Response of Dr. James M. Johnston, Jr.

Additional Questions for the Record

The Honorable Lee Terry

1. You described the Sports Concussion Assessment Tool as part of an examination of an athlete. How accurate is an evaluation of an athlete? Is an evaluation standardized or is there interpretation based on the differences of each individual athlete? How can evaluations be improved?

   The Sports Concussion Assessment Tool Version 2 (and now 3) is a standardized method for evaluating athletes suspected of having a concussion. Each subcomponent of the test (Glasgow Coma Scale (GCS), Maddocks score, physical signs score, coordination score, symptom assessment-Post Concussion Symptom Score (PCSS), Standardized Assessment of Concussion (SAC), and balance examination have shown both reliability and validity in the assessment of concussion (see attached document, Guskiewicz et al). In addition, more recent studies have generated normative data for the SCAT for ages above 12, and the Child-SCAT3 has been introduced and validated for children aged 5-12. It is clear that the SCAT2/SCAT3 represents an important component of the comprehensive evaluation of an athlete suspected of suffering concussion, and streamlines the evaluation process ensuring reliable and useful data for decision making regarding return to play and other interventions. Current studies are underway evaluating the efficacy of other sideline assessments of concussion including the King-Devick Test, reaction time tests, pupillometry and even serum biomarker tests. Whether these tests add significant value to existing concussion assessment protocol will be more clear after larger studies are complete.

2. During your testimony you mentioned that recent studies have identified "potential long term health consequences" that are "associated with repeated head impacts." In medical or research terms, what is the meaning of "associated" regarding how strong the relationship is?

   a. Does that indicate more research is needed? If so, please explain what research is needed and how it could improve overall safety of sports.

   Recent studies have clearly demonstrated significantly higher rates of neuropathology (including depression, dementia, parkinsonian symptoms, and ALS) in professional athletes who have played impact sports (football, hockey) compared to the general population. Dementia pugilistica was first described in boxers more than 80 years ago and is thought to be identical to chronic traumatic encephalopathy (CTE), more recently described in professional, collegiate (and now high school) football players. With the addition of new imaging (PET and MRI) data demonstrating changes in white matter and deep cortical structures in living football players, the evidence has become increasingly strong suggesting a causal relationship between repeated head impacts and long term neurological consequences in professional athletes who have played for many years. More research is needed to determine the prevalence of these injuries in the general population, thresholds for injury in athletes, effects of subconcussive impacts on children, the biomechanics of concussion and design of better helmets, etc. Though we do not have a complete understanding of all of these questions, it has become increasingly clear that repeated head trauma is not beneficial to the developing or mature brain.

3. What is rotational loading? Why is that important? Can a helmet or piece of equipment reduce rotational loading?

Rotational loading refers to the stress and strain in brain tissue that occur as a result of twisting of the head around the neck in three dimensional space. In comparison with a linear impact (ie one helmet striking the side of another helmet and translating the head in a straight line direction with resultant injury to the brain), rotational loading results in a shear type injury pattern that can damage deep grey and white matter structures as well the brainstem. Both linear and rotational loading are thought to contribute to the pathophysiology of both concussive and subconcussive impacts. Currently, there is no helmet or equipment available that is expressly designed or proven to reduce rotational loading. Fortunately, new standards for helmet testing have been proposed by both NOCSAE and Virginia Tech (STAR system) that will include a rotational component in the testing paradigm. Based on experience from the transportation industry, after the advent of these new standards, helmet manufacturers will reorient their design capabilities and manufacture improved helmets that address and mitigate rotational loading.

The Honorable Joe Barton

1. The ISO/IEC and ASNI specify that accredited standards must identify normative references that support specific provisions of a standard. In your prepared remarks and in your testimony, you stated that NOCSAE standards should be overhauled in order "to reflect current understanding of concussion pathophysiology and foster improved helmet design."

2. What specific concussion pathophysiology should be included in helmet standards, and how should that pathophysiology be described for purposes of testing and validation?

   Current helmet standards (NOCSAE, Snell, and DOT) all include testing paradigms that assess protection from linear impact only. New helmet standards will need to include additional tests that also assess a helmet's ability to protect users from tangential impacts that result in rotational acceleration/loading. As mentioned above, rotational loading is known to be a significant contributor to brain injury and concussion, resulting in significant shear type injury to deep brain structures. Fortunately, both NOCSAE and Virginia Tech STAR testing paradigms will include both linear and rotational testing as part of their updated format later this year.

3. Panel experts, including you, seemed to agree that there is no scientific consensus for a concussion specific injury threshold, and that much more research and data collection is needed in that area. Without scientific consensus for a concussion specific threshold for either linear or rotational accelerations, how can those be incorporated into a helmet standard?

   Though current accelerometer-based studies have not found a distinct "threshold" for concussion diagnosis, it has become clear that concussion may be observed after a wide range of impact magnitudes, and involves both linear and rotational acceleration components. Of more concern, recent research has broadened the scope from "concussive" impacts to the concept of "subconcussive" impacts or impact exposure over time. Studies of athletes using advanced MR imaging and neuropsychological testing have demonstrated that structural changes and decreased neurocognitive function are proportional to the number of impacts, even in the absence of concussion. Thus, it becomes more clear that decreasing impact exposure, from both high magnitude (>80G) concussive and lower magnitude (20-80G) subconcussive impacts, is a necessary criterion for new helmet design standards. Again, based on the experience of the automotive/transportation industry, new standards should initially be based on a consensus agreement of "acceptable" protection from the known range of impact conditions, which

typically reflects the higher range of existing helmet performance (ie 4 and 5 star rated helmets in the Virginia Tech STAR system). Over time, as helmet design improves and more data is generated detailing impact conditions and biomechanics of injury, this bar is slowly raised to reflect higher expectations of safety, thus improving helmet design and performance by manufacturers in order to remain competitive in the marketplace. This iterative process generated by transportation safety standards and star ratings is why cars sold today are so much safer than those sold 20 years ago. In stark contrast, the helmet industry has had no comparable change in standards since the introduction of the NOCSAE paradigm since 1973. It is not hard to imagine how different (and safer) our current helmet technology might be now if this standard had evolved and become more demanding at the same rate as those of the automotive industry over that same period.