

Board 9: Work in Progress: A Case Study in Product Liability: Promoting Student Engagement with Standards.

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Work In Progress: Promoting Student Engagement with Standards Through A Moot Court Case Study in Product Liability

Introduction

Public and environmental safety are critical components of engineering ethics that require an understanding of the engineering, business, and legal issues related to the safety concepts and are connected to standards and regulations compliance [1]. Hess & Fore [2] found that many engineering programs have adopted a variety of modalities to teach the engineering aspect of standards and regulations compliance and that the business and legal aspects are less common in engineering education.

Herkert [3] argued that the concept of product liability represents an excellent way to the varied aspects of safety issues to the forefront of the engineering profession as it includes the legal responsibility as well as the technical concepts related to developing safe products. One example of the connection between standards and product liability law is the real-life case study by Forbes & Emplaincourt [4]. While certain classes of FDA-approved medical devices are preempted from Product Liability Law [5], familiarizing biomedical engineers with the concept of product liability is valuable as an exercise in engineering ethics and as an opportunity to discuss compliance with FDA regulations and industry standards. Additionally, biomedical engineers may be called to participate in product liability litigations as engineering expert witnesses, which is becoming increasingly common [6], [7].

One way to teach about product liability which is increasing in popularity is through a moot court class activity. A common practice in law schools, though less so in engineering, moot court represents an engaging active learning technique that uses a case-based approach to solving problems and contributing to the development of student's critical thinking skills [8], [9]. Moot court exercises have been successfully adopted by other disciplines to increase students' understanding of the legal system [10]–[15], including engineering disciplines [16]–[19].

This work reports on the first-time run of a moot court class activity using a fictional medical device cybersecurity breach case study and discusses the challenges encountered, the opportunities to improve the class activity, and the benefits to students we observed. Cybersecurity of biomedical engineering-related product liability was addressed as the topic focus as it represents a growing area of concern. Seen more of a “computer and data sciences” issue, cybersecurity is often overlooked in BME compared to the other “more obvious” potential liabilities related to medical devices (material toxicity, implant failure, etc.).

Process

Creating a case study on standards used in a moot court case requires a systematic approach to gather relevant information and present it in a clear and concise manner to all the stakeholders involved in the process. Our method involved 7 major steps.

1. Identify the moot court learning objectives and measurable learning outcomes. This will shape the selection of design standards to be involved in the case. For this exercise, understanding cybersecurity standards (as related to wearable devices) was identified as the key learning outcome. Case authors identified the specific standards and conducted a literature search on the current legal, ethical, and technical issues that could help frame an interesting case.

2. Formulate a relevant product liability position: Develop a hypothetical legal issue such as non-conforming product, adulterated product, design failure, manufacturing failure or regulatory non-compliance. Next, connect the legal aspects and the design standards.

3. Develop the premise of the moot court case: Analyze how the standards were applied and how their use plays a role in product liability. Identify the key arguments and positions that could be taken by the parties involved, and examine the evidence presented to support these positions.

4. Develop a case study outline: Craft the outline for the case study that includes an introduction (for background information), a description of the standards involved, a summary of one or two potential arguments made by the parties involved, and suggestions for highlights of the key takeaways from the case. At this point it is essential to bring in third parties for review to provide a general “sanity check” on the overall case.

5. Write the case study: With the outline as a guide, write a 2–4-page case summary, including as many details as possible, but leaving room for the student actors to have input and explore for themselves how standards were (or might be) applied in the case. Including hypothetical discussion points, questions or prompts will encourage students to engage with the material.

6. Review and revise: With the revised case study in hand, review it for accuracy, clarity, and assurance that the use of standards will follow from trial arguments, particularly with third party reviewers.

7. Identify case roles and share the case study: There are a wide variety of roles that the students can play that have varying degrees of oration and argument. Identify roles such as judge, plaintiff, defendant, expert witnesses, and jury. Share the case study with the students, deciding in advance how much latitude and creativity you want them to have; the exercise can be a lot of fun, but the more serious nature of the role of standards in design must have center stage.

The first run of this exercise was designed and conducted with BME Senior Design students, a class of approximately 90 students, with 8 of those serving as actors in the case. The exercise

was conducted over a 50-minute class period. Students had been exposed to the concept of standards during a previous lecture. A post-exercise survey (assessed for completion) was used to gauge student engagement with the exercise and understanding of the role of cybersecurity standards for medical devices.

Preliminary Observations & Discussion – Initial Lessons Learned

Enhanced Engagement: Overall, students found the exercise interesting, a good vehicle for presenting the material, and putting into perspective the importance of standards. Novice engineers often erroneously see their work as only “design and development,” ending with the launch of the product. This means of presenting the legal issues that can arise after the engineering work is complete helps to put this into the proper perspective.

Better appreciation of the role of standards: When covering standards, instructors too often focus on the technical aspects separate from their legal and ethical context. By presenting the role of the standards at issue in the moot court exercise as well as the technical details, students gain a better appreciation for the former, even if they were unclear of the latter before the exercise.

Cybersecurity as contemporary issue: While standards cover a breadth of applications, using them in the context of a cybersecurity liability dispute was seen as “timely” by the students. The role of cybersecurity in a medical device as a BME concern was also well illustrated.

Reliance on a few volunteers to act out the case is not advised: For this inaugural run, a limited number of student volunteers were used. This became an issue when a key expert witness actor was unable to attend class. This resulted in the jury deciding the exact opposite of the designed verdict. While interesting, this shows that having a few students cover the required roles can lead to an unpredictable outcome and impact the overall exercise. Due to this, it is advised that all student teams in the class are assigned a role to prepare for and are expected to be able to present the material relevant to that role on the day of the exercise.

Closing the loop: A summary discussion immediately following the exercise would be helpful to review details that may have been missed. Timing remains a question to be answered, whether it can be after the exercise or held the next class period with the same effectiveness.

This class activity showed that conducting a moot court case on design standards has the potential to be an effective way to promote learning, critical thinking, teamwork, and engagement, while also fostering a greater awareness and appreciation for the importance of compliance with design standards in professional practice. We look forward to presenting a more complete review of this work, including an in-depth assessment of students' learning in a later communication.

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