Legal and Ethical Issues in the Regulation and Development of Engineering Achievements in Medical Technology: A 2006 Perspective

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Abstract - **Two papers, Legal and Ethical Issues in the Regulation and Development of Engineering Achievements in Medical Technology parts I and II were written in 1990 by three authors of diverse backgrounds and published in the IEEE Engineering in Medicine and Biology Magazine in March of the same year. Part I of the paper discusses the existing Food and Drug Administration (FDA) requirements that existed in 1990 to regulate the clinical trial process for medical devices, obtaining Marketing Approval and exceptions that may allow the use of unapproved devices. The paper discusses how the FDA has loosened some of the stringent regulations to further its goal of encouraging new development while protecting public health and maintaining ethical standards. Part II of the paper focuses on the ethical implications of the process of introducing a new technology to the market place, specifically in the usage of unapproved technologies for emergency use and feasibility studies. This paper discusses the topics covered in the two papers and the changes that have been made to the FDA guidelines since their publication in 1990.**

I. Introduction

The papers, Legal and Ethical Issues in the Regulation and Development of Engineering Achievements in Medical Technology parts I and II**,** were written by three authors, representing respectively the fields of Engineering, Law and Philosophy and as such providing a comprehensive and concrete analysis of the regulations, laws, and ethical guidelines that govern the creation, test and distribution of new medical devices.

Dr. Joseph D. Bronzino was, at the time, the Director of Biomedical Engineering at Trinity College and the Hartford Graduate Center and also the Chairman of the Health Care Engineering Policy Committee of IEEE. Over the course of his career, Dr. Bronzino has authored over 200 papers, 11 books and has been the chair of the IEEE Technical Policy Council in Washington, President of the Biomedical Alliance and Consortium (BEACON) and is a fellow of American Institute of Medical and Biological Engineering (AIMBE). Dr. Bronzino is a well-known and well-respected engineer who is exceptionally well-versed in "public policy regarding the utilization and regulation of medical technology." His co-author Ellen J. Flannery is a partner in law at the firm Covington & Burling in Washington D.C. specializing in food, drug and medical device law. And Maurice L. Wade, who was at the time an Assistant Professor of Philosophy at Trinity College, has since publication of these papers gone on to co-author several of Dr. Bronzino's books and has become the Philosophy Department Chair, Director of Public Policy and Law Studies and Professor of International Studies at Trinity College.

In short, it would be difficult to find a more qualified trio of authors to have explored the intricacies of the legal and ethical issues concerning medical devices.

II. The FDA Regulations

Since 1976, it has been the responsibility of the FDA to regulate medical devices. Part of this responsibility is to ensure the limitations are imposed for investigations of new devices, making sure that these rules are followed and then providing approval for the new devices. The challenge is to balance encouraging the discovery and development of useful medical devices while protecting the health of the public and upholding ethical standards.

A. Statutory and regulatory requirements for clinical investigations

In the United States, non-approved FDA devices cannot cross-interstate boundaries. A special exemption was made by Congress to allow distribution of medical devices for the purpose of conducting clinical trials. The FDA may provide an Investigational Device Exemption (IDE) to promote clinical trials on new devices. However, an IDE will not be granted without specific information about the scope and duration of the testing, the number of human subjects to be tested, explanations of possible changes to be made to the device to accommodate testing and how the data will be gathered and whether or not that data will be used to obtain FDA approval for the device. It is highly unlikely to obtain an IDE for a device that will not be seeking FDA approval in the future.

Above and beyond the information listed above the sponsor of the new device must provide all information gathered from previous testing, a protocol for testing, assurance that the study participants will each provide informed consent

and that the local Institutional Review Board (IRB) has approved the testing. The IRB has the very important role of ensuring that tests of 'significant risk devices'[2] are completed in a manner that will minimize the risks to the subjects and that these risks are minimal in comparison with the knowledge to be gained and benefit to the subjects. The IRB is also responsible for ensuring that the selection of test subjects is equitable and that the informed consents are adequate, and that the tests are monitored and patient information is protected. The IRB must assess the soundness of the investigation and weigh the "knowledge to be gained" against the "benefits to the subjects", both must be substantial. The IRB must also be aware that although there may be no direct benefits for the participants during the study there are potential benefits for them with the future developments of Health Care based on the research.

B. *Obtaining Marketing Approval*

Marketing approval by the FDA falls into three categories. Devices that are "substantially equivalent" to the other devices on the market can be given approval based on the completion of a 510(k) notification[10]. Sponsor of devices that had been granted an IDE can request Premarket Approval (PMA) once the clinical tests have been completed. The FDA and an expert advisory committee review the data and decide on their approval. The third case involves obtaining a Product Development Protocol (PDP) this method was created by the FDA to expedite the approval process by combining the request for clinical trials with that of market approval, especially for devices that are expensive to produce. This method had never been successfully used at the time of the paper because the PDP assumes that no engineering changes will have to me made to the device from its inception to putting it on the market.

C. *Exceptions*

The FDA recognizes that situations may arise that merit the use of unapproved devices. The FDA categorizes these situations into three groups; emergency use, treatment use and feasibility use. Treatment use deals with drugs and is not permitted for medical devices. Emergency use is permitted only when there is a patient who is critically ill and the device has not yet received its IDE or the physician is not one of the approved investigators of the device in the clinical trials. Feasibility studies can be permitted before an IDE is requested to determine whether or not clinical trials will take place for the device. Feasibility tests are performed on a smaller pool of test subjects and the requirements are not as rigorous as for full IDE clinical tests, since the trials are not as substantial the data gathered cannot be used, on its own, to receive PMA from the FDA.

III. Ethical Issues

The FDA allows non-IDE emergency usage of devices to enable physicians to give the best possible care to their patients in dire circumstances and allows feasibility studies to enable the development of devices in a more efficient manner. But, good intentions by the governing body do not remove the risk of unethical behaviour. In these cases patients are not as protected, because the testing and approval process is not complete; there can be no guarantees as to the end results.

A. *Feasibility Study*

The goal of a feasibility study is to gain generalizable knowledge; this is research to answer the question "should further studies be conducted?" The IDE is not required so the FDA leaves the responsibility of ensuring the study is ethical to the IRB. This can be dangerous since IRBs can be easily influenced by the prestige they stand to gain from a new device. The IRBs must determine whether the study is scientifically sound, ensure that the tests will provide measurable data and that the tests are conducted by people with the relevant scientific competence. Certain of the factors that make up the decision in the granting of an IDE are not examined by the FDA in the case of a feasibility study, but should be examined by the IRB, these include the provision of voluntary and informed consent, and the assurance that subjects will not be subject to undue risk. The authors question where the responsibilities lie in the non-IDE cases and stipulate that the FDA should be even more careful when less is known about the device; using a smaller test pool does not make tests more ethical.

B. *Emergency Use*

Cases for emergency use can be approved by the FDA both in the context of an IDE and outside an IDE. When applying for an IDE the sponsor should indicate if the desire is to use a device in emergency cases, and if said use would be considered research or practice. The authors question whether the emergency use of a device can ever truly be for research or practice. Research is to gain general knowledge so to assume that the very specific case of an emergency use provides generalizable knowledge is naïve. Another danger is that patients who are in danger of death are much more vulnerable to be treated as resources, not people. Using a device in practice presumes a certain outcome, but in these cases there can be no adequate expectation of success. With no guarantee of success the use constitutes non-validated practice; can this still be considered morally justifiable? A second concern is discussed in the paper about emergency use. In cases where the patients are in dire circumstances, they may not be able to make an informed and consensual decision. Will they understand that they can be seriously impaired? Also, the desire to test the device may lead to the physician's role as an investigator to overshadow his/her role as a doctor. Emergency use cases may be approved after the fact by the FDA for non-IDE devices; they still require the patient's consent and the FDA is very clear that the emergency situations cannot be fabricated to provide an occasion to test the device.

IV. Conclusion

The authors' conclude that "the FDA must canvass the range of possibilities and use foresight in adapting procedures to expand the freedom of scientific investigators in developing new medical devices. But those procedures must be clear and concise, allowing flexibility in defined non-IDE contexts that will not jeopardize the safety and welfare of patients."[1]

As discussed in Dr. Monique Frize's Ethics, Research Methods and Standards course it is difficult to foresee and subsequently guard against the misuse of devices, or the unethical behavior of a few[2]. But, it is the responsibility of the FDA to do so. Since the paper was written, the FDA released new guidelines that clarify the relationships between the sponsor, Investigator and IRB – to minimize ethical grey areas in that regard. The FDA also now stipulates that a medical device can only be used once in an emergency use situation as after that the need for the device is foreseeable[2]. Improvements to the guidelines and regulations have been made over the years, and will continue to be made as technology progresses, it is very important for the FDA and other regulatory bodies to remain flexible in their rules and also keep a watchful eye on all involved in the process of developing, testing and bringing new devices to market.

V. Recommendations

The FDA cannot possibly know all the goings-on in the thousands of Institutional Review Boards across the United States. As such, it is important for professionals to participant in ensuring the ethical behavior of their peers. This can be done by participating in the review process by becoming a member of an IRB. Not only would this help broaden the opinions of the IRBs but it would also relieve some of their heavy workload. On the same note, when asked to provide an opinion on a proposed new device and the possible trials that will follow to bring it to market; it is very important that IRB members give their full attention to the assessment of that medical device. Ethical dilemmas may also arise for other hospital staff or employees of the company of production when they may witness their colleagues being placed under pressure to fast track a device to the market. Engineers, like medical professionals, should expect only the best ethical behavior from their peers and from themselves. And unfortunately, part of that behavior may on occasion include reminding their colleagues of their duties or even having to expose blatant or perceived wrongdoings.

[1] Part II's concluding statements, see Reference [1]

[2] The course is based on Dr. Frize's paper "The importance of teaching ethics to biomedical engineers", see Reference [9]

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