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.

Iserson KV, Heine CE, Larkin GL, Moskop JC, Baruch J, Aswegan AL. Fight or flight: The ethics of emergency physician disaster response. *Annals of Emergency Medicine* 2008;51(4):345–53.

Most disaster plans depend on using emergency physicians, nurses, emergency department support staff, and out-of-hospital personnel to maintain the healthcare system's front line during crises that involve personal risk to themselves or their families. Planners automatically assume that emergency healthcare workers will respond. However, the authors believe that we need to ask: Should they, and will they, work rather than flee? The answer involves basic moral and personal issues. This article identifies and examines the factors that influence healthcare workers' decisions in these situations. After reviewing physicians' response to past disasters and epidemics, the authors evaluate how much danger they actually faced. Next, they examine guidelines from medical professional organizations about physicians' duty to provide care despite personal risks, although acknowledging that individuals will interpret and apply professional expectations and norms according to their own situation and values. The article goes on to articulate moral arguments for a duty to treat during disasters and social crises, as well as moral reasons that may limit or override such a duty. How fear influences behavior is examined, as are the institutional and social measures that can be taken to control fear and to encourage health professionals to provide treatment in crisis situations. Finally, the article emphasizes the importance of effective risk communication in enabling healthcare professionals and the public to make informed and defensible decisions during disasters. The authors conclude that *the decision to stay or to leave will ultimately depend on individuals' risk assessment and their value systems. Preparations for the next pandemic or disaster should include policies that encourage emergency physicians, who are inevitably among those at highest risk, to "stay and fight." Educational videos associated with this article discussing scarce resource allocation can be found at* www.crestaznm.org *(English and Spanish versions)*.

Bailey DB Jr, Skinner D, Davis AM. Ethical, legal, and social concerns about expanded newborn screening: Fragile X syndrome as a prototype for emerging issues. *Pediatrics* 2008;121(3):e693–704.

Bioethics, to be relevant, must be proactive. This means looking ahead to what will happen as well as reacting to what has already occurred. Technology soon will make it possible to screen for fragile X syndrome and other conditions that do not meet current guidelines for routine newborn screening. In this extensive review, these authors suggest that this touches on at least eight broad ethical, legal, and social concerns: (1) Early identification of fragile X syndrome, an "untreatable" condition, could lead to heightened anxiety about parenting, oversensitivity to development, alterations in parenting, or disrupted bonding; (2) because fragile X syndrome screening should be voluntary, informed consent could overwhelm parents with information, significantly burden hospitals, and reduce participation in the core screening program; (3) screening will identify some children who are or appear to be phenotypically normal; (4) screening might identify children with other conditions not originally targeted for screening; (5) screening could overwhelm an already limited capacity for genetic counseling and comprehensive care; (6) screening for fragile X syndrome, especially if carrier status is disclosed, increases the likelihood of negative

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self-concept, societal stigmatization, and insurance or employment discrimination; (7) screening will suggest risk in extended family members, raising ethical and legal issues (because they never consented to screening) and creating a communication burden for parents or expanding the scope of physician responsibility; and (8) screening for fragile X syndrome could heighten discrepancies in how men and women experience genetic risk or decide about testing. To address these concerns *they recommend the development of a national newborn screening research network, the development of models for informed decision-making, materials and approaches for helping families understand genetic information and for communicating it to others, and a national forum to address carrier testing and the disclosure of secondary or incidental findings. They also encourage scientists, policy makers, ethicists, practitioners, and other citizens to discuss the desired aims of newborn screening and the characteristics of a system needed to achieve those aims.*

Food and Drug Administration, HHS. Human subject protection; foreign clinical studies not conducted under an investigational new drug application. Final rule. *Federal Register* 2008;73(82):22800–16.

The U.S. Food and Drug Administration (FDA) announced that it is amending its regulations on the acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) (non-IND foreign clinical studies) as support for an IND or an application for marketing approval for a drug or biological product. *The final rule replaces the requirement that these studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki (Declaration) issued by the World Medical Association*, specifically the 1989 version (1989 Declaration), with its requirement that the studies be conducted in accordance with good clinical practice, including review and approval by an independent ethics committee. The final rule updates the standards for the acceptance of foreign clinical studies not conducted under an IND and ''helps ensure the protection of human subjects and the quality and integrity of data obtained from these studies.'' The FDA has had sufficient problems with approving safe medications under the old system. One must wonder where the pressure came from to make this change. We will see what happens now.

Pearce N. Corporate influences on epidemiology. *International Journal of Epidemiology* 2008;37(1):46–53. (A predictable response from the industry about this article is found in *International Journal of Epidemiology* 2008; 37(1)53–9; Dr. Pearce's rebuttal is on pages 65–8.)

When billions of dollars are at stake, kudos should go to the author of this article who bravely (foolishly?) sheds some light on how the medical–industrial giants have corrupted vital epidemiological information. He writes that corporate influences on epidemiology have become stronger and more pervasive in the last few decades, particularly in the contentious fields of pharmacoepidemiology and occupational epidemiology. *For every independent epidemiologist studying the side effects of medicines and the hazardous effects of industrial chemicals, there are several other epidemiologists hired by industry to attack the research and to debunk it as ''junk science.''* Sometimes these activities have gone as far as mounting efforts to block publication. Many academics have accepted industry funding that has not been acknowledged; rather, only the academic affiliations of the company-funded consultants have been listed. These activities are major threats to the integrity of the field and to epidemiology's survival as a scientific discipline. There is no simple solution to these problems. However, for the last two decades there has been substantial discussion on ethics in epidemiology, partly in response to the unethical conduct of many industry-funded consultants. Professional organizations, such as the International Epidemiological Association, can play a major role in encouraging and supporting epidemiologists to assert positive principles of how science should work and of how it should be applied to public policy decisions, rather than simply having a list of what not to do.

Coleman DL. The legal ethics of pediatric research. *Duke Law Journal* 2007;57(3):517–624.

Since the mid- to late 1990s, the scientific and medical research community has sought to increase its access to healthy children for research protocols that involve harm or a risk of harm. This move reverses long-standing policy within that community generally to exclude healthy children from such protocols on the grounds that the research as to them is nontherapeutic, that

they are particularly vulnerable to research-related abuses, and that they are unable themselves to give informed consent to their participation. The research community's new posture has been supported by prominent pediatric bioethicists who have argued that unless healthy children are included as research subjects in harmful or risky research, the pediatric population will continue to suffer relative to the adult population in the extent to which it benefits from modern advances in science and medicine. In their view, it is possible for the research community to self-administer a rule that strikes a balance between protecting healthy children from research-related abuses and allowing their inclusion in cutting-edge pediatric research. In this scheme, parental consent is central to the research community's claims about child protection. This author explores what she sees as the flaws inherent in this ethics of pediatric research. Specifically, she challenges the view from ethical view that the law permits parents to consent to their children's inclusion in harmful or risky research, including actions that meet legal maltreatment standards. More broadly, this article challenges the movement to increase access to healthy children for harmful and risky research on the ground that it represents two important regressions: First, in its willingness to risk harm to individual children in the interests of the group, it threatens the progress the law has made in its development of the concept of the child as an individual worthy of respect in his or her own right, a concept that imagines parents as fiduciaries and that includes strong protections against invasions of bodily integrity. Second, in its failure to assure that the burdens of nontherapeutic research are not placed disproportionately on children of lower socioeconomic and minority status, it violates the antidiscrimination principle, which has only just begun to make good on its promise of equal treatment for all children. *Ultimately, this author argues that harmonization of the rules governing pediatric research with the law of child protection and parents' consent authority is the best way to assure that children are protected in the research setting in these respects and to the same extent they are otherwise in the society.*