed about this topic and inquire about products being used in your facility.

Key Points:

- In December 2013, the U.S. Food and Drug Administration (FDA) issued a Notice of Proposed Rule on Consumer Antimicrobial Handwashes, in which they stated that there is not enough evidence to show that antimicrobial soap products have an added benefit over plain non-antimicrobial soaps in the consumer setting.
- The Proposed Rule does not affect the healthcare environment, where antimicrobial agents may play an important role in preventing healthcare-acquired infections and where the patterns of use and risks of infection are dramatically different than in the consumer setting.
- The FDA is not requiring consumer companies to remove antimicrobial soaps from the consumer market at this time, but is *proposing* to establish new conditions under which consumer antiseptic handwash products are generally recognized as safe and effective based on the FDA's reevaluation of the safety and effectiveness data requirements.
- Alcohol-based handrubs in any setting are not affected by the Proposed Rule and continue to be the preferred method for performing hand hygiene when hands are not visibly soiled.



Antimicrobial active ingredients are used in a wide variety of consumer products, such as hand soaps, toothpaste, toys, footwear, adhesives and fabrics, as both an antimicrobial and a material preservative.^{1,2} The U.S. Food and Drug Administration (FDA) regulates the use of antimicrobial agents in hand hygiene products in its 1994 Tentative Final Monograph, which contains rules for each class of products and describes acceptable active ingredients, doses, formulations, claims and labeling requirements.

On December 16, 2013, the FDA issued a Notice of Proposed Rule on Consumer Antimicrobial Handwashes, in which they stated that there is not enough evidence today to show that antimicrobial soaps used in consumer settings have an added benefit over plain non-antimicrobial soaps.

The Proposed Rule mentions antimicrobial soap products contain chemical ingredients, such as triclosan, which may carry unnecessary risks given that their benefits are unproven for general consumer use. Therefore, there should be clearly demonstrated benefits to balance any potential risks.³

Healthcare workers may have concerns about the Proposed Rule and how it affects the use of antimicrobial soaps in the healthcare setting. The Proposed Rule does *not* affect healthcare settings. Healthcare-acquired infections are a significant problem in U.S. healthcare facilities in terms of morbidity, mortality and cost,⁴ and antimicrobial agents can play an important role in decreasing the incidence of these infections.⁵ Antimicrobial agents have been used in healthcare for over 40 years, beginning when triclosan was first used in surgical scrub. While animal studies have raised concerns about the safety of antimicrobials, such as triclosan, data showing effects in animals don't always predict effects in humans when used as a rinse-off handwash.⁶ For example, in one study, animals were exposed to much higher levels of the agent than the typical level of exposure in humans and by an unusual route (i.e., direct injection into the abdominal cavity),⁷ which differs from the pattern of use during handwashing (applying, lathering and rinsing a product off of the hands). As part of their 2000 Summaries and Recommendations of the Council on Scientific Affairs Report, the American Medical Association's published statement on the use of antimicrobials in consumer products summarized available data on the effectiveness

of antimicrobial ingredients in consumer products and the implications of such use on antimicrobial resistance. They reported that antimicrobial agents in consumer products have not been studied extensively, that no data exist to support the efficacy of these agents in consumer products, and that increasing data suggest a growing acquired resistance to these agents and possibly to antibiotics, though further research is needed. Therefore, they concluded, it may be prudent to avoid the use of antimicrobial agents in consumer products and called for further research on the use of these agents in consumer settings. Conversely, they stated that significant data exist that indicate that antimicrobial agents play an important role in preventing healthcare-acquired infections in the healthcare setting, where the patterns of use are dramatically different.⁵

The target of the Proposed Rule is the overuse in a wide range of consumer products, not the appropriate use in select situations and settings.

Overuse of antimicrobial handwash products in the consumer setting cannot be extrapolated to overuse in healthcare where there may be a need for such products. Stewardship of antimicrobial products, much like antibiotic stewardship, is needed to ensure safe and appropriate use.

As stated above, healthcare facilities are not affected by the Proposed Rule, as the healthcare setting is recognized as a unique environment with difficult challenges, such as the spread of healthcare-acquired infections.

Antimicrobial handwashes are one tool that can be used to combat this problem. Furthermore, the FDA is not requiring consumer companies to remove antimicrobial soaps from the market at this time, but is proposing to establish new conditions under which consumer antiseptic handwash products are generally recognized as safe and effective based on the FDA's reevaluation of the safety and effectiveness data requirements.³ The FDA encourages consumers, clinicians, environmental groups, scientists, industry representatives and others to discuss and weigh in on the Proposed Rule and the data it discusses during a 180-day comment period that ends June 16, 2014. The Proposed Rule will then be finalized within

two years, and consumer product manufacturers will have one year to comply by submitting data supporting antimicrobial claims to the FDA. If not, they will have to reformulate or relabel products.

The Centers for Disease Control and Prevention (CDC) allows healthcare facilities the choice of providing either antimicrobial or non-antimicrobial soap to healthcare workers for use when hands are visibly soiled or contaminated with proteinaceous material, blood or other bodily fluids, but otherwise recommends alcohol-based handrub (ABHR) for routine decontamination of hands,⁸ and these guidelines remain unchanged. ABHR contains ethyl alcohol, an FDA Category I agent that is considered generally safe and effective for use under the 1994 Tentative Final Monograph. The research cited in the CDC Hand Hygiene Guidelines for healthcare workers demonstrate ABHRs are more effective and less damaging than soap and water,⁸ and that a well-formulated ABHR can actually improve skin condition.⁹

While there are some non-alcohol-based hand sanitizers on the market, the CDC specifically recommends ABHR for healthcare settings, which typically do not include other active ingredients like triclosan, chloroxylenol (PCMX), etc.

Finally, ethyl alcohol does not have the propensity to cause antimicrobial resistance because it is rapidly germicidal when applied to skin, but has no appreciable residual activity.⁸ Good hand hygiene is critically important in healthcare. Both antimicrobial and non-antimicrobial soaps as well as ABHR are valuable options for reducing the risk of infection in healthcare settings. The selection of specific products is an individual facility decision and each facility should continue to evaluate all aspects of hand hygiene products when making a selection.

Reference List

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Biography



Megan DiGiorgio has worked in infection prevention for 10 years, spending the last eight years at the Cleveland Clinic in Cleveland, Ohio. Megan received her bachelors of science in nursing and masters of science in nursing from Case Western Reserve University. Megan has a background in pediatric nursing in addition to her infection prevention experience. She published an article in the journal *Infection Control and Hospital Epidemiology*, reflecting her work around a definition for central-line associated bloodstream infection (CLABSI) in the hematology-oncology population, which garnered the attention of the Centers for Disease Control and Prevention (CDC). Megan worked with the CDC on their creation of a new subset of CLABSI called "mucosal-barrier injury," which was reflected in the updated 2013 surveillance definitions for specific types of infections. She has presented posters and oral abstracts at several national conferences, and is active in her local northeast Ohio Association of Professionals in Infection Control chapter, serving as president in 2012. Megan began working at GOJO in 2013 as a Clinical Specialist for healthcare.

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¹Healthcare Personnel Handwash Study #111016-101, March 19, 2012, BioScience Laboratories, Bozeman, MT.

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