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STANDARDS-BASED REGULATION OF ATHLETIC PROTECTIVE HEADGEAR – POLICY BACKGROUND, MECHANISMS AND EVALUATION

STEPHEN D. PFRIEM*

I. INTRODUCTION.....	55
II. STANDARDS, STANDARDIZATION AND STANDARDS DEVELOPMENT ORGANIZATIONS: AN OVERVIEW	56
A. <i>Standards</i>	57
B. <i>Standardization</i>	59
C. <i>Standards Development Organizations</i>	60
1. Voluntary Consensus Standards	61
2. How	61
3. Who.....	62
III. STANDARDS-BASED REGULATION: LAW AND MECHANISMS.....	63
IV. PUBLIC POLICY CONTEXT OF PRIVATE STANDARDS-BASED “QUASI-REGULATION”	63
A. <i>How Do Private Standards Regulate Products?</i>	67
B. <i>How Do Private Standards Regulate Athletic Headgear?</i>	68
1. Hockey	70
2. Football, Baseball and Lacrosse	71
V. EFFECTIVENESS OF STANDARDS-BASED REGULATION FOR ATHLETIC PROTECTIVE HEADGEAR.....	74
A. <i>Criticism</i>	75
B. <i>Context, Considerations and Recent Developments</i>	76
C. <i>Effectiveness</i>	79
VI. RECOMMENDATIONS	81
A. <i>Develop the Integrity of Conformity Assessment Systems for Helmets</i>	81
B. <i>Continue Private Standards-Based Regulation with CPSC Support</i> ...	82
C. <i>Coverage of New Equipment Technology by Private Regulation Structure</i>	83
VII. CONCLUSION	84

I. INTRODUCTION

Sports-related brain injury has recently been at the forefront of discussion in countless fields. It continues to receive increasing media coverage. In the wake of high profile player-deaths and legal settlements, the issue of concussion and related traumatic brain injury in sports is a topic of interest for a variety of professional disciplines as well as the common sports enthusiast or news consumer. Conversation about brain injury in sports has permeated the national awareness and has captured the attention of contemporary legal curiosity.

Considerations of the legal aspects of brain injury in sports are often concerned primarily with topics in the realm of traditional litigation, like personal injury and class action lawsuits. However, the issues that arise at the intersection of law and sports-related brain injuries are nearly limitless. Lately, there has been no shortage of

symposia held by the academic world or conferences that see participation from Sto proliferate and there are always new theories or novel new angles at which to analyze this issue.¹

This paper considers the regulatory reality of sports equipment that is at the center of this brain trauma in sports issue. It reveals that not all regulation concerning athletic head injuries occurs in the public sector. It goes on to explain that in the case of sports helmets, very little is performed by the government and explains how the private sector executes this regulation instead.

Protective equipment (helmets, by and large) are regulated, or more precisely, “quasi-regulated”² by a structure defined largely by private technical standards. This paper offers an introduction to these standards and explains the key elements and differences between the private regulatory models for helmets. It also evaluates the effectiveness of standards-based regulation of athletic headgear and concludes with recommendations for adjustments to the existing conformity assessment systems and undertakings by the helmet standards community that would serve the end of providing excellent private regulation for equipment that faces the serious challenge of reducing brain injury in sports.

II. STANDARDS, STANDARDIZATION AND STANDARDS DEVELOPMENT ORGANIZATIONS: AN OVERVIEW

A discussion of how standards define the private world that “quasi-regulates”³ sports equipment designed to mitigate head injury first requires an understanding of standards themselves. What exactly are standards? How are they developed and implemented? Who are the participating individuals and groups in a private standards-based regulatory system? This section of the article will provide an introduction to standards and the concept of “standardization.” A discussion of the entities that are

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¹ *Concussion Conundrum*, VILLANOVA UNIV. SCH. OF LAW - JEFFREY S. MOORAD SPORTS L. J. ANN. SYMP. (Mar. 15, 2013), <http://lawweb2009.law.villanova.edu/sportslaw/wp-content/uploads/2013/03/Moorad-Program.pdf>. See also *State of Concussions: Protecting Athletes Through Advances in Law, Public Health and Science*, UNIV. OF MARYLAND J. OF BUS. AND TECH. L. SYMP. (Mar. 7, 2014), http://digitalcommons.law.umaryland.edu/jbtl_symposia/sym20140307. See also *The Impact of Concussion Lawsuits on the Future of Football*, UNIV. OF MISSISSIPPI, MISSISSIPPI SPORTS L. REV. 2012 FALL SYMP., <http://mssportslaw.olemiss.edu/files/2013/05/Transcript-p.34.pdf>. See also International Concussion Symposium, SPORTS SAFETY INTERNATIONAL, (Jul. 17, 2014). See also *Concussion: A National Challenge*, NATIONAL ACADEMY OF ENGINEERING; INSTITUTE OF MEDICINE; CASE WESTERN RESERVE UNIVERSITY; METROHEALTH; TAIPEI MEDICAL UNIVERSITY (Jun. 23-24, 2015), <http://www.concussion2015.org/>. See also *Sports Concussions: Problems and Proposed Solutions*, SANTA CLARA LAW, <http://law.scu.edu/sportslaw/2013-sports-law-symposium/>.

² John D. Graham & Cory R. Liu, *Regulatory and Quasi-Regulatory Activity Without OMB and Cost-Benefit Review*, 47 Harv. J. of L. & Pol’y 42 (2013).

³ *Id.*

responsible for standards – SDOs,⁴ will illustrate how their structure, membership and procedural guidelines demonstrate characteristics which, although based in the private sector, are essentially “governmental” and “legislative.”⁵

A. Standards

Merriam-Webster’s dictionary defines a standard as “a level of quality, achievement, etc. that is considered acceptable or desirable.”⁶ In the sense that I will be using the term, a standard is a “technical standard”, meaning a set of characteristics or qualities that describes features and/or performance of a product, process or service. At the conceptual level, “standards”, technical and otherwise, are not easily distinguished from law.⁷ They both have the same essential tendencies: to require, to order or provide for order, to establish a “level” or “common denominator” for the given subject of the standard.⁸ The *National Technology Transfer and Advancement Act*⁹ provides the following official definition of a technical standard, “*the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality/quantity in describing materials, processes, products, systems, services or practices; test methods and sampling procedures.*”¹⁰ The International Organization for Standardization offers this slightly more concise definition: “A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.”¹¹

Standards are best understood by way of how they function. They help to ensure the quality and safety of production processes, products and services and to prevent negative impacts on health and the environment.¹² From an economic perspective, standards aid producers and consumers by promoting quality, compatibility, uniformity and other desirable characteristics in any marketplace. For example, a

⁴ Resources: Standards Developing Organizations (SDOs), ANSI, http://www.standardsportal.org/usa_en/resources/sdo.aspx.

⁵ See generally *Voluntary Consensus Standards Development*, SAE INTERNATIONAL, <http://www.sae.org/about/government/voluntary-consensus-standards-development/>.

⁶ *Standard*, MERRIAM-WEBSTER DICTIONARY (2015), <http://www.merriam-webster.com/dictionary/standard>.

⁷ Chris Sagers, *Standardization and Markets: Just Who Exactly is the Government and Why Should Antitrust Care?*, 89 OR. L. REV. 785, 793 (2011).

⁸ See generally Salil Deshpande & John W. Nazemetz, Ph.D., *Global Harmonization of Standards*, OKLAHOMA STATE UNIVERSITY: STEP PROJECT, http://www.okstate.edu/ind-engr/step/WEBFILES/Papers/Global_Harm_index.html.

⁹ 15 U.S.C. §3701.

¹⁰ *What are Standards*, NATIONAL INSTITUTE OF STANDARD AND TECHNOLOGY, <http://www.nist.gov/standardsgov/definestandards.cfm>.

¹¹ Standards, INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, <http://www.iso.org/iso/home/standards.htm>.

¹² Dieter Ernst, *America’s Voluntary Standards System: A ‘Best Practice’ Model for Asian Innovation Policies*, East-West Center – Policy Studies – 66 at 9 (2013).

standard describing the geometry of hypodermic needles helps the health care profession be more safe and efficient. It provides different medical equipment manufacturers with the assurance that their devices will integrate with needles as intended. It also gives practitioners the confidence that the materials they use will have characteristics fit for the purpose that they were selected for. Some good historical examples of standards include the necessity of standardizing railroad track widths and rail gauges as well as the thickness and thread of hardware (screws, bolts, hose connectors, etc.). There are standards for the ways that computer networks communicate with one another, standards for the components of fluorescent lamps, and standards describing how to run a business's management system so that it promotes quality.¹³

In the current global economy, there are technical standards for almost anything and everything. Some technical standards are developed in the public sector. They are often encountered as mandatory regulations, although an increasing number of regulations that are assumed to be public are private developed standards that have been incorporated by reference into a government regulation.¹⁴ Privately developed standards, which offer comparative efficiency and are favored over mandatory standards by public policy, now outnumber public regulations.¹⁵ They offer wider, more detailed and more specialized topical coverage, which would be unrealistic to expect from governmental agencies given their resources and knowledge base.

The theme that underlies standards themselves is, unsurprisingly, "standardization". Standardization is an activity that has long been central to human societies. Without standardized monetary systems or a standard system for weights and measures, both trade and science as we know them would be impossible. Standardization is a phenomenon with tremendous positive externalities for society. It facilitates safety, reliability, and generally helps people interact with both the physical world they inhabit and other. As noted, when very broadly defined, standardization is sometimes performed by Congress when it makes laws or when local governments make ordinances. These efforts "standardize" behavior. When more narrowly defined as the process of developing and implementing *technical* standards, some standardization is still performed in the public sector, by executive agencies within the government, like the FDA or NHSTA. However, in the United States the majority of standardization is performed in the private sector by standards development organizations (hereinafter "SDOs").¹⁶

¹³ Quality Management Systems – Requirements, *ISO 9000 Quality Management*, ISO, http://www.iso.org/iso/iso_9000. See also, *IEEE Standard for Ethernet, IEEE Standard for Ethernet*, IEEE 802.3-2012, <https://standards.ieee.org/findstds/standard/802.3-2012.html>. See also *Lamp Caps and Holders*, IEC 60061, <http://std.iec.ch/iec60061>.

¹⁴ See generally Stacy Baird, *Symposium: Ethical Reflections on the Future of Technology Policy: The Government at the Standards Bazaar*, 18 *STAN. L. POL'Y REV.* 35, 53 (2007).

¹⁵ See Emily S. Bremer, *The Thirty-First Annual Federalist Society National Student Symposium: Bureaucracy Unbound: Can Limited Government and the Administrative State Co-Exist?: Article: Incorporation by Reference in an Open-Government Age*, 36 *HARV. J.L. & PUB. POL'Y* 131, 147 (2007). See also *Incorporating Private Standards into Public Regulations*, REG BLOG (Jan. 26, 2015), <http://www.regblog.org/2015/01/26/series-incorporation-by-reference/>.

¹⁶ See Ernst, *supra* note 12 at 1.

SDO's are non-governmental bodies that create voluntary private standards.¹⁷ They exist all over the world. Private technical standards in Japan are curated by JIS (Japanese Industrial Standards);¹⁸ technical Standards in Europe are maintained by CEN (European Committee for Standardization);¹⁹ and finally, the International Organization for Standardization (ISO) represents the "pinnacle" SDO.²⁰ It coordinates the resources and participation of national standards bodies and their personnel to create unified international technical standards.²¹ ISO documents truly encompass the spirit of "standardization". However, given its relatively brief existence (since 1947) and the complexity of creating standards that represent global input, ISO does not have standards for all areas and topics. This is the case for athletic protective equipment. Standards for helmets, goggles, padding, and the like are most sophisticated and recognized at the national level, and in the case of Europe, regional level.

B. Standardization

While private standardization at the international level is overseen by ISO, domestic standardization is coordinated by a cooperative effort between two entities: "ANSI" and "NIST."²² "ANSI" is the American National Standards Institute.²³ It is a private non-profit organization that oversees the creation, promulgation and use of standards in the U.S.²⁴ Founded in 1918, ANSI's mission is "enhance the global competitiveness of US business and the US quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity."²⁵ "NIST" stands for the National Institute of Standards and Technology.²⁶ NIST is a government agency that was founded in 1901 and is part of the U.S. Department of Commerce.²⁷ Its mission statement, "to promote US innovation and industrial competitiveness by advancing measurement science,

¹⁷ See *The Value of Standards Development Organizations*, NATIONAL FIRE PROTECTION ASSOCIATION, <http://www.nfpa.org/codes-and-standards/the-value-of-standards-development-organizations>.

¹⁸ See JAPANESE INDUSTRIAL STANDARDS COMMITTEE, <https://www.jisc.go.jp/eng/>.

¹⁹ See *Who We Are*, EUROPEAN COMMITTEE FOR STANDARDIZATION, <https://www.cen.eu/about/Pages/default.aspx>.

²⁰ See *About ISO*, INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, <http://www.iso.org/iso/home/about.htm>.

²¹ *Id.*

²² See *About ANSI*, AMERICAN NATIONAL STANDARDS INSTITUTE, http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1. See also *NIST and ISO*, GRAINGER, <http://www.grainger.com/content/qt-nist-and-iso-194#> (last updated May 2014).

²³ See AMERICAN NATIONAL STANDARDS INSTITUTE, *supra* note 22.

²⁴ *Id.*

²⁵ *Id.*

²⁶ See GRAINGER, *supra* note 22.

²⁷ See *NIST General Information*, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, http://www.nist.gov/public_affairs/general_information.cfm (last updated May 12, 2015).

standards and technology in ways that enhance economic security and improve our quality of life”, aligns with ANSI’s and creates the foundation for the private-public cooperation between the two bodies.²⁸

ANSI and NIST usually function cooperatively and often partner in overseeing standards. NIST also oversees weights & measures in addition to conducting expansive research, and it more or less defers to ANSI’s leadership on standards, making ANSI the primary steward of standardization in the United States.²⁹ With its function of standard-stewardship, ANSI coordinates the efforts of the many organizations that develop standards, which are aptly known as “standards develop organizations.”³⁰

C. Standards Development Organizations

The most well-established standards development organizations in the U.S. came about during the American Industrial Revolution to coordinate manufacturer interoperability and to address safety concerns for labor and consumers.³¹ Many of the first SDOs were trade associations, like the National Fire Protection Association (“NFPA”, founded 1896) and the Industrial Safety Equipment Association (“ISEA”, now the “International Safety Equipment Association, founded in 1933).³² Other early U.S. SDOs were professional organizations, some of which are now the most prominent and robust standards bodies in the world. The American Society of Mechanical Engineers (“ASME”) was formed in 1880 and developed its first standard: a uniform test method for boilers in 1884.³³ To date, it has developed over six hundred technical standards.³⁴ These standards are used internationally and are managed by 700 committees through the work of over 4,700 volunteer professionals.³⁵

Another standards development organization with an engineering heritage that had its genesis in the industrial revolution is ASTM International.³⁶ Formerly known as the American Society for Testing and Materials, ASTM was founded in 1898.³⁷ ASTM’s primary function is the development and publication of technical standards and it is currently responsible for more than 12,000 active technical standards, including many standard performance specifications and standard test methods for

²⁸ *Id.*

²⁹ *See Sagers supra* note 7 at 796.

³⁰ *See Ernst supra* note 12 at 21, 33.

³¹ *See Sagers supra* note 7 at 797.

³² *See About NFPA*, NATIONAL FIRE PROTECTION ASSOCIATION, <http://www.nfpa.org/about-nfpa>. *See also About ISEA*, INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION, <https://safetvequipment.org/about-isea/>.

³³ *See Engineering History*, THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS, <https://www.asme.org/about-asme/engineering-history>.

³⁴ *Id.*

³⁵ *See About ASME Standards and Certification*, THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS, <https://www.asme.org/about-asme/standards>.

³⁶ *See The History of ASTM International*, ASTM INTERNATIONAL, http://www.astm.org/ABOUT/history_book.html.

³⁷ *Id.*

athletic equipment.³⁸ More than 30,000 members from 140 countries contribute to ASTM's standards activities.³⁹

1. Voluntary Consensus Standards

The above-discussed bodies are preeminent standards development organizations and they all can be described as producing "voluntary consensus standards", or alternatively, be regarded as "voluntary consensus standards bodies". Voluntary consensus standards are technical standards that are established by private sector organizations according to accepted procedures.⁴⁰ They are further defined as having the attributes of "openness", "balance of interests", "due process", an "appeals process" and "consensus."⁴¹ Not all SDO's produce standards that qualify as voluntary consensus standards, but those that do are able to release standards through a more thorough and fair process. The above-listed tenets that designate an SDO as "voluntary consensus" are crucial to the development of a standard that has credibility. "Openness" can be interpreted several ways, but is embodied by organizations like ASTM, which allow participation by anyone who wishes to join the organization for a nominal (\$75) fee.⁴²

2. How

Standards development organizations, especially those that fit within the voluntary consensus category, develop standards according to a process that is highly collaborative and akin to the legislative process.⁴³ Some commentators have described large SDO's as "pseudoagencies."⁴⁴ Most organizations abide by established due-process guidelines for the way they develop standards.⁴⁵ The organizations and standards that are accredited by ANSI conform to its detailed Essential Due Process Requirements, which adds to the requirements of being a voluntary consensus standard: additional characteristics like "lack of dominance", reasonable notification requirements, and consideration of all views and objections are mandated by ANSI.⁴⁶ Standards development often is a highly structured form of document development

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ See Franklin D. Raines, *Memorandum for Heads of Executive Departments and Agencies*, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, <http://www.nist.gov/standardsgov/ombal19.cfm> (last updated Feb. 10, 1998).

⁴¹ *Id.*

⁴² See *Membership*, ASTM INTERNATIONAL, <http://www.astm.org/MEMBERSHIP/MemTypes.htm>.

⁴³ See Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U.L. REV. 543, 642 (Jun. 2000).

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ See AMERICAN NATIONAL STANDARDS INSTITUTE, ANSI ESSENTIAL REQUIREMENTS: DUE PROCESS REQUIREMENTS FOR AMERICAN NATIONAL STANDARDS (2015). See also *Standards Activities Overview*, AMERICAN NATIONAL STANDARDS INSTITUTE, http://www.ansi.org/standards_activities/overview/overview.aspx?menuid=3.

with deadlines and associated recordkeeping of the process.⁴⁷ Drafts of technical standards are usually developed and revised through multiple review cycles in committees, subcommittees and working groups or task groups.⁴⁸ They are then finally approved by the entire SDO.⁴⁹ ASTM standards, for example, go through three tiers of peer review.⁵⁰ Collaboration between SDO participants involves the circulation of documents, supporting research and comments.⁵¹ As a standard becomes more developed, formal consensus tools are introduced to the process: voting, public comments, and appeals.⁵² It should be noted that consensus has been defined to not necessarily require unanimity, but rather general agreement with resolution, or at least cognizance, of the substance of objections.⁵³

3. Who

The membership of standards development organizations depends on the industry and the participants involved in the development and maintenance of a given standard is dependent on the subject matter.⁵⁴ Generally, SDO members are experts in their field.⁵⁵ To achieve a balance of interests, the committees of voluntary consensus standard development organizations often have prescribed percentages of participation from different interests (producers, users, consumers, general interest).⁵⁶ With respect to athletic headgear standards, contributions are regularly made by academics, doctors, attorneys, sporting goods manufacturers (product designers & product engineers), regulators (the CPSC), coaches, league officials, and testing and certification entities.⁵⁷ Standardization has been accurately described as a knowledge-intensive activity that required contribution from well-educated and highly

⁴⁷ See *ANSI Essential Requirements*, *supra* note 46.

⁴⁸ See *How Standards Are Developed*, AMERICAN NATIONAL STANDARDS INSTITUTE, <http://www.astm.org/MEMBERSHIP/standardsdevelop.html>.

⁴⁹ See *Frequently Asked Questions: Standards Developing Organizations*, THE UNICODE CONSORTIUM, <http://unicode.org/faq/sdos.html> (last updated June 28, 2012).

⁵⁰ *How Standards Are Developed: Creating New Documents, Modifying Existing Documents, How Standards Are Produced*, ASTM INTERNATIONAL, <http://www.astm.org/MEMBERSHIP/standardsdevelop.html>.

⁵¹ *Id.*

⁵² See *ANSI Essential Requirements*, *supra* note 46.

⁵³ See *Raines*, *supra* note 40 at § 4(a)(1)(v).

⁵⁴ See generally *ANSI Membership, A Value Proposition*, AMERICAN NATIONAL STANDARDS INSTITUTE <http://www.ansi.org/membership/overview/overview.aspx?menuid=2>.

⁵⁵ See *Resources*, *supra* note 4.

⁵⁶ See *Ernst*, *supra* note 12 at 47.

⁵⁷ See *History and Purpose*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT <http://nocsa.org/about-nocsa/history-and-purpose/> (The National Operating Committee on Standards for Athletic Equipment (NOCSAE) conducts research for athletic equipment in order to reduce injury). See generally *NOCSAE Board of Directors*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT <http://nocsa.org/board-of-directors/>.

experienced professionals.⁵⁸ While modern American standardization was developed by engineers, it now incorporates the input of the legal community, the government, and various business and consumer interests.⁵⁹ Because voluntary consensus standards development organizations incorporate multiple interests and expert perspectives into thorough and fair procedures, the standards that result are ideal tools for promoting quality and safety and encouraging the necessary innovation to advance both.

III. STANDARDS-BASED REGULATION: LAW AND MECHANISMS

With varied membership rosters, structured document development procedures and due process requirements, SDOs, especially voluntary consensus SDOs, can begin to resemble the bureaucracy. Yet in the case of athletic protective headgear, with the exception of bicycle helmets, none of that equipment is directly regulated by the government.⁶⁰ Instead, a private “quasi-regulatory” system defined by technical standards serves to promote the quality and safety of helmets and other athletic equipment while facilitating essential innovations and healthy competition.⁶¹ The prevalence of privately-developed technical standards in the US regulatory scheme is backed by longstanding government policies favoring their use.⁶² This section will review the trajectory of public policy that facilitates and even encourages standards-based regulation. It will explain the general ways by which standards-based systems can regulate in place of direct government regulation. Finally, it will describe the standards-based regulatory schemes for hockey, football, baseball and lacrosse helmets.

IV. PUBLIC POLICY CONTEXT OF PRIVATE STANDARDS-BASED “QUASI-REGULATION”

The current status of the technical standards system in the US is the result of clearly iterated policy intended to foster a regulatory system based on voluntary consensus standards that are created by non-governmental SDOs.⁶³ The private sector has contributed a majority of the volume of technical regulations currently in existence.⁶⁴ The government’s most notable contribution has been its policies of intentional deference-to and endorsement-of private standards.⁶⁵ Over time, the government has decreased its own role in the standards system to correspond with the

⁵⁸ See Ernst *supra* note 12 at 10.

⁵⁹ *Id.*

⁶⁰ See *FAQs*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT <http://nocsa.org/about-nocsa/faq/>.

⁶¹ See *Football Helmet Standards Overview*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT at 1, <http://nocsa.org/wp-content/uploads/2011/10/NOCSAE-Football-Helmet-Standards-Overview-1-2015.pdf>.

⁶² See Bremer, *supra* note 15 at 147. See also *Incorporating Private Standards into Public Regulations*, *supra* note 15.

⁶³ See Ernst, *supra* note 12 at 1.

⁶⁴ *Id.*

⁶⁵ *Id.*

larger trends of market deregulation and government downsizing.⁶⁶ The public sector has circumscribed its own role in direct standard-setting and has clearly and repeatedly encouraged the proliferation of sound private technical standards.⁶⁷

As mentioned earlier, the connection between public and private sectors in the standards world exists in the cooperative efforts of the National Institute of Standards and Technology and the American National Standards Institute. The relationship between NIST and ANSI being fundamentally that of a shared mission is established in a Memorandum of Understanding between the agency and the organization.⁶⁸ With its central theme of cultivating a unified approach to guiding standards development, the memo charges NIST with the responsibility of increasing government support for ANSI activities and encouraging agencies to use ANSI-accredited SDOs.⁶⁹

The United States Standards Strategy (USSS) is a publication that states the purpose and ideals of domestic standard's development and US participation in international standardization activities.⁷⁰ The USSS identifies a "market –driven private sector-led approach to global standardization", and although NIST participated in its development, the document was approved and published by ANSI.⁷¹ Although it reads like a statement of top-level government policy on standards, the USSS was published by a non-governmental organization, and is a good example of ANSI's leadership role and NIST's deference with respect to standards policy issues.

A public policy that endorses the efficacy of privately-developed technical standards is the longstanding and frequent practice by government of incorporating standards into law by reference. While the main theme of this article is how private-standards regulate athletic headgear is an alternative to true regulations, it should be noted that many standards become codified regulations.⁷² As of March 2014, the Code of Federal Regulations contained more than nine thousand "incorporations by reference" of private standards.⁷³ The Food and Drug Administration, the Nuclear Regulatory Commission, the Federal Aviation Administration, and the Occupational Health and Safety Administration are some of the many agencies that incorporate consensus standards into their regulations.⁷⁴ In fact, this practice of adopting private

⁶⁶ See Ernst *supra* note 12 at 3. See also, Sagers, *supra* note 7, at 794.

⁶⁷ See generally Sagers, *supra* note 7.

⁶⁸ Memorandum of Understanding Between the Am. Nat'l Standards (ANSI), and the Nat'l Inst. Of Standards and Tech. (NIST) (Aug. 31, 2000) <http://gsi.nist.gov/global/docs/ANSINISTMOU2000.pdf>.

⁶⁹ *Id.*

⁷⁰ 15 AMERICAN NATIONAL STANDARDS INSTITUTE, UNITED STATES STANDARDS STRATEGY 2 (2010).

⁷¹ *Id.* at 5.

⁷² See Freeman, *supra* note 44, at 551.

⁷³ Nina A. Mendelson, *Private Control Over Access to the Law: The Perplexing Federal Regulatory Use of Private Standards*, 112 MICH. L. REV. 737, 739 (Mar. 2014). See also Adele L. Abrams, *Legal Implications of Voluntary Consensus Standards*, http://www.insafetyconf.com/media/PDF/safety_conf_2015/materials/Abrams_CS1.pdf.

⁷⁴ *Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards*, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (Sep. 17, 2007).

documents as public law was the primary method for establishing OSHA regulations upon its creation as an agency.⁷⁵ Incorporation by reference as a government practice has critics, who allege that issues of copyright, public notice and access to referenced standards render it flawed.⁷⁶ Those concerns aside, it is a well-established lawmaking practice that sees the public sector valuing and relying extensively on the products of the private standards system when making regulatory law.

Utilizing voluntary consensus standards is well recognized as more efficient than bureaucratic rulemaking.⁷⁷ Beyond efficiency, it is also compatible with clearly articulated public policy favoring the proliferation and government-use of private standards. Both the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119 unequivocally call for the use of voluntary consensus standards by government agencies.⁷⁸ The National Technology Transfer and Advancement Act of 1995, also referred to as Public Law 104-113, requires that all federal agencies and departments use technical standards developed and adopted by voluntary consensus standards bodies, and use such standards to carry out policy objectives.⁷⁹ The act also requires that “Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies, and shall participate with such bodies in the development of technical standards.”⁸⁰

The OMB Circular A-119 was last revised in 1998.⁸¹ The circular, which is a memorandum of information and instruction to federal agencies from the executive branch’s Office of Budget and Management, expounds on the themes of Public Law 104-113.⁸² Circular- A-119 sets an official definition for voluntary consensus standards development organizations by enumerating the earlier mentioned “tenets” that are embraced by organizations that earn the label.⁸³ It goes on to state that agencies must use voluntary consensus standards in-lieu of developing government unique standards. [SC 20] A-119 directs agencies to get involved with voluntary consensus standards development organizations, specifying that agencies should consult with SDOs and participate in private standards development as well as actively participate in their development. It gets so detailed as to list permissible involvement, including participation in SDO’s by agency personnel, technical support, administrative support and direct financial support.⁸⁴ The policy of encouraging the

⁷⁵ See Freeman, *supra* note 44, at 640.

⁷⁶ See generally Mendelson, *supra* note 73.

⁷⁷ CONSUMER PRODUCT SAFETY COMMISSION: A More Active Role in Voluntary Standards Development Should be Considered, U.S GOV’T ACCOUNTABILITY OFFICE, GAO-12-582, (2012).

⁷⁸ See Abrams *supra* note 73.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, REVISION OF CIRCULAR A-119 “FEDERAL PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY CONSENSUS AND IN CONFORMITY CONFORMITY ASSESSMENT ACTIVITIES” (2014).

⁸² *Id.*

⁸³ *Id.*

⁸⁴ See Memorandum for Heads of Executive Departments, *supra* note 40.

use of private technical standards highlights the government's willingness to allow consensus standards to continue to grow as the foundation of a significant amount of regulation.

To date, the regulatory policy toward athletic headgear has embraced the theme of deference to private sector standards. The agency whose jurisdiction helmets fall within is the Consumer Products Safety Commission ("CPSC").⁸⁵ Created in 1972, the agency is responsible for:⁸⁶

- a) regulating certain consumer products,
- b) addressing products that pose an unreasonable risk of injury,
- c) assisting consumers in using products safely, and
- d) promoting research into product-related deaths, injuries and illnesses.

In general, the CPSC cooperates extensively with private standards groups and diverts a substantial part of its resources to monitoring and participating in standards development.⁸⁷ Representatives from the CPSC participate in the ASTM F08.53 Headgear subcommittee of the large ASTM F08 Committee for sports equipment, facilities and playing surfaces.⁸⁸

An outlier from the usual monitoring and participation approach to helmet standards is the CPSC's treatment of bicycle helmets. At the direction of Congress, the CPSC developed its own standard test method and performance standard for bike helmets, which was published as a federal regulation and became effective in 1999.⁸⁹ The agency's standard was essentially an amalgamation of multiple consensus standards that already existed for bicycle helmets.⁹⁰ This type of mandatory standard is the exception rather than the rule. Of all products that the CPSC has jurisdiction over, only 1 in 10 is governed by a mandatory standard.⁹¹ The CPSC has been far more deferential to standards for other helmets, allowing private standards to form their regulatory structure.

⁸⁵ Consumer Product Safety Commission, 63 Fed. Reg. 46, 11711, 50,11712 (Mar. 10, 1998).

⁸⁶ 12.4 Consumer Product Safety Act, Pub. L. No.92-573; 86 Stat. 1207 (Oct. 27, 1972) (codified at 15 U.S.C. §§ 2051-2809).

⁸⁷ *Voluntary Standards*, Consumer Product Safety Comm'n., <http://www.cpsc.gov/en/Regulations-Laws--Standards/Voluntary-Standards/> (last visited Oct. 9, 2015).

⁸⁸ *Recreational Helmets*, Consumer Product Safety Comm'n., <http://www.cpsc.gov/Regulations-Laws--Standards/Voluntary-Standards/Topics/Recreational-Helmets/> (last visited Oct. 3, 2015).

⁸⁹ *Id.* See also *Safety Standard for Bicycle Helmets; Final Rule*, 63 Fed. Reg. 46, 11712 (Mar. 10, 1998) (to be codified at 16 C.F.R. pt. 1203).

⁹⁰ See 16 CFR Part 1203, *supra* note 89 at §4. See also ASTM INTERNATIONAL, STANDARD SPECIFICATION FOR HELMETS USED IN RECREATIONAL BICYCLING OR ROLLER SKATING, DESIGNATION F 1447 (2002); AMERICAN NATIONAL STANDARDS INSTITUTE, INC., AMERICAN NATIONAL STANDARD FOR PROTECTIVE HEADGEAR- FOR BICYCLISTS, z90.4 (1984); SNELL, 1995 STANDARD FOR PROTECTIVE HEADGEAR FOR USE WITH BICYCLES, B95 (1995).

⁹¹ See U.S GOV'T ACCOUNTABILITY OFFICE *supra* note 77 at 4.

Public policy has favored the development of a strong consensus-standards system.⁹² Legislative initiatives and executive directives clearly urge the public regulatory arms to defer to the private sector.⁹³ This acknowledgement of the regulatory abilities of voluntary consensus standards is not arbitrary or misguided. It is a testament to how well private technical standards are able to accomplish the goals of regulation. While many standards become law via incorporation by reference, many others provide multi-faceted “regulation” while remaining outside of codified regulations.⁹⁴

A. How Do Private Standards Regulate Products?

Multiple factors combine to produce the regulatory effect that private standards have over the subjects they cover.⁹⁵ Forces of the market, the intersection of standardization with tort law and organizational endorsement allows standards to regulate in the absence of true compulsory government regulations.⁹⁶ The regulatory effects are made possible by the growing credibility of private technical standards and societal value that is attached to them.⁹⁷ Very generally, “standards development organizations regulate in the sense that their standardizing acts have some sort of influence”.⁹⁸

Market forces and the value that segments of any given industry attach to voluntary standards often create economic incentives to comply with the requirements of standards.⁹⁹ Manufacturers and retailers of products can achieve a competitive advantage by conforming to an authoritative technical standard through product differentiation or solidifying consumer confidence.¹⁰⁰ When conformity to a standard can be claimed for any given product, that claim frequently carries an intimation of safety, value, or fitness for a purpose (performance).¹⁰¹ This market-based phenomenon interestingly comes full-circle to bolster the market’s perception of a standard credibility, and “when the affixation of the seal of a given standard or SDO

⁹² See OFFICE OF MGMT. & BUDGET, *supra* note 81. See also INTERNATIONAL ORGANIZATION FOR STANDARDS, INTERNATIONAL STANDARDS AND “PRIVATE STANDARDS” (2010).

⁹³ See Freeman, *supra* note 43.

⁹⁴ See U.S GOV’T ACCOUNTABILITY OFFICE, *supra* note 77, at 1.

⁹⁵ See OFFICE OF MGMT. & BUDGET, *supra* note 81.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ See Sagers, *supra* note 7, at 802.

⁹⁹ INTERNATIONAL STANDARDS ORGANIZATION, <http://www.iso.org/iso/home/standards/benefitsofstandards.htm> (last visited Oct. 1, 2015).

¹⁰⁰ Robert O. Herrmann, James McCabe, Jeanne Bank, Bruce J. Farquahr, *Voluntary Standards - Why Should Consumer Interests Be Represented?*, CONSUMER INTEREST ANNUAL, Vol. 50, 156 (2004).

¹⁰¹ *Id.*

gains the ability to indicate quality, the standard development organization tends to accrue influence over manufacturers of an essentially regulatory kind".¹⁰²

The role that technical standards play, or may hypothetically play, in litigation also achieves a type of regulatory effect over the products, industries and markets that are subject to them. In product liability actions, courts generally consider non-compliance with an applicable voluntary standard as relevant evidence when establishing a product defect or to otherwise show negligence.¹⁰³ Performance standards for products and processes are frequently used as a basis for establishing industry norms and "best practices".¹⁰⁴ For many industries where products are not expressly government regulated, the requirements of voluntary consensus standards can be acknowledged and complied with in the name of due diligence and "duty of care".¹⁰⁵

A third mechanism by which standards regulate privately is when they are endorsed or required by organizations. This is especially true in the case of athletic equipment. Athletics themselves have long been privately "governed" by various leagues and associations. These entities establish the rules of play and otherwise "regulate" athletics at varying levels of play and within defined geographic limits. Many leagues and athletic associations mandate that equipment used during play conform to the requirements of a consensus-developed performance standard.¹⁰⁶ Mandates like this are perfect examples of private standards-based regulation, and through the decisions of the private governing bodies for athletes, the standards for athletic take on authoritativeness. The requirement by leagues that athletic equipment meet performance specifications of standards is a widespread practice¹⁰⁷ that takes regulatory function of standards that is often implied by the market and legal concerns to the next level. The next section of this article will examine in detail how standards-based regulation of helmets for football, lacrosse, baseball and hockey is achieved.

B. How Do Private Standards Regulate Athletic Headgear?

In the case of football, lacrosse, baseball and hockey, helmets are "regulated" in part through league, association and school district rules.¹⁰⁸ These organizations that govern athletics require that equipment used during play and/or practice conform to specified standards.¹⁰⁹ Enforcement of these equipment rules is often charged to coaches or officiating personnel. Increasingly, the type of standard-conformity that is required by leagues or associations requires that athletic equipment be tested and certified according to a specified standards-based "conformity assessment" system.¹¹⁰

¹⁰² See Sagers, *supra* note 7, at 794.

¹⁰³ See U.S GOV'T ACCOUNTABILITY OFFICE, *supra* note 77, at 10.

¹⁰⁴ See Abrams *supra* note 73.

¹⁰⁵ *Id.*

¹⁰⁶ NAT'L. COLLEGIATE ATHLETIC ASSOC., 2013-114 NCAA SPORTS MEDICINE HANDBOOK (24th ed. 2013).

¹⁰⁷ *Id.*

¹⁰⁸ See generally NAT'L. COLLEGIATE ATHLETIC ASSOC, *supra* note 106.

¹⁰⁹ Shlomi Feiner, *Regulation of Playing Equipment by Sports Associations: The Antitrust Implications*, 10 U. Miami L. Rev. 585 (2014).

¹¹⁰ See NAT'L. COLLEGIATE ATHLETIC ASSOC, *supra* note 106, at 106.

This combination of organizational equipment rules and conformity assessment of equipment produces a complete private regulation of athletic headgear.

Conformity assessment is a structured standards-based mechanism for evaluating whether or not objects of assessment, in this case, helmets, meet applicable safety and performance requirements.¹¹¹ The International Organization for Standardization defines conformity assessment as the “demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”, and goes on to enumerate the fundamental activities that comprise conformity assessment, which are: testing, inspection, certification, and the accreditation of testing and certification bodies.¹¹² Conformity assessment provides confidence to both the end user and the potential regulator of a product that it meets the performance and safety requirements of applicable technical standards.¹¹³

Standards define the components of any conformity assessment system, and are used not only as the documents that products are tested against, but dictate how the testing is performed and regulate how testing and certification are performed.¹¹⁴ Product testing in a conformity assessment system implicates two types of technical standards.¹¹⁵ The first is the performance specification, which “specifies” minimum material and functional qualities that a product must possess to conform to that standard.¹¹⁶ The second is a standard test method, which is a document that explains the procedures used to test whether or not a product meets the requirements of the performance specification standard that the test method corresponds to.¹¹⁷

Testing for goods that are manufactured on an industrial scale is almost always performed on a representative sample of the total production.¹¹⁸ This testing can be performed by the manufacturer of the product at their own (“in-house”) testing facility or by a third party organization that specializes in testing, usually referred to as a laboratory.¹¹⁹ Testing performed by a third party imparts a higher degree of confidence in conformity, because third party testing laboratories’ decision-making process is

¹¹¹ See NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, STANDARD PERFORMANCE SPECIFICATION FOR NEWLY MANUFACTURED FOOTBALL HELMETS, NOCSAE DOC (ND)002-13M13 (2013).

¹¹² INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, IS/ISO/IEC 1700, CONFORMITY ASSESSMENT- VOCABULARY AND GENERAL PRINCIPLES, 3(2004).

¹¹³ Gordon Gillerman, *Making the Confidence Connection: Conformity Assessment System Design*, ASTM STANDARDIZATION NEWS (Dec. 2004), http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html.

¹¹⁴ AM. ASSOC. FOR LAB. ACCREDITATION, R101- GENERAL REQUIREMENTS: ACCREDITATION OF ISO/IEC 17025 LABORATORIES (2015).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ PETROS KARKALOUSOS & ANGELOS EVANGELOPOULOS, QUALITY CONTROL IN CLINICAL LABORATORIES 331 CH. 17, APPLICATIONS AND EXPERIENCES OF QUALITY CONTROL (Ognyan Ivanov, ed. 2011).

¹¹⁹ See Gillerman, *supra* note 113.

independent from the business relationship between the producer and the consumer.¹²⁰ Testing laboratories that participate in conformity assessment must often be “accredited”, which means that they are subject to oversight by accreditation bodies.¹²¹ These accreditation bodies conduct audits of test laboratories to verify that they operate according to management and technical requirements designed to ensure their competence and the validity of the test results.¹²² These requirements are specified in a consensus standard.¹²³

Depending on the type of conformity assessment scheme that is in place, there are several ways that a product’s conformity can be proclaimed once testing has demonstrated such. When the provider of a product outwardly represents that a product meets requirements, this is called self-declaration or simply “declaration”.¹²⁴ In the case of declaration, there is frequently little oversight of the decision to declare, and the manufacturer is responsible for its claims of products conforming to a standard.¹²⁵ More thorough conformity assessment systems utilize “certification”, which is a statement made by a third-party that a product meets applicable requirements.¹²⁶ The two hallmarks of certification are: a) it is conducted by a non-governmental independent third party organization, and b) it includes some form of surveillance to ensure ongoing compliance of certified products after initial certification has been declared by the third-party.¹²⁷ Like testing provided by independent bodies, certification performed by certification agencies, especially those that operate according to the principles of a voluntary consensus standard for the certification process, imparts a valuable element of objectivity.

Certification agencies often perform functions like the review of test results, system audits of manufacturer’s management systems and production facilities to the requirements of ubiquitous ISO 9001 standard, and market surveillance to ensure ongoing compliance.¹²⁸ Entities that perform certification activities can be accredited to standards that specify requirements for how they must operate in order to provide a competent and confident certification.¹²⁹

1. Hockey

The conformity assessment scheme that regulates hockey helmets in the United States is built around standards developed and published by ASTM International and

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ See GENERAL REQUIREMENTS, *supra* note 114.

¹²⁴ See CONFORMITY ASSESSMENT, *supra* note 112.

¹²⁵ See Gillerman, *supra* note 113.

¹²⁶ See Conformity Assessment, *supra* note 112.

¹²⁷ See Gillerman, *supra* note 113.

¹²⁸ See Conformity Assessment, *supra* note 112.

¹²⁹ See generally INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, ISO/IEC 17065, CONFORMITY ASSESSMENT-REQUIREMENTS FOR BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES, 4-26 (2012).

involves the Hockey Equipment Certification Council, or HECC.¹³⁰ At the request of USA Hockey, the governing body of amateur American hockey, HECC was established in 1978 to provide independent certification of hockey helmets and other equipment.¹³¹ Helmets are tested by HECC's equipment validator, which is an accredited third-party test laboratory, to various ASTM standard performance specifications.¹³² The testing itself is also specified by an ASTM standard, ASTM F1446-13 "Standard Test Methods for Equipment and Procedures Used in Evaluating the Performance Characteristics of Protective Headgear".¹³³ After testing and surveillance activities are performed, HECC certifies the equipment if all requirements are met, which then enables hockey equipment manufacturers to label their helmets as "HECC Certified".¹³⁴ The regulation is effected via leagues and organizational rules requiring that equipment have said certification. From small regional hockey associations to USA Hockey, there is a requirement that all helmets be HECC certified.¹³⁵ In 1985, The National Federation of High School Associations required that all high school hockey players use HECC certified facemasks.¹³⁶ In 1992, the NFHS recommended that all helmets used be HECC certified and since 1995, HECC helmets have been required.¹³⁷ The current NCAA Ice Hockey Rulebook states that all players must wear a HECC approved helmet.¹³⁸

2. Football, Baseball and Lacrosse

Football, baseball and lacrosse helmets are subject to the same conformity assessment scheme.¹³⁹ It differs from the structure of the system for hockey and is currently undergoing a major transition.¹⁴⁰ The standards that are the basis for private regulation of helmets for these three sports are developed by the National Operating

¹³⁰ COMM. ON THE CERTIFICATION OF PERS. PROTECTIVE TECHNOLOGIES, *Certifying Personal Protective Techs.: Improving Worker Safety* (2011) at 26.

¹³¹ *About HECC*, HOCKEY EQUIPMENT CERTIFICATION COUNCIL, <http://www.hecc.net/about.html>.

¹³² ANNUAL BOOK OF ASTM STANDARDS F1045 (ASTM INT'L 2013) at 127. *See also* ANNUAL BOOK OF ASTM STANDARDS F1587 (ASTM INT'L 2012) at 269. *See also* ANNUAL BOOK OF ASTM STANDARDS F513 (ASTM INT'L 2012) at 44.

¹³³ ANNUAL BOOK OF ASTM STANDARDS F1446 (ASTM INT'L 2013) at 231.

¹³⁴ *HECC FAQ*, HOCKEY EQUIPMENT CERTIFICATION COUNCIL, <http://www.hecc.net/about.faq.html>.

¹³⁵ *See* About HECC, *supra* note 131. *See also*, *Hockey Equipment – Equipment Needs*, NORTHERN KENTUCKY YOUTH HOCKEY ASSOCIATION, <http://nkyha.com/Page.asp?n=50164&org=nkyha.com>.

¹³⁶ *NFHS Rules Changes Affecting Risk (1982-2014)*, NATIONAL FEDERATION OF STATE HIGH SCHOOL ASSOCIATIONS, <http://www.nfhs.org/media/1014277/nfhs-risk-minimization-rules-changes-1982-2014.pdf>.

¹³⁷ *Id.*

¹³⁸ NATIONAL COLLEGIATE ATHLETIC ASSOCIATION, *NCAA ICE HOCKEY, 2014-16 RULES AND INTERPRETATIONS 19* (Steve Piotrowski et al. eds., 2014).

¹³⁹ SAFETY EQUIPMENT INSTITUTE, *SEI CERTIFICATION PROGRAM MANUAL 3* (2014).

¹⁴⁰ *Id.*

Committee on Standards for Athletic Equipment (NOCSAE).¹⁴¹ NOCSAE was created in 1969 as a response to growing concern over deaths that resulted from head injuries sustained by football players.¹⁴² In 1973, NOCSAE published its first test method and performance requirement for the evaluation of football helmets.¹⁴³ NOCSAE currently maintains many standards for an array of athletic equipment.¹⁴⁴ It also has developed standards that specify requirements for reconditioning of sports helmets and conducts research in the areas of athletic equipment and sports injuries.¹⁴⁵

Until 2015, NOCSAE has required that manufacturers have helmets tested annually by third-party accredited test laboratories but has permitted them to declare (self-certify) that they meet NOCSAE's other requirements for certification (e.g. minimum quality control and recordkeeping activities).¹⁴⁶

NOCSAE is now transitioning to a conformity assessment scheme that incorporates third-party certification by the Safety Equipment Institute (SEI).¹⁴⁷ The certification activities of SEI are accredited by ANSI to ISO/IEC 17065, the paramount international standard for requirements of certification bodies.¹⁴⁸ This means that SEI's operation and the certifications it issues meet ANSI's standardized requirements as well as those that ISO has promulgated.¹⁴⁹

Under the new paradigm for football, baseball and lacrosse, SEI will coordinate testing by third-party accredited labs and will also conduct management system audits of manufacturers, facility audits of manufacturer's production operations, reviews of user instructions and labeling and conduct market surveillance.¹⁵⁰ NOCSAE decided to require third-party certification because it "adds a level of objective certainty and

¹⁴¹ *NOCSAE History and Purpose*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, <http://nocsae.org/about-nocsae/history-and-purpose/>.

¹⁴² *Id.*

¹⁴³ P. David Halstead, et al., *Historical Evolution of Football Headgear*, (forthcoming).

¹⁴⁴ *NOCSAE FAQs*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, <http://nocsae.org/about-nocsae/faqs/>.

¹⁴⁵ *Id.* See also *NOCSAE*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, <http://nocsae.org/>.

¹⁴⁶ *NOCSAE Decision to Void Certification of Warrior Regulator and Cascade R Lacrosse Helmets Frequently Asked Questions*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, <http://nocsae.org/wp-content/uploads/2014/12/Lax-QA-12-8-2014-Copy.pdf>.

¹⁴⁷ *NOCSAE Advances Development in Athletic Equipment Standards*, PRNEWSWIRE.COM (Jun. 18, 2015), <http://www.prnewswire.com/news-releases/nocsae-advances-development-in-athletic-equipment-standards-300101670.html>.

¹⁴⁸ *SEI Company Overview*, THE SAFETY EQUIPMENT INSTITUTE, <http://www.seinet.org/aboutsei.htm>.

¹⁴⁹ *American National Standards Institute, Certificate of Accreditation and Scope of Accreditation: Product Certification* (Valid to Jun. 1, 2017), <https://www.ansica.org/wwwversion2/outside/..%5CANSICAfiles%5CCertificates%5C829%5COGICJSXG.pdf>.

¹⁵⁰ NOCSAE, *NOCSAE Third-Party Certification*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, <http://nocsae.org/wp-content/uploads/2011/10/NOCSAE-3P-Fact-Sheet-1-17-2015.pdf> at 1.

integrity to equipment performance that is above and beyond the requirements of and sport standard organization.”¹⁵¹ NOCSAE certified football helmets are required by both the NFHSA and the NCAA.¹⁵² US Lacrosse, the NCAA lacrosse rules, and NFHSA all require that NOCSAE compliant helmets be used.¹⁵³ Little League and the NFHSA require used of NOCSAE approved batters and catcher’s helmets.¹⁵⁴ The NCAA rulebook requires that all batters helmets meet applicable NOCSAE standards and recommends that catcher’s helmets do as well.¹⁵⁵

The conformity assessment system for hockey and the system for the other three sports helmets have as many differences as they have things in common. Both use technical standards as the source of the requirements and test methods and by the middle of 2016, both will incorporate an independent certification body. The test methods that are the basis for evaluation each system’s respective performance standards are fundamentally similar. Both call for drop tests and force measurement equipment to measure impact attenuation, as well as weighted retention tests, and projectile impact tests.¹⁵⁶ In the tests that evaluate impact attenuation, both NOCSAE and ASTM tests currently measure only linear acceleration.¹⁵⁷ Both testing protocols subject the helmets to a range of environmental conditions. There are technical testing differences between the test methods, one being the head forms used for each. The NOCSAE test head form is more biofidelic (human-like) than the ASTM head form and forces for NOCSAE tests are measured in Severity Index units, whereas force in ASTM tests are measured in peak g levels.¹⁵⁸

¹⁵¹ See NOCSAE *supra* note 147.

¹⁵² See Halstead *supra* note 143.

¹⁵³ Corey McLaughlin, *Update: NOCSAE Voids Certification of Cascade R, Warrior Regulator Helmets*, LACROSSE MAGAZINE (Dec. 5, 2014), <http://laxmagazine.com/genrel/112414-nocsae-says-cascade-r-and-warrior-regulator-helmets-dont-meet-standard>.

¹⁵⁴ See *NFHS Rules Changes Affecting Risk (1982-2014)* *supra* note 136. See also *Equipment Checklist: Keep Your Players Safe*, LITTLE LEAGUE, (Spring 2009), http://www.littleleague.org/Assets/forms_pubs/asap/EquipmentChecklist.pdf.

¹⁵⁵ NATIONAL COLLEGIATE ATHLETIC ASSOCIATION, NCAA BASEBALL, 2015 AND 2016 RULES 19 (Jim Paronto et al. eds., 2014).

¹⁵⁶ P. David Halstead, et al., *Hockey Headgear and the Adequacy of Current Designs and Standards*, AMERICAN SOCIETY FOR TESTING AND MATERIALS (1998).

¹⁵⁷ STANDARD TEST METHOD AND EQUIPMENT USED IN EVALUATING THE PERFORMANCE CHARACTERISTICS OF PROTECTIVE HEADGEAR/EQUIPMENT NOCSAE DOC (ND) 001-13m15c (NOCSAE 2015). See also STANDARD PROJECTILE IMPACT TEST METHOD AND EQUIPMENT USED IN EVALUATING THE PERFORMANCE CHARACTERISTICS OF PROTECTIVE HEADGEAR, FACEGUARDS OR PROJECTILES NOCSAE DOC (ND) 021-12m15c (NOCSAE 2015). See also ANNUAL BOOK OF ASTM STANDARDS F1446 (ASTM INT’L 2013).

¹⁵⁸ See Halstead *supra* note 143. See also *Standard Test Method and Equipment Used in Evaluating the Performance Characteristics of Protective Headgear/Equipment*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, NOCSAE DOC (ND) 001-13m15c, Modified: Jun. 2015. See also STANDARD TEST METHOD AND EQUIPMENT USED IN EVALUATING THE PERFORMANCE CHARACTERISTICS OF PROTECTIVE HEADGEAR/EQUIPMENT NOCSAE DOC (ND) 001-13m15c (NOCSAE 2015). See also STANDARD PROJECTILE IMPACT TEST METHOD AND EQUIPMENT USED IN EVALUATING THE PERFORMANCE CHARACTERISTICS OF PROTECTIVE HEADGEAR, FACEGUARDS OR PROJECTILES NOCSAE DOC (ND) 021-12m15c

Some of the most significant differences lie in the characteristics of the SDO's themselves rather than the contents of their standards. NOCSAE, unlike ASTM is not a voluntary consensus standards development organization. Its development of standards is guided by a small Board of Directors that does not operate under the same limitations and procedural guidelines as ASTM.¹⁵⁹ ASTM's helmet standards are the consensus product of more than 500 members.¹⁶⁰ ASTM's primary resource is the time, experience and expertise donated by its member-participants throughout the process of developing and maintaining standards.¹⁶¹ NOCSAE is funded primarily by sporting goods manufacturers, who pay licensing fees for the rights to claim certification to its standards and to mark their products accordingly.¹⁶² For hockey helmets, certification fees or licensing fees do not fund the SDO responsible for the authoritative standards (ASTM).¹⁶³

V. EFFECTIVENESS OF STANDARDS-BASED REGULATION FOR ATHLETIC PROTECTIVE HEADGEAR

Private standard-setting (and by extension, private regulatory systems based on technical standards) in general is not without its critics. In fact, it has always been subject to concerns related to antitrust.¹⁶⁴ Any issue, product or scenario that requires regulation is one that almost always involves an inextricably complex intersection of interests. The fact that standardization's outcome for a given product or industry could have positive or negative effects on the market interests for both producers and consumers has long been one of many concerns about standards.

The concerns about possible abuses of standards are of one the many reasons for the bureaucratic (seemingly to the point of being inefficient) procedural requirements of voluntary consensus standards development, like openness, balance and due process.¹⁶⁵ Skepticism that the various monetary stakes involved might, or indeed do, interfere with the most safe and complete regulatory ends is an indispensable part of holding a regulatory scheme accountable.¹⁶⁶ The current standards-based conformity assessment paradigms for athletic helmets in the United States are not immune to the

(NOCSAE 2015). *See also* ANNUAL BOOK OF ASTM STANDARDS F1446 (ASTM INT'L 2013) at 232.

¹⁵⁹ *See Halstead supra* note 143.

¹⁶⁰ ASTM Int'l, *Committee on F08 on Sports Equipment, Playing Surfaces, and Facilities*, ASTM INT'L, <http://www.astm.org/COMMITTEE/F08.htm>.

¹⁶¹ *Id.*

¹⁶² *NOCSAE Overview*, NATIONAL OPERATING COMMITTEE ON STANDARDS FOR ATHLETIC EQUIPMENT, <http://nocsae.org/wp-content/uploads/2011/10/NOCSAE-Overview-1-2015.pdf> at 2.

¹⁶³ *Id.*

¹⁶⁴ *See Sagers supra* note 7 at 785. *See Ernst supra* note 12 at 15. *See also* Alan Devil, *Standard-Setting and the Failure of Price Competition*, 65 N.Y.U. ANN. SURV. AM. L. 217, 219 (2009). *See also* George S. Carey, *Antitrust Implications of Abuse of Standard-Setting*, 15 GEO. MASON L. REV. 1241, 1242 (2008).

¹⁶⁵ *Ernst, supra* note 12.

¹⁶⁶ *Halstead, supra* note 156.

general qualms about private-standards. Nor are they free from more specific criticism that is likely related to the exponentially growing awareness that brain injury in sports is a serious issue.¹⁶⁷ However, when the performance of standards-based regulation of athletic helmets is viewed within a balanced context of the issue, it is both effective and more desirable than feasible alternatives.

A. Criticism

Skeptics of the conformity assessment systems for athletic helmets are quick to allege that both the test methods and standard requirements are outdated to the point of being archaic.¹⁶⁸ On the surface, this would appear to be true. The drop-style impact tests that both ASTM and NOCSAE test methods are based on have been used since 1981 and 1973, respectively, and have not substantially changed since then.¹⁶⁹ As more scientists and clinicians get behind the theory that the rotational acceleration involved in trauma to the head is more responsible for concussions than the linear acceleration that also occurs, critics have asked why there are no standard test methods and standard performance requirements that limit and evaluate the attenuation of forces that induce angular (rotational) acceleration.¹⁷⁰ Currently, the authoritative performance standards and standard test methods for all athletic helmets only specify and analyze performance by reference to linear acceleration.¹⁷¹

There has been more directed criticism of NOCSAE specifically. Some believe that NOCSAE's current situation as the SDO for football, lacrosse and baseball helmets is problematic.¹⁷² Specifically, they argue that NOCSAE's relationship to equipment producers and its exclusivity as an organization is preventing an acceptable standards-based regulation of that equipment.¹⁷³ NOCSAE's process for developing standards lacks the "voluntary consensus" tenets that are required by ANSI and observed by SDO's like ASTM.¹⁷⁴ Recent pointed criticism has been directed at NOCSAE for its lack of openness, transparency and due process by Senator Tom Udall and the Chairman of Consumer Product Safety Commission Elliot Kaye.¹⁷⁵

¹⁶⁷ Dan Polnerow, *Solving Football's Concussion Problem*, NU WRITING (NORTHEASTERN UNIVERSITY) at 5, <http://www.northeastern.edu/nuwriting/solving-footballs-concussion-problem/>.

¹⁶⁸ *See Id.*

¹⁶⁹ ASTM Int'l, *The History of ASTM International*, ASTM INT'L, http://www.astm.org/ABOUT/history_book.html. *See also* NOCSAE FAQs, *supra* note 144.

¹⁷⁰ *See* Polnerow *supra* note 167 at 4.

¹⁷¹ *Id.* at 2.

¹⁷² Brooke de Lench & Lindsey B. Straus, *Standard-Setting by Non-Governmental Agencies in the Field of Sports Safety Equipment: Promoting the Interests of Consumers or Manufacturers?*, 10 J. BUS. & TECH. L. 47, 48 (2014), <http://digitalcommons.law.umaryland.edu/jbtl/vol10/iss1/4>.

¹⁷³ *Id.* at 50.

¹⁷⁴ *See* ASTM Int'l, *supra* note 169.

¹⁷⁵ Senator Tom Udall, *Tom Warns About Potentially Dangerous 'Anti-Concussion' Marketing Claims for Kids' Soccer Headgear*, YOUTUBE (Jun. 17, 2015), <https://www.youtube.com/watch?v=41S5e6kKILc&feature=youtu.be>.

NOCSAE is funded primarily through licensing fees paid by manufacturers.¹⁷⁶ This coupled with the fact that helmet manufacturers control exactly one quarter of the 16 total votes of NOCSAE's Board of Directors has led consumer advocates in the areas of athletic equipment Brooke De Lench and Lindsey Barton Strauss to identify the arrangement as possibly collusive.¹⁷⁷ Professor Stefan Duma, an impact biomechanics researcher who leads the Virginia Tech and Wake Forest University School of Biomedical Engineering and Sciences and has developed the influential star-rating system for helmets, has stated that NOCSAE's financial relationship with manufacturers "is the definition of a conflict of interest" and that "if nearly 100 percent of your money comes from the manufacturers, then it's difficult to say you are independent of them".¹⁷⁸

De Lench and Barton Straus curate the website "MomsTeam.com, a resource for parents of young athletes. They have posited that the manufacturer interests that participate in the development of standards for helmets have little incentive to advance the requirements of the standards and the associated technology because the status quo offers sufficient insulation from liability.¹⁷⁹ Government officials have joined the voice of consumer advocates in questioning the length of time it has taken to improve standards. Tom Udall, one of New Mexico's U.S. Senators has expressed alarm at NOCSAE's lack of progress in updating its standards for football helmets.¹⁸⁰

These criticisms must be thoroughly weighed in any analysis of the effectiveness of standards-based helmet regulation. Given the relatively recent high profile that the issue of brain injury in sports has assumed, it is no surprise that scholars and consumer advocates are impatient for changes and progress. A helmet, like other personal protective equipment, is thought of as a solution to the risk of injury. This association has created in many people an expectation of ideal athletic headgear and perfect technical standards to regulate it. However, it is important to recognize the nature of concussion as an injury and the state of research and technology in the areas of both understanding this type of injury and designing equipment to reduce or prevent it. The challenge of reducing sports-related brain injuries is complex and it is both impossible and unsafe to hastily attempt to advance the conformity assessment schemes for athletic helmets.

B. Context, Considerations and Recent Developments

The perception that athletic equipment and standards that regulate it have stagnated or failed because the rate of concussion is not decreasing obscures the reality of several things: a) the original intent of helmet standards and the limitations of equipment, b) the engineering considerations that must be integrated into helmet design, c) how much remains to be discovered about the biomechanics of concussion, d) the requirements of developing scientifically sound performance standards and standard

¹⁷⁶ Bob Hohler, *Conflicts Arise in Sports-Related Concussions Fight*, BOSTONGLOBE.COM (Aug. 10, 2014), <https://www.bostonglobe.com/sports/2014/08/10/concerns-arise-over-group-certifying-head-impact-sensors/gh5mJDYV8jcS8Ik7DiF6kN/story.html>.

¹⁷⁷ See de Lench, *supra* note 172 at 53.

¹⁷⁸ *Id.* at 54.

¹⁷⁹ *Id.* at 47.

¹⁸⁰ See Udall, *supra* note 175.

test methods, and e) the recent developments within the conformity assessment systems for protective headgear in the U.S.

Helmets and helmet standards were not intended to protect against concussions and are unlikely to ever be capable of preventing all brain injury in contact sports.¹⁸¹ Both the NOCSAE and ASTM conformity assessment systems were designed primarily to prevent catastrophic head injuries, such as skull fracture and cerebral hematoma.¹⁸² For this reason, the performance of helmets was specified and tested according to limits set on linear acceleration, rather than rotational acceleration, as acute linear acceleration is the primary cause of catastrophic brain injury.¹⁸³ Helmets for football, lacrosse, baseball and hockey that are subject to the current standards-based private regulation have been convincingly effective at preventing those injuries.¹⁸⁴ To expect equipment to protect against a different risk of injury (concussion) which was not a performance goal that it was originally (nor is it currently) designed or regulated to protect against, would be irrational.

Further, equipment is one of many facets of the game that may mitigate, to a degree, concussion and other traumatic brain injury. Changes to the rules of play have proved in the past to be a highly effective means of reducing brain injuries in sports and adjustments to rules of play will likely continue to have a role in mitigating concussions in the future.¹⁸⁵ Similarly, requiring that coaches at all levels of play teach and enforce proper checking and tackling techniques is also an important aspect of a comprehensive effort to prevent head, brain, and neck injury in sports.¹⁸⁶ Finally, issues surrounding protocols for on-field diagnoses, mandatory rest and “return-to-play” rules, as well as underreporting of concussions by coaches and players, all play a significant role in the concussion management discussion. It does not start and end with equipment, although equipment will always play a role.

Most sports helmets are designed with the primary purpose of protecting the head of the wearer from impact forces. Stated simply, this is accomplished by lengthening the duration of an impact by using materials that transfer and/or absorb impact energy as the materials compress.¹⁸⁷ Called “force attenuation”, it is only one of many significant functions that must be considered if the goal is to provide an optimally protective helmet.¹⁸⁸ Proper fit, visibility, ventilation and durability all must be

¹⁸¹ See Polnerow, *supra* note 167 at 2.

¹⁸² See Halstead *supra* note 143; see also Polnerow, *supra* note 167.

¹⁸³ Daniel H. Danshevar et al., *Helmets and Mouth Guards: The Role of Personal Equipment in Preventing Sport-Related Concussions*, CLIN. SPORTS MED. 1, 3-4 (2011), <http://www.sciencedirect.com/science/article/pii/S0278591910000840>.

¹⁸⁴ *Id.* NOCSAE Approves Development of First Football Helmet Standard to Address Concussions, PRNEWswire.COM (Jan. 24, 2014), <http://www.prnewswire.com/news-releases/nocsae-approves-development-of-first-football-helmet-standard-to-address-concussions-241802141.html>.

¹⁸⁵ See Halstead *supra* note 143 at 4. See also Steven Rowson et al., *Can Helmet Design Reduce the Risk of Concussion In Football?*, JOURNAL OF NEUROSURGERY 919, 919 (2014), <http://thejns.org/doi/pdf/10.3171/2014.1.JNS13916>.

¹⁸⁶ See Rowson, *supra* note 185.

¹⁸⁷ See Danshever, *supra* note 183 at 3.

¹⁸⁸ *Id.*

incorporated into the design of a helmet.¹⁸⁹ Weight is also a consideration.¹⁹⁰ A hypothetical helmet that boasts great force attenuation properties because it uses three times more padding than other helmets would likely suffer from being dangerously heavy and result in neck injuries.¹⁹¹ Further, helmets must be designed to reduce the chances that they may cause injury to persons other than the wearer.¹⁹² The performance attributes of a helmet must be carefully balanced, which in many ways precludes a “quick-fix” from the perspective of helmet design.

Perhaps the most essential piece of background information to this issue is the fact that concussions are far from well understood by medical and engineering communities. A concussion is an injury that is a complex pathophysiological process affecting the brain, induced by biomechanical forces.¹⁹³ Experts generally agree that concussions are caused by a combination of linear and rotational acceleration of the brain within the skull that results from an impact force.¹⁹⁴ However, the science of concussion is still not completely understood.¹⁹⁵ Every single study done related to brain damage in football has concluded with a call for additional research.¹⁹⁶ When a casual observer from the general public is unable to understand why the concussion issue in sports persists, it is likely that they are unaware how complex the injury is and how many “research hurdles” must be cleared before the medical and engineering fields’ understanding of minor traumatic brain injury is no longer incomplete and/or inconclusive.

As additional research is done and concussions become better understood, the standards-based conformity assessment for helmets will be increasingly better positioned to create sound requirements and test methods. Standards development organization responsible for the authoritative helmet standards, specifically NOCSAE, have come under fire for failing to update requirements and test methods to incorporate angular (rotational) acceleration.¹⁹⁷ However, both NOCSAE and ASTM have been actively conducting research and methodically developing needed changes to standards and test methods.¹⁹⁸

Developing equipment standards that address an issue as nebulous as concussive forces in athletics is an undertaking that requires multiple cycles of research and testing. NOCSAE proposed new test method for football helmets that includes

¹⁸⁹ *Id.*

¹⁹⁰ *See* Halstead, *supra* note 156.

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ Paul McCrory et al., *Consensus Statement on Concussion in Sport – The Fourth International Conference on Concussion In Sport*, BRITISH JOURNAL OF SPORTS MEDICINE 250, (2012), <http://bjsm.bmj.com/content/47/5/250.full>.

¹⁹⁴ *Id.*

¹⁹⁵ *See* McCrory, *supra* note 193.

¹⁹⁶ *See* Polnerow, *supra* note 168.

¹⁹⁷ *See* Polnerow, *supra* note 168.

¹⁹⁸ *Id.*

rotational forces as early as 2006.¹⁹⁹ However, the rotational standard was not officially approved until 2014. The NOCSAE board did not feel comfortable advancing the new standard until three related NOCSAE-funded research projects were evaluated by the SDO at the end of 2013.²⁰⁰ The new test method, which at the time of writing is in its final stages of development via laboratory-results comparison studies, will supplement the drop test method with a pneumatic linear impactor.²⁰¹ This new test will finally incorporate rotational acceleration into the evaluation of helmets, which is the biomechanical force that is believed to be the strongest cause of concussions and other traumatic brain injury in athletes.²⁰² It also improves upon the longstanding drop method of testing by finally testing helmets with their faceguards in place, and will represent the first athletic helmet standard to specifically address concussions.

Other activities in the area of standards development for helmets provide evidence that the private regulatory system is committed to making changes to address the concerns over brain injury in sports, but is doing so at a rate that is consistent with the research and scientific consensus that is required on these issues. The ASTM subcommittee responsible for the performance specification for football helmets initiated the revision process for the standard in May of 2015.²⁰³ Both NOCSAE and ASTM continue to conduct research into standard requirements specifically for youth helmets.²⁰⁴ The organizations maintain that additional research in these areas of equipment design and performance is required before a youth specific can be developed.²⁰⁵

C. Effectiveness

Standards-based private regulation of athletic equipment has demonstrated its effectiveness and its capability of responding to new challenges. In general, standardization in America continues to thrive and the unique arrangement of the private sector leading consensus standards development has been recognized as a driver of innovation and technology across multiple industries and fields.²⁰⁶ ANSI itself has held that “no change to the current private-sector-led and public-sector-

¹⁹⁹ *Id.*

²⁰⁰ *See* NOCSAE, *supra* note 184.

²⁰¹ *See* NOCSAE, *supra* note 147. *See also* STANDARD LINEAR IMPACTOR TEST METHOD AND EQUIPMENT USED IN EVALUATING THE PERFORMANCE CHARACTERISTICS OF PROTECTIVE HEADGEAR AND FACEGUARDS, NOCSAE DOC (ND) 081-04m04 (NOCSAE Proposed 2006).

²⁰² *NOCSAE Approves Development of First Football Helmet Standard to Address Concussions*, PR NEWSWIRE, <http://www.prnewswire.com/news-releases/nocsae-approves-development-of-first-football-helmet-standard-to-address-concussions-241802141.html> (last visited Oct. 18, 2015).

²⁰³ *NOCSAE Advances Development in Athletic Equipment Standards*, NOCSAE, <http://nocsae.org/wp-content/uploads/2015/06/NOCSAE-2015-June-Standards-Meeting-Release-6-18-15.pdf> (last visited Oct. 18, 2015).

²⁰⁴ *See* NOCSAE, *supra* note 147.

²⁰⁵ *Id.*

²⁰⁶ *See* Ernst, *supra* note 12.

supported standardization system is warranted, as the current system works well.”²⁰⁷ In its recent report on the activities of the CPSC, the US Government Accountability Office concluded that the voluntary standards process is both faster than mandatory rulemaking and more likely to result in compliance, as the effected regulated parties are able to more fully participate in development.²⁰⁸

Standards rely on the current state of the art in the field they regulate. The participants in standards development possess the knowledge, experience, equipment and materials that facilitate both the safest possible products and the best (and most timely) standards and test methods for those products. In the area of athletic headgear, all involved parties, but especially manufacturers, have an incentive to conduct the best research and develop the best test equipment. The stakeholders in the standards development process and conformity assessment of athletic equipment are close to the issues and developments that must be explored to develop meaningful performance standards. The participation in standards development by manufacturers, conformity assessment bodies, and the research community lends an invaluable resource capital to the process.

A private standards-based regulatory system is well equipped to spur efficient research into sports-related brain injury topics and to drive innovation for protective equipment that may reduce (or ideally eliminate) the risks of those injuries. Until recently, there were doubts that helmet design could reduce concussion.²⁰⁹ However, new research suggests that differences in helmet design are in fact capable of reducing the risk of concussion.²¹⁰ In light of this knowledge, it is essential that equipment engineers, medical experts, biomechanics specialists and the countless other individuals who participate in the standards development process continue their current agenda of advancing the performance requirements and test methods that serve as the backbone for regulation of athletic helmets.

Corresponding to the steady rise of concern over sports-related brain injury has been a constant stream of research activities that inform the development and revision of technical documents that have the real capability of improving the performance of athletic equipment. Standards-based regulation of athletic headgear benefits from the participation of countless experts from various fields and interests. This community is committed to improving player safety and is in the best position to do so. SDO's are developing improved performance requirements and test methods. The conformity assessment schemes for major sports helmets in the US that provide confidence in compliance have been improving. While some commentators have perceived a delay in improving both the standards and the conformity assessment systems they define, it remains that there is a clearly established need for more research at the intersection of equipment performance and traumatic brain injury. Standards development organizations have a social and scientific responsibility to publish standards only when there is a firm basis in the available research, which both justifies the change and confirms that it will not compromise a protective or performance aspect or otherwise have a negative-sum impact on the helmet/helmet-users.

²⁰⁷ *Id.*

²⁰⁸ *See* Consumer, *supra* note 77.

²⁰⁹ *See* Danshever, *supra* note 183; *See* British Journal, *supra* note 193.

²¹⁰ *See* Rowson, *supra* note 185.

VI. RECOMMENDATIONS

The current standards-based regulatory system for athletic headgear has demonstrated its adequacy and aligns with public policy regarding the use of voluntary consensus standards. Yet, the system must improve in order to provide the best available regulatory effects as the athletic world takes on the challenge of brain injury in sports. The organizations that develop standards and operate the conformity assessment system for athletic helmets should all embrace standardized principles for their operation and procedures. The Consumer Product Safety Commission should maintain its position in allowing the private sector to lead the regulation of athletic headgear, and would best serve consumers if it increased its supportive and active role in standards development. Finally, the standards development community must move swiftly to understand emerging technologies in sports equipment related to brain injury so that these devices can be properly integrated-into and regulated-by the private standards-based conformity assessment structures.

A. Develop the Integrity of Conformity Assessment Systems for Helmets

The current conformity assessment systems for athletic protective headgear in the United States are not perfect and changes need to be made. Fortunately, given that standards, rather than laws, serve as the foundation for those systems, they are ideally situated to implement the necessary changes so that equipment designed to protect against brain injury in sports is most optimally regulated. For the benefit of public safety as well as their own reputation, SDO's that have regulatory influence should adhere to procedural rules designed to promote information disclosure, rational decisions and fairness. The authoritative standards-based conformity assessment structures for helmets must evolve and truly base their systems, requirements and processes on the principles that make standards-based regulation both effective and credible.

NOCSAE is responsible for developing the authoritative standards for football, baseball and lacrosse helmets. Its development process lacks transparency, openness and falls short of observing the most fundamental due process requirements for standards development. These "voluntary consensus" tenets lend technical standards the integrity that has allowed government to defer regulatory functions to the private standards sector. By failing to embrace these procedural elements, NOCSAE damages its credibility and accountability as an organization. Should NOCSAE refuse to improve its process to one where standards are no longer developed behind closed doors, there are other standards-based solutions for the regulation of football, baseball and lacrosse helmets. Standards development organizations that do heed due process requirements and operate in the spirit of "voluntary consensus" are available to supplant NOCSAE as the SDO for those sports. In fact, during discussion of athletic equipment standards, the Chairman of the CPSC has openly endorsed ASTM as an alternative to NOCSAE, and in his opinion, the means of achieving the best standards-based solutions.²¹¹

While only one of the two prominent athletic helmet SDO's adhere to basic procedural guidelines, only one of the two certification organizations for sports helmets operate by standardized principles for certification agencies. SEI, the agency that is currently transitioning into the role of certifying football, lacrosse and baseball

²¹¹ See Udall, *supra* note 175.

helmets is ANSI- accredited to ISO/IEC 17065.²¹² However, HECC, the certification council for hockey, is not accredited and claims no adherence to standardized requirements for a certification body.²¹³ 17065 specifies requirements for certification bodies of products, processes and services. For the same reasons that NOCSAE should abide by all or most of ANSI's due process requirements, both helmet certification organizations should operate under standardized principles and ought to consistently maintain accreditation to that standard. Accreditation of HECC to ISO/IEC 17065 would provide objective and independent assurance of its competence in the major role it plays in the conformity assessment regulation of hockey helmets.

B. Continue Private Standards-Based Regulation with CPSC Support

Despite the changes that need to be made to some of the processes of authoritative SDO's (and possible rearrangements to their financial relationships with other elements of the athletic conformity assessment structure), regulation of athletic headgear should remain in the hands of the private sector and should be accomplished with standards-based conformity assessment. Some critics of the current system have called for a government agency, namely, the CPSC, to become involved in setting standards for protective athletic equipment.²¹⁴ There is an historical example of this taking place. The CPSC developed its own mandatory performance standard and test method for bicycle helmets.²¹⁵ This route of regulation would not be beneficial to the end of advancing athletic headgear as a possible part of the solution to brain injury in sports. The CPSC bicycle standard is inconsistent with 1981 amendments to the Consumer Product Safety Act, which directed the CPSC to defer to voluntary standards rather than issue mandatory standards.²¹⁶

The expertise on the topics of concussion biomechanics and equipment design that resides in the medical, academic and manufacturing communities makes voluntary consensus standards organizations far better suited to develop and maintain helmet standards. The best role for the CPSC is active participation in the activities of private-sector standard development. Given the massive challenge of adequately researching athletic brain injury, the CPSC would also serve the consumer interests it is charged with protecting by providing additional funding to SDOs that are currently attempting to improve helmet standards. Monetary support of SDOs by the CPSC is consistent with articulated public policy. Circular A-119 contemplates that agencies may provide financial assistance to a standard development organization to complete a standard, particularly when its timely development appears unlikely in the absence of such support.²¹⁷

I recommend that the CPSC provide direct funding to the standards development organizations that currently are endeavored to provide needed standards that address

²¹² *SEI Certification Program Earns ANSI Accreditation*, CARNEGIE MELLON UNIVERSITY, <http://sei.cmu.edu/newsitems/ANSI-CERT.cfm>.

²¹³ ANSI, HOCKEY STANDARDS PROTECT THE PLAYERS AND GUIDE THE GAME (Apr. 4, 2005).

²¹⁴ *See de Lench, supra* note 177.

²¹⁵ *Id.*

²¹⁶ *See Consumer, supra* note 77.

²¹⁷ *See Mendelson, supra* note 73 at 750.

both youth-size helmets and standards that include rotational acceleration. To encourage more transparency and procedural credibility by the developers of helmet standards, the CPSC should provide this funding to organizations that observe due process requirements in their standard development. Monetary assistance from the CPSC would not only expedite the development of well-informed helmet standards for young athletes and to address angular impact forces, but would also facilitate the development of standards for a vast array of new equipment related to brain injury in sports: impact sensors.

C. Coverage of New Equipment Technology by Private Regulation Structure

The fastest growing segment across the board of the sporting goods industry is technology products (think “Fitbits” and fitness apps).²¹⁸ There has been particularly fast growth in the development of tech-centric products that aim to track forces to the head that athletes experience during impacts.²¹⁹ These force-tracking sensors and apps are a response to the relatively recent mass-awareness of CTE and how dangerous concussions may be. Although force sensors have been used in many studies that have contributed to the development of standards, there is still no performance standard or test method for the force sensors themselves. This must change, as force sensors are offered as consumer products to supplement and integrate-with helmets. I recommend that SDOs direct sufficient resources to incorporate this new type of athletic safety equipment into the sphere of standards-based regulation. SDOs should develop scientifically-grounded voluntary consensus performance specifications and standard test methods for the evaluation of sensors.

The standard development community for athletic helmets must reckon with the fact that these sensors will eventually become ubiquitous. The Arena Football League already equips all of its helmets with impact sensors and maintains a policy that mandates their use.²²⁰ The force sensors, although a new and possibly imperfect indicator of concussion (which is itself not completely understood) have many valuable applications. They may help prevent what is known as “second impact syndrome”²²¹ - the experience of a second concussion by an athlete who has not yet fully recovered from a prior concussion. The medical community is in agreement that immediate removal from play and evaluation is one of the important aspects of treating concussions.²²² Research has also revealed a tendency for athletes to underreport brain

²¹⁸ Cadie Thompson, *Wearables at work mean big business, says Fitbit CEO*, CNBC (Jan. 8, 2014).

²¹⁹ Bob Roble, *Football Helmet Technology: Sensors Make Impact on Head Injuries*, (Nov. 25, 2013), <http://iq.intel.com/making-an-impact-on-head-injuries-the-tech-behind-football-helmets/>.

²²⁰ Don Coble, *Helmet sensors become mandatory equipment in Arena Football League*, (Jun. 26, 2014), <http://jacksonville.com/sports/football/sharks/2014-06-26/story/helmet-sensors-become-mandatory-equipment-arena-football>.

²²¹ *Id.*

²²² Lindsey Barton Straus, JD, *Athletic Trainer Plays Critical and Unique Role In Concussion Safety*, Moms Team, <http://www.momsteam.com/health-safety/athletic-trainer-plays-key-role-in-concussion-recognition-evaluation-on-sports-sideline#ixzz3oxJscqR1>.

injury symptoms.²²³ Impact sensors are well poised to address these two issues. If the standards-based conformity assessment systems for athletic equipment truly wish to effectively regulate athletic equipment, they must develop standards that address the new technology that interfaces with helmets and appeals to consumers concerned with brain injury.

VII. CONCLUSION

The design and performance of athletic protective headgear has the capability to mitigate the risk of brain injuries. That fact alone demands optimal regulation of helmets. Third party testing and certification according to CPSC supported and endorsed private voluntary consensus standards creates the best regulatory atmosphere to encourage the most innovative, functional, effective and most safe athletic protective headgear. Standards development organizations for sports helmets will benefit from adjusting their procedures to embrace standardized procedural and organizational requirements. SDOs that develop performance specifications and standard test methods for helmets through a voluntary consensus process should receive a continuing endorsement from the CPSC to lead in the area of helmet regulation. Additional participation and financial assistance from the public regulatory sphere will aid the standards community in addressing the issue of brain injury in sports and how athletic equipment, including emerging technologies, might contribute to reducing and possibly preventing it.

²²³ Courtney Humphries, *The Traumatized Brain*, HARVARD MAGAZINE, Mar. – Apr. 2012.