Abstracts of Note: The Bioethics Literature

This section is meant to be a mutual effort. If you find an article you think should be abstracted in this section, do not be bashful—submit it for consideration to feature editor Kenneth V. Iserson care of *CQ*. If you do not like the editorial comments, this will give you an opportunity to respond in the letters section. Your input is desired and anticipated.

Kurosu M, Mukai T, Ohno Y. Regulations and guidelines on handling human materials obtained from medico-legal autopsy for use in research. *Legal Medicine* 2003; 5(Suppl 10):S76–83.

For many decades, Japanese researchers have used human materials obtained from medicolegal autopsies, usually without consent from surviving relatives. In recent years, informed consent has become a key principle of Japanese medical practice, as has an increased emphasis on patient privacy. With that in mind, these authors investigated the country's regulations and guidelines regarding the research use of human materials obtained from medicolegal autopsies. The Autopsy Law, enacted in 1949, has no provisions covering the use of human materials in research, although it permits the preservation of such materials as specimens for medical education or research. The Ethics Guidelines for Human Genome/Genetic Analysis Research, enacted in 2001, allows the use of such materials provided that (1) the decedent had no intention of refusing organ donation during life, (2) surviving relatives consent, (3) the ethics review committee approves, and (4) the director of the researcher's institution gives permission. The 2002 guidelines of the Ethics Committee of the Japanese Society of Legal Medicine make obtaining consent from surviving relatives a fundamental part of the process. However, an alternative method is obtaining approval from the institutional or academic society's ethics committee. The authors conclude that *since Japan has no domestic law governing the research use of human materials obtained from autopsies, new legislation on this issue should be enacted, as soon as possible, to protect human rights and dignity and to promote medical research.*

Liberati A. Research Ethics Committees: Can they contribute to the improvement of clinical research in Europe? *Journal of Ambulatory Care Management* 2004;27(2):154–65.

Dr. Liberati, from the Centro Valutazione Efficacia Assistenza Sanitaria (CeVEAS), Modena, Italy, believes that *there is an increasing crisis of credibility in clinical and epidemiological research—especially throughout Europe. This stems from a lack of transparency in identifying research priorities, the increasing dominance of commercial interests over patients' problems, diminishing funds available for independent research, and a lack of awareness that clinical research is integral to the duties of clinicians as patients' agents.* Research Ethics Committees (RECs) are an important component of the research community, and they are expected to be able to protect patients and improve clinico-epidemiological research. Many people, however, still believe that RECs' primary tasks are to safeguard the ethical and informed consent issues related to research protocols, rather than assessing research projects' scientific and clinical importance and validity. Others argue that RECs' duties should expand to include assessing study validity, with the feeling that scientifically invalid research is in itself unethical. They believe that RECs should embrace a full range of issues, from assessment of the core content of research (objectives, non-redundancy, clinical relevance, and likelihood of reaching the stated goals) to the protection of publication and dissemination rights of researchers from the intrusiveness of commercial sponsors. This debate is further complicated in countries where RECs' decentralization has made their operation less homogeneous and reproducible, causing widespread discontent about their processes and outcomes. To bolster his argument for expanded and uniform REC mandates, Liberati describes the main differences in the functioning of RECs across Europe, and then discusses the new European Directive on Clinical Trials and its potential problematic impact

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on publicly funded trials. He then suggests a series of actions to improve RECs' functioning and outlines the cultural changes necessary for research of better methodological quality and of greater relevance to patients.

Keim SM, Mays MZ, Grant D. Interactions between emergency medicine programs and the pharmaceutical industry. *Academic Emergency Medicine* 2004;11(1): 19–26.

These authors examined the beliefs and practices of emergency medicine program directors regarding interactions with the pharmaceutical industry. They also sought to study the prevalence of program policies and the desire for organizational policies concerning such interactions by using a Web-based, 30-item survey. Specifically, they asked emergency medicine program directors about their beliefs and practices regarding industry sponsorship of speakers, social events, drug samples, and travel to conferences, as well as the educational value of marketing representatives. They also asked about respondents' awareness of existing guidelines and whether they desired additional regulatory policies governing interactions with the pharmaceutical industry. Of the 85% of all program directors that responded, most (72%) said that they "never" or "very rarely" allowed unrestricted interactions between pharmaceutical representatives and residents at work. However, only 52% of these respondents said they "never" or "very rarely" allowed pharmaceutical representatives to give residents free drug samples at work. Only 46% said they "never" or "very rarely" allowed pharmaceutical representatives to teach residents. Of note, two thirds of the respondents desired additional guidelines regarding interactions with the pharmaceutical industry, although they were the ones less likely to allow pharmaceutical representatives to teach residents ($p = 0.001$) or to allow pharmaceutical representatives unrestricted interactions with residents ($p = 0.05$). It seems that *most medical educators, at least within this specialty, recognize the problems inherent in abandoning the fiduciary relationship physicians have with their patients and desire more guidelines to help them to maintain an arms-length relationship with industry.*

Huston P. What does the public think of placebo use? The Canadian experience. *Science & Engineering Ethics* 2004;10(1):103–17.

Canada's National Placebo Initiative included national public consultations in 2003, based on the belief that the views of the public should inform Canadian policy development on what constitutes appropriate placebo use. The interview formats were designed to facilitate the consideration of complex issues and build consensus. The placebo debate was characterized as having three distinct approaches and each were explored. The first approach, "Maximize Patient Protection," identified the need for experts to determine appropriate placebo use and that placebos should only be allowed under very restricted conditions. The second approach, "Maximize Medical Knowledge," identified that placebos give essential information about the safety and efficacy of new drugs and are appropriate when researchers ensure the rights, safety, and well-being of research participants. The third approach, "Maximize Patient Autonomy," found that the current system of regulating placebo use is paternalistic and suggested that patients should be able to define what is in their best interests and have more leeway to determine for themselves whether they wish to participate in a placebo-controlled trial. Advantages and disadvantages of each approach were considered and feedback on what constitutes appropriate placebo use was sought. The major findings were that (1) *Canadians believe that although placebo-controlled trials are a valuable and acceptable part of advancing medical knowledge, research using placebos must be valid and justifiable*. (2) Researchers need to foster a patient-centered approach to these trials. (3) Patient autonomy (choice) should be a first consideration and take clear precedence in trials of low to medium risk. (4) Patient protection (or health) may need to "trump" patient autonomy at higher levels of risk or patient vulnerability. (5) Placebos are not a violation of the duty of care, as duty of care is best met by identifying a choice for patients, whenever a choice is available. These consultations clearly were not designed to produce conclusive evidence, but rather to provide some useful insights into what the public may think about placebo use; additional studies are indicated.

Taylor SD. Predictive genetic test decisions for Huntington's disease: Context, appraisal and new moral imperatives. *Social Science & Medicine* 2004;58(1):137–49.

Predictive testing is one of the new genetic technologies, which, in conjunction with developing fields such as pharmacogenomics, promises many benefits for preventive and population health. Understanding how individuals appraise and make genetic test decisions is increasingly relevant as the technology expands. "Lay" understandings of genetic risk and test decisionmaking may be influenced by individuals' family relationships, and may have varying impact, depending on the nature of the disease. The predictive test for Huntington's disease (HD), a serious, mature-onset, untreatable disorder, is regarded as a model for such testing. This paper reports on a qualitative Australian study that investigated predictive test decisionmaking by individuals at risk for HD, the contexts of their decisions and the appraisals that underpinned them. In-depth interviews were conducted in Australia with 16 individuals at 50% risk for HD, with variation across testing decisions, gender, age, and selected characteristics. Findings suggested *predictive testing was regarded as a significant life decision with important implications for self and others, and the right "not to know" genetic status was staunchly and unanimously defended*. Multiple contexts of reference were identified within which test decisions were located, including intra- and interpersonal frameworks, family history and experience of HD, and temporality. Participants used two main criteria in appraising test options: perceived value of or need for the test information for self or significant others and degree to which such information could be tolerated and managed, short- and long-term, by self and others. The author also discusses some of the moral and ethical considerations involved in these decisions, patient and family psychosocial vulnerabilities caused by the availability of genetic tests, and the clinical and sociopolitical contexts in which predictive testing is located.