

March 15, 2013

Jim Simons  
Information Dissemination Guidelines  
National Highway Traffic and Safety Administration  
US Department of Transportation  
Washington, D.C. 20590

Dear Mr. Simons:

As a citizen of Maryland who regularly rides a bicycle in New Jersey and the District of Columbia, and on behalf of the Washington Area Bicyclists Association, I respectfully submit this request for correction of statements by the National Highway Traffic Safety Administration (NHTSA) concerning the effectiveness of bicycle helmets, under the federal Data Quality Act and the Department of Transportation's Information Dissemination Quality Guidelines.<sup>1</sup> NHTSA exaggerates the effectiveness of bicycle helmets by stating that they "are up to 85% effective" in mitigating head injuries, without mentioning material caveats. Versions of that statement appear many places on NHTSA's web site. We also request that NHTSA either substantiate or remove statements that wearing a helmet is the most effective way for a cyclist to avoid a head injury.

NHTSA's statement that helmets are "up to 85% effective" is, at best, a biased and misleading summary of a common mischaracterization of the results from a 1989 study of Seattle, which is out-of-date. The 1989 study did not show that helmets are 85% effective. Rather it found an odds ratio of 0.15, and then made a common oversimplification by assuming that an odds ratio of 0.15 implies effectiveness of 85%, though an estimate 73–77% would have been equally reasonable. Even if the 85% had been correct, NHTSA's statement would be biased, because it presents the most optimistic end of the range of study results (up to 85% effective) without mentioning the pessimistic end. Perhaps more importantly, the 1989 study is out-of-date: more than a dozen similar studies conducted since then show helmets to be substantially less effective. Finally, the statements are misleading, for two reasons: First, providing a single estimate implies that effectiveness has been accurately estimated, when in fact it is very uncertain. Second, helmets increase the risk of neck injuries, which appear to offset almost half the decline in head injuries. No one has established that the protective effect of helmets is more important than the increased risk of neck injuries for all classes of cyclists (e.g. a crash with an automobile or a helmet that is worn incorrectly).

Helmets usually reduce head injuries. But NHTSA has been unable to document its claim that "a helmet is the single most effective way to prevent head injury resulting from a bicycle crash<sup>2</sup>." Without such documentation, the statement seems to be an enthusiastic exaggeration.<sup>3</sup> A reasonable person might assume that running lights, well-maintained brakes, and avoiding a crash are more important than wearing a helmet.

## 1 OBJECTIVE OF THIS REQUEST

We seek correction of statements on the NHTSA web site asserting that bicycle helmets reduce head injuries 85% (with or without the "up to" qualifier), as well as similar statements based primarily or solely on a selective reading of the literature. We also seek an end to the practice of stating helmet effectiveness with a single number, unless that number reflects the *conservative* end of the range of uncertainty from a balanced reading of published research. Correction could mean converting quantitative statements to qualitative statements, or providing a revised quantitative estimate consistent with the existing peer-reviewed scientific literature. For balance, we ask that quantitative or qualitative presentation of the reduction in head injuries include a comparable mention of known side effects, such as the risk of increased neck injuries.

We also ask that statements about the comparative effectiveness of helmets either be removed, or be revised to be consistent with and cite the peer-reviewed literature.

Because it would be more efficient for NHTSA to do so, we have not identified every NHTSA web page that make these erroneous statements, but we do provide a partial list to ensure that our request is clear. While the phrasing of these claims has varied, Administration staff has confirmed that NHTSA continues to promote these two claims. (See the Appendix for email traffic.) The following pages in html claim that helmets are 85 or 88% effective (with the year in parentheses when the page is clearly dated):

<http://www.nhtsa.gov/people/injury/pedbimot/bike/easystepsweb/> (2006)  
<http://www.nhtsa.gov/people/injury/pedbimot/bike/bikehelmetuselawsweb/pages/5Analysis.htm>  
<http://www.nhtsa.gov/people/injury/pedbimot/bike/10smartroutesbicycle/pages/smartroutes.htm>  
[http://www.nhtsa.gov/people/injury/buses/Getting\\_to\\_School/child\\_pass.html](http://www.nhtsa.gov/people/injury/buses/Getting_to_School/child_pass.html) (2001)  
[http://www.nhtsa.gov/people/injury/buses/Getting\\_to\\_School/article3.html](http://www.nhtsa.gov/people/injury/buses/Getting_to_School/article3.html)  
<http://www.nhtsa.gov/people/injury/pedbimot/bike/safe-routes-2002/forms.html>  
[http://www.nhtsa.gov/people/injury/buses/Getting\\_to\\_School/article2.html](http://www.nhtsa.gov/people/injury/buses/Getting_to_School/article2.html)  
<http://www.nhtsa.gov/About+NHTSA/Press+Releases/1997/ci.Cleveland+Kids+Participate+in+Bicycle+Safety+Event.print>

The following pdf files also make the claim:

[http://www.nhtsa.gov/nhtsa/whatsup/SAFETEAWeb/FY11/FY11ARs/CA\\_FY11AnnualReport.pdf](http://www.nhtsa.gov/nhtsa/whatsup/SAFETEAWeb/FY11/FY11ARs/CA_FY11AnnualReport.pdf)  
[http://www.nhtsa.gov/nhtsa/whatsup/SAFETEAWeb/FY11/FY11ARs/FL\\_FY11AnnualReport.pdf](http://www.nhtsa.gov/nhtsa/whatsup/SAFETEAWeb/FY11/FY11ARs/FL_FY11AnnualReport.pdf)  
<http://www.nhtsa.gov/people/injury/new-fact-sheet03/bicyclehelmetuse.pdf>  
<http://www.nhtsa.gov/people/injury/pedbimot/bike/BikeHelmetUseLawsWeb/images/BicycleHelmetUseLaws.pdf> (2002)  
<http://www.nhtsa.gov/DOT/NHTSA/Communication%20&%20Consumer%20Information/Articles/Associated%20Files/810886.pdf> (2008 Traffic Safety Facts)  
[www.nhtsa.gov/people/injury/TSFLaws/PDFs/810886.pdf](http://www.nhtsa.gov/people/injury/TSFLaws/PDFs/810886.pdf) (2008 Traffic Safety Facts)  
<http://www.nhtsa.gov/people/injury/new-fact-sheet03/bicyclehelmetuse.pdf> (2004 Traffic Safety Facts)  
<http://www.nhtsa.gov/DOT/NHTSA/SafeCommunities/Articles/PDFFiles/july2008-newsletter.pdf> (2008)  
<http://www.nhtsa.gov/DOT/NHTSA/Traffic%20Injury%20Control/Articles/Associated%20Files/BikeSafetyforAdults.pdf>

The following pages make the claim that a helmet is the single most effective way (or device) to prevent head injury resulting from a bicycle crash, but again this list is not exhaustive:

<http://www.nhtsa.gov/people/injury/new-fact-sheet03/bicyclehelmetuse.pdf>  
<http://www.nhtsa.gov/people/injury/TSFLaws/PDFs/810886.pdf>  
<http://www.nhtsa.gov/nhtsa/announce/press/PressDisplay.cfm?year=1997&filename=pr051397.html>  
<http://www.nhtsa.gov/DOT/NHTSA/Traffic%20Injury%20Control/Articles/Associated%20Files/811110.pdf>  
<http://www.nhtsa.gov/people/injury/pedbimot/bike/easystepsweb/>  
<http://www.nhtsa.gov/nhtsa/announce/press/PressDisplay.cfm?year=1996&filename=pr012496a.html>

Some of these publications are press releases or only on the website for archival purposes, and hence not subject to the Data Quality Act guidelines. Nevertheless, we ask that measures be taken to ensure that a typical reader who finds those publications on the NHTSA website would realize that NHTSA no longer claims that helmets are 85% effective. Even experienced journalists sometimes mistake websites provided for archival purposes as representing the current opinion of an agency. (See e.g. Ashley Halsey, *Washington Post*, February 7, 2013. "The Centers for Disease Control and Prevention says helmet use reduces head injuries by 80 percent."<sup>4</sup>). If certain safety fact sheets are provided through search engines without a disclaimer that they no longer represents NHTSA's opinion, it would be more accurate to say that NHTSA is still disseminating them than to say that they are only on the site for archival purposes.

## 2 THE SPECIFIC REASONS FOR BELIEVING THE INFORMATION DOES NOT COMPLY WITH OMB OR DOT GUIDELINES AND IS IN ERROR.

The OMB and DOT guidelines for information quality require that information disseminated be objective, accurate, and unbiased.<sup>5</sup>

“Objectivity” includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information... so that the public can assess for itself whether there may be some reason to question the objectivity of the sources.... In addition, objectivity involves a focus on ensuring accurate, reliable, and unbiased information.

The following subsections show that statements on the NHTSA website violate the OMB and DOT guidelines because they are inaccurate or unsupported: The “up to 85%” estimate (§2.1) is an outdated outlier, (§2.2) overstates the certainty about helmet effectiveness, (§2.3) is based on a statistical oversimplification, and misleads people by (§2.4) ignoring the increased risk of neck injuries and (§2.5) using the phrase “up to” instead of the more neutral “less than”. (§2.6) NHTSA has been unable to document any basis for the statement that helmets are the most effective way to avoid a head injury. But first, we briefly discuss the problem of bias.

The evolution of how NHTSA phrased the claims of helmet effectiveness creates the appearance that program objectives have dictated the information that NHTSA disseminates, rather than the other way around.

- In 1989, the first high-quality case-control study of helmet effectiveness provided a valid estimate that the odds ratio for the protective effect of helmets from head injuries is 0.15. Based on a generously high estimate that 24% of cyclists (40% of people over 15) were using helmets in 1987, the authors calculated that helmets had been 85% effective.
- Although the limitations of that study were evident to any epidemiologist or statistician who read the 1989 paper, NHTSA repeated the 85% claim without qualification.
- As additional studies showed helmets to be less effective than 85%, NHTSA continued to state that helmets are 85% effective.
- When two meta-analyses showed the entire confidence range of helmet effectiveness to be less than 85%, NHTSA attempted to salvage the 85% figure by changing its claim that helmets are 85% effective, to a claim that helmets are “up to 85% effective,” without mentioning that studies also showed that effectiveness could be as little as 10–20 percent.
- As evidence has mounted that helmets increase neck injuries, NHTSA has chosen to not even mention that side effect *qualitatively*—a stark contrast with NHTSA’s decision to tout the 85% effectiveness for head injuries based on a single study.
- Similarly, NHTSA once claimed that helmets are the “single most effective” way to prevent deaths and head injuries.<sup>6</sup> Staff has indicated that this claim has been modified to “single most effective *piece of safety equipment* to prevent brain injury *in the event* of a bicycle crash.”<sup>7</sup>

The appearance of bias need not imply that NHTSA was intentionally biased. NHTSA may have simply repeated claims made by seemingly authoritative public health<sup>8</sup> and safety advocates.<sup>9</sup> The public health community adopted a similarly selective reading of the scientific literature, in an effort to promote wider use of helmets and enactment of mandatory helmet laws.<sup>10</sup> Nevertheless, the imperatives for government agencies and public health advocates may be different: Public health advocates often need a simple, clear statement to get people to pay attention. Caveats can leave people with a mixed message, while creative exaggeration is often inherent to good marketing. Government information, by contrast, must be accurate and unbiased, even if the true state of knowledge is a mixed message or difficult to explain.

### **2.1 NHTSA’s estimate of 85 percent is not even within the uncertainty range of the three meta-analyses of published case-control studies of helmet effectiveness.**

While the NHTSA web pages generally do not cite the source, NHTSA staff has provided me with documentation clearly showing that the source of the 85 percent estimated reductions in head injuries came from a case-control study of injured cyclists in Seattle by Thompson et al. (1989)<sup>11</sup> [hereinafter “Thompson”]. That

study included the statement “we conclude that safety helmets reduce the risk of head injury by 85 percent and of brain injury by 88 percent.”<sup>12</sup> It was a good study, and accomplished much, but it is also an outlier.

The Thompson study did not formally estimate 85 or 88 percent reductions in injuries. Rather it estimated the odds ratios to be 0.15 and 0.12 for head and brain injuries respectively, and simply equated odds ratio with relative risk, in what turned out to be the most widely cited sentence of the study. The convention for case-control helmet studies is to estimate the odds ratio, which is defined as

$$\text{Odds} = \frac{H_{\text{case}}/E_{\text{case}}}{H_{\text{control}}/E_{\text{control}}}$$

where  $H$  equals the number of people wearing helmets and  $E$  represents people with exposed heads, for the case and control populations. The odds ratio is generally less than relative risk. This distinction is often unimportant, but not always; so many studies understate relative risk and overstate helmet effectiveness. See Section 2.3.

Table 1 shows the reported odds ratios (95% range) from published case-control studies during the last quarter century.<sup>38</sup> What stands out is that none of the ten studies conducted after 1991 found an odds ratio of head injuries as low as the Thompson (1989) study. Even the more in-depth study of Seattle by the same team in 1996 found the entire confidence range for the odds ratio of head injuries to be greater than the estimates from their 1989 study, on which NHTSA has relied for all these years.<sup>39</sup> And most studies by other authors in different cities have found helmets to be substantially less effective than the Thompson team found for Seattle.

Three meta-analyses have developed summary estimates by combining the results from all the published studies meeting specified criteria. The right three columns of Table 1 show which studies were included in each. The most thorough assessment by Attewell et al.<sup>40</sup> found the odds ratios for head, brain, and face injuries to be 0.4, 0.42, and 0.53, respectively. Ten years later, Elvik<sup>41</sup> updated the Attewell analysis by adding the results of newer studies and employing newer techniques for meta-analysis. The newer studies alone brought the odds ratio up to 0.5 and 0.74 for head and face injuries, respectively. With the newer analytical techniques as well, the odds ratios are 0.58, 0.47, and 0.83 for head, brain, and face injuries, respectively.

A smaller meta-analysis was conducted by Thompson et al. (1999), also known as a “Cochrane Review.”<sup>42</sup> Their summary estimate of helmet effectiveness was the same as their 1996 estimates for Seattle, partly because their calculations only included results from two studies outside of Seattle.<sup>43</sup> As Table 1 shows, they also judged the McDermott study to be reliable, but excluded their results from the meta-analysis because the McDermott study reported the actual results and simple odds ratio but did not undertake a regression analysis to adjust for other factors. Had Thompson et al. (1999) included the McDermott results, the summary results of their Cochrane Review would have been close to the results of the meta-analysis by Attewell.

<b>Table 1: Odds Ratio<sup>13</sup> of Injury With Helmets</b>						
<b>Head Injuries (95% range)</b>				Study included in meta-analysis?		
<i>Case Control Studies</i>				Thompson	Attewell	Elvik
Lead Author	Year	Low	High			
Dorsch <sup>14</sup>	1987	0.12	0.47		✓	✓
Thompson <sup>15</sup>	1989	0.07	0.29	✓	✓	✓
Spaite <sup>16</sup>	1991	0	0.23		✓	✓
McDermott <sup>17</sup>	1993	0.47	0.79	<sup>18</sup>	✓	✓
Maimaris <sup>19</sup>	1994	0.11	0.83	✓	✓	✓
Thomas <sup>20</sup>	1994	0.32	0.84	✓	✓	✓
Finvers <sup>21</sup>	1996	0.11	0.90		✓	✓
Thompson <sup>22</sup>	1996	0.26	0.38	✓	✓	✓
Jacobson <sup>23</sup>	1998	0.20	0.70		✓	✓
Linn <sup>24</sup>	1998	0.49	0.83		✓	✓
Shafi <sup>25</sup>	1998	0.61	3.1 <sup>a</sup>		✓	✓
Hansen (hard) <sup>26</sup>	2003	0.21	0.6			✓
Hansen (soft) <sup>27</sup>	2003	0.41	1.7 <sup>a</sup>			✓
Heng <sup>28</sup>	2006	<sup>29</sup>				✓
Amoros <sup>30</sup>	2009	0.44	0.88			✓
<i>Meta-Analyses of all Qualifying Studies</i>						
Attewell <sup>31</sup>	2001	0.29	0.55			
Thompson <sup>32</sup>	1999	0.26	0.37			
Elvik <sup>33</sup>	2011	0.45	0.75			
<b>Neck Injuries (meta-analyses only)</b>						
Attewell <sup>34</sup>	2001	1.00	1.86			
Elvik <sup>35</sup>	2011	1.01	1.72			
<b>Head &amp; Neck Injuries (meta-analyses only)</b>						
Attewell <sup>36</sup>	2001	0.50	0.59			
Elvik <sup>37</sup>	2011	0.74	0.98			
a. Greater than 1.0 signifies that people wearing helmets had higher rate of injuries.						

## **2.2 By stating that helmets reduce the risk by 85 percent, NHTSA implies that helmet effectiveness can be estimated to two significant digits when in fact, it cannot be estimated to within one significant digit.**

A quick glance at Table 1 shows that the odds ratio of bicycle helmets has an uncertainty of at least a factor of two. Results from individual studies show the odds ratios ranging from around 0.2 up to 0.8. The original study by Thompson reported a range of 0.07 to 0.28.

For the more comprehensive meta-analyses by Attewell and Elvik, the upper end of the confidence range for the odds ratio is about 0.3 greater than the lower end. The meta-analyses rely on the convenient assumption that the various case-control studies are independent and unbiased so that uncertainty declines with the square root of the number of studies undertaken. If the case-control studies have inherent (but unknown) bias or measurement error<sup>44</sup>, or the goal is to inform people what the effectiveness is likely to be for them (rather than for the entire population<sup>45</sup>), then a better estimate of our uncertainty would be the range of results, without discounting the variance by the number of studies.

Those in the public health community have traditionally assumed that most people making decisions need a single number, and that conveying the range of uncertainty will leave too many people with the impression that scientists don't know enough to justify action. But that view is changing, and the trend is increasingly toward a transparent communication of what is and what is not known—and a confidence range.

Leaving aside the fact that the Thompson studies did not actually estimate the effectiveness of bicycle helmets, and the question of whether their 1989 study was an outlier, it was always clear that there is a very wide confidence range. Failing to communicate that uncertainty, in effect, asks the public to have more faith in a given estimate than the researchers have about their own results.

## **2.3 NHTSA's 85-percent estimate is based on a common oversimplification, which is to assume that the relative risk between wearing and not wearing a helmet is equal to the odds ratio that the case-control studies calculate; but if the odds ratio is less than 1.0, relative risk always is greater than the odds ratio—sometimes significantly so.**

The NHTSA website repeatedly states that helmets reduce the risk or frequency of head injuries by 85 percent, but the study on which that statement is based did not directly estimate effectiveness. It estimated that the odds ratio is 0.15, and then assumed that helmets reduce injuries by 85 percent. In effect, the researchers made a common oversimplification by assuming that the relative risk must be 0.15, which would have implied risk reduction of 0.85.<sup>46</sup> A more careful evaluation of their results, however, would have shown that relative risk might have been about 50% greater.

Helmet effectiveness is equal to one minus the relative risk. We define  $\mathbf{P}(\text{case})$  as the probability of a head injury,  $\mathbf{P}(\text{no-case})$  and as the probability of not sustaining a head injury in an accident. We can define relative risk ( $R$ ) as

$$R = \mathbf{P}(\text{case}/\text{helmet})/\mathbf{P}(\text{case}/\text{exposure})$$

where “helmet” means that the cyclist is wearing a helmet and “exposure” means she is not wearing a helmet. We also define “control” as a sample group of people who did not sustain a head injury. In a study based on random trials, we could estimate relative risk as

$$\hat{R} = \frac{H_{\text{case}}/(H_{\text{control}}+H_{\text{case}})}{E_{\text{case}}/(E_{\text{control}}+E_{\text{case}})} = \frac{H_{\text{case}}/E_{\text{case}}}{(H_{\text{control}}+H_{\text{case}})/(E_{\text{control}}+E_{\text{case}})}$$

In the case-control studies, one does not directly measure either of these conditional probabilities. Instead, one has a case and a control group, which allows one to measure

$$\begin{aligned}\hat{P}(\text{helmet}|\text{case}) &= H_{\text{case}}/N_{\text{case}}, & \hat{P}(\text{exposure}|\text{case}) &= 1 - \hat{P}(\text{helmet}|\text{case}) = E_{\text{case}}/N_{\text{case}} \\ \hat{P}(\text{helmet}|\text{no-case}) &= H_{\text{control}}/N_{\text{control}}, & \hat{P}(\text{exposure}|\text{no-case}) &= 1 - \hat{P}(\text{helmet}|\text{no-case}) = E_{\text{control}}/N_{\text{control}}\end{aligned}$$

where  $N = H + E$ , that is  $N$  is the total number of people in the group. These four estimators are the quantities needed to estimate the odds ratio:

$$\widehat{Odds} = \frac{H_{\text{case}}/E_{\text{case}}}{H_{\text{control}}/E_{\text{control}}}$$

Although  $P(\text{case}|\text{helmet})$  is not the same as  $P(\text{helmet}|\text{case})$ , Cornfield (1951)<sup>47</sup> pointed out that the odds ratio provides a good estimate of relative risk for rare diseases (in this case, provided that head injuries are rare) (Notice that the numerators are the same in our equations defining *Odds* and  $\hat{R}$ , and that the denominators converge if  $H_{\text{case}}$  and  $E_{\text{case}}$  are very small.<sup>48</sup>). The relationship between the two quantities in the underlying population is:

$$R = Odds \frac{P(\text{helmet}|\text{no-case})/P(\text{exposure}|\text{no-case})}{P(\text{helmet})/P(\text{exposure})} = Odds \frac{P(\text{helmet}|\text{no-case})/P(\text{helmet})}{P(\text{exposure}|\text{no-case})/P(\text{exposure})}$$

The ratio must be greater than 1.0 if helmets are effective. The formulation on the right shows that this ratio is simply the ratio of the fraction of helmeted cyclists who do not get a head injury, to the fraction un-helmeted cyclists who do not get a head injury. The formulation on the left emphasizes the potential for the ratio to equal 1.0: If head injuries are rare, then any statement or proportion that applies to people who do not get a head injury must be very similar to the statement or proportion for all cyclists.

These probabilities suggest alternative ways to estimate relative risk, given an estimate of the odds ratio. Whether or not cases are rare,  $H/E$  for the control group is a reasonable estimate of the numerator of the first ratio:  $P(\text{helmet}|\text{no-case})/P(\text{exposure}|\text{no-case})$ . There are a number of different ways to estimate the denominator:  $P(\text{helmet})/P(\text{exposure})$

1.  $H/E$  for the entire study population may be appropriate if the process of selecting the case and control samples provides unbiased estimates of both their relative sizes and the proportions that use helmets.
2. Researchers might simply assume that the ratio is 1.0 if head injuries are rare and the sample control population is a random sample of all cyclists having an accident but no head injury.
3. An alternative data source may provide an accurate contemporary survey of the proportion of cyclists who use helmets.

The third possibility requires extra effort. But the first possibility provides a readily available alternative to simply assuming that relative risk equals the odds ratio, especially for those studies that obtain the case and control data from the same source.

Are helmet injuries rare? As a fraction of the total number of all bicycle crashes, yes. But as a fraction of the total number serious accidents requiring hospitalization or a police report, probably not. In the case-control studies that draw both case and control samples from a common source (e.g., hospitalization), the proportion of people with head injuries is usually significant. Given the lower use of helmets by the case group, the proportion of cyclists wearing helmets in the control group is much greater than the proportion for all cyclists in the study. If the study sample is representative of the entire population, then the control group can not be representative of the overall population of cyclists that do not experience a head injury, i.e.,

$$H_{\text{control}}/E_{\text{control}} > P(\text{helmet}|\text{no-case})/P(\text{exposure}|\text{no-case}).$$

That would not be surprising: If someone is involved in a bike crash serious enough to go to the hospital but still avoids a head injury, she is more likely to have been wearing a helmet than the average cyclist in a crash, since some cyclists will get a head injury. If the cyclists who avoided a head injury because of the helmet

generally reported to the hospital anyway, perhaps because of another injury, then the case and control populations may be a valid sample of helmet use by people having a serious accident. In that case, one could use the same formula as for a randomized trial to calculate relative risk. Expressed as a multiple of the odds ratio, we would have:<sup>49</sup>

$$\hat{R} = Odds \frac{H_{control}/(H_{control} + H_{case})}{E_{control}/(E_{control} + E_{case})}$$

On the other hand, if cyclists who avoid a head injury because of the helmet do not report to the hospital, then that formula would have to be adjusted to account for the underestimate of the number of helmeted cyclists involved in a serious accident.<sup>50</sup> That adjustment would roughly yield the same estimate as the odds ratio. Not knowing whether these cyclists are in the control group or not, it might be reasonable to consider both approaches rather than only the odds ratio.

Table 2 calculates relative risk using both approaches, for the studies reviewed by Atwell. The two columns at the right show the odds ratio and relative risk, based on the observations of *E* and *H* for the case and control populations. The table suggests that mistakenly using the odds ratio when the other formula is more appropriate will generally overstate the effectiveness of helmets by more than 10 percent.

The table uses the term “quasi relative risk” as a reminder that the calculated relative risk is only a valid estimator in a random trial experiment, or if the study is otherwise designed so that the fraction of cyclists who use helmets in the study matches the fraction of all cyclists involved in crashes who are wearing helmets.

<b>Table 2: Comparing the Odds Ratio and Relative Risk of Head Injury With and Without Helmets</b>									
	Case		Control		% Injured		% head injuries	Odds ratio	Quasi Relative Risk
Lead Author	H	E	H	E	H	E			
Dorsch	62	61	60	14	51	81	62	<b>0.24</b>	<b>0.62</b>
Thompson <sup>a</sup>	17	218	103	330	14	40	35	<b>0.25</b>	<b>0.36</b>
Spaite	1	37	115	131	1	22	13	<b>0.03</b>	<b>0.04</b>
McDermott	90	468	276	876	25	35	33	<b>0.61</b>	<b>0.71</b>
Maimaris	4	100	110	828	4	11	10	<b>0.30</b>	<b>0.33</b>
Thomas	31	67	126	140	20	32	27	<b>0.51</b>	<b>0.61</b>
Finvers	4	72	92	531	4	12	11	<b>0.32</b>	<b>0.35</b>
Thompson <sup>b</sup>	222	535	1497	1137	13	32	22	<b>0.32</b>	<b>0.40</b>
Jacobson	18	38	97	76	16	33	24	<b>0.37</b>	<b>0.47</b>
Linn	101	467	226	668	31	41	39	<b>0.64</b>	<b>0.75</b>
Shafi	21	107	10	70	68	60	62	<b>1.37</b>	<b>1.12</b>
a = Thompson (1989), b = Thompson (1996). Source: First 8 columns are from Attewell. See text for how relative risk is calculated. “Quasi relative risk” would be a valid estimate of relative risk if the study had been designed so that the proportion of people with head injuries and/or wearing helmets in the study reflected the proportions in the general population.									

Because that was not necessarily part of the design in most of the studies summarized in Table 2, the quasi relative risk calculations are shown mainly to illustrate how the odds ratio *would* underestimate relative risk if the study *was* designed to estimate relative risk. Many of the authors appear to be content to estimate an odds ratio. But if one does not know whether to view helmets as rare within the context of the data used for the control population, the two sets of estimates may provide a useful way to bound the estimates of effectiveness.

Because Attewell used the simple odds ratio from each study, Table 2 shows an odds ratio of 0.25 for the Thomas

study. Using their adjusted odds ratio of 0.15 would imply quasi helmet effectiveness of 73–77%.<sup>51</sup> Unlike many case-control studies, Thomas considered the possibility that the odds ratio might not provide a valid estimate of relative risk, took the extra step of examining a second set of data on helmet use, provided by a health insurance company. Because that data set reported the same proportion of helmet use in 1987 as the control group (24%), Thomas concluded that the control group had provided a valid estimate of the proportion of cyclists using bicycle helmets. A more detailed survey by a Thomas co-author, however, suggested that helmet use might have been significantly less for children than implied by that data set.<sup>52</sup> One can always second-guess a study after it is published; the fact that people continue to second-guess that study a quarter century later is a tribute to how well it was done. Nevertheless, as people ponder why that study seems to be an outlier, a strong candidate is that helmet usage by the general cycling public was less than 25% during 1987.<sup>53</sup>

## **2.4 Case-control studies imply that increased neck injuries offset about half the reduction in head injuries from helmets; NHTSA's failure to emphasize this adverse side effect embodies the type of bias prohibited by the OMB Guidelines.**

Most doctors and drug companies recognize an ethical duty to warn of side effects, even when those side effects are almost certainly less harmful than the medical condition being treated. Table 1 shows that the risk of increased neck injuries offsets approximately half the head injuries caused by helmets. Interestingly, the incidence of neck injuries is negatively correlated with head injuries, so that the variance of all head and neck injuries is less than the variance of either head or neck injuries alone.

Four of the case-control studies that quantify the reduction in head injuries have also quantified the risk of neck injuries from helmets, and that effect has been included in the meta-analyses by Attewell and Elvik. This side effect is understood even less than the extent to which helmets reduce head injuries. An advocacy organization that wants to encourage the use of helmets might be inclined to avoid mentioning the side effect of neck injuries until they are better established. For NHTSA to follow that approach, however, tends to show bias, for two reasons. First, NHTSA was willing to broadcast<sup>54</sup> estimates of the effectiveness of helmets based on only one study. Second, NHTSA is providing quantitative estimates of helmet effectiveness based on case-control studies; and once an agency enters that arena, it has a duty to present both the positive and negative results from the body of research on which it relies, not merely those results that support its preferred policy.

## **2.5 By emphasizing the high end of the confidence range while omitting the low end, NHTSA's statements about helmet effectiveness are biased in a way that is prohibited by the OMB Guidelines.**

The statement that helmets are “up to 85 percent” reflects a recognition that 85 percent is at the high end of the range of estimated effectiveness. Because the older web pages simply state that helmets are 85 percent effective, while later pages add the qualifier “up to” (or equivalent modifiers), it appears that NHTSA made a conscious decision to keep using the 85 percent figure, even as it realized that it was not a valid central estimate. Such may sometimes be justified, as Mercer and Arlen (1944) pointed out:

You've got to accentuate the positive  
Eliminate the negative  
Latch on to the affirmative  
Don't mess with Mister In-Between

You've got to spread joy up to the maximum  
Bring gloom (down) down to the minimum  
Otherwise (otherwise) pandemonium  
Liable to walk upon the scene<sup>55</sup>

Advocates attempting to motivate other people to take action often present a simple vision of what can be achieved; so it might be reasonable for advocacy organizations to accentuate the optimistic end of the uncertainty range. But the Data Quality Act requires agencies to give equal emphasis to the positive and the negative, or present the central estimate (Mister In-Between).

In the case of safety equipment, it is especially unreasonable to only emphasize the optimistic end of the uncertainty range. When risks are uncertain, the conservative approach of equipment vendors and risk managers is to pay close attention to the pessimistic end of the range. As an example, consider the case where engineers calculate that the odds of a bridge collapsing over the course of a year from continued rail traffic are somewhere between 1-in-a-billion and 1-in-100. People thinking about boarding a train would generally feel more entitled to be warned that by doing so, their chances of being alive tomorrow could be as low as 99%, than being told that their chances of living are up to 99.9999999%. Similarly, the purchasers of a product often expect more accurate information on the minimum performance, than the maximum performance of a product.

The phrase is also misleading. Some people who hear the phrase “up to 85%” interpret it as implying that the actual estimate is close to 85%. This month, the Maryland Department of Transportation recommended legislation, with one of the reasons being that “NHTSA further reports that bicycle helmets are 85 to 88%



effective in mitigating head injuries.”<sup>56</sup> While the phrase “up to 85% effective” means the same thing as “between 0 and 85% effective,” many people take away a different meaning.

## **2.6 NHTSA has been unable to substantiate the claim that bicycle helmets are the single most effective way to avoid a head injury or death.**

NHTSA has repeatedly stated that helmets are the most effective way (or device) to prevent head injuries and fatalities, but my requests to obtain documentation for the claim have been unsuccessful.<sup>57</sup> NHTSA did provide one document that seems to suggest that efforts by safety advocates to get people to wear helmets may be more effective than other *efforts that safety advocates* might take,<sup>58</sup> although the document largely leaped to that conclusion rather than carefully estimating the costs and results from alternative advocacy efforts. But regardless of the validity of that conclusion, the website states that wearing a helmet is the most effective thing a *cyclist* can do, which is very different from being the most effective thing for NHTSA to advocate.

Many cyclists in the Washington area doubt NHTSA’s claim.<sup>59</sup> They believe that the most effective way to avoid a head injury or a fatality is to ride safely and not have a crash. Avoiding the use of a cell phone and/or headphones may be more important than wearing a helmet. Among the types of safety equipment, helmets are not at the top of the list. Working brakes and running lights may be more important. Even wearing sunscreen may do more to prevent premature death than helmets.

Thus NHTSA violates the Data Quality Act by making a claim that it is unable to substantiate, in the face of reasonable alternative theories.

## **3 THE SPECIFIC RECOMMENDATIONS FOR CORRECTING THE INFORMATION;**

### **3.1 Highest priority: Remove inaccurate information from program web sites and relatively new informational materials**

We recommend that NHTSA stop claiming that bicycle helmets are 85% effective and that helmets are the single most important way to prevent a head injury from a bicycle crash.

To carry out this recommendation, NHTSA should take a complete inventory of all documents on its web site (i.e., both html web pages and pdf files) that make one of the erroneous claims, and divide them into three categories:

1. Documents that are clearly meant to represent NHTSA’s current opinion (e.g. program web sites, recently issued fact sheets and instructional materials)
2. Documents that no reasonable person would construe as representing NHTSA’s current opinion (e.g. press releases from the 1990s, peer-reviewed journal articles with a disclaimer, reports from state agencies)
3. Documents that could easily be construed as still representing NHTSA’s official opinion, even though they do not (e.g. fact sheets from 2004–2008, pdf files with undated instructional materials)

For category (1), we recommend that NHTSA immediately delete phrases that quantify the risk reduction from bicycle helmets, at least temporarily. For example, the statement “bicycle safety helmets reduce the risk of head injury from a bicycle crash by up to 85 percent” could be either deleted or changed to “bicycle safety helmets reduce the risk of head injury from a bicycle crash.” If the statement is not deleted, then two caveats should also be added, concerning neck injuries and the possibility that helmets improperly worn do not provide significant protection. So this particular sentence might read: “Bicycle safety helmets reduce the risk of head injury from a bicycle crash. A helmet can also increase the risk of neck injury, so wearing it correctly is important.”

We also recommend that NHTSA delete all statements in category (1) documents asserting that wearing a helmet is the single most effective way (or device) to prevent a head injury, unless this claim has been substantiated by a peer-reviewed study showing that helmets are more effective than other ways or devices for preventing head injuries.

These changes can be made rapidly at little expense. It is up to NHTSA to decide to continue providing the public with quantitative information about the consequences of wearing a bike helmet. But doing so accurately would take time, so it would be best to first remove the inaccurate estimates, before deciding whether (and if so how) to develop a revised set of estimates of the effectiveness of helmets.

### **3.2 NHTSA should either develop new estimates of helmet effectiveness or take steps to ensure that people who read the claims in old documents will realize that they no longer represent NHTSA's view.**

Many people have become accustomed to citing NHTSA's estimates for helmet effectiveness. The fact that the information has been wrong all of these years, and yet people kept using it anyway, suggests that the public needs NHTSA to provide this type of information. NHTSA has many statisticians with the ability to develop a reasonable assessment of the literature with a relatively modest effort.

If NHTSA chooses to adopt a revised estimate of helmet effectiveness, we recommend an uncertainty range rather than a single number. That uncertainty range should encompass the entirety of the uncertainty ranges from the three published meta-analyses by Attewell et al., Thompson et al., and Elvik, which would imply, for example, an odds ratio of 0.26 to 0.75 in the case of head injuries (see Table 1). Doing so would reflect greater uncertainty than any single meta-analysis alone, but that is appropriate. The published analyses are all designed to estimate the mean population parameter. But most people want to know how effective the helmet might be for them or their loved ones in the places where they ride, which is inherently more uncertain than the best estimate of the mean helmet effectiveness across all cyclists and places (which the published studies are designed to estimate). Given the side-effect of increased neck injuries, NHTSA should also present the range of odds ratios for head and neck injuries, which appears to be 0.5 to 0.98. Because relative risk will be greater than the odds ratio, NHTSA should not automatically assume that they are the same thing, but carefully evaluate whether relative risk is likely to be higher than the odds ratio.

We also recommend that NHTSA keep its web site reasonably up-to-date. A first step would be to provide the complete references for quantitative estimates of helmet effectiveness on html pages that provides the estimate, and add a date to all pdf files, so that people maintaining the web site and the public will realize how old the sources are for particular claims.

If NHTSA revises the category 1 websites with a substantially different set of effectiveness estimates, we think that most people who need such an estimate will use the revised estimates. People generally visit the category 1 pages, whether or not they also view archival material. Most people who notice significantly different estimates on the new and old pages will figure out that NHTSA has revised its estimate.

On the other hand, if NHTSA simply removes the quantitative estimates on the new pages without making changes to the older pages, some people will mistakenly assume that the old estimates remain valid, and that NHTSA simply did not choose to provide a quantitative estimate on every page. Therefore, merely removing the quantification from the category 1 pages is not enough, because for all practical purposes, NHTSA would still be disseminating the incorrect information through its older pages. One possibility would be to revise all category 3 websites as well. Yet there may be reasons to not alter materials that are on the website for archival purposes, even when they disseminate incorrect information. Another alternative would be to (a) explain on the category 1 websites that a study in 1989 once estimates that helmets are 85 percent effective, but that NHTSA no longer believes that estimate to be valid and (b) limit the likelihood that someone views the category 2 and 3 documents without being offered a warning that the documents do not represent NHTSA's official position by inserting "metatags" to prevent the documents from being indexed by search engines. People could still reach these older materials "through the front door," that is, by linking from pages that inform someone that the pages they are downloading are provided for archival purposes only.

#### 4 HOW THE PERSON SUBMITTING THE COMPLAINT IS AFFECTED BY THE INFORMATION ERROR.

The Washington Area Bicyclists Association (WABA) conducts bicycle safety classes in the Washington area. A component of those classes includes providing the students with information related to helmets. We wish to convey accurate information.

WABA has 5000 members and more than 30,000 supporters in the Washington area, all of whom ride bicycles. Most use helmets most of the time, but might occasionally have to choose between riding without a helmet, or skipping a ride altogether because their helmet is misplaced, somewhere else, or needs to be replaced. The decision whether to ride under those circumstances involves a balancing of risks. A relative risk of 88% implies that the risk of injury without a helmet is 8 times as great as riding with a helmet, while a relative risk of 25% implies that such a ride is only 33% more risky. Many people might reasonably take the ride if the risk is only 33% greater, because the health benefits of cycling appear to offset the risk of an accident, and one might compensate for the extra risk by taking a shorter ride or riding more carefully. But those same people might choose not to ride that day if the risk without the helmet is 8 times as great. So our members need to know whether the relative risk is 88% or something closer to 25%.

As an individual, I personally face the same consequences. Moreover, I regularly shuttle back and forth on a bicycle worth less than \$40 between the family cottage on Long Beach Island (New Jersey) and either the my sailboat or the ocean, both of which are approximately 1000 feet from the house, often towing a trailer with tools or beach equipment. I don't wear a helmet on these rides because I am not going to leave a bike helmet exposed to the sunlight on the beach or a dock for several hours just for a 1000-foot ride. I'm far more likely to get a neck injury body surfing or a head injury when the boom hits my head than on that short of a ride. Moreover, the minimal risk of injury on such a short is probably outweighed by the risk of damage to the helmet from sunlight and the resulting increased risk of head injury during the later portion of the helmet's 5-year life. Please realize that I am hyperconscious about safety to the point where I will run 200-lumen front and rear blinking lights in the day time, because I have observed that drivers make left turns or pull out of parking spaces in front of me when I don't run the lights. If I thought that the risk of a head injury was 8 times greater without a helmet, I would wear a helmet even for these 1000-foot rides. But as it stands, the NHTSA has no credibility with me on the subject of bike helmets, given its glib and biased repetition of old studies without any evidence of a critical review.

Finally, the Maryland House of Delegates is considering a bill that would make Maryland the first state to require all adult cyclists to wear helmets. The sponsors appear to have been influenced in part by the repeated assertion that helmets stop 85-88% of head injuries, which NHTSA has continued to repeat. The Maryland Department of Transportation's analysis in support of that bill stated that "NHTSA further reports that helmets are 85 to 88 percent effective at mitigating head injuries."<sup>60</sup> Thus, a state law may be enacted based on misinformation disseminated by the NHTSA website. Such a law would place all of our members in legal jeopardy whenever they ride a bike in Maryland without a helmet, which as mentioned, may happen from time to time even with people who try to wear a helmet whenever possible. That law would make the bikeshare programs infeasible, leading some of our members who work in Maryland to drive when they might otherwise take mass transit and ride a bike the last mile or two. Another direct consequence of the misinformation is that our staff and volunteer advocates are spending inordinate time this year working to stop that bill, instead of spending such time with their family or doing volunteer work that benefits the community. As an individual, I have or expect to experience all of these consequences as well.

5 THE NAME, MAILING ADDRESS, TELEPHONE NUMBER, E-MAIL ADDRESS, AND ORGANIZATIONAL AFFILIATION, IF ANY, OF THE INDIVIDUAL MAKING THE COMPLAINT.

This request for correction is being submitted by James G. Titus as an individual, and on behalf of the Washington Area Bicyclists Association. My contact information is as follows:

James G. Titus,  
6718 Glenn Dale Road,  
Glenn Dale Maryland, 20769  
Cell: 301-602-5421  
Email: [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

\* \* \* \* \*

Thank you for the opportunity to provide my views on the need to correct this information on bicycle helmets. We know that you are dedicated to improving the health and safety of Americans, and so are we. Some people may think that exaggerating the benefits of safety equipment is an appropriate way to promote public safety, but we prefer accurate and up-to-date information, and we hope you agree.

Yours truly,



James G. Titus  
Citizen of Maryland and Member of the Board of Directors of WABA

## Notes and References

<sup>1</sup> US Department of Transportation. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Department of Transportation (DOT)*.

<[http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject\\_areas/statistical\\_policy\\_and\\_research/data\\_quality\\_guidelines/html/guidelines.html](http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/statistical_policy_and_research/data_quality_guidelines/html/guidelines.html)>

<sup>2</sup> "Traffic Safety Facts: Bicyclists and Other Cyclists" (June 2012). <http://www-nrd.nhtsa.dot.gov/Pubs/811624.pdf>

<sup>3</sup> In her February 19 email to me, NHTSA's Paula Bawer stated: "Therefore, our agency finds the bicycle helmet to be the single most effective piece of safety equipment to prevent brain injury in the event of a bicycle crash." That would be a narrower claim than the versions that we have found on the web site. Because that claim could be true even if helmets accomplish less than riding safely, maintaining one's brakes, or using running lights, it is so narrow that it is almost a tautology. It is unclear to me whether that statement appears on the NHTSA web site.

<sup>4</sup> Apparently Mr. Halsey obtained this statement after failing to observe the caveat at <http://www.cdc.gov/program/performance/fy2000plan/2000xbicycle.htm>

<sup>5</sup> See OMB, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication." 67 *Federal Register* 8452-8460. The DOT Guidelines implementing the Data Quality incorporate by reference the standards of information quality set forth in the OMB Guidelines.

<sup>6</sup> Bicycle helmets are... the single most effective way to reduce head injuries and fatalities resulting from bicycle crashes. NHTSA (2004). "Bicycle Helmet Use Laws." *Traffic Safety Facts: Laws*.

<http://www.nhtsa.gov/people/injury/new-fact-sheet03/bicyclehelmetuse.pdf>. Cf. NHTSA press release, Tuesday, May 13, 1997. "A bicycle helmet is the single most effective safety device available to reduce head injury and death from bicycle crashes." <http://www.nhtsa.gov/nhtsa/announce/press/PressDisplay.cfm?year=1997&filename=pr051397.html>.

<sup>7</sup> See note 3

<sup>8</sup> E.g. American Academy of Pediatrics, Committee on Injury and Poison Prevention. 2001. "Bicycle Helmets." 108 *Pediatrics* 1030-32 ("The bicycle helmet ... can prevent the occurrence of up to 88% of serious brain injuries....Wearing a bicycle helmet is one of the most effective safety measures a child can take to avoid injury.") This 2001 report repeated the common mathematical error of equating the odds ratio with relative risk, and relied entirely on the studies by Thompson et al., though a dozen other estimates were available with generally lower estimates.

<sup>9</sup> For example, the Bicycle Helmet Safety Institute has long maintained that the 85% estimate is consistent with unpublished field observations or observations by club cyclists. "Although other studies have found lesser effects, this one [the 85 percent estimate] remains close to the reality that club cyclists observe." Bicycle Helmet Safety Institute. <http://www.helmets.org/negativs.htm>

<sup>10</sup> E.g. American Academy of Pediatrics, Committee on Injury and Poison Prevention. 2001. "Bicycle Helmets." 108 *Pediatrics* 1030-32 ("The bicycle helmet ... can prevent the occurrence of up to 88% of serious brain injuries....Wearing a bicycle helmet is one of the most effective safety measures a child can take to avoid injury.") This 2001 report repeated the common mathematical error of equating the odds ratio with relative risk, and relied entirely on the studies by Thompson et al., though a dozen other estimates were available with generally lower estimates.

<sup>11</sup> Thompson, R.S., Rivara, F.P., Thompson, D.C., 1989. A case-control study of the effectiveness of bicycle safety helmets. 320 *New England Journal of Medicine*, 1361–1367.

<sup>12</sup> Id. at 1365.

<sup>13</sup> All of the studies cited here report results based on the so-called odds ratio, rather than the relative risk. The odds ratio is a ratio of two ratios. It is based on the odds that someone having a head injury was wearing a helmet, compared with the odds that someone who did not have a head injury was wearing a helmet. The numerator of the odds ratio is calculated from a sample population of cyclists with head injuries as the ratio of people wearing helmets to people without helmets. The denominator is calculated from a separate sample population of people who did not have a head injury, as the number of people wearing helmets divided by the number not wearing helmets. Relative risk, by contrast, measures the probability that someone wearing a helmet will or will not get a head injury. Although the studies only calculate the odds ratio, they often present the results as if they had calculated relative risk. The studies generally do not calculate relative risk because to properly do so under Bayes Theorem, they would need to estimate the unconditional probability of either wearing a helmet or having a head injury when involved in an accident, neither of which can be estimated with the hospital data alone. Under some circumstances, however, the odds ratio is a good approximation of relative risk. One challenge for case-control studies is determining whether that those circumstances apply. This table includes all studies evaluated by Attewell et al. or Elvik, except for one study published in Norwegian.

<sup>14</sup> Attewell, R.G., Glase, K., McFadden, M., 2001. Bicycle helmet efficacy: a meta-analysis. *Accident Analysis and Prevention* 33, 345, 349 Table 3 (citing Dorsch, M.M., Woodward, A.J., Somers, R.L., 1987. Do bicycle safety helmets reduce severity of head injury in real crashes? *Accident Analysis Prevention* 19, 183–190).

<sup>15</sup> Thompson, R.S., Rivara, F.P., Thompson, D.C., 1989. A case-control study of the effectiveness of bicycle safety helmets. *New England Journal Medicine* 320, 1361–1367.

<sup>16</sup> Attewell at 349 (citing Spaite, D.W., Murphy, M., Criss, E.A., Valenzuela, T.D., Meislin, H.W., 1991. A prospective analysis of injury severity among helmeted and nonhelmeted bicyclists involved in collisions with motor vehicles. *Journal Trauma* 31, 1510–1516).

<sup>17</sup> Id. (citing McDermott, F.T., Lane, J.C., Brazenor, G.A., Debney, E.A., 1993. The effectiveness of bicyclist helmets: a study of 1710 casualties. *Journal Trauma* 34, 834–845).

<sup>18</sup> The Thompson et al. meta-analysis treated this study as a qualifying study, and reported its results, but did not include the results in its summary odds ratio, apparently because the study reported a crude odds ratio but not an adjusted odds ratio. Of the five studies that Thompson et al. deemed worthy of consideration, this study had a far higher odds ratio than the others; so its exclusion lowered the summary odds ratio substantially.

<sup>19</sup> Attewell, *supra* note 14 (citing Maimaris, C., Summers, C.L., Browning, C., Palmer, C.R., 1994. Injury patterns in cyclists attending an accident and emergency department: a comparison of helmet wearers and non-wearers. *British Medical Journal* 308, 1537–1540).

<sup>20</sup> Id. (citing Thomas, S., Acton, C., Nixon, J., Battistutta, D., Pitt, W.R., Clark, R., 1994. Effectiveness of bicycle helmets in preventing head injury in children: case control study. *British Medical Journal* 308, 173–176).

<sup>21</sup> Id. (citing Finvers, K.A., Strother, R.T., Mohtadi, N., 1996. The effect of bicycling helmets in preventing significant bicycle-related injuries in children. *Clinical Journal Sport Medicine* 6, 102–107).

<sup>22</sup> Id. (citing Thompson, D.C., Rivara, F.P., Thompson, R.S., 1996b. Effectiveness of bicycle safety helmets in preventing head injuries. A case control study. *Journal American Medical Association* 276, 1968–1973).

<sup>23</sup> Id. (citing Jacobson, G.A., Blizzard, L., Dwyer, T., 1998. Bicycle injuries: road trauma is not the only concern. *Australian New Zealand Journal Public Health* 22, 451–455).

<sup>24</sup> Id. (citing Linn, S., Smith, D., Sheps, S., 1998. Epidemiology of bicycle injury, head injury and helmet use among children in British Columbia: a five year descriptive study. *Injury Prevention* 4, 122–125).

- <sup>25</sup> Id. (citing Shafi, S., Gilbert, J.C., Loghmanee, F., Allen, J.E., Caty, M.G., Glick, P.L., Carden, S., Azizkhan, R.G., 1998. Impact of bicycle helmet safety legislation on children admitted to a regional pediatric trauma center. *Journal Pediatric Surgery* 33, 317–321).
- <sup>26</sup> Hansen, K.S., Engesæter, L.B., Viste, A., 2003. Protective effect of different types of bicycle helmets. *Traffic Injury Prevention* 4, 285–290. Considering only the data collected for hard shell helmets.
- <sup>27</sup> Id. For soft shell helmets.
- <sup>28</sup> Heng, K.W.J., Lee, A.H., Zhu, S., Tham, K.Y., Seow, E., 2006. Helmet use and bicycle-related trauma in patients presenting to an acute hospital in Singapore. *Singapore Medical Journal* 47, 367–372.
- <sup>29</sup> Heng et al. stated in the text that the odds ratio for head injuries was 0.14, but that they were not reporting it in the table because it was not statistically significant.
- <sup>30</sup> Amoros, E., Chiron, M., Ndiaye, A., Laumon, B., 2009. Cyclistes victimes d'accidents (CVA). Partie 2. Études cas-témoins. Effet du casque sur les blessures à la tête, à la face et au cou. In: *Convention InVS J06-24*, INRETS, Lyon. Based on logit regression coefficients reported on page 21.
- <sup>31</sup> Attewell supra note 14.
- <sup>32</sup> Thompson DC, Rivara F, Thompson R. Helmets for preventing head and facial injuries in bicyclists. *Cochrane Database of Systematic Reviews* 1999, Issue 4. Art. No.: CD001855. DOI: 10.1002/14651858.CD001855.
- <sup>33</sup> Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." *Accident Analysis and Prevention*. 43 (2011) 1245–1251.
- <sup>34</sup> Elvik, citing results from Attewell, supra note **Error! Bookmark not defined..**
- <sup>35</sup> Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." *Accident Analysis and Prevention*. 43 (2011) 1245–1251.
- <sup>36</sup> Elvik, citing results from Attewell, supra note **Error! Bookmark not defined..**
- <sup>37</sup> Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." *Accident Analysis and Prevention*. 43 (2011) 1245–1251.
- <sup>38</sup> Many researchers report both the odds ratio as defined above, as well as one or more adjusted odds ratios that attempt to take into consideration difference between the case and control populations, so that the results do not attribute the all differences in the proportion of head injuries to helmets when it is reasonable to assume that other factors play a role as well.
- <sup>39</sup> The Thompson team has backed away from the 85 and 88 percent effectiveness numbers (odds ratio of 0.15 and 0.12) in several respects. In their 2009 Cochrane review of case-control studies, they reported that the 95% confidence range for the adjusted odds ratio from the 1989 study was 0.14 to 0.49, with a best estimate of 0.26. Their 1996 best estimate was 0.31 with a range of 0.26 to 0.37. Similarly, the best estimate for brain injuries in their 1989 study was 0.19 with a range of 0.06 to 0.57, they said in 2009; and their 1996 revision was 0.35 with a range of 0.25 to 0.48. Thus, by 1996 the Thompson team had revised their estimates of helmet effectiveness to be substantially less than shown on the CDC website, and by 2009 Thompson et al. even viewed their 1989 study as showing less effectiveness than shown by the CDC's characterization of their 1989 study.
- <sup>40</sup> Attewel, supra note **Error! Bookmark not defined..**
- <sup>41</sup> Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." *Accident Analysis and Prevention*. 43 (2011) 1245–1251.
- <sup>42</sup> Thompson, D.C., Rivara, F., Thompson, R., 2009. Helmets for preventing head and facial injuries in bicyclists. *Cochrane Review*. The Cochrane Library (1), 2009.
- <sup>43</sup> The Thompson et al. meta-analysis treated this study as a qualifying study, and reported its results, but did not include the results in its summary odds ratio, apparently because the study reported a crude odds ratio but not an adjusted odds ratio. Of the five studies that Thompson et al. deemed worthy of consideration, this study had a far higher odds ratio than the others; so its exclusion lowered the summary odds ratio substantially.
- <sup>44</sup> See e.g. Cochran, *Sampling Statistics* (chapter on measurement error showing that when there is measurement error, additional observations decrease the portion of the total variance dues to sampling error but not the portion dues to measurement error).
- <sup>45</sup> Helmet effectiveness is likely to vary across people, due to differences if riding conditions, habits, and helmet variations. Additional data allows for an increasingly precise estimate of the mean effectiveness for the entire population, that is, the variance of the mean declines. But the population variance does not decline as the sample increases.
- <sup>46</sup> Thompson, R.S., Rivara, F.P., Thompson, D.C., 1989. A case-control study of the effectiveness of bicycle safety helmets. *New England Journal Medicine* 320, 1361–1367.
- <sup>47</sup> Cornfield, J. 1951. "A method of estimating comparative rates from clinical data: Applications to cancer in the lung, breast, and cervix." 11 *Journal of the National Cancer Institute* 1269-75.
- <sup>48</sup> Rodrigues, L. and B.R. Kirkwood. 1990. Case-control designs in the study of common diseases: Updates on the demise of the rare disease assumption and the choice of sampling scheme for controls." 19 *International Journal of Epidemiology* 205-213 at 206. Other researchers have pointed out that although the odds ratio is not the same as relative risk, it is possible to design a case-control experiment to estimate relative risk as well. See e.g. *id.*

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<sup>49</sup> Cf. id. at 208, Table 1 (providing formulas for relative risk and odds ratio, with identical numerators).

<sup>50</sup> In the traditional formulation  $R = \frac{a/(a+b)}{c/(c+d)}$  which is also  $R = \frac{(c+d)/c}{(a+b)/(a)}$  the adjustment becomes  $R = \frac{(c+d)/c}{(a+b+a/R)/a}$  and solving we get  $R = \frac{((c+d)/c) - 1}{(a+b)/a}$ . This is, of course, an extreme assumption.

<sup>51</sup> Using the formulas derived in this section, if one alters each of the four quantities provided in Table 2 one at a time so that the odds ratio becomes 0.15, then relative risk becomes 0.23 or 0.27.

<sup>52</sup> See DiGuseppi CG, FP Rivara TD Koepsell and L. Polissar L, 1989. Bicycle helmet use by children. Evaluation of a community-wide helmet campaign. J Amer Med Assoc 262:2256-61. Based on observations of 4500 children, the study found that 4.6% of children in Seattle wear helmets. This is similar to Thompson's hospital control group, but not the insurance company data which found 24% of children to wear helmets. The inference one might make is that the insurance company data overstated the proportion of cyclists wearing helmets with other age groups as well, in which case the hospital control group is representative of people who have serious accidents but do not experience a head injury, rather than the general population of cyclists.

<sup>53</sup> Helmet use by children in two Maryland counties that promoted helmets was less than 10% as late as 1991. A L Dannenberg, A C Gielen, P L Beilenson, M H Wilson, and A Joffe. 1993. "Bicycle helmet laws and educational campaigns: an evaluation of strategies to increase children's helmet use." Am J Public Health. 1993 May; 83(5): 667-674.

<sup>54</sup> Press releases by NHTSZ have regularly included the 85-percent estimate.

<sup>55</sup> Copyright 1944. Johnny Mercer and Harold Arlen. "Ac-Cent-Tchu-Ate the Positive."

<sup>56</sup> Maryland Department of Transportation, Statement in Support of House Bill 339. Revised statement provided after the hearing held February 12, 2013 <<http://bike.risingsea.net/docs/Legislation/helmet/MDOT-revised-position-HB0339-backdated.pdf>>

<sup>57</sup> See email traffic in the Appendix, especially February 19 email from Paula Bawer.

<sup>58</sup> National Highway Traffic Safety Administration. 2001. *Countermeasures that Work*. Chapter 9. At the beginning of each section there is a small table with the word "Effectiveness" followed by a number of stars. It is clear from the text that the report is discussing particular government initiatives, rather than the effectiveness of actions by a specific cyclist. The most highly rated option is "bicycle laws for children", with 5 stars. Lighting and adult helmet laws each get 3 stars.

<sup>59</sup> E.g. Washcycle. <http://www.thewashcycle.com/2010/05/the-helmet-facts.html> (comment by jeff),

<sup>60</sup> Maryland Department of Transportation, Statement in Support of House Bill 339. Revised statement provided after the hearing held February 12, 2013.

## APPENDIX : Email traffic between NHTSA and me on this issue

**From:** [NHTSAHotline@telesishq.com](mailto:NHTSAHotline@telesishq.com)

**Sent:** Thursday, February 14, 2013 5:49 PM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Subject:** Incorrect characterization of traffic hazard research on web site ISSUE=512725 PROJ=12When replying, type your text above this line.

---

### Notification of Case Change (All times are GMT-0500)

**Workspac** NHTSA Hotline Center  
**e:**

**Case:** Incorrect characterization of traffic hazard research on web site

**Case Number:** 512725

**Date:** 02/14/2013 **Time:** 17:49:38

**Creation Date:** 02/14/2013 **Creation Time:** 14:02:32

### Symptom:

*Entered on 02/14/2013 at 17:49:38 EST (GMT-0500) by TBent:*

Thank you for contacting the U.S. Department of Transportation's Vehicle Safety Hotline Information Center.

Motorcycle Safety Program (Behavioral Issues)

1. Michael Jordan, 202-366-0521 (recognizing counterfeit helmets)
2. William Cosby, 202-366-4969

We hope that you find this information helpful. However, if you need additional information on our services please feel free to contact us at 1-888-327-4236 .

Thank you,

NHTSA.dot.gov Response Team

Disclaimer: "This response is for information purposes only and does not constitute an official communication of the U.S. Department of Transportation. For an official response, please write U.S. Department of Transportation, National Highway Traffic Safety Administration, 1200 New



Jersey Ave, SE, West Building, Washington, DC 20590.

*Entered on 02/14/2013 at 14:02:32 EST (GMT-0500) by nhtsa.webmaster@dot.gov:*

Sender Name: Jim Titus

Sender Email: [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

Subject: Incorrect characterization of traffic hazard research on web site

Comments: The information on bicycle helmets appears to be based on studies from the late 1980s, and is at odds with research from the last few decades. There are also a few hyperbolic statements that may never have been supported by research. Please tell me to whom I should write for notifying incorrect and/or out-of-date characterization of traffic safety information.

**Contact Information:**

**Last Name:** Titus      **First Name:** Jim

**Country:** United States      **Email Address:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Contact Source:** Owner

**From:** [Jim Titus](#)

**Sent:** Friday, February 15, 2013 8:56 AM

**To:** [NHTSAHotline@telesishq.com](mailto:NHTSAHotline@telesishq.com)

**Subject:** Re: Incorrect characterization of traffic hazard research on web site ISSUE=512725 PROJ=12

Thanks for your quick reply. Could you doublecheck that William Cosby is the contact and provide email addresses? I tried emailing Mr. Cosby and the email was returned, and when I called his number, I got a woman whose voicemail says that she does pedestrian safety. She might actually be the person who does bicycles as well, since bicycles are often lumped in with pedestrians (and rarely lumped in with motorcycles). But I could not make out her name from the voicemail.

Thanks

Jim

**From:** [Jim Titus](#)

**Sent:** Tuesday, February 19, 2013 12:21 PM

**To:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Subject:** Can you tell me NHTSA's contact for bicycle helmets?

Dear Ms; Bawer,

I am trying to understand why the NHTSA web site says in numerous places that “bicycle helmets are 85 percent effective in preventing serious head injury” (or words to that effect). The NHTSA hotline referred me to Bill Cosby of the motorcycle safety program, but his emails are returned and the phone number they gave me was for someone who does pedestrian safety, not motorcycles.

I noticed that you wrote an article for the NHTSA newsletter [SAFE COMMUNITIES](#) which made the same statement, so I would think that you probably know who in NHTSA is the person I need to speak with (or perhaps it is you).

As you might imagine, my concern is that the suggestion that helmets are 85% effective appears to be misleading [see the postscript], at least given what I know about the research, though it probably was a fair characterization of the research 20 years ago (except for the term “proven”).

I am interested in understanding NHTSA’s thinking about helmet effectiveness, and in particular whether and how it has been revised to incorporate the research published since the year 2000, institutional inertia that might prevent NHTSA from keeping pronouncements current with the available literature, and communications philosophies that might lead to selective emphasis of research results to avoid overwhelming the public with too much information.

Can you tell me who has the lead within NHTSA on such matters and/or forward this along to her?

Best regards,

Jim

PS: Just to give you a flavor for why one might consider the NHTSA web site to be a bit misleading regarding bike helmets, here are three considerations.

1. Since the turn of the millennium, case-control studies have found that helmets make less of a difference than suggested by pre-1995 studies. In 2001, Attewell et al., (2001) synthesized all studies and concluded that the odds ratio was 0.39-0.55 (which would be 45-71% effectiveness if the populations had been random). In 2011, with additional studies added to the mix and using the more complex models that statisticians prefer, Elvik’s found the odds ratio to be 0.45-0.75 (25-55% effective if population were random). Both of these estimates show helmets to be far less effective than the 85 percent estimate repeated on the NHTSA web site, or the results from Thompson, Rivera, et al. (1989, 1995).

2. Helmets have an important side effect: increased neck injuries. Just as doctors and drug companies warn about side effects, federal agencies touting safety equipment should warn about risks from the safety equipment. This is especially the case when the side effects are not perfectly correlated with the primary benefit, so that some people are more threatened by the side effects than they are helped by the primary benefit. Helmets are designed to be most effective at slow speeds, while the risk of neck injuries increases with speed. Both the Attewell et al., and Elvik reviews found that helmets increase the risk of a neck injury by approximately 0-80%. The increased risk of neck injuries means that the net benefit of a helmet is less than one would expect considering only the head injuries avoided. When they include the increased neck injuries, the Attewell study implies that helmets reduce injuries 41-50%, and the Elvik study estimates 2-26%.

3. Strictly speaking, few if any of the studies actually estimate “effectiveness”. They estimated the “odds ratio” which is not the same thing at all. It is like the difference between the percentage of people with head injuries that wore a helmet, and the percentage of people wearing helmets that have a head injury. The actual estimate of effectiveness will probably be within the margin of error for 1 minus the odds ratio, but a government agency should not make inaccurate statements about what is being estimated. There are relatively simple ways to conservatively calculate the effectiveness (relative risk) given the estimates of the odds ratio.

**From:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Sent:** Tuesday, February 19, 2013 2:40 PM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Subject:** RE: Can you tell me NHTSA's contact for bicycle helmets?

Jim- I am the correct person if you are specifically referring to bicycle helmets. I am pretty swamped right now so have to defer to discussions with you for next two weeks. The proper statement from NHTSA should be “up to 85% effective.” There have been a number of studies with varying results... our position is to save lives and NHTSA will make similar claims regarding seatbelts. The agency that regulates helmet safety is Consumer Product Safety Commission and if anyone would report on side effects, it would be them.

Again- our position is simply that wearing helmets designed for bicycling, that have a sticker designating it meets the minimum safety standards (CPSC) – others are stricter (ANSI, etc.), are worn and fit properly, are up to 85 % effective in mitigating injury to the brain. Therefore--- our agency finds the bicycle helmet to be the single most effective piece of safety equipment to prevent brain injury in the event of a bicycle crash. Those bicycling regardless of age or skill ability are encouraged to wear a bicycle helmet every ride. Paula

**From:** [Jim Titus](#)

**Sent:** Tuesday, February 19, 2013 7:10 PM

**To:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Subject:** Re: Can you tell me NHTSA's contact for bicycle helmets? [2]

Hi Paula,

Thanks for getting back to me. Could we pick a time to meet or talk by phone roughly 3 weeks hence? I could provide a list of my questions beforehand, in case some of the answers lie within the memory of someone else, or in a document that you have not committed to memory.

Best regards

Jim

**From:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Sent:** Wednesday, February 20, 2013 10:48 AM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Subject:** RE: Can you tell me NHTSA's contact for bicycle helmets? [2]

Could you please explain who you are and your concern? Thanks! I cannot commit a lot of time to doing research for you – I truly don't mean to be rude but I am busy already, have inherited a number of projects from a person who has retired and from someone else who has moved on. I am also working very hard right now on ped/bike initiatives with all of ped/bike advocates and the Secretary.

Is it possible that the Bicycle Helmet Safety Institute can be of help from you? Randy Swart is a tremendous wealth of knowledge!! He can be reached at [randy@helmets.org](mailto:randy@helmets.org) or 703-486-0100. You can tell him I referred you to him. Thanks! Paula

**From:** [Jim Titus](mailto:jtitus@risingsea.net)

**Sent:** Wednesday, February 20, 2013 1:02 PM

**To:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Subject:** Re: Can you tell me NHTSA's contact for bicycle helmets? [3]

Hi Paula,

I did not mean to suggest that I am asking the government to do research for me. Rather I am asking the government to justify factual statements it is making to the public. For many federal agencies, quantitative statements (including statements that rank options) must be supported by published research to be legitimate, and any citizen is entitled to ask for the supporting research. If you or someone can send me the studies (or give the references for the studies) that are the basis for (a) the 85% figure (b) the change from 85% to "up to 85%" made a few years ago and (c) the comparison of different types of safety equipment that justified the conclusion that helmets are more effective than the other forms of safety equipment, that would be a start.

You probably lack the time to read my entire biography, but this month I seem to be the volunteer statistician for several people interested in the consequences of House Bill 339 in Maryland. Their overall concern is that proponents of the bill are citing NHTSA as support, but that the NHTSA statements—if made by a helmet manufacturer or retailer—would result in severe legal liability problems. So no one seems to be accountable for statements that, in the view of some people, are severe exaggerations of the benefits of helmets.

Yet over the decades I have observed that often people in agencies have explanations for what they are doing that would have never occurred to anyone outside the government, so I am trying hard to understand from NHTSA's perspective why NHTSA does what it is doing. The downside, is that my effort to be fair to your agency takes up more of your time than if I simply joined the bandwagon that assumes the worst. The beginning of my quest to understand is to get the studies for each claim, or confirmation that no study underlies a given claim. The end of that quest would be to learn how NHTSA responds to those who think a federal agency's responsibility to tell the whole story is at least as great as the duty of a helmet manufacturer.

Enough detail? Do you have the studies I seek?

Thanks

Jim

-----Original Message-----

From: Randy Swart

Sent: Wednesday, February 27, 2013 5:28 PM

To: Jim Titus

Cc: jim.sebastian@dc.gov ; Paula.Bawer@dot.gov

Subject: Re: FW: Can you tell me NHTSA's contact for bicycle helmets? [3]

Paula Bawer of NHTSA asked me to help her out with the references to studies that you are seeking.

We have a page up with a long list of scientific journal articles that pertain to bicycle helmet efficacy and use. The ones NHTSA used to find their numbers are among them. The page is at <http://www.helmets.org/journals.htm>

Among the most prominent is the one that established the 85% number for the first time, done by the Seattle team of doctors and researchers who later produced other studies that indicated the percentage may be lower. Over the years since their first study was published, most of the injury prevention community has stayed with the 85% figure because that seems to correspond to actual long-term field observation. It is also a clear number, as opposed to the more recent tendency to establish probability-based ranges that are scientifically satisfying but difficult to explain to consumers.

I hope that helps with your enquiry. Numbers used by government agencies are developed over time, and with budget constraints few agencies keep current records of all the places where they found the numbers they use.

My apologies to Paula for taking so long to get this response out.

Randy Swart

---

Randy Swart

[randy@helmets.org](mailto:randy@helmets.org)

Bicycle Helmet Safety Institute

Arlington, VA USA

703-486-0100

[www.helmets.org](http://www.helmets.org)

-----Original Message-----

From: Jim Titus

Sent: Friday, March 01, 2013 11:51 AM

To: Randy Swart

Cc: jim.sebastian@dc.gov ; Paula.Bawer@dot.gov

Subject: NHTSA's contact for bicycle helmets, continued

Dear Mr. Swart:

Thank you for your reply to my email to Paula Bawer which I gather she forwarded to you. I have seen your web page many times in the last month. it is probably the best single resource for information on bicycle

helmets--and that's not just my opinion: it is the first web site one gets for all sorts of bicycle helmet queries.

Your reply does indeed help to answer my question about why the NHTSA web site says that helmets reduce the risk of injury by up to 85%. Does NHTSA agrees with what you have said?

If I follow you, the 85% estimate is based on Thompson et al. (1989).

That makes sense. Then, when other studies came along with lower estimates, the injury prevention community did not revise the assessment downward because 85% seems to correspond to actual long-term field observation. Can you tell me the source for the long-term field observations? Is there a report or is it a data set?

Thanks for your help!

Best regards,

Jim

PS: I understand why we are copying Paula Bawer, but why are we copying Jim Sebastian? Is he a helmet guru too? Or does it have to do with DDOT funding?

-----Original Message-----

From: Paula.Bawer@dot.gov

Sent: Friday, March 01, 2013 2:50 PM

To: jtitus@risingsea.net

Subject: RE: NHTSA's contact for bicycle helmets, continued

Jim- see if what you need is in here. Sorry-- I am just swamped. Yes I turned to Randy or Jim to see if they could help you. Pauls

<http://www.nhtsa.gov/staticfiles/nti/pdf/811614.pdf>

**From:** [Jim Titus](#)

**Sent:** Wednesday, March 06, 2013 10:10 AM

**To:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Cc:** [Jim Titus](#)

**Subject:** NHTSA and Bicycle Helmet--next steps

Dear Paula,

Thank you very much! You have been very helpful.

While this may be small comfort to you, I too have had my life disrupted by the need to get a handle on the accuracy of claims about the effectiveness of bicycle helmets. (Time that my friends and I would have spent with family or joyfully working to fund transportation in Maryland, instead was spent arguing about helmets. If the gas tax fails by 1-2 votes, that will be the biggest casualty of the helmet bill.)

Anyway, summarizing where I think we are, I think you answered the most important question but not the two less important questions.

1. You and Randy **have** both provided a sufficiently thorough explanation of the sources for me to understand why NHTSA uses the 85% effective figure. That was the most important question.

2. Neither you nor Randy explained why NHTSA shifted from “85%” to “up to 85%” instead of saying “X to 85%” or “at least X% effective,” where X is the low end of the effectiveness range from the set of studies for which 85% is at the high end.

3. Neither you nor Randy provided me with documentation on the basis for NHTSA's statement that "our agency finds the bicycle helmet to be the single most effective piece of safety equipment to prevent brain injury in the event of a bicycle crash." Randy stated that funding cuts made it impractical for NHTSA to maintain documentation for assertions on the web site.

For me, the next step is to formally request that NHTSA modify and/or remove the unsupported statements, and provide adequate support for the "single most effective" statement. If NHTSA does have documentation for the "single most effective piece of safety equipment" statement, it may ultimately save us all time if someone sends me that documentation before I send the formal request. What you have provided already, no doubt, will prove to save us time because otherwise I would have had to send (and NHTSA address) separate requests asking for the documentation, and then send a second request challenging the substance of the 85% statement. Given the time it will take to write up the request and check whether any local cycling organizations wants to join the request, I estimate that it will take up to 90 days to send the request ;-)

If I understand how the process works, I will next send my formal request to Jim Simons, who handles questions about NHTSA statistics. I'd offer to not give him your name, but I suspect he would find you anyway ;-)

Thanks again,

Jim

**From:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Sent:** Wednesday, March 06, 2013 12:47 PM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Subject:** RE: NHTSA and Bicycle Helmet--next steps

Hi Jim- I'll keep looking for an appropriate response for you. My boss has offered to assist me. Paula

**From:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Sent:** Wednesday, March 06, 2013 1:18 PM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Subject:** RE: NHTSA and Bicycle Helmet--next steps

<http://ntl.bts.gov/lib/46000/46600/46662/811444.pdf>

Hi Jim- this is the latest I am looking at "Countermeasures that Work" to see if we have something there that offers a reference for you. See Chapter 9 is bicycles. Paula

**From:** Jim Titus [mailto:[jtitus@risingsea.net](mailto:jtitus@risingsea.net)]

**Sent:** Thursday, March 07, 2013 8:03 AM

**To:** Bawer, Paula (NHTSA)

**Cc:** Jim Titus

**Subject:** Re: NHTSA and Bicycle Helmet--next steps

Thanks! I read this last night. I can imagine how someone might take that chapter and draw a conclusion similar to the "most effective" claim and then how someone else might revise that into what we have now. That does not mean that this is the source, since it does not make the precise statement the way the Thompson articles actually estimated 85%. But for constructing my request this would probably suffice if you think this is the source.

Of course, that assumes Nhtsa did not make the claim until 2011. You have been at Nhtsa since before 2011. Do you think that Nhtsa did not say that helmets are " the most effective..." until 2011?

So we are getting close on question 3 below. I would guess that question 2 would be documented in an internal memo or a memo to or from a contractor if at all. But if the 85% figure is removed as we will request, question 2 will be moot anyway.

Thanks  
Jim

PS I am assuming that you don't really have time to digest the underlying substantive argument that I will be making, i.e., you are simply trying to be responsive to my request for documentation, so I am not going into that each time.

Sent from my iPhone



**From:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Sent:** Thursday, March 07, 2013 2:53 PM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Cc:** [Philip.Weiser@dot.gov](mailto:Philip.Weiser@dot.gov)

**Subject:** RE: NHTSA and Bicycle Helmet--next steps

<http://pediatrics.aappublications.org/content/108/4/1030.full>

See #5 and #6 in the footnotes for the resources for the helmet effectiveness that NHTSA has used to show variance.

I will need to discuss with researchers and our legal office for concurrence to consider changing the formal % effectiveness of helmets or dropping the number entirely to say merely that helmets have been proven to be effective....

To our knowledge there is no other equipment that protects the head besides a bicycle helmet in the event of a bicycle crash. I'm still looking.

**From:** [Jim Titus](#)

**Sent:** Friday, March 08, 2013 6:45 AM

**To:** [Paula.Bawer@dot.gov](mailto:Paula.Bawer@dot.gov)

**Cc:** [Philip.Weiser@dot.gov](mailto:Philip.Weiser@dot.gov)

**Subject:** Re: NHTSA and Bicycle Helmet--next steps

Very good! Since the abstract of that report even uses the phrasing "up to 88%" it seems possible that you have now documented the source of NHTSA's using the one-sided confidence interval, and the novelty of emphasizing the optimistic end of the uncertainty range.

Like you, I have my doubts that there is much (if any) research on equipment other than helmets designed to prevent head injuries in the event of an accident, which was my original reason for wondering about the origins of the claim. In fact, the claim almost sounds like the definition of a helmet, rather than a research finding. (With a bit of editing "our agency finds the bicycle helmet to be the single most effective piece of safety equipment to prevent brain injury in the event of a bicycle crash" becomes "our agency ~~finds~~ DEFINES the bicycle helmet AS A to be the single most effective piece of safety equipment to prevent brain injury in the event of a bicycle crash". It's hard for me to know whether NHTSA originally had a research finding that helmets were the most effective safety equipment, and then later qualified that claim to the point of being a fairly meaningless superlative, or if the origins were something else.

So if you are able to find something else, that would be great. Otherwise, I guess I should start drafting the request. Noting your concern that "I will need to discuss with researchers and our legal office for concurrence," I certainly do not mean to burden you with too much coordination. Hopefully the statisticians and data quality people to whom I have to send the request will do most of the work. My request is about how the body of research is being characterized, not your program. The actual effectiveness of helmets is still sufficient to justify the many NHTSA voluntary programs, though less than the exaggerated claims from the 20th century.

Thanks again!

Jim

**From:** Jim Titus [mailto:jtitus@risingsea.net]  
**Sent:** Friday, March 01, 2013 8:33 AM  
**To:** Wood, Steve (NHTSA)  
**Subject:** Who is the NHTSA official under the Data Quality Act?

Dear Mr. Wood,

I am following up on a voicemail I left yesterday morning. Neil Eisner of DOT referred me to you as the person in NHTSA to ask about request for corrections under the Data Quality Act.

When I go to the DOT information quality web site and click on NHTSA, I get a warning message about using an old bookmark, which makes me wonder whether it is really sending me to where I need to go, or if the whole site is about to be moved or disabled. The URLs I get are below. There is a place to upload files, but no information on what happens after that, so it is unclear to me whether and how I can track that NHTSA did or did not get my submission.

Shall I just call you back after I upload it to see if you got it?

Thanks

Jim

<http://www.regulations.gov/#!documentDetail;D=NHTSA-2007-0002-0001;oldLink=false>

<http://www.regulations.gov/#!submitComment;D=NHTSA-2007-0002-0001>

**From:** [Steve.Wood@dot.gov](mailto:Steve.Wood@dot.gov)  
**Sent:** Friday, March 01, 2013 9:21 AM  
**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)  
**Cc:** [Jim.Simons@dot.gov](mailto:Jim.Simons@dot.gov) ; [Larry.Blincoe@dot.gov](mailto:Larry.Blincoe@dot.gov)  
**Subject:** RE: Who is the NHTSA official under the Data Quality Act?

Jim

Sorry I missed your call.

Data quality issues are handled by our economists.

Try either [jim.simons@dot.gov](mailto:jim.simons@dot.gov)

Or [larry.blincoe@dot.gov](mailto:larry.blincoe@dot.gov)

They shd be able to tell you about the uploading process or direct you to someone in their part of the agency who can. You probably already know more about the process than I do.

Steve

**From:** [Jim Titus](mailto:Jim Titus)  
**Sent:** Friday, March 01, 2013 9:40 AM  
**To:** [Steve.Wood@dot.gov](mailto:Steve.Wood@dot.gov)  
**Cc:** [Jim.Simons@dot.gov](mailto:Jim.Simons@dot.gov) ; [Larry.Blincoe@dot.gov](mailto:Larry.Blincoe@dot.gov)  
**Subject:** Re: Who is the NHTSA official under the Data Quality Act?

Steve,

Great! Thanks for providing the names.

Gentlemen: Any insights are welcome, and if someone else is the key contact, please let me know. Otherwise, I'll go ahead and submit something and if the system does not generate an automatic acknowledgement, I'll call you both to ask what to do next.

Best regards,

Jim

**From:** [Jim.Simons@dot.gov](mailto:Jim.Simons@dot.gov)  
**Sent:** Friday, March 01, 2013 9:39 AM  
**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)  
**Cc:** [Steve.Wood@dot.gov](mailto:Steve.Wood@dot.gov) ; [Larry.Blincoe@dot.gov](mailto:Larry.Blincoe@dot.gov)  
**Subject:** clarification question - data quality

- (a). Are you trying to fix something that you entered into the docket? Or
- (b). Are you questioning data that NHTSA has presented in the docket? OR
- (c). Are you questioning data that NHTSA has presented elsewhere?

If it is the first one (a), then you are probably right in trying to go through Regulations.gov  
If your attempt doesn't work, get back to me and I'll let you know who in the docket section can help you.

For either (b) or (c), the easiest for you would be to send the request to me, and I'll figure out who in NHTSA should respond.

Thanks

**From:** [Jim Titus](#)  
**Sent:** Friday, March 01, 2013 11:06 AM  
**To:** [Jim.Simons@dot.gov](mailto:Jim.Simons@dot.gov)  
**Cc:** [Larry.Blincoe@dot.gov](mailto:Larry.Blincoe@dot.gov) ; [Steve.Wood@dot.gov](mailto:Steve.Wood@dot.gov)  
**Subject:** Re: clarification question - data quality

Thanks for the offer. The answer is c.

I am questioning information provided on the NHTSA website, without specific sources being provided. I will either (a) file a request that merely asks for the sources and then possibly file a second request to correct the error or (b) simply file a single request to correct the errors.

I have contacted the program staff but so far I am somewhat unclear about whether or not the staff will be able to provide the sources. I think we may have insufficient institutional memory combined with a factoid that has been repeated for 20 years, and the people who know whence it came have all left the government or never were government employees to begin with. Whether NHTSA will be able to ratify the judgement of an NGO remains to be seen, at which point I'll know which petition to file and send it to you.

Thanks again!

Jim

PS: Just so you know what led me to you all: The DOT guidelines for implementing the data quality act are at [http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject\\_areas/statistical\\_policy\\_and\\_research/data\\_quality\\_guidelines/html/guidelines.html](http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/statistical_policy_and_research/data_quality_guidelines/html/guidelines.html)

with more background at

[http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject\\_areas/statistical\\_policy\\_and\\_research/data\\_quality\\_guidelines/index.html](http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/statistical_policy_and_research/data_quality_guidelines/index.html)

But in addition to that, there are also some OMB guidelines that DOT guidelines incorporate by reference.

The suggestion to go to the docket comes from

<http://docketsinfo.dot.gov/Dataquality.cfm>

**From:** [US Department of Transportation Reference Service](#)

**Sent:** Friday, March 08, 2013 11:38 AM

**To:** [jtitus@risingsea.net](mailto:jtitus@risingsea.net)

**Subject:** Seeking Information Quality official for DOT or NHTSA [Incident: 130222-000011]

Recently you requested assistance from the US Department of Transportation. Below is our response to your request.

**Subject**

Seeking Information Quality official for DOT or NHTSA

**Discussion Thread**

**Response Via Email (US DOT Reference Service)**

03/08/2013 11:38 AM

Please contact the National Highway Traffic Safety Administration (NHTSA) web master at:

Mark Chin

202-366-0618

[Mark.Chin@dot.gov](mailto:Mark.Chin@dot.gov).

Sincerely,

Reference Services

National Transportation Library

Bureau of Transportation Statistics

Research and Innovative Technology Administration

U.S. Department of Transportation

**Customer By Email**

02/22/2013 09:25 AM

Greetings,

Can you provide me with the contact information for the information quality (or data quality) official for either DOT or NHTSA? My concern is that there are some undocumented (and I believe clearly wrong) statements on the NHTSA part of the web site, and efforts to secure documentation from the program for the statements have been unsuccessful.

But I learned that when systemic errors are found on the web site, it is more appropriate to contact the data quality people anyway, rather than the program people. See

[http://www.rita.dot.gov/bts/sites/rita.dot.gov/bts/files/subject\\_areas/statistical\\_policy\\_and\\_research/data\\_quality\\_guidelines/html/guidelines.html](http://www.rita.dot.gov/bts/sites/rita.dot.gov/bts/files/subject_areas/statistical_policy_and_research/data_quality_guidelines/html/guidelines.html)

That web site implies that there is an online form for data correction requests but the link is dead. Please help me find the right person.

Thanks

Jim

**Question Reference #130222-000011**

**Mode of Transportation:** Highway

**Date Created:** 02/22/2013 09:25 AM

**Last Updated:** 03/08/2013 11:38 AM

**Status:** Solved

[---001:001372:05564---]