Career Imperative. Is it Legal? Is it Ethical?

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Abstract- This paper gives sample ethical case vignettes and discussions that will be presented at the 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC'14) special session of the Ethics and Professional Responsibility Committee. The session includes additional cases with audience participation and panel discussions.

I. Overview

Biomedical Engineering ethics is often looked upon by students and practitioners alike as a boring area that only professors get excited about. But the challenges of biomedical engineering that result from today's rapid technological advances and the ethical considerations that impact our day-to-day work, can be not only exciting to explore, but also important to understand for career success. Many ethical situations arise on a daily basis. This paper will highlight examples that include perception, differences and consideration of practical, every day, real-life issues. The authors will not draw any final conclusions about the various situations, but rather will present example vignettes and some of the ethical or legal dilemmas they pose. Many additional ethical situations will be explored at the conference.

II. Ethical Cases

Case 1: Your boss asks you for a research report he needs for a corporate board meeting in two days and you are in the midst of a big project. Time is short so you decide to Google the details. You find exactly what you

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need out on the net so you do a bit of quick cut-andpaste, getting the finished document to your boss in record time. Your boss is elated and so are you. Is it legal? Is it ethical?

Discussion 1: Before trying to analyze this scenario, we are forced to consider what would be relevant. The following are among the relevant ethical considerations:

- 1. Accuracy. Engineers as professionals are bound by what sociologist Talcott Parsons calls "disinterestedness," the requirement that a professional do his/her best work every time. There are two main reasons for this requirement: there is no good reason for a professional not to do his/her best, all else being equal, and because laymen are unable to judge the quality of professional work. What counts as one's "best" work in this case? What is the relationship of the values of accuracy and meeting the deadline in the case?
- 2. Credit. In searching for the answer do you find "exactly what you need" or is your result a function of what you look for? This suggests your confidence in the accuracy of the information found. First, is there any problem in crediting (or not) the source of the information, be it data or interpretation? Is this document a research report, for internal consumption, to be published? What difference, if any, does this make? Second, has the engineer really contributed an "engineer's value?" Is this "cut-and-paste" comparable to providing an exhaustive set of calculations for a design?
- 3. *Consequences*. Aside from the self-interest of your boss and yourself (which is, of course, well worth considering), the engineer should ask whether there are any safety considerations first, and, secondarily what bearing the report may have on the welfare of the company and/or the people who rely upon it. Furthermore, there can be incredible consequences to the engineer and the company for copyright violations., Have the impact of these violations been considered if the report or any part of it are ever published?

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4. *Reasonability*. Engineers as professionals are not mere employees. They are expected to exercise their judgment autonomously, even when it may annoy their superiors. There are many cases in the engineering ethics literature of engineers being placed in ethical dilemmas by unrealistic deadlines imposed on them. Is this one of those cases and will the engineers' acquiescence to the demands increase the probability of being asked to do so again when the potential harm may be greater?

Case 2: You are the principal engineer in developing a patient signal amplifier. The company you work for stands to make millions of dollars in sales from this device. The project is already significantly delayed and the scheduled announcement is in two weeks. Some of your beta sites have reported issues with signal offset. Your software engineers tell you they can correct it with software. The hardware engineers are telling you that the offset needs to be fixed because there is no telling what other issues may arise. Your supervisor is pushing for release on time in two weeks. Do you go with the software engineers or the hardware engineers? Is it legal? Is it ethical?

Discussion 2: Most successful engineers become managers at some point in their careers. This case brings attention to the tensions between the two roles—tensions that are especially acute for engineers who are close to both roles, as would seem to be the case with this engineer. With which role do you primarily identify? Managers are primarily responsible for the welfare of their company; engineers, with public safety. What do you do when you are both?

Sometimes ethical dilemmas can be neutralized through the creative identification of options. The project is already three years behind schedule, how hard is the two-week deadline? For that matter, would even the software solution be ready in that time frame? In attending to the language of the case, the software engineers speak of a "correction"; the hardware engineers, of a "fix". Could the software solution be introduced first, with the hardware solution to follow? What are the risks? Are the hardware engineers being hyperbolic in saying that "there is no telling what other issues may arise"? It's more likely that they can identify potential problems before being able to determine their probability. How do engineers and managers differentially judge risks?

Case 3: You are working as part of a team on a new AED for wide-spread distribution in public spaces. You are convinced there are both battery and electromagnetic interference issues but other members of your team disagree. Nobody seems to be listening to you. As an employee of a large corporation, you are under a very strictly enforced non-disclosure agreement. Do you keep quiet, take your concerns to the president of the company, or go to the public media with your feelings? Is it legal? Is it ethical?

Discussion 3: Many ethical disputes involve differences in ethical judgment between people of good will. What is the nature of the disagreement here? Is it normative, that is, is it about a difference in opinion about what is right or good given an agreement on the facts? Or are the facts themselves in dispute? It would be important to get clear on this point before doing anything else. It's alarming that "no one seems to be listening." Are you secure in your own perceptions of the situation? It is characteristic of engineering ethics that engineers are sometimes caught between their obligation to public safety and "bureaucratic loyalty" to their employer. At the same time, organizations also provide the resources of others to whom one can turn. Whom can you trust to voice your concerns so that you might finally obtain(?) the honest response you need? If you are secure in your judgment, would you be able to convince the people you would tell? Would your decision be supported in court if you were terminated and filed an action against your employer for unjust termination?

Case 4: Having just become the director of a large, hospital-based clinical engineering program, you are tasked with redesigning and implementing a meaningful and accreditation-required medical equipment management and control program. Hospital administration was being updated regularly on the status and progress of this lengthy and complex redesign. Within a few months of beginning this project, however, the hospital was being surveyed by the (then) Joint Commission. At the end of their first day of inspections, a surveyor asked to see all of your history files on operating room tables. Your department had none. The hospital associate administrator called and told you in no uncertain terms that he needed all of your OR table maintenance files 'first thing in the morning'. After repeatedly saying that you had no such records, his extremely intense and parting words were, "I don't care

what you have to do just have them on my desk first thing in the morning." Is it legal? Is it ethical?

Discussion 4: The falsification of records (usually test data) is a staple of the engineering and business ethics literature. The great 18th century German philosopher, Immanuel Kant, famously argued that there are no "white" lies, since any lie universalized would undermine communication itself¹. More prosaically, we know that lying usually ends badly, if only because it reinforces the propensity and expectation by others, particularly in organizational contexts, of the readiness to do it. The absence of records for the OR tables was not an oversight, but the consequence of an orderly and well-considered and well-communicated overhaul of reporting procedures. The director might feel secure in that report's being made to the JCAH. It would not be surprising if the director were to be suspicious of the timely discovery of the previously unknown records. It would be the director's judgment as to whether their legitimacy would be worth pursuing.

Case 5: In the x-ray imaging of the coronary arteries and in assessing the function of the left ventricle via fluoroscopy, radiopaque contrast agents are typically injected under very controlled conditions and under relatively high pressures. Normally, these machines include considerable design safeguards to prevent inappropriate injections and/or use errors. Through a set of unforeseen circumstances, a patient received a massive 100 ml bolus of air and subsequently died. It was later learned that the manufacturer of this particular contrast injector had a simple air emboli detection attachment for its syringe that would have simply disabled the machine before any air could be injected into the patient. But . . . such an 'accessory' was optional and was not routinely provided with this particular machine nor did the hospital request this option. Is it legal? Is it ethical?

Discussion 5: Engineers are somewhat insulated from blame for the results of negligence, since they are generally removed from the actual use of their designs. They are responsible, of course, for what they should know, and in particular, for the standards of practice pertaining to particular designs. This is problematic nonetheless because we are most comfortable holding people accountable for what they know they are doing. Negligence implies a degree of ignorance. What the negligent professional can be held ethically accountable for is the carelessness that inheres in negligent conduct. To what extent does one know that he is being careless? Broadly, when we blame someone for carelessness, we say that he *should* have known what *might* happen. Usually, in professional practice, that is bad enough.

In this particular case, is it reasonable to expect the procedure to preclude the need for automatic emboli detection? How difficult is it to test the syringe for air after it is in place? The case also raises questions about the compromise of a design in the process of the introduction of a product. Is it possible that the emboli detection function was integral to the original design, and was only subsequently made an option? How responsible is an engineer for her design?

Case 6: An automobile accident just left a 35 year-old female quadriplegic. After recovering from her acute injury, she was transferred to a rehabilitation facility where she was placed in a bed with a special low-loss air mattress to prevent skin ulcers.

After approximately 12 hours of having been on this mattress, the patient was found to be unresponsive and having an axillary temperature of 107.9° F. The patient subsequently died of severe hyperthermia. It was later determined that the air inlet for the mattress' integral blower motor was inadvertently covered with a bed sheet causing the mattress' surface temperature to rise to unacceptably high levels. Is it legal? Is it ethical?

Discussion 6: Apart from legal questions of negligence, from an ethical perspective we would ask again whether this incident indicates carelessness in the design. Given the strong suggestion that the market for the product includes rehabilitation and extended-care facilities, is it reasonable to expect that quadriplegic patients would be among its likely users? Understanding risk as *magnitude of harm x probability of harm*, who decides what is an acceptable risk? To what extent does the attractiveness of the integral blower motor as a design feature justify the increased risk of overheating?

The case offers a pointed example of the prudence of a "safe exit" as a design principle recommended by Martin and

¹ Immanuel Kant, *Fundamental Principles of the Metaphysic of Morals in Critique of practical Reason and other Works on the Theory of Ethics*, ed. and trans. Thomas K. Abbott (London: Longman, Green and Co., 1909) pp. 48-9.

Schinzinger in their text *Introduction to Engineering Ethics*.² Since no product can be guaranteed against failure, the best one can do is to assure that when a product fails, (1) it will fail safely, (2) it can be abandoned safely, or (3) the user can safely escape the product.

III. Conclusion

The ethical and legal dilemmas faced by engineers are continually testing the limits of right and wrong, should or shouldn't, desire and control, and lead one to be challenged on how to handle such potentially life changing events. There is no currently available compendium of such deliberations. This paper is a precursor to a special session at the EMBS 2014 Annual Meeting where many of these issues, including the ones above, will be openly discussed and possible solutions offered. Participation in this session will compare students and practitioners. The panel will consist of "experts" willing to opine on the vignettes.

Acknowledgement

The authors gratefully acknowledge the valuable advice and editorial input of Barbara Oakley, PhD, PE in the preparation of this manuscript.

² Mike W. Martin and Roland Schinzinger, *Introduction to Engineering Ethics*, 2nd ed., (New York: McGraw-Hill, 2010), p. 127.