* Consumer Federation of America * Safe Infant Sleep * U.S. Public Interest Research Group *

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Comments of Consumer Federation of America, Safe Infant Sleep, and U.S. Public Interest Research Group to the U.S. Consumer Product Safety Commission on the Notice of the Proposed Mandatory Toy Safety Standards: Requirements for Neck Floats

(CPSC Docket No. CPSC-2024-0039)

Consumer Federation of America (CFA), Safe Infant Sleep, and U.S. Public Interest Research Group (PIRG) submit the following comments in response to the U.S. Consumer Product Safety Commission's (CPSC or Commission) request for comments in the above-referenced matter.

While we commend the commission for taking action to address the significant hazards associated with the products, there is no feasible consumer product safety standard that can adequately protect the public from the unreasonable risk of injury associated with this product. We urge the Commission to consider a ban under Section 8 of the Consumer Product Safety Act.

1. Demonstrable, Unreasonable Risk of Injury and Death

Drowning is the leading cause of death for children four years and younger. A false sense of security for caregivers is a built-in feature of neck floats. In water-related accidents, seconds matter, and a device that leads to distraction can be deadly. Incidents of drowning and near-drowning have been reported, despite the presence of adults, underscoring the product's unreasonable risk of injury, and thus the need for immediate action. The product, by its nature, creates an illusion of safety and misplaced confidence. Alarmingly, from January 2019 through January 2024, CPSC staff identified at least 115 incidents in CPSRMS associated with neck floats. The reported incidents were children, ranging from 17 days to 12 months old.

Staff identified four hazard patterns of drowning.

- Slip-through not associated with inflation

Fifty-two reported incidents involved an infant slipping through the product despite the neck float showing no signs of deflation, underinflation, or any other reported product issues. Forty-four of these incidents reported a child's mouth and/or nose submerging under the water, posing a risk of drowning or otherwise aspirating water. The other seven incidents involved a caregiver's immediate intervention, preventing submersion.

Victims ranged from 17 days old to 8 months old. One fatal incident involved the drowning of a 6-month-old child submerged, unresponsive, while the neck float was found on the surface of the water. The child was hospitalized and succumbed to her injuries six days later. In another example, the victim was in a bathtub with only approximately 5 inches of water when the victim was suddenly and fully submerged in the water.

- Slip-through associated with inflation

In 54 incidents, children slipped through or risked slipping through because the neck floats were more pliable or compressible at lower pressure levels or deflated during use. Thirty-three victims actually slipped through the product.

Victims ranged from 28 days old to 10 months old. Two drowning injuries and one drowning death were reported in this category and involved leaks or deflation during use. Notably, fifty-two CPSRMS incidents involved holes, tears, or other leaks in neck floats at the time of the incident. A fatal incident involving a 4-month-infant who was found unresponsive floating face down without the neck float. The neck float was still secured in a closed position by both a Velcro strap and a buckle but appeared to be losing air. Another 10-month-old infant was found limp and cyanotic with his face underwater, and the neck float was found to be partially deflated due to a leak in the seam.

Some incidents involved tears, like a 3-month-old infant slipping through the neck float that had a tear near the safety clip, and a 2-month-old who slipped through a product after it began to deflate due to a leak directly under the chin strap portion of the product. Several incidents involved neck floats deflating during use due to problems with the air valve, such as the valve either opening or not being fully closed.

- Slip-through associated with restraint systems failures

Failure of the restraint system is likely to result in the child's mouth and nose being submerged in water, whether from disconnecting entirely or loosening. One report detailed a 7-month-old infant slipping out of the product due to a latch/restraint failure.

- Submersion without slip-through

Children can be submerged in water while wearing neck floats without slip-through or fastening and restraint system failures, presenting a significant risk of drowning. Victims ranged from 3 to 6 months old. In at least three incidents, children reportedly tilted, rotated, and/or flipped in the neck float such that their faces contacted the water. Further, it is common for children wearing neck floats to exhibit a wide range of body positions and movements. In one example, an infant was pulled down into the water by an inflatable neck float that filled with water.

This alarming list of incidents likely underrepresents the actual frequency of such occurrences. These examples demonstrate the substantial, potentially catastrophic, risk of injury and death associated with neck floats. The only way to effectively mitigate this risk is to remove the hazardous products from the market.

2. Standards Cannot Address Fundamental Design Flaws and Inherent Hazards of Neck Floats

A performance-based regulatory standard cannot address the fundamental design flaws of neck floats because the products are, by their very nature, inherently hazardous. The risks include drowning, restricted airway access, and an overestimation of safety. Under the proposed rule, compliant products could still fail under real-world conditions, resulting in catastrophic consequences. For example, maximum circumference requirements could lead to the product applying pressure to vulnerable areas of an infant's neck, even if the device remains in place, resulting in labored or difficult breathing, particularly for infants whose airways are smaller. Further, real-world factors such as an infant's posture, movements, and water conditions will reduce the effectiveness of any buoyancy standards. Finally, the demographic for which neck floats are marketed for use – infants, small children, and individuals with disabilities – are particularly vulnerable and susceptible to harm because they may lack the motor skill to react when a float fails and be unable to signal distress or extricate themselves. No feasible performance standard can sufficiently mitigate risks to make the product safe for these vulnerable populations.

3. Inadequacy of Warnings and Labeling

While the proposed rule provides improved warnings and labels, such measures are insufficient to mitigate the catastrophic risks described in the incident data. These products, in particular, create the illusion of safety and provide misguided confidence. As such, warnings about the limitations of flotation devices and the need for supervision are often ineffective because many caregivers place an undue level of trust in the device's ability to prevent drowning. Further, drowning can occur in as little as twenty seconds, and it is often not accompanied by the typical splashing or yelling that people may expect. This makes it very difficult for caregivers to notice early signs of distress even if they're in the same room. Finally, manufacturers market these products as "safe" and "trusted," while also touting benefits like "therapeutic use" or "unrestricted movement." The claims undermine even the clearest warnings.

4. Public Health and Cost Implications

The emotional trauma and lasting societal consequences of infant deaths are immeasurable. By acting decisively to ban these products, the CPSC would fulfill its mission to protect society's most vulnerable members—infants and small children—from an unreasonable risk of harm.

5. The FDA's Concern About Other Consequences

The Food and Drug Administration has discouraged the use of neck floats for babies because it can cause neck strain and may not help the development of muscle strength and motor skills. In an <u>advisory in June 2022</u>, the FDA said: "The use of these products can lead to death or serious injury ... especially with babies with developmental delays or special needs."

The FDA also noted the cases of one baby who died and another who was hospitalized in connection with the use of neck floats.

6. Neck Floats vs. Life Vests

The CPSC's proposed rule frames this as a possible mandatory toy safety standard and discusses labeling requirements for aquatic toys. We would argue that neck floats are not a toy like a rubber duck or inflatable beach ball. Caregivers use neck floats as a safety device, not an amusement or intellectual stimulant.

Neck floats are quite different from life jackets/life vests, which fall under the U.S. Coast Guard. However, the CPSC <u>shares jurisdiction</u> on life vests for children. Life jackets and vests for adults and children must meet strict safety standards. By virtue of what they are, neck floats can't be made safely. A more traditional flotation device, such as a life vest, provides buoyancy across a larger portion of the body, helping to distribute weight more evenly. Because neck floats focus solely on the head and neck, they can be more easily overwhelmed by the infant's body weight, especially if the child is heavier or moves unpredictably.

If caregivers aim for safety, they should use a life jacket, which must comply with <u>strict</u> standards.

7. Precedent for Regulatory Action

The Commission has used bans to address hazardous products in the past, such as infant sleep products. The precedent supports a similar decisive action against neck floats to protect the same vulnerable populations – infants and small children. Given the known risks associated with neck float devices, their continued availability is a public health concern.

Conclusion

Given the significant risk associated with neck floats and the limitations of standards in addressing these hazards, we strongly urge the Commission to adopt a ban under Section 8 of the Consumer Product Safety Act. There is no feasible standard that can adequately protect vulnerable infants and small children from unreasonable risk of injury and death. A ban is essential to safeguard society's most vulnerable members.

We appreciate the opportunity to provide comments on the CPSC proposed rulemaking for neck floats, and we look forward to the Commission's decisive action.

Courtney Griffin
Director of Consumer Product Safety
Consumer Federation of America
cgriffin@consumerfed.org

Michelle Barry
President
Safe Infant Sleep
michelle.barry@safeinfantsleep.org

Teresa Murray
Consumer Watchdog Director
U.S. Public Interest Research Group
tmurray@pirg.org