Analysis and expert opinion on the Federal Motor Carrier Safety Administration's (FMCSA) Methodology for Valuing Health Benefits as presented in 2010-2011 Hour of Service Rule Regulatory Impact Analysis (RIN 2126-AB26) Section 5.

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1.1 Introduction

This report represents a response to a request from the American Trucking Association, Inc. (ATA) to provide an expert opinion on the Federal Motor Carrier Safety Administration's (FMCSA) calculation of health-related benefits associated with changes proposed to the federal hours-of-service (HOS) rules as reflected in a Notice of Proposed Rulemaking (75 Fed. Reg. 82170) published on December 29, 2010 and its accompanying Regulatory Impact Analysis dated December 20, 2010. In particular, the review (a) focuses on the Agency's use and application of various medical studies related to the effect of the duration of sleep periods on individual's mortality expectations, including the study by Ferrie J et al. (2007)[1], referenced by the Agency in the Regulatory Impact Analysis, (b) provides a scientific critique including an expert opinion as to whether the Agency has applied the findings from the reviewed studies correctly, (c) an expert opinion, based on available medical data on this subject, of what, if any, the Agency's assumed changes in average sleep duration would have on the driver/subjects analyzed in the RIA.

In the preparation of the present report and in keeping with the brief, only a limited number of relevant documents have been consulted and analyzed, referring to Chapter 5 of the 2010-2011 Hours of Service Rule Regulatory Impact Analysis RIN 2126-AB26 by the Analysis Division Federal Motor Carrier Safety Administration published on December 20, 2010. A more comprehensive review of the overall subject is therefore beyond the scope of the present review. The primary documents reviewed are listed at the end of this document.

1.2 Federal Motor Carrier Safety Administration's (FMCSA) calculation of health-related benefits associated with changes in sleep duration.

From the Executive Summary:

> *"The Regulatory Impact Analysis (RIA) provides an assessment of the costs and benefits of potential changes in Department of Transportation (DOT) Federal Motor Carrier Safety Administration (FMCSA) Hours of Service (HOS) regulations. The HOS regulations address the number of hours that a commercial motor vehicle (CMV) driver may drive, and the number of hours a CMV driver may be on duty before rest is required, as well as the minimum amount of time that must be reserved for rest and the total number of hours a driver may be on duty in a "work-week."" This analysis considers and assesses the consequences of four potential regulatory options. […]*

[1] Ferrie JE, et al. (Sleep 2007). The study investigated associations of sleep duration and change in sleep duration with all-cause, cardiovascular, and non-cardiovascular mortality in the Whitehall II study, a prospective cohort of 10,308 white-collar British civil servants aged 35-55 at baseline. 9,781 participants with complete data were included in the analyses at Phase 1 (1985-8), and 7,729 of the same participants were included in the analyses at Phase 3 (1991-3) and the analyses of change in sleep duration, with mortality follow-up of 17 and 12 years respectively. This is the first study to show that both a decrease in sleep duration and an increase in sleep duration are associated with an increase in mortality via effects on cardiovascular death and non-cardiovascular death respectively.

After profiling the affected industry, this RIA contains chapters describing the methodology for estimating the costs and benefits of HOS rule Options 2 through 4 relative to Option 1. […]

Safety benefits are estimated as the monetized reductions in crashes that can be anticipated to follow from reductions in fatigue. […]

For the estimation of health benefits, the analysis focused on reductions in mortality risk due to the decreases in daily driving time and thus possible increases in sleep. For this analysis, we used low, medium, and high baseline levels of sleep to analyze the impacts of changes in hours worked on expected mortality risk to obtain a range of possible health impacts from changes in hours worked. Results of this analysis indicate that the measurable health benefits of reducing the maximum hours of work allowed per week could well be as great as the costs, and other possible health benefits (which have not been included in the quantitative analysis) could add even further to these benefits. The health benefits of Options 2 through 4 were estimated for three different levels of baseline sleep by drivers (shown in Exhibit ES-5). For the assumption of a high level of baseline sleep for Options 2 and 4, it is interesting to note that the benefits are negative (to a relatively minor extent for Option 2), indicating that it is not beneficial for individuals to get additional sleep if they are already getting adequate sleep.

1.3 Methodology for Valuing Health Benefits

In Chapter 5 of the RIA, FMCSA presents the methodology for estimating the health benefits of the proposed HOS rule. These benefits are assessed as reductions in all-cause mortality risk that would result from a decrease in total daily and weekly duty time, assuming the latter would result in increases in sleep.

The analysis is carried out in separate steps.

Step 1. FMCSA carries an overview of the epidemiological evidence linking shot sleep to mortality

Step 2. FMCSA estimates the health benefits associated with increased average sleep time for drivers starting from the estimated baseline levels of sleep drivers according to their 'intensity' category estimate.

Step 3. FMCSA uses an internal analysis of the correlation between work hours and sleep hours to estimate the changes in sleep hours that would result from a reduction in work hours under the proposed HOS option.

Step 4. FMCSA then calculates the predicted changes in mortality that would derive from the estimated changes in sleep hours under the HOS option, modeling the effects on data extracted from Ferrie JE et al. (2007).

1.4 Overview

The overview of the literature focuses on all-cause mortality as *"one of the simplest and more robust pathways"*[2] linking excessive hours of work, through reduced average sleep, to increased mortality risk. The report relies exclusively on observational epidemiological data and it is acknowledged that the evidence produced from such studies does not demonstrate or even imply a cause-effect relationship. This is a very important caveat that should be considered at all times when evaluating the extrapolations and modeling that will follow, to justify decisions on interventions for policy changes. In general terms, epidemiological observations are one important scientific step towards assessing causality by informing studies of intervention to test specific hypotheses.

The studies considered have no doubt made an important contribution in highlighting an issue of potential public health impact, i.e. that a sustained short duration of sleep could contribute to long-term ill health. These studies also describe a similar association with long duration of sleep. The causality of these observations, however, is unproven.

Besides the fact that these studies do not prove cause-effect relationship, there are many other limitations. All studies used sleep questionnaires to determine self-reported sleep duration. This method does not allow to differentiate time asleep from time in bed or to estimate number and duration of naps. Sleep duration was assessed at one point in time in all studies, and it is possible that a single measure of exposure may not fully capture the sustained effects of sleep duration over time when relating them to mortality or long term cause-specific vital outcomes. It is likely that the population studies did not exclude from the analyses subjects suffering from sleep-related conditions, including obstructive sleep apnea, themselves direct risk to health. Whilst most studies have allowed for potential confounders, residual confounding is always a possibility in the absence of proven mechanism(s) of action.

There is an assumption that *"because of the curvature of the relationship, the impact on mortality rates per lost hour of sleep also increases the further a person falls below the ideal"*[3]*.[…] On the other hand, having the chance to get slightly more sleep per night can be crucial for the health of those drivers working so hard that they are usually sleep deprived".*[4]

The description of a so-called U-shaped relationship between duration of sleep and risk of death is currently insufficient to justify an interpretation of a 'graded and continuous' relationship between exposure (sleep duration) and outcome (death). Invariably all epidemiological prospective studies published so far have assessed sleep duration through questionnaires estimating self-reported sleep duration into categories[5], i.e. ≤5, 6, 7, 8, 9+ hours per night. This

[2] RIA, p. 5-1
[3] RIA, p. 5-1
[4] RIA, p. 5-2
[5] Cappuccio FP et al, (Sleep 2010) reviewed all prospective population studies relating both short and long duration of sleep with all-cause mortality. The study (a systematic review and meta-analysis) included data from 27 independent cohorts from 16 published studies including 1,382,999 participants followed up for 4 to 25 years and

measure is a gross approximation of the average duration of sleep, and it does not allow a further brake down of the effects in fractions of hours. Firstly, the report assumes that for an individual reporting 6 hours, this maps an interval (from 5.5 to 6.5h)[6]. However, this is a free interpretation not currently supported by more direct evidence using objective measures of sleep duration, like sleep questionnaire, wrist actigraphy or polysomnography. Secondly, the modeling applied to the data assumes a graded and continuous relationship (whether linear, quadratic, exponential or polynomial) discounting the possibility of a 'threshold' effect whereby only sustained sleep duration of ≤5 (or ≤6h) per night would trigger long-term health effects. The presence of the U-shaped relationship should not discount the findings on the other hand of the distribution of sleep time, that is, sleeping more than 8h (or 9h) per night is also associated with increased mortality risk.

The current model proposed does not take into account these possibilities, still considered by the scientific community in the light of current knowledge. This is summarized in Cappuccio FP et al (2010): *"Currently, there is no evidence that sleeping habitually between 6 and 8h per day in an adult is associated with harm and long term consequences. In terms of prevention, consistently sleeping 6 to 8h per night may therefore be optimal for health."*[7]

1.5 Baseline sleep time and estimated sleep time changes

To estimate the impact of the HOS rule change on expected mortality risk, FMCSA uses four categories of drivers (described in previous chapters of the report) according to 'intensity' of average hours worked: moderate (average 45h per week), high (60h), very high (70h) and extreme (80h). They then use low, medium and high baseline levels of sleep for each driver, the 'low' estimates are derived from Hanowski RJ et al. (2009)[8], the 'high' estimates from Balkin T et al. (2000)[9], and the 'medium' estimates are calculated as an average of the two[10]. Exibit 5-2[11] summarizes the estimated baseline levels of sleep as follows:

accruing 112,566 deaths. The pooled analysis showed a greater risk of death in short sleepers (1.12, 95% CI 1.06 to 1.18; p<0.01) and in long sleepers (from (1.30, 1.22 to 1.38; p<0.0001).

[6] RIA, p. 5-6

[7] Cappuccio FP et al. (Sleep 2010), p. 591

[8] Hanowski RJ et al. (Accidents Analysis & Prevention, 2009). The study evaluated the impact of an additional driving-hour (from 10 to 11h) on critical incident risk, measured as critical incidents per hour. The study showed no consistent significant difference in critical incidents between hours 2 through 11. It showed, however, a strong positive correlation with national traffic density data, concluding that there was no support to the hypothesis that there is an increased risk resulting from CMV drivers driving in the 11th driving-hour as compared to the 10th driving-hour, or any hour.

[9] Balkin T et al. (FMCSA 2000). This study was undertaken to gather data on representative wake-sleep cycles of CMV drivers operating in uncontrolled, naturalistic, settings (field study), to determine (in a laboratory setting) the effects of schedules involving different amounts of sleep (3,5,7 and 9h) on driving task performance and driver's responses, to extend and validate a model of performance prediction based on prior wake-sleep cycles, sleep quality and quantity and circadian state. In the field study 50 CMV drivers (21-65 yrs) were divided in 'short-haul' and 'long-haul' schedules. Wrist actigraphy and sleep logs recorded timing and duration of sleep over 20 days during work and off-duty time. Both long- and short-haul drivers averaged approx. 7.5h of sleep per night. Time off-duty was positively correlated with total sleep time for both groups. There was no off-duty duration for either group that guaranteed adequate sleep. Large day-to-day variations in total sleep time were also evident for drivers in both groups. The authors concluded: *"although work/rest schedules can be devised to help minimize commercial driver sleep debt, optimal enhancement of driver alertness and performance will require additional approaches"*.

[10] RIA, p. 5-4

'Intensity ' category	Average weekly hours worked	Average sleep time (hours)	Low – High sleep time (hours)
Extreme	80	6.23	**5.87** – 6.59
Very high	70	6.64	6.28 – 7.00
High	60	6.91	6.55 – 7.27
Moderate	45	7.02	6.66 – 7.38

In bold values ≤6h per night, cut-off for short sleep in some epidemiological studies

One consideration to make is that, once accepting the validity of these calculations, none of these groups have an average baseline sleep time ≤5h per night, the cut-off used in most studies and in Ferrie's study, and currently associated with an increased mortality risk. If we consider ≤6h per night as the cut-off, as in some studies, only the low estimate in the extreme group may meet these criteria. It is therefore reasonable to assume, on the evidence available from epidemiology, that the vast majority of these drivers, most definitely those in the 'very high', 'high' and 'moderate' categories, have a baseline average sleep time within levels not associated with evidence of harm, at least regarding mortality risk.

FMCSA then used the correlations between work hours and sleep hours for long-haul drivers from their internal analysis[12] to derive the changes in work hours for drivers in each 'intensity' category and HOS option into changes in sleep time, finally applying them (in their own judgment), to the baseline level of sleep for each category of drivers.[13] Exhibit 5-2[14] again summarizes the estimated changes in hours worked per day under each Option. The next step is to predict the change in sleep projected under the proposed HOS Options. This is the most obscure part of the modeling since the reader is not given the full tabulation but he/she is left with a complex equation from which to work out the final numbers.[15] Notwithstanding this caveat, the reported sleep gained for the very high intensity group with low baseline sleep would be of 0.091 hours, increasing average sleep from 6.28 to 6.37 hours per day, i.e. approximately 5.5 min per day.

Firstly, there is no evidence from the epidemiological literature to indicate what the benefits would be of increasing regular sleep time by 5 min per day. The level of precision of these measurements is one order of magnitude smaller than the minimum level of discrimination of measurements of exposure (by 1h category) used in the epidemiology reviewed earlier.

Secondly, none of the short-term, highly controlled, laboratory-based sleep deprivation or prolongation studies in human volunteers have ever demonstrated health effects (neuro-hormonal or metabolic) within these minimal changes of sleep time[16], so that it is arguable, based on current evidence, that such a small effect would exert any benefit at all.

[11] RIA, p.5-5
[12] Balkin T et al. (2000)
[13] RIA, p. 5-4
[14] RIA, p.5-5
[15] RIA, p. 5-5
[16] Spiegel K et al. (Nat Rev Endocrinol 2009)

Thirdly, FMCSA assumes that if drivers worked fewer hours they would use the extra time (or significant part of it) to sleep[17]. This assumption is unsupported and there are studies indicating that this is not necessarily the case, and that other initiatives ought to be taken in order to direct the off-duty time to sleep. For instance, the study by Balkin T et al. in truck drivers shows that time off-duty was positively correlated with total sleep time for both short- and long-haul drivers. However, there was no off-duty duration for either group that guaranteed adequate sleep. Large day-to-day variations in total sleep time were also evident for drivers in both groups. The authors concluded: *"although work/rest schedules can be devised to help minimize commercial driver sleep debt, optimal enhancement of driver alertness and performance will require additional approaches".* This concept has also been shown in other occupational groups, like junior doctors both in the US[18] and the UK[19]. In these studies reduced weekly work hours led to an increase in sleep time because other approaches were taken at the same time as the reduction in work hours to encourage and facilitate the workers to sleep longer and to recover better from previous shifts. These measures include important components based on well-established principles of sleep medicine and circadian biology: limit consecutive night shifts in order to reduce the build-up of chronic partial sleep deprivation due to the limited sleep between night shifts; limit shift duration in order to minimize acute sleep deprivation; design the sequence of shifts to abolish 'slam shifts'; instruct workers and facilitate naps; and also reduce the proportion of long work weeks. These approaches are effective on performance and reduce errors. No evidence of efficacy on health outcomes is yet available.

1.6 Predicted changes in mortality

In the next step of the calculation of health benefits, FMCSA translates the predicted increased sleep time due to the HOS rule changes into decreased mortality risk[20]. They use a regression technique modeling mortality on the expected value of hours of sleep (also using a quadratic parameter). I will address only the basic model since the RIA reports no differences when using the quadratic parameter.

FMCSA uses data from the Ferrie's study. Ferrie's study basically reports three sets of data: the relationship between (a) self-reported duration of sleep at Phase 1 (1985-8; including 9,781

[17] Lockley SW et al. (New Engl J Med 2004). Twenty interns were studied during two three-week rotations in intensive care units, each during both the traditional and the intervention schedule. The intervention was designed to maximize the chance to get extra sleep during the reduced work hours. Subjects completed daily sleep logs that were validated with regular weekly episodes (72 to 96h) of polysomnography and work logs. Interns worked >80h per week during the traditional schedule and <80h per week during the intervention schedule. On average, interns worked 19.5h per week less and slept 5.8h per week more.
Cappuccio FP et al. (Q J Med 2009). This is a study of the effects on patient's safety and doctors' work-sleep patterns of implementing an EWTD-compliant 48h work-week compared to a 56h work-week in a single-blind intervention study carried out over a 12-week period in a British hospital. Sleep and work logs and wrist actigraphy assessed sleep-wake cycle. The 48h work-week group had a rota designed to increased their chance to sleep and was instructed to take regular naps and to follow measures of sleep hygiene. At the end of the study they increased their sleep time of an average 0.5h per day.
[18] Lockley SW et al. (2004).
[19] Cappuccio FP et al. (2009).
[20] RIA, pp. 5-5, 5-6

participants and 566 deaths), (b) at Phase 3 (1992-3; 7,729 participants and 292 deaths)[21] (c) and changes in sleep duration between Phase 1 and 3[22], and all-cause mortality (relevant to this report). As FMCSA acknowledges in the RIA, the subjects' average hours of sleep was reported as ordinal categories in hours of sleep time, not as continuous variables in minutes of sleep time. An assumption is made that these categories would map intervals that could then be converted fitting a normal distribution. From these calculations they derive the expected number of hours of sleep. Finally FMCSA regresses the published point estimates of the mortality Hazard Ratios versus the expected number of hours. Exhibit 5.4 displays the sleep mortality function[23].

There are several problems with this approach. There is no indication in the RIA as why FMCSA has chosen data from Phase 1 rather than from Phase 3. Phase 1, whilst using a greater sample size and a larger number of events (hence greater statistical power), reports data that is not statistically significant. In particular the fully adjusted model for ≤5h per night of sleep time (when compared to the reference category of 7h per night) yields a non significant effect (1.24; 0.92 – 1.67). Conversely, at Phase 3 the fully adjusted model for the same comparison yields a statistically significant increased mortality risk (1.78; 1.17 – 2.71), despite lower statistical power. This may suggest a difference in the two periods. Possible explanations could include: more reliable assessment of sleep time at Phase 3, less variability in the estimate of exposure, different distribution. Indeed the paper states *"self-reported measures of sleep duration […] were not identical at the two Phases and did not explicitly ask participants to differentiate time asleep from time in bed"*[24]. It is therefore unclear why FMCSA chose results that could not exclude chance findings ignoring those that were ruling out the play of chance. This point is rather academic, though, as a different choice of data would not have addressed more important pitfalls. There is no justification for the extrapolation of categorical data to smooth log-linear regression models. This model is misleading in two ways: first it attributes the effects of very small changes in sleep time (minutes) that are well below the level of precision used in Ferrie's study and in any other large population study, second it assumes a 'graded' relationship between sleep time and mortality risk that is not demonstrated in any of the population studies. There is still debate as whether a 'threshold' effect at around 5h per night may be an alternative explanation. Finally, inherent the studies of population, it is still under debate whether a single self-reported assessment of sleep time is a reliable measure of 'sustained' sleep pattern, then implying a possible causal effect on long term health outcomes. This point is clearly made in Ferrie's study when studying the effect of change in sleep time over five years and its relation to mortality risk.

It is unclear why FMCSA have not applied their approach to long sleep. Ferrie's study and Cappuccio's meta-analysis both concur in describing a significantly increased mortality risk for sleep time of >8h per night. From the FMCSA's sleep mortality function in Exhibit 5.4 we can observe an increase in mortality risk for sleep time >7.5h per night. This is a value that would be compatible with the high baseline sleep time in the moderate category under the proposed HOS rule change. This is in my view inaccurate and can be misleading.

[21] Ferrie JE et al. (2007), Table 1, p.1661
[22] Ferrie JE et al. (2007), Table 4, p.1664
[23] RIA, p. 5-8
[24] Ferrie JE et al. (2007), p.1663

Clearly more research is needed to improve the assessment of exposure, to clarify the shape of the relationship, to rule out the possibility of residual confounding, to understand whether there is plausibility for causality or whether short sleep is a co-variate of some as yet unknown factor directly causing long term consequences.

Guaranteeing sufficient sleep time to a number of occupational groups is an accepted and scientifically proven concept to improve safety. The avoidance of sleep deprivation reduces excessive daytime sleepiness, tiredness and fatigue that are responsible for reduced alertness and performance, increased rate of accidents and errors. However, it is premature to use the mortality outcome to support policy changes in occupational groups.

1.7 Conclusions

In summary, after reviewing and appraising the RIA, having reviewed the source scientific evidence and in light of current knowledge,

1. the current evidence, in particular the studies by Ferrie JE et al. (2007) and Cappuccio FP et al. (2010), do not support the conclusions of the FMCSA that a small increase in sleep duration of a few minutes following the HOS Options proposed, particularly in the groups with baseline daily sleep >6h per night, is likely to decrease the mortality risk of individuals or groups.

2. there is no evidence to prove that, without additional measures, a simple reduction in work hours will result in increased sleep time.

3. FMCSA's interpretation of the paper by Cappuccio FP et al. (2010) is incorrect as (a) the level of precision of sleep time is within an hour unit (and not fractions of it), (b) there is no indication of a 'gradual' relationship across sleep time used as continuous variables to support the used model, (c) the data do not exclude a 'threshold' effect at $\leq$5h per night, (d) the data does not identify any significant change in mortality risk between 6 and 8h per night, (e) the data also indicate an increased mortality risk for sleep time >8h per night.

4. there is no evidence available to date to support the view that a few minutes of increased sleep time per day would exert a beneficial effect on mortality risk.

5. it is premature to address specific policy changes on the basis of the published relationships between sleep time and mortality risk in epidemiological studies of general population samples. Specific new research needs to address the gap in evidence to support future policies.

1.8 Primary References

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