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Chapter 1 : AgBioForum 3(4): The Codex Alimentarius and Labeling for GM Foods

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Practicing medicine today often involves decisions about ethical and other patient issues. A medical intern doing volunteer work in Sri Lanka. During the past decade, biomedical ethics commonly called bioethics has become a popular topic for media coverage. This is largely due to increased complexity of caring for patients and the difficult decisions that new technologies demand. Examples include high-visibility issues like the completion of the human genome project, cloning, patenting of human tissue products, and transplants. However, doctors worry or should worry more often about less visible but more common issues such as ensuring patient self-determination and proper informed consent for medical procedures, end-of-life decision making, research ethics, reproductive medicine, and managed care and related economic issues. Students and physicians need education about ethical issues and laws. Despite the trendy nature of cloning and other hot issues, there are numerous ways in which the knowledge that practicing physicians have about medical ethics and law can have a more direct impact on the type and quality of care that the average patient receives. In order to provide medical care in an ethical and humane way, physicians need to be better educated about specific aspects of ethical medical practice and learn to think critically about the increasingly complex world of medical practice. Routine bioethics education for medical students and resident physicians, and continuing medical education for practicing doctors, are the best ways to accomplish this goal. What skills and characteristics in physicians in addition to scientific expertise are necessary for them to practice good medicine? Familiarity with medical law is crucial. It is vital that physicians understand basic aspects of law and the legal system in order to practice good medicine. My own research suggests that physicians know substantially less about medical law when they get such legal information from other physicians. Other research has demonstrated that how people think about risk like the risk of malpractice lawsuits affects the way they react to it, creating ethical consequences. Thus, law and ethics are inevitably intertwined in clinical medicine. Knowledge of the health care delivery system is vital. Understanding social and institutional aspects of health care delivery is also vital. Doctors should know how hospitals and other medical institutions function and how different health care providers and administrators work together. Bioethicists can assist physicians-in-training to understand how such institutional relationships may function differently from those to which they are accustomed and help them assimilate to new institutional structures. Good physician-role-models also play a significant part in this process. Bioethicists can teach doctors and students about clinical ethics. Practical application of bioethics concepts is essential for the well-being of both patients and physicians. This usually occurs in at least two ways, first by educating physicians-in-training, and second, by conducting clinical ethics consultations, which have both an educational role and are designed to assist with a particular ethical problem in a clinical setting. In this setting, the bioethicist provides services that assist specific patients and their families, as well as health care providers. By modeling good clinical ethics practice, bioethicists can teach physicians ways to better perform these functions. Physicians should be aware of current health policies and legislation. Understanding health policy and the legislative process is an important part of delivering good health care in the modern world. Some good examples of issues from the realm of health policy, of which physicians should be aware, include: Physicians having a strong interest in one or more of these issues may wish to become active in advocating a particular piece of legislation or other policy. Because many physicians do not ordinarily think in these terms, bioethicists can make them aware of ways that health care providers can become more active in the public policy process. Bioethicists can also introduce physicians to medical humanities. Knowledge and experience of the humanities is a key element of caring for patients as persons. For example when physicians read poetry or fiction that explores aspects of human illness and suffering, it provides them with exposure to the human experience of health care that may become lost in the daily activities of technological medicine. Physicians should be wary of conflict-of-interest situations. A good

example is the increasing impact of conflicts of interest. Critical thinking is the stock-in-trade of bioethicists and they can foster it in many ways with physicians. Why are bioethicists the best persons to accomplish this educational mission? Bioethicists have the expertise to examine the complex issues facing the medical profession. Bioethicists are generally trained in philosophical ethics and law, as well as the social sciences and humanities. However, the level and type of training among individuals varies to a significant extent, so physicians seeking bioethics consultations should be aware of the particular type of expertise they need and search out a bioethicist with proper background when possible. Bioethicists can provide a more objective and balanced view of complex ethical issues in health care settings. In other words, bioethicists can often provide an outside perspective on medical care. However, as bioethics practice becomes a more routine part of medicine there is a danger of bioethicists being co-opted by the system they are charged with improving. For this reason, bioethicists should be scrupulous in maintaining their objectivity where possible. Many bioethicists have extensive experience in analyzing and resolving actual dilemmas in clinical medicine. Educational efforts specifically targeted to teach bioethics issues to physicians are effective. Recent research suggests that after a course in bioethics, physicians have a more subtle understanding of ethical issues and are better able to analyze relevant issues critically. An excellent example of the importance of all these factors is the ongoing debate over control of severe pain in terminally ill patients. First, because of the risk of diversion of narcotic medications into illegal markets, there are strong legal restrictions placed on prescribing of these drugs. Improved legal knowledge among physicians may reduce fear and misunderstanding and may increase prescribing of appropriate levels of medication for pain relief. However, knowledge of these unintended effects is also necessary among policy makers and legislators. The misnamed Pain Relief Promotion Act of is but one example of how policy and medical care may collide in ways that have negative effects on patient care. This recently-proposed bill was designed to override the physician-assisted suicide law currently in effect in Oregon and to prohibit other states from enacting similar laws. As part of this effort, physicians could be active in public education about the impact of such legislation as well as contacting legislators directly to voice the concerns of the health care community and make clear the possible unintended consequences. Thus, legal, social, institutional, policy, and humanistic factors all play a role in such analysis. What are barriers to these goals and what are their implications? Bioethics education is underfunded. The most critical barrier to achieving uniform bioethics education in the medical curriculum is financial constraints. Most bioethics programs in medical schools are not funded in a way that ensures their continuation. Instead, bioethics programs usually depend on funds set aside by the dean or other discretionary sources such as federal grants that could rapidly dry up. For example, when the department of biochemistry receives a grant from the National Institutes of Health some of the overhead money from that grant may be used to benefit bioethics program. The risk in this approach is that bioethics may come to be viewed as marginal to the mission of the medical school and therefore expendable. Another barrier to bioethics implementation throughout medical curricula is that there remains substantial variation in the quantity and quality of curriculum. However, the proliferation of graduate programs awarding Ph. Bioethics courses are often meager in content. Another barrier is giving bioethics lip service but not substance. Although accrediting organizations require institutions to address ethics issues to some extent, the compliance bar is set fairly low. Institutions with ethics programs that only satisfy the minimum requirement of accrediting agencies do not have adequate services to ensure ethical patient care. Physicians who are mentors and teachers must indicate to students and trainees that ethics is an crucial part of what they are learning. This message must permeate the educational environment. In all these efforts, however, the role of the bioethicist should be one of a colleague possessing specialized knowledge and skills, who is working with doctors, rather than an outside professional seeking to monitor physician behavior. Patient care may suffer if physicians are not educated about bioethical issues. The most important implication of these barriers is for patient well-being. If young physicians are not taught the importance of bioethics issues for their clinical practice, patients may suffer needless pain, their legal rights of self-determination may be disregarded, and their experience of health care will be less than optimal. If this is to be avoided, bioethics must receive a higher priority in medical education in the future than it has occupied in the past. Bioethics education should be mandatory for medical students and physicians. One way to

convince medical institutions that bioethics is necessary may be to appeal to their bottom line. If having an excellent bioethics program in a medical school and affiliated teaching hospitals can reduce exposure to legal risks, then administrators may begin to view it as more important. Whichever rationale is more persuasive, bioethics education should emerge as a permanent and routine part of medical education. Educators have permission to reprint articles for classroom use; other users, please contact editor actionbioscience. He received a Ph. His previous experience includes appointments at Baylor College of Medicine, University of Houston Law Center, University of Florida College of Medicine, and University of Copenhagen, as well as two years in the private practice of law.

Chapter 2 : Microbiology - Wikipedia

Biotechnology is the use of a living organism, or some component of a living system, to make a useful product. Learn more about modern biotechnology and how it is used in research and biomedical applications.

Indeed, the cultivation of plants may be viewed as the earliest biotechnological enterprise. Agriculture has been theorized to have become the dominant way of producing food since the Neolithic Revolution. Through early biotechnology, the earliest farmers selected and bred the best suited crops, having the highest yields, to produce enough food to support a growing population. As crops and fields became increasingly large and difficult to maintain, it was discovered that specific organisms and their by-products could effectively fertilize , restore nitrogen , and control pests. Throughout the history of agriculture, farmers have inadvertently altered the genetics of their crops through introducing them to new environments and breeding them with other plants â€" one of the first forms of biotechnology. These processes also were included in early fermentation of beer. In brewing , malted grains containing enzymes convert starch from grains into sugar and then adding specific yeasts to produce beer. In this process, carbohydrates in the grains broke down into alcohols, such as ethanol. Later, other cultures produced the process of lactic acid fermentation , which produced other preserved foods, such as soy sauce. Fermentation was also used in this time period to produce leavened bread. Darwin added to that body of work with his scientific observations about the ability of science to change species. In selective breeding, organisms with desirable characteristics are mated to produce offspring with the same characteristics. For example, this technique was used with corn to produce the largest and sweetest crops. In , Chaim Weizmann first used a pure microbiological culture in an industrial process, that of manufacturing corn starch using Clostridium acetobutylicum , to produce acetone , which the United Kingdom desperately needed to manufacture explosives during World War I. In , Alexander Fleming discovered the mold Penicillium. His work led to the purification of the antibiotic compound formed by the mold by Howard Florey, Ernst Boris Chain and Norman Heatley â€" to form what we today know as penicillin. In , penicillin became available for medicinal use to treat bacterial infections in humans. Cohen Stanford significantly advanced the new technology in by transferring genetic material into a bacterium, such that the imported material would be reproduced. The commercial viability of a biotechnology industry was significantly expanded on June 16, , when the United States Supreme Court ruled that a genetically modified microorganism could be patented in the case of Diamond v. Revenue in the industry is expected to grow by This section needs to be updated. Please update this article to reflect recent events or newly available information. The biotechnology sector has allowed the U. By increasing farm productivity, biotechnology boosts biofuel production. For example, one application of biotechnology is the directed use of organisms for the manufacture of organic products examples include beer and milk products. Another example is using naturally present bacteria by the mining industry in bioleaching. Biotechnology is also used to recycle, treat waste, clean up sites contaminated by industrial activities bioremediation , and also to produce biological weapons. A series of derived terms have been coined to identify several branches of biotechnology, for example: Bioinformatics also called "gold biotechnology is an interdisciplinary field that addresses biological problems using computational techniques, and makes the rapid organization as well as analysis of biological data possible. The field may also be referred to as computational biology, and can be defined as, "conceptualizing biology in terms of molecules and then applying informatics techniques to understand and organize the information associated with these molecules, on a large scale. An example would be the selection and domestication of plants via micropropagation. Another example is the designing of transgenic plants to grow under specific environments in the presence or absence of chemicals. One hope is that green biotechnology might produce more environmentally friendly solutions than traditional industrial agriculture. An example of this is the engineering of a plant to express a pesticide , thereby ending the need of external application of pesticides. An example of this would be Bt corn. Whether or not green biotechnology products such as this are ultimately more environmentally friendly is a topic of considerable debate. An example is the designing of an organism to produce a useful chemical. White biotechnology tends to consume less in resources than traditional processes used to produce industrial goods.

This includes biotechnology-based approaches for the control of harmful insects, the characterisation and utilisation of active ingredients or genes of insects for research, or application in agriculture and medicine and various other approaches. One application is the creation of enhanced seeds that resist extreme environmental conditions of arid regions, which is related to the innovation, creation of agriculture techniques and management of resources. Biotechnology has contributed to the discovery and manufacturing of traditional small molecule pharmaceutical drugs as well as drugs that are the product of biotechnology â€" biopharmaceutics. Modern biotechnology can be used to manufacture existing medicines relatively easily and cheaply. The first genetically engineered products were medicines designed to treat human diseases. To cite one example, in Genentech developed synthetic humanized insulin by joining its gene with a plasmid vector inserted into the bacterium Escherichia coli. Insulin, widely used for the treatment of diabetes, was previously extracted from the pancreas of abattoir animals cattle or pigs. The resulting genetically engineered bacterium enabled the production of vast quantities of synthetic human insulin at relatively low cost. The application of biotechnology to basic science for example through the Human Genome Project has also dramatically improved our understanding of biology and as our scientific knowledge of normal and disease biology has increased, our ability to develop new medicines to treat previously untreatable diseases has increased as well. In addition to studying chromosomes to the level of individual genes, genetic testing in a broader sense includes biochemical tests for the possible presence of genetic diseases, or mutant forms of genes associated with increased risk of developing genetic disorders. Genetic testing identifies changes in chromosomes , genes, or proteins. As of several hundred genetic tests were in use. Agriculture[edit] Genetically modified crops "GM crops", or "biotech crops" are plants used in agriculture , the DNA of which has been modified with genetic engineering techniques. In most cases, the main aim is to introduce a new trait that does not occur naturally in the species. Examples in food crops include resistance to certain pests, [36] diseases, [37] stressful environmental conditions, [38] resistance to chemical treatments e. These have been engineered for resistance to pathogens and herbicides and better nutrient profiles. GM livestock have also been experimentally developed; in November none were available on the market, [50] but in the FDA approved the first GM salmon for commercial production and consumption. Industrial[edit] Industrial biotechnology known mainly in Europe as white biotechnology is the application of biotechnology for industrial purposes, including industrial fermentation. It includes the practice of using cells such as micro-organisms , or components of cells like enzymes , to generate industrially useful products in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles and biofuels. By using renewable raw materials to produce a variety of chemicals and fuels, industrial biotechnology is actively advancing towards lowering greenhouse gas emissions and moving away from a petrochemical-based economy. Vallero and others have argued that the difference between beneficial biotechnology e. Regulation of genetic engineering and Regulation of the release of genetic modified organisms The regulation of genetic engineering concerns approaches taken by governments to assess and manage the risks associated with the use of genetic engineering technology, and the development and release of genetically modified organisms GMO , including genetically modified crops and genetically modified fish. There are differences in the regulation of GMOs between countries, with some of the most marked differences occurring between the USA and Europe. For example, a crop not intended for food use is generally not reviewed by authorities responsible for food safety. Depending on the coexistence regulations, incentives for cultivation of GM crops differ. Each successful application is generally funded for five years then must be competitively renewed. Graduate students in turn compete for acceptance into a BTP; if accepted, then stipend, tuition and health insurance support is provided for two or three years during the course of their Ph.

Chapter 3 : Library Resource Finder: Table of Contents for: Comprehensive biotechnology : the princi

biotechnology: v 4 (focus on biotechnology) kindle edition by m hofman, p thonart download it once and read it on your kindle device, pc, phones or tablets use features like bookmarks, note taking and highlighting while reading engineering and.

Supreme Court decided a case involving a software-enabled invention and clarified the analysis the lower courts should use to analyze Section cases. Previously in Mayo, the Court considered a patent that claimed a method of administering a drug based on the measurement of a metabolite of that drug. Referencing prior opinions concerning natural phenomena and natural laws, including the Funk Brothers case discussed in the last installment , the Court then looked at the rest of the claimed subject matter to see if the claims did more than simply apply the law of nature, i. Alice Corporation owned the rights to patents that disclosed a computer-implemented process for mitigating the risk in a transaction that only one party to the transaction would pay or perform using a third-party intermediary. In the patents at issue, a computer was used to act as the third-party intermediary. The Court noted that the practice of using a third-party intermediary in this manner had been in public use for at least a century and the improvement recited in the patent appeared to be implementing this practice on a computer. Supreme Court clarified that the two-part test used in Mayo is the appropriate test to use to analyze Section questions. First, the Court is to determine if the claims are directed to a patent-ineligible concept, such as a law of nature or an abstract idea. Supreme Court concluded that the process of mediating settlement risk using a third party was an abstract idea. Second, the Courts are to determine if the elements of the claims, considered individually and in combination, transform the ineligible concept into patent-eligible subject matter. Supreme Court reviewed the claims and determined that the remaining elements of the claims recited nothing more than a process of implementing the abstract idea on a computer and that was not enough to transform the claimed elements into patent-eligible subject matter. Practitioners have widely criticized the Alice Corp. So, the last word from the U. Supreme Court confirms that if the patent claims recite an existing business practice being implemented on a computer, then the claims are merely directed to an abstract idea and are not patent-eligible under Section In doing so, the Court affirmed the earlier holding in Mayo that claims applying a law of nature using conventional techniques are also not valid under Section Prior cases also leave us with a rule against claiming a naturally occurring product or phenomenon. In the next installment of this article, recent cases from the Federal Circuit discussing Section will be reviewed to demonstrate how the lower courts are applying the Alice Corp. Russell is a native of Wilmington, N. Prior to that, he worked in Chapel Hill and Durham as a research technician on teams exploring RNA-based gene therapies, viral fusion inhibitors, and the role Galactocerebroside plays in protein localization near nodes of Ranvier. After passing the patent bar in and becoming a registered patent agent, Russell received his law degree from Georgetown in He began his legal career representing clients in personal injury matters but later left personal injury to provide patent prosecution services to law firms in China and Taiwan prior to joining The Humphries Law Firm in Russell helps individuals and businesses protect their innovations, creations and business information using strategies based in patent, trademark, copyright and trade secret law. His work includes both strategic planning and dispute resolution. He assists clients who want to buy and sell businesses, and license or transfer their intellectual property assets. Other Posts from Russell Nugent.

Chapter 4 : New Biotechnology - Journal - Elsevier

Biotechnology is the broad area of biology involving living systems and organisms to develop or make products, or "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (UN Convention on Biological Diversity, Art. 2).

It is hoped that the CCFL will continue to meet its objective of protecting consumers while facilitating trade by developing the best labeling policies for harmonization. Membership in Codex is open to all member nations of the United Nations UN and currently countries participate. The Food Standards Program strives to protect consumer health and ensure fair trade practices involving food as demonstrated by the over 4, standards, recommendations, and guidelines that have been accepted to date. The Food Standards Program involves the determination of priorities and provides guidance for the preparation and finalization of standards that are referred to in the World Trade Organization WTO Sanitary and Phytosanitary SPS Agreement, and which are published either as regionalor worldwide standards. Once a Codex standard has been adopted, member countries are encouraged to incorporate it into any relevant domestic rules and legislation. However, under the WTO SPS Agreement, member countries retain the right to unilaterally impose more stringent food safety regulations deemed necessary to ensure domestic consumer protection, provided the different standards are scientifically justifiable and otherwise consistent with WTO SPS rules. The Codex Committee On Food Labeling The Codex Committee on Food Labeling, hosted and chaired by Canada, examines international food-labeling issues; drafts labeling provisions that are applicable to all foods; and endorses labeling provisions prepared by Codex Committees charged with drafting standards, codes of practice, and guidelines. The high controversy generated by many issues before the CCFL demonstrates the importance given by member countries to the development of international labeling standards. The CCFL is considering the major issues around the labeling of biotechnology-derived foods. The principle is to develop a standard that bears the input from all governments. All the meetings discussed below were held in Ottawa, Canada, and were attended by representatives of someof the Codex member countries, international consumer groups, private industries, and by representatives from the Codex Secretariat and observers. The paper identified a number of issues as areas where further elaboration and comments should be sought. During these initial discussions, countries either favored mandatory labeling only for the introduction of any potential health or safety concerns to food products, or advocated that labeling be required under all circumstances. Some countries thought that it was too early to determine particular rules for products obtained through biotechnology and that labeling should be required only when the food or ingredient is significantly different from its traditional equivalent, or if safety concerns are involved, such as in the case of the introduction of an allergen. They reasoned that consumers should be able to make choices based on several considerations, including food origin, production method, agronomic practices, and personal values. Some observers also suggested the public be notified, through labeling, of specific concerns relative to safety, nutrition, and food composition. It was further suggested that these concerns be the subject of scientific evaluation. The European Union EU stated that taking a position on such matters would be premature as member countries were still reviewing their respective situations. Canada indicated that its policy on the labeling of biotechnology-derived foods was still being developed. Noting the lack of consensus, the CCFL agreed to seek guidance from the Codex Executive Committee on how labeling guidelines might be composed. VI , the Executive Committee proposed that foods that are not equivalent to existing non-biotechnology foods with respect to composition, nutritional value, or intended use, should be labeled. The document also contained suggested approaches for addressing allergens. A review comprising these comments was released in February VI were again discussed. The proposal for labeling foods that are non-equivalent to existing foods, based on composition, nutritional value, or intended use, remained intact. This Session provided an opportunity for Codex members to comment as to whether all genetically modified foods, or foods that contain genetically modified material, should be so labeled. This time, progress was made in refining the definition of products obtained through biotechnology and on the mandatory labeling of foods with allergens, with the exception of food products that are non-equivalent compositionally, nutritionally, or in

their intended use. Several European countries, along with India, expressed a preference for the mandatory method of production labeling of all biotechnology-derived foods. Canada, US, Australia, New Zealand, Peru, and Brazil supported the labeling of foods based on safety, composition, intended use, and nutrition, which was consistent with their respective labeling laws. The CCFL agreed to forward to the Commission for adoption at Step 5, the definitions related to biotechnology and the provisions on allergens and to return all other sections of the Proposed Draft Recommendations Codex, a, pars. VII for further consideration. Canada was selected to coordinate and chair the group that comprised representatives from 23 member countries, the European Union, and nine international non-governmental organizations NGOs. The Drafting Group reviewed and revised the texts for the following: The definition of biotechnology-derived foods. The two labeling options being considered by the CCFL. It must be emphasized that the mandate given to the Working Group was to develop more fully the two options in front of the CCFL. The first option requires labeling of products when they are obtained through biotechnology and differ significantly from the corresponding food with regard to composition, nutritional value, or intended use. The second option requires the declaration of the method of production. The establishment of a threshold level in food or in food ingredients for the presence of food or food ingredients obtained through modern biotechnology, below which labeling would not be allowed. The establishment of a minimum threshold level for "adventitious" or accidental inclusion in food or food ingredients, of food or food ingredients obtained through biotechnology. The Working Group was also asked to table a paper on key issues and questions associated with the labeling of these foods. At that meeting, some additional options were developed for consideration during the April , 29th Plenary Session. Two substantive matters were considered with respect to food biotechnology labeling. In the first instance, the Committee agreed to use the definition of "modern biotechnology" adopted by the Cartagena Protocol and moved the definitions to stage eight for decision, which is a critical step. The following terms were agreed upon: Conclusion The GM labeling issue is a good example of the complexity of the Codex process; it also demonstrates how narrow technical issues, once only of interest to specialists, have become public policy issues of huge economic importance, imbued with differing social, cultural, and political values. Standard setting and dispute resolution are particularly difficult where science is relevant but not determinative, and where an international standard will clearly create economic winners and losers. The current debate within Codex concerning labeling of foods derived from biotechnology is clearly indicative of how biotechnology is perceived from country to country. The Codex process for standards development is based on reaching international consensus. Building upon its past accomplishments in developing labeling standards for other food products, it is hopeful that the CCFL will continue to meet its objectiveâ€”to protect the consumer and facilitate trade by developing the best labeling policies for harmonization. Endnotes 1 There are 8 steps taken in the setting of Codex standards Codex, c, pp. These steps are as follows, The Commission decides to elaborate a Standard and assigns the work to a Committee. A decision to elaborate a Standard may also be taken by a Committee. The Proposed Draft Standard is sent to governments and international organizations for comment. The Secretariat forwards comments to the Committee. The Draft Standard is then sent back to governments and international organizations for comment. The Draft Standard is returned to the Commission for adoption as a Codex Standard to be sent to governments for final acceptance. References Codex Alimentarius Commission Codex. Available on the World Wide Web: Codex Alimentarius Commission Codex. Procedural manual 10th ed. The process of developing labeling standards for GM foods in the Codex Alimentarius. AgBioForum, 3 4 ,

Chapter 5 : PubMed Journals will be shut down | NCBI Insights

Biotechnology is a multidisciplinary field which deals with the practical use of microbial, plant or animal cells to produce goods or perform services for industry, trade and commerce.

Chapter 6 : Biotechnology | Biology | Science | Khan Academy

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