Universal Arm Board for Cardiovascular Medicine

(Technical Paper)

Physicians' Roles in Promoting America's Opioid Crisis

(STS Paper)

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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General research problem

How can the opioid crisis in America be mitigated? Since 1999, the number of opioid prescriptions in the US has quadrupled; more than 200,000 deaths have been attributed to prescription opioid overdose (CDC, 2019). Prescription opioid use can lead to illicit opioid use, notably of heroin (UDOH, 2017). Numerous campaigns at all levels of government publicize the danger of opioids, and support treatment facility and law enforcement expansion. Many states and local governments have sued pharmaceutical companies and top pharmaceutical executives for their role in causing the epidemic.

Universal Arm Board for Cardiovascular Medicine

How can the comfort and efficacy of the surgical arm board used in cardiovascular medicine be maximized? The advisor of this biomedical engineering capstone project is Dr. Nishaki Mehta, MD, of UVA Cardiovascular Medicine, and collaborators include 4th year undergraduate BME students, Jason Woloff and Radu Serbulea, and graduate BME student, Katerina Morgaenko.

The arm board is used in various surgical procedures to ensure proper restraint and comfortable positioning of the patient's arm. The department of cardiovascular medicine at the University of Virginia currently uses two flawed arm board models. The electrophysiology (EP) lab primarily uses the Siemens model, while the catheterization (cath) lab uses the Banjo model (**figure 1**). According to 30 surveyed medical professionals at UVA, the Siemens arm board is easy to clean but has durability issues, while the Banjo arm board has greater stability, but often splinters and breaks when cleaning.

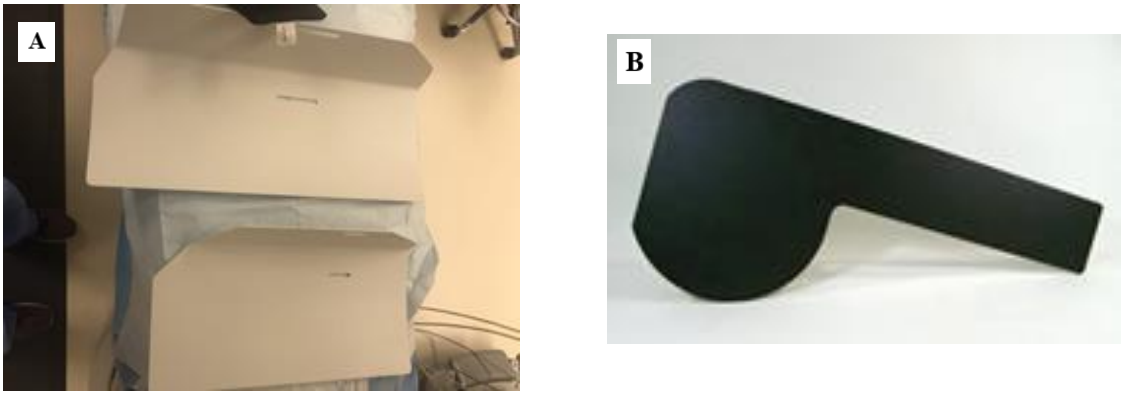

Figure 1: UVA cardiovascular medicine arm boards. (**A**) The Siemens model. (**B**) The Banjo model

The goals of this project are to shadow and interview additional medical staff, design and prototype a new universal arm board, and test the prototype on volunteer patients. The prototype will satisfy the limitations of the Siemens and Banjo models through optimizing its material and geometry. It will enhance stability and comfort, while retaining design simplicity. Preliminary models will be prototyped using computer-aided design (CAD), and the final model will be 3-D printed and assembled. Time permitting, the model will be tested on volunteer patients, who, along with the treating professionals, will be interviewed about their experience. The universal arm board model will ideally promote more efficient procedures by medical professionals, improve patient experience, and lower costs.

Physicians' Roles in Promoting America's Opioid Crisis

How did physicians contribute to the opioid crisis? Through litigation and publicity, critics of pharmaceutical companies and top executives have sought to hold them accountable for contributing to the epidemic, but physicians' roles have been discounted. The participants include patients who have been prescribed opioids, opioid manufacturers, physicians funded by opioid manufacturers, state and local governments that sued opioid manufactures, and practicing

physicians who prescribe opioids. The Rx Awareness campaign publicizes the addictive potential and other dangers of prescription opioids, reporting the stories of patients whose lives they damaged (CDC, 2019). The American Medical Association's Opioid Task Force is a group of physicians that calls for physicians to enhance treatment for and reduce stigma against opioid addicts, and for policymakers to reform laws and rehabilitation centers (AMA, 2019). Many other groups call for similar reform, united in their commitment to mitigate the epidemic and to alleviate the afflictions of those with opioid use disorder.

Over 2,000 municipal governments and 40 states have sued manufacturers of prescription opioids, accusing them of "aggressively" advertising them and downplaying their addictive properties (Dyer, 2019). In August 2019, Oklahoma judge Thad Balkman, ordered Johnson & Johnson to pay the state $572 million for contributing to the epidemic; Oklahoma's attorney general praised the ruling as a precedent for other states: "That's the message for other states: We did it in Oklahoma. You can do it elsewhere" (Dyer, 2019). In 2007, Purdue Pharma, manufacturer of OxyContin, was the first firm to face legal charges for the misbranding of OxyContin; the company and three of its top executives were ordered to pay $634 million in fines (Jones, 2007). In mid-September, 2019, Purdue Pharma and its owners, the Sackler family, reached a tentative settlement and filed for Chapter 11 bankruptcy in a federal case in Ohio to settle over 2,000 lawsuits against them (Perrone, 2019).

Purdue Pharma's marketing of OxyContin between 1996 and 2001 has been well documented by Van Zee (2009), who reviewed primary documentation of their marketing plan. Purdue held over 40 all-expenses-paid, pain-management symposiums for medical professionals, where industry-sponsored physicians alleged that opioids are safe and non-addictive for treating non-cancer related pain. To justify these claims, they cited flawed research from Porter & Jick

(1980), who found the opioid addiction rate to be less than 1%, and Perry & Heidrich (1982), who found no addiction among 10,000 burn victims treated with opioids. However, both studies were solely based on hospitalized patients, where opioid administration was carefully controlled by doctors, and did not apply long-term to patients after leaving the hospital. Purdue expanded the treatment protocol for opioids from patients with cancer-related pain to patients with all types of pain. From 1996 to 2000, OxyContin prescription rates increased 1800%, while the rates of other commonly prescribed opioids, such as hydrocodone and morphine, increased only 23% (United States Senate, 2002). By 1999, the non-malignant pain market constituted 89% of the opioid market and primary care physicians became the most frequent prescribers of opioids (Van Zee, 2009).

Dr. Russel Portenoy, MD, was among the pain specialists speaking on behalf of the safety and efficacy of opioids for non-cancer related pain. Chairman of Pain Medicine and Palliative Care at Beth Israel Hospital in New York, Portenoy was an acclaimed expert in pain-management and dubbed the "King of Pain" by *Time Magazine* (Gale, 2016). He argued that opioids should be destigmatized to rid doctors of "opioidophobia," citing the statistic from Porter & Jick (1982) that less than 1% of patients get addicted (Perez, 2012). Dozens of opioid manufacturers, including Purdue, funded Portenoy millions of dollars. He defended these relationships: "My viewpoint is that I can have those relationships, they would benefit my educational mission, they benefit in my research mission, and to some extent, they can benefit my own pocketbook, without producing in me any tendency to engage in undue influence or misinformation" (Perez, 2012). In a 2002 congressional hearing on balancing the risks and benefits of OxyContin, Portenoy took a more neutral stance. He advocated for improved education of physicians and pharmacists, and for research "to define the risk of abuse and

addiction"; however, he strongly opposed those calling to remove OxyContin from the market, indicating that "opioid drugs can be safe and effective, but are medically underused" (United States Senate, 2002). He has since backtracked and admitted wrongdoing: "I gave innumerable lectures in the late 1880s and '90s about addiction that weren't true" (Perez, 2012). In April 2019, Portenoy agreed to testify against Purdue in return for immunity (Feeley, 2019).

Until 1996, most opioid prescribers were oncologists and pain specialists. Thereafter, most were primary care doctors, whose training in pain management and addiction is typically limited (Van Zee, 2009). In a 2001 interview with the *New York Times*, Portenoy admitted that these doctors "may not have the skill set required to prescribe it responsibly" (Tough, 2001). Moreover, family doctors typically see many patients, and thus have less time for each. Primary care physicians may have been less inclined to question pain specialists marketing OxyContin as a safe, non-addictive treatment for non-malignant pain. Some hospital lawyers warned physicians that their patients could file malpractice suits for inadequate pain treatment (Gale, 2016).

The American Medical Association enforces rules requiring disclosure financial conflicts of interest. Because physicians have a professional obligation to patients, they are responsible for evaluating the integrity of the research that guides their care. Many physicians claim they acted on the basis of publicized research, not pharmaceutical advertisements (Avorn et al., 1982; Jenike, 1990). Most physicians claim that all-expenses-paid symposia held by pharmaceutical companies would not influence their prescribing (Orlowski & Wateska, 1992). However, the results of studies from Orlowski & Wateska (1992) and Avorn et al. (1982), and Purdue's successful marketing of OxyContin, demonstrate otherwise.

Avorn et al. (1982) studied the influence of commercial sources of information on physicians' prescribing. They interviewed primary care physicians and found that most of them denied advertising influences – either because of social desirability bias or because they were unaware of it. Physicians clearly did not base their prescriptions on publicized research. Orlowski & Wateska (1992) found that physicians who attended all-expenses-paid trips to pharmaceutical symposia prescribed differently than others. None of the physicians in the study reported that attending the symposium would make them more likely to prescribe a medication. Sponsored physicians who praised the safety of opioids, and physicians whose practices are in a professional conflict of interest, are affected by such endorsements at symposia.

Commercialized medicine fosters and exploits such conflicts of interest. Practicing physicians must be skeptical of claims from physicians and researchers funded by pharmaceutical companies. Physicians attending all-expenses-paid symposia must be alert to their conflicts of interest. They should review published research carefully. Had the physicians who prescribed opioids too liberally adhered to their professional responsibilities, the opioid crisis might have been prevented.

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