

**“Comment on Regulatory Approaches”**

**MARTIN MOORE-EDE, M.D.**

*CIRCADIAN*



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Coming last, after all the leaders in the aviation industry and the leaders in the science of fatigue have spoken, is a little bit of a challenge!

We all really do have to stop and congratulate the Federal Aviation Administration (FAA) for the extraordinary proactive leadership that they have shown through organizing this conference, and on this whole issue of fatigue risk management.

This has been an extraordinary opportunity to share and exchange knowledge amongst such a broad range of stakeholders, and to bring an entire industry up to speed. This is a remarkable achievement that we all can recognize as being an important step forward.

In 25 years we have come a very long way. Twenty-five years ago a young slim congressman, who later became Vice- President Al Gore, invited to testify before him in a Congressional hearing a young slim Harvard professor - that would have been me- about the science of sleep and circadian rhythms and how it applied to industry.

I had just completed a study with Chuck Czeisler, one of my colleagues, of an industrial shift work facility that had called us up and said, “We have problems with sleep here, and our workers are falling asleep on the job. We have accidents. We have low productivity.”

In response to this challenge we had taken that nascent science and actually built what probably was the first fatigue risk management system, -- scheduling, education, training and so forth within an industrial shift work facility. We found that when you started to apply this science, that really so far had been largely bench science, safety improved and accidents went down. Health ratings improved. Productivity went up 22 percent, which really caught their attention. Specifically, the number of tons of product leaving that site went up 22 percent without any more people being hired or any more capital investment.

After we wrote up the results and published it in Science, Al Gore decided to invite us to come and testify on the Hill about this research, and what the potential might be.

At that time he also invited a panel of representatives from four federal agencies, including the FAA and the NRC. At that panel three out of those four federal agencies said, on cross examination by Al Gore, fatigue is not an issue! So you can see how far we have come today.

We have come an enormous distance. But I can tell you it has been a challenge. It has been a culture shift. And it has been not just in the agency; it has been in the industry; it has been in the unions. Everyone’s awareness and interest

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has advanced considerably, and the opportunity before us now is really an extraordinary one.

In the last 25 years we have seen the science mature. I am not saying there are not a lot of remaining scientific questions, but the core scientific principles have actually become well established. When I recently convened a panel of 11 scientists who were polled separately on a technical issue about how to schedule sleep and duty hours, all 11 agreed precisely on the core scientific principles independently of each other. And I must say in a scientific community that loves to debate each other on every single point this was remarkable. For example, even Greg Belenky, who is sitting beside me, was one of the people who actually agreed with everybody else!

This just shows you that the core science that fatigue risk management is based on is firmly established. The core of this science is no longer what attorneys call “emerging science”. Of course, beyond this core, there are a lot of great discoveries being made in circadian genetics, and other aspects of circadian and sleep physiology.

Over the last 25 years, there has been a comprehensive set of tools developed across multiple industries, and we really need to become aware of these tools. There are tools for not only education and training; there are tools for fatigue risk modeling. There are tools for accident investigation, for what is the probability of fatigue being a causal factor in an accident. There are proportional staffing tools that address the problem we have heard about balancing staffing versus workload.

All of these tools exist and are used, day in and day out, in multiple different industries that employ 24/7 workforces.

In addition, the process of creating in an organization a “just culture” has been very well developed. One of the very important lessons about just cultures is that it helps if you have got a concrete issue to work that just culture around.

It cannot be a theoretical issue. Fatigue risk management is the perfect issue, because there is so much win-win, there is so much gain for everybody out of this process including quality of life, health, personal safety, corporate productivity and efficiency, and corporate budget ROI. All those things come out as a real win-win from this fatigue risk management process. The just culture comes about by working on a project like this together. Once you've got that just culture, guess what? All sorts of other things can then be addressed through that collaborative process.

The challenge, of course, is how to operationalize this science and shiftwork experience in the aviation industry. This has been a large part of this conference. I can tell you that the aviation industry is the most complex industry by far - and I have worked across many, many industries. All the moving parts and moving equipment and moving people, and all the time zones and geographical locations and times of day, make it the most complex of challenges.

In a sense, for us scientists, this is the pinnacle of fatigue risk management. You have whetted our appetite. This is an opportunity to take everything we know and move it forward.

The just culture, of course, involves some key principles, as we have been talking about. One is truth telling. One is protection of people who tell the truth. And the third is leadership to actually do something about the truth and continuously improve. These three principles are actually the key to the whole just culture process.

My mandate is to talk a little bit about the regulatory issue. One vital truth is that we have a regulatory paradox, and it is not just in this industry – it is in every other industry that has prescriptive work-rest regulations. The critical paradox, that we have been talking about at this

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conference, is that you can be legal but unsafe, or you can be safe but illegal.

As long as we have this regulatory paradox it just numbs the mind, and, in fact, it is a prohibitive barrier to dealing with the fatigue issue. Because if everyone ignores this paradox, how can we address everything else and claim we are telling the truth at the same time?

The challenge, then, is how do we deal with this issue? This regulatory paradox actually has a very real cost to it. It has a safety cost to it. It has a health cost to it. It has a productivity cost to it.

And so just as fatigue risk management systems have to find their proper interface and plug into safety management systems, fatigue risk management systems also have to find their proper interface and be plugged into the regulatory structure. And that is going to take some regulatory innovation, just as it is going to take some innovation on the safety management side.

We were delighted to hear during the course of the conference that the FAA is already working hard on this issue. We were delighted to learn they are ahead of the game. They are thinking about this issue, and how do you can do it.

The scenario is going to happen very soon, stimulated by this conference, where one or more airlines are going to come to the FAA and say, “We have got together with our union and we need an exemption or waiver from certain aspects of the flight-time duty-time regulations that run counter to fatigue risk management. We have worked out a real fatigue risk management approach - we are ready to really move this thing forward, and we just want to go full steam ahead while everyone understands the issue and has got the energy”.

The airline will say to the FAA “We have got a well developed fatigue risk management system. We have documented it, and we have got it all in place, and we are implementing it as a continuous improvement process. We are bringing you the scientific evidence for safety equivalence, but we need your help to do something with the prescriptive rules that are getting in the way of this safety solution.”

That rule could be something like, for example, the eight-hour limit on the two-person cockpit. If we stay on duty for nine hours you could have people fly during the daytime instead of having to flip them, and have them come back for productivity reasons overnight.

So the request to the FAA might be something like that. But whatever the request is, that airline is going to come to the agency and is going to say, “How do we do this? How do we go forward? Do we go the exemption route? Do we go through the Part 11 exemption process? Do we need an alternative rule like AQP, the Advanced Qualification Program, or alternatively under Part 121 subparts N & O – so you see, I'm learning some of the lingo here! Or do we address the flight-time, duty-time regulations, and revise the whole regulation?”

First of all revising the whole regulatory framework is a huge headache, and if you want to see how difficult it is, look at the trucking industry and what the FMCSA have been bashing their head against for year after year.

So clearly one of the questions is how do we fast track important safety improvements? What happens if we don't have a facilitated, thought out mechanism that is transparent, that's peer reviewed, that has been through the appropriate due diligence? If it is not in place when that airline arrives seeking approval for a creative solution to fatigue risk, there is a substantial cost of waiting.

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The cost of waiting is loss of energy. When the request arrives from an airline everyone is energized. If they cannot move promptly ahead team members get assigned to other duties, so the team that was together, that put this whole creative solution together, starts dissipating.

Furthermore airlines have to make a decision on whether to invest in a fatigue risk management system. Any change like this is going to require a significant investment in systems and processes and costs to make this work. The energy required for an airline to make that commitment is going to be dissipated- and management is going to hang back unless the regulatory exemption process moves forward in a timely way.

I have seen these problems with regulatory innovation in a number of industries, including railroads and trucking. Most recently we have helped a major trucking fleet file an application for an exemption from certain hours of service rules, which is pending before the Federal Motor Carrier Safety Administration (FMCSA). We submitted it over a year ago, and are still waiting for the answer. In the meantime the company, Dart Transit, has won the Innovator of the Year Award from the trucking industry for this comprehensive fatigue risk management solution which they cannot implement until the FMCSA approves it. Safety equivalence has been demonstrated; a dozen letters from leading fatigue and sleep scientists are supporting it; support has come from the American Trucking

Association, driver organizations and the industry. But it is a challenge to move even such a big opportunity for safety improvement forward, and it is a challenge to a regulatory agency to deal with such a request.

When the Dart Transit exemption request was published in the Federal Register, it received almost 100% completely positive comments. Only one public advocacy group opposed it, but they have never been known to like anything proposed by the industry. That goes with the territory.

The question today is how do we move regulatory innovation forward in the aviation industry? That is the challenge. What can we do to give the confidence to the airlines and the unions to encourage them to invest in the intellectual capital, the monetary capital, the human capital, to make this happen?

So the biggest challenge I have heard from this conference is where is the home for this fatigue risk management process within the regulatory structure? I am convinced that the industry would have the energy, and would be willing to move this whole fatigue risk management process rapidly forward if the regulatory issues are seen to be promptly addressed.

A copy of Dr. Martin Moore-Ede's biographical information is provided in Appendix C.