December 7, 2015

Dr. Stephen Ostroff
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Docket No. FDA-2015-N-0701, "General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet."

Dear Dr. Ostroff:

On behalf of organizations dedicated to the health and safety of children, we appreciate the opportunity to comment upon the Food and Drug Administration's (FDA) proposed rulemaking on pediatric medical cribs and medical bassinets. These comments reflect the input of the American Academy of Pediatrics, Consumer Federation of America, Consumers Union, and Kids In Danger.

The American Academy of Pediatrics (AAP) is a non-profit professional organization of 64,000 primary care pediatricians, pediatric medical sub- specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults.

The Consumer Federation of America is an association of more than 250 nonprofit consumer groups that was established in 1968 to advance the consumer interest through research, advocacy, and education.

Consumers Union, the policy and advocacy arm of Consumer Reports, is an expert, independent, nonprofit organization with more than one million online activists whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. Consumer Reports is the world's largest independent product-testing organization, which uses its more than 50 labs, auto test center, and survey research center to rate thousands of products and services annually.

Kids In Danger is a nonprofit organization dedicated to protecting children by improving children's product safety.

Introduction

We commend the FDA for analyzing adverse events related to pediatric medical cribs and medical bassinets and proposing to make these devices safer. Infants and children undergoing medical care are among our most fragile; the risks they face from illness and injury should not be compounded by hazards associated with the very devices intended to allow them to rest and to

heal. Overall, we are supportive of the proposed rule; however, there are some ways in which the proposal could be strengthened. Our specific comments are below.

Prescription Use Only Designation

We support the proposal that medical cribs and medical bassinets be used in homes and daycares under authorized prescription only and when medically necessary. The prescription requirement may provide an opportunity for caregivers in these settings to be informed of the hazards associated with drop-side cribs, as well as the importance of snug-fitting crib and bassinet mattresses. In 2011, after dozens of infant and toddler deaths due to suffocation and strangulation in drop-side cribs, the U.S. Consumer Product Safety Commission (CPSC) banned all drop-side cribs for consumer use.[1],[2] That same year, the CPSC set mandatory safety standards for cribs; these standards ensure that crib mattress support, slats, and hardware are more durable and that manufacturers test products to these stringent requirements to prove compliance before being sold.

It is logical that medical cribs would need to retain the drop-side rails in order to provide medical care, but the entrapment dangers from medical cribs remain a concern. These dangers can be mitigated by ensuring that medical cribs cannot be obtained freely by consumers, but only when authorized by prescription. We urge FDA to go one step further and require that the medical cribs prescription be accompanied by robust user education about avoiding entrapment hazards in medical cribs, so that the protections afforded by the CPSC's 2011 crib safety requirements are also realized for infants and children in medical care settings. We also recommend that FDA consider ways to mitigate any potential risk that medical cribs, once obtained by via prescription for day care providers for infants and children with disabilities, are not used in perpetuity, even after industry-wide safety standards have improved. This would ensure that the spirit of the 2011 revised crib safety standards, which required child care providers to purchase new, safer cribs, would also apply to infants and children undergoing medical care.

In addition, given that user error/misuse was an element of the adverse events that FDA analyzed, we recommend that the agency develop specific education materials to address the user errors identified in the adverse event reports, and to prevent the kind of medical crib misuse that could negate the very improvements that the agency seeks to create with this proposed rule (e.g., failure of the drop-side rail to latch). Recognizing that failure of the drop-side latch mechanism is within the realm of the foreseeable outcomes, especially when dealing with very busy medical personnel and urgent medical cases, the FDA's proposed safety standard should make it as easy as possible for users to prevent such foreseeable errors through clearly-marked instructions and training.

Finally, while the proposed rule incorporates performance testing to portions of the ASTM crib standard, (F1169), without the certification process required by CPSC of traditional cribs, cribs that do not meet these performance tests could still be offered for sale. We suggest that FDA require certification of testing for this standard before sale.

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[1]http://onsafety.cpsc.gov/blog/2011/06/14/the-new-crib-standard-questions-and-answers/.

[2]http://www.nbcnews.com/id/40678788/ns/health-childrens_health/t/after-dozens-deaths-drop-side-cribs-outlawed/#.VltZkHvfBuQ.

Mattress Flammability Standards

We appreciate that FDA is proposing to update flammability standards for mattresses used in medical cribs and medical bassinets. To the extent that any of these mattresses do not already meet these flammability standards, the FDA's proposal would create a uniform standard for all manufacturers. However, to the extent that medical crib and medical bassinet mattresses contain organohalogen flame retardants, we urge the FDA to consider revising its proposed standard in the future to address concerns raised by our organizations and others regarding these chemicals.

Organohalogen flame retardant chemicals, as a class, are toxic due to their physical, chemical and biological properties. These chemicals have been associated with many adverse human health impacts, including: reproductive impairment(e.g., abnormal gonadal development, reduced number of ovarian follicles, reduced sperm count, increased time to pregnancy); neurological impacts (e.g., decreased IQ in children, impaired memory, learning deficits, altered motor behavior, hyperactivity); endocrine disruption and interference with thyroid hormone action (potentially contributing to diabetes and obesity); genotoxicity; cancer; and immune disorders. These chemicals also have a disproportionately negative health effect on vulnerable populations, including children.[3]

Our groups have joined a number of scientific, environmental, and consumer organizations asking that the CPSC ban the use of organohalogen flame retardants in four categories of consumer products, including mattresses.[4] We also urge FDA to consider instead whether non-chemical options (e.g., barriers) can provide adequate flammability protection in medical crib and bassinet mattresses, rather than chemical flame retardants. We agree wholeheartedly with the goal of protecting all infants and children from fire hazards, especially given the free-flowing oxygen in health care settings, but we urge FDA also to consider the hazards to infants and children who may be breathing in chemicals flame retardants while lying in the hospital.

Continuous Improvement

We appreciate that this proposed rule seeks to address damage to medical bassinets from both cleaning and tipping hazards. In addition, we support FDA's proposal to classify medical bassinets separately from medical cribs to allow for better post-market surveillance. This surveillance will help FDA to determine the effectiveness of the proposed special controls, and whether any adjustments need to be made to the regulation.

Finally, as FDA's proposed rule is based on part on standards established by the ASTM voluntary standard development organization, it should be noted that ASTM standards are subject to periodic change and updating as hazards are better understood and as technology

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[3] *See*https://www.cpsc.gov/Global/Regulations-Laws-and-Standards/Petitions/PetitionHP151RequestingRulemakingProductsContainingOrganohalogenFlameRetardentsJuly12015.pdf.

[4] https://www.cpsc.gov/Global/Regulations-Laws-and-Standards/Petitions/PetitionHP151RequestingRulemakingProductsContainingOrganohalogenFlameRetardentsJuly12015.pdf.

changes. We therefore strongly recommend that if these ASTM standards are improved further in the future, FDA should make the corresponding safety improvements to the medical crib standards as well.

Conclusion

We appreciate the opportunity to provide input as you consider these important safety standards. If you have any questions please do not hesitate to contact Ami Gadhia at 202/347-8600 or agadhia@aap.org.

Sincerely,

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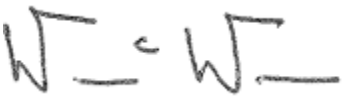

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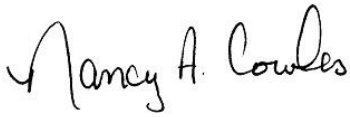

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