Matthew R. Maltese, PhD
215 Knoll Road
Wallingford, PA 19086

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Docket Management Facility, M-30
U.S. Department of Transportation
West Building, Ground Floor, Room W12-140
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

Re: **Docket No. NHTSA–2020–0093,** FMVSS 213 NPRM comments

To Whom it May Concern,

Recently, the National Highway Traffic Safety Administration (NHTSA) released a Notice of Proposal Rulemaking (NPRM) for FMVSS 213. In the NPRM, NHTSA proposes to amend S5.5.5(f) of the current standard to adjust the minimum occupant weight for booster seats. As a part of their justification, NHTSA references an agency-authored study "Booster Seat Effectiveness Estimates based on CDS and state data" DOT HS 811 338 published in July 2010 (Sivinski 2010). I have conducted an analysis of the methods and findings of the Sivinski report as it pertains to the NPRM. With deep collegial respect for Mr. Sivinski and the NHTSA staff, my analysis and findings are described below. My purpose in submitting these comments is not to argue for or against the proposed change in the minimum occupant weight for booster seats, but rather to provide a critique of the justification for the change and some suggestions to improve the analysis.

Briefly, my professional backgrovghund is as follows. I hold Bachelor of Science and Masters degrees in mechanical engineering, and doctorate (PhD) in bioengineering. In 1994, I began a decade-long career at NHTSA in the biomechanics and crashworthiness research divisions. During this time, I conducted research and published on topics including human tolerance to impact, side impact interaction of children with airbags, abdominal injury patterns, injury criteria for child restraint evaluation, and crash test dummy biofidelity. I also conducted research and authored reports that contributed to federal motor vehicle safety standard (FMVSS) 208 (frontal impact), FMVSS 213 (child restraints) and FMVSS 214 (side impact) that are archived in the federal docket and peer-reviewed literature. Between 2004 and 2019, I held positions in biomechanics research at the Center for Injury Research and Prevention at the Children's Hospital of Philadelphia, and as a research assistant professor in the Perelman School of Medicine at the University of Pennsylvania. During this time I published 60+ peer-reviewed scientific and engineering articles and book chapters, on the biofidelity of pediatric anthropomorphic test devices (ATDs), epidemiology of injuries to children in side impact crashes, and performance of child restraints in sled and crash tests.

Presently, I am a part-time lecturer in the Department of Bioengineering at the University of Pennsylvania, a senior fellow at the Center for Injury Research and Prevention at the Children's Hospital of Philadelphia, a visiting research professor in the School of Biomedical Engineering, Science and Health Systems at Drexel University, and a faculty member at the McGowan Institute for Regenerative Medicine at the University of Pittsburgh. Most recently, I was retained by NHTSA through the Calspan Corporation to conduct the repeatability and reproducibility testing and analysis of the updated FMVSS 213 frontal standard seat assembly (Maltese and Horn 2019); that research was used to support the upgraded seat assembly in this

NPRM. My work has been recognized by my peers through several awards, and I am presently a member of the Abbreviated Injury Scale (AIS) Content Subcommittee of the Association for the Advancement of Automotive Medicine (AAAM). From 2013 to 2020 I served as an associate editor of the journal Traffic Injury Prevention.

Based upon the Sivinski report, NHTSA states in the NPRM that there "was as much as a 27 percent increased risk in non-incapacitating to fatal injury when restrained in booster seats compared to car safety seats." However, the NPRM does not outline several limitations of the Sivinski report, including limitations stated in the Sivinski report itself, when NHTSA states this finding. Briefly, as to the primary question of whether boosters are inferior to CRS in mitigating injury, the Sivinski results show that in most analyses there is no scientifically discernible difference between the protective effects of boosters compared to CRS in the real world, and in most of the results shown by Sivinski the confidence intervals indicate the possibility of benefit of boosters compared to harness restraints. That boosters would show benefit compared to CRS is certainly supported by other data, as CRS are 3 times more likely to be misused compared to boosters, and boosters are more effective in reducing head excursion which, in turn, mitigates head injury; head injury is by far the leading serious injury to children including CRS- and booster-restrained children, and thus head injury is the primary driver of field performance evaluations such as the Sivinski study. Adding to the aforementioned concerns are several fundamental flaws in the dataset itself. More specifically, it is important to note that during the early years of the study cohort, half of all boosters in use were shield boosters, and Sivinski does not discuss any effort to remove shield boosters from the study cohort. Additional limitations include known inaccuracies in the injury coding system that potentially could have been mitigated through published methods but were not, and the questionable combining of NASS CDS and state data as a single representative sample. Justification of the aforementioned points of criticism are outlined below, followed by several recommendations for future research.

1) **Sivinski shows little discernible difference between booster and CRS –** Firstly, the fundamental problems with the Sivinski cohort and analytical methods as outlined in points 2 through 5 below, call into question the validity of any results from the Sivinski report. With that said, it still worth noting that the Sivinski results show little discernible difference between booster and CRS real-world performance. That is, in Tables 7, 8 and 9, Sivinski shows results of 18 different statistical tests (3 age groups, 3 injury levels, 2 confidence interval calculations) that examine the question "Are 3 to 4 year old children restrained in booster seats at greater risk of injury compared to children in child restraints?" Sivinski's analysis yields two types of data. First, the point estimate is the percent injury increase in boosters compared to child restraint systems. The second is the "95%"confidence interval, which is two numbers that indicate a range within which the point estimate will fall 95% of the time. Of note, 13 of the 18 statistical tests addressing the aforementioned question show a negative value in the lower bound of the confidence interval, indicating that there is a possibility that booster seats are beneficial compared to CRS. It is not surprising that the Sivinski analysis shows little discernible difference between booster seat and harness CRS performance. Forward-facing harness CRSs have misuse rates that are 3 to 4 times that of booster seats (Misuse: forward facing CRS 57%, highback booster 15%, backless booster 21%)(Greenwell 2015), and some misuses (such as a lack of top tether usage) yield increased risk of head impact with the vehicle interior in CRS compared to belt-positioning boosters (Weber et al. 2013). Studies have shown that top tethers are only used 51% of the time. (Decina and Lococo 2007)

2) **Inaccuracies in injury coding** - In the report, Sivinski correctly notes that "injury coding may be inconsistent or inaccurate." (Page 11, Limitations section). The KABCO[1] injury scoring system used in the Sivinski report has been evaluated for its accuracy by comparing the KABCO injury scores with medical personnel-reported abbreviated injury scale (AIS) scores, which is considered a more reliable standard. From 66% to 70% of cases that were scored as "A-Incapacitating" on the KABCO scale were found to have only minor (MAIS 2 or less) injury (Farmer 2003; Tarko et al. 2010; Burdett et al. 2015). Non-injury factors (alcohol impairment, gender and vehicle type) contribute to these errors in KABCO scores. Certainly, the aforementioned findings are based primarily upon data from injured adults, and these inaccuracies in the KABCO scores may not exist in child crash occupants. However, since Sivinski used the KABCO injury score of the adult drivers as the control in the matched pair analysis, errors in the control cohort KABCO scores would influence the analysis of the effectiveness of the booster, CRS and belt restraints in mitigating injury in children. Further, the accuracy of the injury coding in the Sivinski CDS cohort could have been investigated by NHTSA by comparing the CDS-reported injuries with the police-reported injuries.

3) **Characteristics of the control group are unknown** – In the Sivinski study, the method of analysis is a double-pair comparison where the number of adult drivers at a particular KABCO injury level is used as a control for confounding factors such as exposure and crash severity. As stated by Sivinski, this technique was originally proposed by Evans (1986). Evans noted a key assumption of the method is that the probability that the control occupant is injured is independent of the restraint type of the child, and that this assumption could be violated if drivers of booster seated children were more (or less) prone to injury than drivers of CRS-restrained children. This phenomenon, which has been further elucidated in Cummings et al (2003), is particularly concerning since the inclusion criteria included drivers from age 14 to 97 years old and drivers across this age spectrum will have very different injury outcomes, all else being equal. This is important since it has been shown that the age of the driver is correlated to the type of child restraint used[2]. To confirm Siviniski's assumption that the control groups are uniform across restraint type stratifications, the characteristics of the adult control group including the distribution of age, gender and child restraint type should have been provided in the Sivinski study.

4) **Statistical viability of combining NASS CDS and state data** – The Sivinski cohort includes data from NASS CDS (unweighted) and data from three states. By design, the NASS CDS is a sample of severe crashes and the state data collection program is a sample of police reported crashes. While the double-pair comparison approach employed by Sivinski likely controls for the differences in crash severity between the CDS and state sub-cohorts, one cannot rule out selection bias in the CDS data that would cause exclusion of cases with minor injuries. Statistical methods for combining data from sample and census data collection instruments have been employed and should be given due consideration (Elliott et al. 2006; Griffin et al. 2012). In addition, because the data collection instruments for NASS CDS and 3 states rely on police reports, there is a chance that crashes were double counted in the Sivinski study.

5) **Prevalence of shield boosters in the Sivinski cohort** - The Sivinski dataset is made up of crash cases from 1999 to 2008. In the early part of that range of crash years (1999-2002), a separate study based upon crashes reported to an insurance company found that greater than half of all under 40 lb boosters in use in the real world were shield boosters (Winston et al. 2003), and in 2002 a NHTSA report indicated that shield boosters were available for purchase (NHTSA 2002). Use of shield boosters continued to diminish in the

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[1] The KABCO is a 5 level injury scale that is used by law enforcement personnel to characterize the injury to vehicle occupants.

[2] For example, children in seat belts are more likely to be driven by younger drivers as compared to children in belt-positioning booster seats. (Durbin, Elliott, and Winston 2003)

ensuing years and by 2006-2007 a field observational study reported less than 2% of all boosters used were shield boosters (O'Neil et al. 2009). Examination of the data element dictionaries of the three states used by Sivinski (State of Nebraska 2005; State of Kansas 2006; State of Washington 2006) reveal no unique code to distinguish shield boosters from belt-positioning boosters. Sivinski does not mention shield boosters in his report, though a footnote in each table suggests that seating was limited to outboard positions; convenience samples of crashes indicate shield boosters are likely to be found in outboard seating positions (Edgerton, Orzechowski, and Eichelberger 2004; Whitman et al. 1997). The implication of all of this is that shield boosters and belt-positioning boosters differ in their biomechanical method of restraint and their performance, and thus the shield booster field performance is not reflective of the belt-positioning booster field performance. NHTSA could explore this further by comparing booster type indicated in the police reports with the CDS crash investigation data.

Conclusions and Recommendations

When implementing any safety device through regulation, the potential for unforeseen negative consequences always exists, especially where the effectiveness of the current intervention is already quite high. NHTSA's approach in the 2003 FMVSS 213 final rule is sound reasoning and pertinent to the matter at hand:

"Thus, to maximize the total safety benefits of its efforts to extend and upgrade its restraint requirements, the agency [NHTSA] must balance those improvements against impacts on the price of restraints. The agency must also consider the effects of improved performance on the ease of using child restraints. If the use of child restraints becomes overly complex, the twin problems of misuse and nonuse of child restraints could be exacerbated." (NHTSA 2003)

In the present NPRM, the agency must be careful to ensure that its ban of booster use by a portion of the population does not cause harm to that population. Banning an easy-to-use safety intervention (BPB) for a portion of the population and replacing it with a frequently misused restraint (harness restraint), without a compelling real-world safety benefit as evidenced by an epidemiological study, would be bad safety policy. I recommend that the agency repeat the Sivinski study to support or refute the proposed change in booster minimum weight, and below are some recommendations to be considered in the repeated study:

1) Add more years and states – Sivinski's concluding statement that the "analysis will benefit from more years of collection and inclusion of other States" is correct and is now possible given that a decade has passed since the original work. Thus, a future analysis by NHTSA should include more years of data and, if possible, more states. The increase in data should obviate the need for combining the CDS and state data as in the current Sivinski study.

2) Limit the years of inclusion to minimize the number of shield boosters in the dataset – As detailed above, shield boosters were likely a large part of the Sivinski cohort, and there is no apparent method to discern shield from belt-positioning boosters in the state data. Thus, I recommend creating a revised state data cohort that begins when the prevalence of shield boosters is near zero. Child restraint use data suggest circa 2006 as a good start date for a dataset that would have minimal numbers of shield boosters.

3) Test cohort robustness - To test the robustness of the state data and thereby increase reader confidence in the results, expand the analysis to test related hypotheses that have been validated in

other datasets. For example, one could use the state data to examine the effectiveness of CRS compared to seat belts, and compare the results with those of Elliott et al who used a combined FARS / NASS dataset to examine the same question (Elliott et al. 2006). In addition, the outcomes of each type of child restraint (booster, harness restraint, or belt) could be compared with the unrestrained occupant. If the findings of the aforementioned analyses match previously published reports from insurance, NASS, FARS and other data sources for similar time periods, then the confidence in the findings will increase.

4) Employ techniques to mitigate errors in KABCO injury severity scores - KABCO injury severity scoring has been shown to be inaccurate, with alcohol use, gender, vehicle type and lighting conditions influencing the accuracy of the KABCO score. Of note, mathematical models have been developed to adjust the KABCO score to overcome the aforementioned deficiencies using variables available in most state data crash reports (Burdett 2014). Such mathematical models improve the KABCO classification scores from 18% to 33% accuracy without the model, to 51% to 77% accuracy with the model at the A and B injury levels. Thus, in a future analysis NHTSA could adjust the KABCO score and then apply Evans' double-pair comparison analysis.

5) Validate the uniformity of the control group – As detailed above, it is possible that the benefit (or disbenefit) of the restraints is driven in whole or in part by differences in age or other characteristics in the adult control groups. To confirm that this control group bias does not exist, compare key characteristics of the control groups (the adult occupants) that correlate to injury vulnerability. In short, the control groups should be in vehicles of similar vintage and size, and their ages and gender should be similar. Restraint type of the adults is also an important factor, which Sivinski has opted to control through inclusion criteria. An example of comparing the statistical difference in occupant groups in state crash data can be found in Table 1 of Anderson et al (2017).

I am grateful for the opportunity to provide comments on this important upgrade in child passenger safety. Please do not hesitate to contact me should you have any questions.

Sincerely,

Matthew R. Maltese, PhD

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