U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

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Flaura Koplin Winston, MD. Ph.D.
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Dear Dr. Winston:

This letter concerns your letter of December 18, 2000, in which you asked the Consumer Product Safety Commission to regulate the safety of bicycle handlebar ends by way of a performance standard regarding energy dissipation and distribution during impact. On January 23, 2001, your request was docketed as petition number HP 01-1 pursuant to the Federal Hazardous Substances Act (FHSA).[1] As discussed in detail below, under applicable regulations the Commission has voted 2-1 to deny the petition because, based on available information, it cannot find preliminarily that:[2, 3]

- Bicycle handlebar ends present an unreasonable risk of injury[4]
- A mandatory performance standard is reasonably necessary to eliminate or reduce the risk in question[5]

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[1] 15 U.S.C. 1261-1278.

[2] Chairman Stratton and Commissioner Gall voted to deny. Commissioner Moore voted to defer pending action by the ASTM Bicycle Handlebars and Stems Task Group. Commissioner Moore's statement is available from the CPSC Office of the Secretary.

[3] The December 18, 2000 submission also described a proprietary design concept for a retractable handlebar end that it was asserted would reduce handlebar-related trunk injuries by reducing the impact force by approximately 50 percent. The CPSC Engineering Sciences staff evaluated that concept and concluded that the information you provided did not demonstrate that the retractable handlebar end approach would address the reported injuries in a quantifiable manner. Staff Briefing Package at 7-8 and TAB E thereto.

[4] 16 CFR 1051.9(a)(1).

[5] 16 CFR 1051.9(a)(2).

- Failure to begin rulemaking would unreasonably expose consumers to the risk of injury in question[6]

In reaching its decision, the Commission considered your letter of December 18, 2000 and the materials submitted with it; the extensive materials prepared by the Commission staff and presented in the staff briefing package *Bicycle Handlebars Petition HP 01-1*, (the Staff Briefing Package), June 2003; the 42 comments received on the petition; and other information. As required by applicable regulations, the Commission also considered the relative priority of the risk of injury associated with bicycle handlebar ends and Commission resources available for rulemaking activities with respect to that risk of injury.[7]

1. Do bicycle handlebar ends present an unreasonable risk of injury (16 CFR 1051.9(a)(1)).

a. Deaths and Injuries

The CPSC staff estimates that in 1998 approximately 85.3 million people age 2 to 75 rode bicycles. Of these, about 32 million, or 38 percent, were under 16 years old.[8] Staff also notes that the less than sixteen age group rides most frequently, averaging 300 hours per year.[9]

Over the eleven-year period January 1, 1991 to June 1, 2002, the Commission received reports of eight children who died after bicycle handlebar-related incidents. Striking the end of the handlebar, the risk noted in petition HP 01-1, was specifically reported in two of the eight incidents. The children who died ranged in age from four to seventeen years. Over that time an additional 19 children died of injuries to the trunk after a bicycle-related incident. However, contact with the handlebars was not reported for these incidents.[10]

The staff estimates based on data from the CPSC National Electronic Injury Surveillance System (NEISS) that approximately 352,000 children ages two through seventeen visited hospital emergency departments in 2001 due to bicycle-related injuries. Five thousand or so of these incidents were estimated to have involved trunk injuries due to contacting a bicycle handlebar. According to staff, the NEISS data often does not state the specific point of contact with the handlebar, e.g., the handlebar end addressed by the petitioner's submission. Staff also notes that it is particularly difficult to obtain reliable information about the specific point of impact with the handlebars through follow-up investigation. Furthermore, even for incidents reportedly involving handlebar ends, information on the mechanics of the event such as rider

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[6] 16 CFR 1051.9(a)(3).

[7] 16 CFR 1051.9(b).

[8] The Staff Briefing Package at 3.

[9] *Id.*

[10] The Staff Briefing Package at 3-4.

speed at the time of the incident, angle of the rider's impact with the handlebar end and the force of that impact is seldom if ever subsequently available.[11]

The approximately five thousand emergency room visits for trunk injuries reported in 2001 as resulting from contact with some portion of the handlebar amount to approximately 1.4 percent of all bicycle injuries resulting in emergency room visits for that year. Of these five thousand or so children, 92 percent were treated and released the same day. The remaining approximately 430, or 0.12 percent of the total of 350,000 children visiting emergency rooms due to incidents involving bicycles, were held for observation, admitted, or transferred to another facility for further treatment.[12]

Assuming bicycle ridership by children in the two to sixteen year old age group has remained relatively stable over the period 1991 through 2001, this is contrasted with approximately 30 million or more children each riding an average of 300 hours per year. Moreover, the available data do not permit an accurate assessment of how many of the deaths or these estimated 430 or so serious injuries per year associated with handlebars result from contacting the handlebar ends. Furthermore, it is unclear whether further study of bicycle incidents would be able to eliminate this uncertainty due to the lack of reliable information on the details of such incidents.[13]

In contrast, you estimated that approximately 894 children per year 19 years old and younger suffer serious abdominal or pelvic organ injuries that require hospitalization as a result of contact with bicycle handlebars.[14] However, CPSC staff states that these estimates may lack statistical validity because the data are based on a group of hospitals that may not be representative of the nation as a whole.[15] In addition, because the Children's Hospital of Philadelphia is a trauma center, and was also known to be collecting data on handlebar-related incidents, the proportion of handlebar-related injuries to all bicycle injuries could be greater than that of hospitals in general. Furthermore, you have not provided estimates for incidents related to contact with any specific point on the handlebar, including the end of the handlebar.

b. "Unreasonable Risk"

What constitutes an "unreasonable risk" of injury for purposes of the FHSA has been addressed by several federal circuit courts of appeal. One such court provided the following guidance:

> The requirement that the risk be "unreasonable" necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the

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[11] *Id.*

[12] The Staff Briefing Package at 4.

[13] The Staff Briefing Package at 14.

[14] *Estimates of the Incidence and Costs Associated with Handlebar-Related Injuries in Children*, Archives of Pediatric Adolescent Medicine 2002; 156:922-928, September 2002.

[15] The Staff Briefing Package at 12.

> injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.

Forester v. Consumer Product Safety Commission, 559 F.2d 774, 789 (D.C. Cir. 1977).

The degree of information required to support a finding of unreasonable risk has also been addressed by the federal judiciary. Although the Forester court stated that the Commission does not need "a precise 'body count' of actual injuries" to regulate, the Commission does have to show that there is a "real" risk.[16] *Id.* at 788-9

In D.D. Bean & Sons v. CPSC, 574 F.2d 643 (1st Cir. 1978) the court complained that the Commission lacked data on several hazards that the standard at issue was intended to address. For example, the court noted that the record identified only two injuries as arguably caused by delayed match ignition, and only one injury (with no information on cause or severity) arguably attributable to afterglow. *Id.* at 650. The court stated "[a] single injury , so inadequately described in terms of cause and degree, is not substantial evidence of an "'unreasonable risk of injury.'" *Id.*

In Gulf South Insulation v. CPSC, 701 F.2d 1137 (5th Cir. 1983), the court concluded that the in-depth investigations that had been conducted did "identify a real problem" but did not show how likely it was that the problem would occur. *Id.* at 1147-8. "Predicting how likely an injury is to occur, at least in general terms, is essential to a determination of whether the risk of injury is unreasonable." *Id.*

Here, given the uncertainty as to whether the reported handlebar-related deaths and injuries are in fact related to contact with the handlebar ends and that it may well be impossible to gather the information necessary to assess whether any particular performance standard approach would reduce the incidence of such injuries, the Commission has concluded that available information does not permit it to find preliminarily that the product in question presents an unreasonable risk of injury.

2. Whether a rule is reasonably necessary to eliminate or reduce the risk of injury (16 CFR 1051.9(a)(2)).

In light of the uncertainty as to what portion of handlebar-related trunk injuries are caused by contact with the end of the handlebar and whether data could be gathered to form the basis for designing a mandatory standard to reduce or eliminate such injuries from contact with handlebar ends, the Commission has concluded that available information does not support a finding that a rule such as that requested is reasonably necessary.

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[16] It should be noted that Forester was decided before statutory amendments required the Commission to determine that (1) there is a reasonable relationship between a regulation's benefits and its costs and (2) the rule imposes the least burdensome requirement necessary to address the risk of injury. 15 U.S.C. 1262(i)(2)(B) and (C). Thus, the analysis to support a rule such as that sought by Petition HP 01-1 would have to meet a higher standard today than when Forester was decided in 1977.

3. Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product (16 CFR 1051.9(a)(3)).

Given the deficiencies in the available bicycle handlebar injury data and the fact that the information needed to develop a mandatory standard to address injuries caused by handlebar ends may be difficult, if not impossible to obtain, the Commission has found that it is not appropriate to commence rulemaking on a mandatory standard for bicycle handlebar ends at this time.

Conclusion

Based on the foregoing analysis and the information before it, the Commission has denied the petition. In making that decision, the Commission also considered the relative priority of the risk of injury associated with handlebar ends and the Commission's resources available for rulemaking activities with respect to that risk of injury.[17] In this case, injuries that can be associated with bicycle handlebar ends apparently constitute a small percentage of overall injuries suffered by children from riding bicycles. Gathering sufficient additional information to support an effort to develop a mandatory performance standard may be impossible, if not highly resource intensive.

Improved design and performance requirements for handlebars could help reduce the number and severity of injuries. Accordingly, the CPSC staff will continue to work with the ASTM Task Group for Bicycle Handlebars and Stems to explore the feasibility of addressing the risk of injury associated with contacting the handlebar ends during a fall from a bicycle.

In closing, the Commissioners have asked me to convey their thanks to you for bringing the complex issue of bicycle handlebar-related injuries to the attention of the CPSC.

Sincerely,

Todd A. Stevenson

[17] 16 CFR 1051.9(b).

STATEMENT OF THE HONORABLE THOMAS H. MOORE

ON THE PETITION REQUESTING MANDATORY PERFORMANCE STANDARDS

FOR BICYCLE HANDLEBARS

July 14, 2003

Few items are more important to a child than their bicycle. Most of us remember getting our first bike and the sense of freedom it gave us. That makes it all the more troubling to read of the serious internal injuries and deaths that have resulted from children falling off their bikes and landing on the end of the handlebar. I appreciate the difficulties that our staff has identified in terms of our proceeding with a rulemaking on this issue. I also agree that the petitioner's proposed handlebar redesign may not be the optimal solution. However, it does appear that changes can be made to bicycles to reduce the instances of this type of injury. If we can do it, we should do it. Parents expect their children's bicycles to be as safe as they can be.

This may be one of those times where the greater freedom inherent in the voluntary standards process can provide us with a faster solution than would be possible under a regulatory one. While I am pleased that an ASTM subcommittee is working on this issue, I think it is premature to assume that they will necessarily adopt any changes. For this reason, I am voting to defer action on this petition until I see whether the subcommittee intends to move forward with a voluntary standard that would address these serious liver, kidney, pancreas, spleen and other abdominal wounds that are killing and seriously injuring our children.