

Bioethics Education in Professional Science Master's Programs at California State University Channel Islands

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Abstract

Life science is increasingly facing complex ethical and social issues, making bioethics an ever more important field with which to contend. While students in the professional science master's (PSM) programs at California State University Channel Islands (CSUCI) receive high quality preparation in science and technology, it is essential that they become aware of the ethical dilemmas and challenges they will face as professionals in the workplace and develop the critical thinking skills necessary to navigate successfully as science professionals and scholars. As is the case at many universities in California, our students enrolled in the MS Biotechnology and Bioinformatics as well as MS Biotechnology and MBA Dual degree programs, the two PSM programs, are culturally heterogeneous and can have different world views. Some come from professional backgrounds and are well versed in the requirements for human testing, for example. However, they often work in fairly narrow technical jobs, mostly at Baxter, Invitrogen and Amgen, local biotechnology companies. Increasingly, the incoming students are recent graduates from CSUCI and other universities, having had no work experience in the biotechnology world. Approximately 7 percent of our students are from developing nations where there are no regulatory authorities for pharmaceuticals and little, if any, biotechnology and many have never held a job in the industry. A working knowledge of biotechnology combined with a solid industry overview is a powerful combination for the 21st century biopharmaceutical workforce. Exposure to bioethics puts each student, regardless of her/his background, in a position to deal with issues in her/his own environment from a common starting point. To accomplish this educational goal, CSUCI PSM programs take both a *focused* and an *integrative* approach to bioethics education to provide students with the framework as well as the breadth and depth of understanding of bioethics. By introducing first, an overview of bioethical issues in a conceptual framework captured in a required course, Biotechnology Law and Regulation, and then integrating bioethics into the overall curriculum, including required and elective courses such as DNA and Protein Sequence Analysis, Project

Management, Molecular Structure, Pharmacogenomics and Pharmacoproteomics, Stem Cell Technology and Laboratory Management, and the culminating Team Project, the students benefit in two ways: first, everyone is on the same page at the beginning of their program of study; second, students have the tools to be aware of bioethical conundrums in a real world context. In sum, bioethics education has been a key component of the curriculum for the PSM programs since their inception. All students completing the PSM programs at CSUCI have received a solid bioethics education as a result.

Background of Bioethics Education

Life science is increasingly facing complex ethical and social issues, making bioethics an ever more important field. Policy-makers, scientists, managers, and executives of organizations within any scientific context or setting must frequently evaluate the ethics of how technologies and scientific practices can profoundly affect life and death. With the advancement of science and its myriad applications in industry, we need to ensure that technologies are applied for the "good" of society *and* for the "good" of its individual members. As scientific knowledge advances exponentially, training in bioethics is increasingly more urgent. Moreover, scientific practices are increasingly more interdisciplinary, many involving emerging and nascent fields, and these practices operate within many organizational levels and multiple societal contexts, which compels bioethics education to reach beyond the field of life sciences.

Professional Science Master's (PSM) Programs at California State University Channel Islands (CSUCI)

Due to the vision of the leadership at CSUCI and its proximity to multi-national biotechnology companies, the PSM programs have developed and nurtured extensive industry contacts and partnerships. Because of the innovative approach to program administration, CSUCI has employed tenure-track faculty, senior industry executives, and scientists as instructional faculty for the PSM

programs. The adjunct faculty members readily serve as expert advisors for students' team projects. Students benefit by learning from these adjunct professors who have a deep understanding of the biopharmaceutical industry. Along with the tenure-track and tenured professors in the program, the adjunct faculty developed specific courses, largely based on experiences working in the biotechnology industry and in scientific research and development. They work within the guidelines of the campus course proposals with its description, content, and student learning outcomes written and submitted by tenured and tenure-track faculty members in the program and approved by the Curriculum Committee of the Academic Senate.

The main goal of the PSM programs is to train the 21st century workforce in the biotechnology, pharmaceutical and biomedical research and development fields. To work in these highly regulated and technically dense fields, having the "35,000-foot view" of the biotechnology industry is invaluable. While PSM students receive high quality preparation in science and technology, it is essential that they become aware of the ethical dilemmas and challenges they will face as professionals in the workplace and develop the critical thinking skills necessary to navigate successfully as science professionals and scholars.

Characteristics of PSM Students at CSUCI

As is the case at many universities in California, our students are culturally heterogeneous and have differing world views. Some come from

professional backgrounds and are well versed in the requirements for human testing, for example. However, they often work in fairly narrow technical jobs, mostly at Baxter, Invitrogen and Amgen, local biotechnology companies. Increasingly, incoming students are very recent graduates from CSUCI and other universities with no work experience in the biotechnology world. Approximately 7 percent of our students are from developing nations where there are no regulatory authorities for pharmaceuticals and little, if any, biotechnology and many have never held a job in the industry.

Naturally, these students have had neither the opportunity nor the experience to grasp the "big picture" of how the industry works as a whole. Additionally, due to economic pressures, the biotechnology industries are reducing on-the-job training opportunities, thus increasing the need for "industry-ready" trained professional workers. Moreover, workers need to be continually retrained and redeployed into areas of expertise needed by industry and government. A working knowledge of biotechnology combined with a solid industry overview is a powerful combination for the modern biopharmaceutical workforce. Exposure to bioethics puts students, regardless of their backgrounds, in a position to deal with issues in their own environments from a common starting point.

Incorporation of Bioethics Education in the Curriculum

CSUCI PSM programs take both a *focused* and an *integrative* approach to bioethics education to provide students with a framework as well as the breadth and depth of understanding of bioethics. By introducing first, an overview of bioethical issues in a conceptual framework, and then integrating bioethics into the overall curriculum, the students benefit in two ways: first, everyone is on the same page at the beginning of their

programs of study; second, students have the tools to be aware of bioethical conundrums in a real world context.

1. The Focused Approach

To meet this educational need, we developed a course, Biotechnology Law and Regulation, which devotes its first 4 hours out of a total of 48 hours of presentations and discussions specifically to bioethics. The program has hired a legal professional specializing in this particular field as the instructor for the course. She has extensive experience working as a patent law attorney in the biotechnology industry. She has developed cases that address individual and organizational responsibility in R&D and commercialization of biotechnology, intellectual property, privacy, government and industrial regulation, liability, ethics, and policy responses to societal concerns in the U.S. and abroad. The bioethics portion of these cases examines bioethical issues in six broad areas in human testing, animal testing, reproductive medicine (including stem cell technology), tissues and organ transplantation, research ethics in the behavioral and neurosciences (i.e. "neuroethics"), and scientific fraud. To focus every student's attention to bioethical issues, all students are required to take this course at the beginning of their program of study.

Case studies are used extensively throughout the discussions in the Law and Regulation course, including those directly related to working in the biopharmaceutical industry. For example, what are the ethical issues in reducing the costs of clinical trials by using vulnerable populations such as prison inmates as test subjects? Or what are the ethical implications of outsourcing research to contract organizations in other countries? Other issues include those on the horizon: reproductive ethics for pre-implantation genetic selection and human cloning; neuroethical considerations for

legal liability; and ethical considerations surrounding organ transplants. This 4-hour section is an overview of bioethical "big issues." This thorough overview of bioethics brings students with different educational and cultural backgrounds to a common awareness of the major ethical issues in biotechnology and the relevant laws and regulations dealing with these issues. Towards the end of the class, students are required to complete a project report and many times they choose topics involving bioethical concerns. This activity allows the students to further develop their critical thinking skills and apply their knowledge learned from the class.

2. The Integrative Approach

Bioethical considerations are ever-present and bioethical questions permeate many aspects of our common practices. For example, should a graduate student re-run the experiment or just submit the data as is? Do researchers need to find the mode of action for a particular molecular drug candidate or can they just start human clinical trials without it? What is wrong with having a medical writer compose the paper so long as it is factually accurate? To contend with these daily ethical concerns, the CSUCI PSM programs have taken an integrative approach in bioethics education and have blended bioethical considerations in a variety of courses throughout the curriculum.

For instance, in the Biotechnology Law and Regulation class, in addition to the initial bioethics component, there are bioethical considerations in every area ranging from financial and competition laws (e.g., should generic companies take money not to sell?) to intellectual property (e.g., is there a public interest in enjoining a competitor from infringing one's patent?). Students also have practical training in bioethics issue spotting and analysis. Although the students themselves may not be in an industry

position to make definitive decisions, they will be aware of the information needed by the decision makers. Thus, when they see unusual data, they will understand the importance of asking questions. They will see where their work fits into the overall commercial program and develop an appreciation of the important values that need to underlie it, and be able to recognize significant information for management review.

DNA and Protein Sequence Analysis, a required introductory course for PSM students, is a logical place to introduce an ethics component because there are so many ethical issues surrounding public genetic databases. The professor introduces the students to abundant ethical issues (mostly privacy and patenting) surrounding sequencing human genomes, SNPs, and so forth, and then puts these data into accessible databases. Class discussions are also centered on gene expression profiling which is another area where there are ethical concerns—again, in the realm of privacy.

The Project Management course, another requirement for PSM students, provides the perspective of designing clinical studies to ensure ethical treatment of subjects independent of project timelines and goals. The purpose is to ensure the studies include considerations of central ethical issues such as standards of care instead of assuming a placebo treatment, if applicable.

The Molecular Structure class has a section on the cost of manufacturing human therapeutics. Topics include the strict standards that are required by the FDA, the time it takes to bring a drug to market and the filing of the Inventive New Drug and Biological License Agreement. Students learn that bioethics will come into play in the very near future as the early biotechnology products will be going off patent in a couple of years. The Biosimilar issue is going to heat up soon as there will be a call from the major biotech companies to

require that the new biosimilars have identical biological activity and efficacy. The balance is the cost of manufacturing, utility of drug, who is going to pay for it, and the overall profitability of the drug for companies. Ethics for all stake holders will be challenged.

The Pharmacogenomics and Pharmacoproteomics class discusses bioethics formally during a four-hour period. The students read an ethics overview article from the literature regarding responsible conduct of scientific research; one group makes a brief presentation about it; and the whole class then discusses it. Led by the professor, the class returns to this topic over and over again, sometimes superficially during the term as the context warrants, and sometimes more in-depth during case study reviews and discussions.

In our newly implemented Stem Cell technology and Laboratory Management PSM program, ethical considerations involving procurement, subsequent handling, the ultimate use of the stem cells and technology, developing embryonic stem cell lines and human cloning (including therapeutic and reproductive cloning) are organically built in the class curriculum including lectures, labs and seminars, making bioethics one of the pivotal parts of the training and education.

The Team Project course is a required culminating experience for PSM programs. Student teams, supervised by scientists from industry, conduct extensive research projects derived directly from the forefront of research and

development of the biotechnology industry. Due to the repeated coverage and discussions of bioethics throughout their program of study, students naturally build ethical considerations in their team project reports. For example, one recently completed project has proposed a concept to develop biosimilars for developing nations. The students contend that as the birthplace of biotechnology, the United States has the expertise to develop the original bioproducts at cost of goods manufacturing. By partnering with individual governments in developing countries, they propose to use the PSM programs at CSUCI to train students from these countries into scientists with business expertise who will then transfer knowledge to emerging countries. This could be a model for social business and certainly has ethical implications.

In sum, bioethics education has been a key component of the curriculum for the PSM programs at CSUCI since their inception. All students completing PSM programs at CSUCI have received a solid bioethics education. The combination of focused and integrative approaches in bioethics education has better prepared our graduates for their careers and has strengthened our PSM programs to meet workforce development needs in the State of California and the nation. As we expand our PSM programs into new interdisciplinary areas in the future, bioethics education will continue to provide the requisite knowledge and skills that are applicable to the broad field of biotechnology and will remain an essential element permeating throughout the curriculum.