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.

Tattersall MH, Dimoska A, Gan K. Patients expect transparency in doctors' relationships with the pharmaceutical industry. *Medical Journal of Australia* 2009; 190(2):65–8.

Doctors frequently interact with the pharmaceutical industry. Contacts with industry influence doctors' decisionmaking and prescribing practices. Though research has shown that such interactions undermine public trust in the profession, little is known about patients' views on doctor–industry affiliations. The study investigated patients' knowledge of and attitudes toward family doctors' relationships with industry and their wishes for disclosure of this information. Nine hundred six patients attending three general practices in Sydney during October–November 2007 completed an anonymous, confidential survey. The survey contained demographic questions and 18 statement-type items exploring patients' awareness of doctors' competing interests, what types of benefits they wanted to know about, their views on disclosure, and the effects disclosure might have on their decisionmaking and confidence in providers. Of 1,129 patients approached, 906 completed the survey (80% response rate). Most patients (76%) were not aware of any competing interests their doctors may have with drug companies. The majority of patients wanted to know if their doctors received any benefits in cash or kind (71%), financial incentives for research participation (69%), or sponsorship to attend conferences (61%). Eighty-one percent of patients were not aware of any benefits their doctors might obtain for prescribing a particular drug, and an average of 79% of patients wished to know about any such treatment-related incentives. Forty-nine percent of patients did not believe their doctors were unduly influenced by receiving perks from industry, 27% thought doctors were influenced by such incentives, and 24% of patients were uncertain. Patients who spoke languages other than English were less likely to report undue influence by industry incentives. Most patients (84%) indicated that disclosure of competing interests by doctors is important, and 78% thought that such disclosures would help patients make better-informed treatment decisions. Eighty percent of patients reported that they would have more confidence in their doctors' treatment decisions if competing interests were revealed, and 78% of patients supported verbal disclosure during visits. *Improved disclosure of doctors' interactions with the pharmaceutical industry may help patients make better-informed treatment decisions and increase patient confidence in doctors' decisions.*

Vogeli C, Koski G, Campbell EG. Policies and management of conflicts of interest within medical research Institutional Review Boards: Results of a national study. *Academic Medicine* 2009;84(4):488–94.

Though there has been a large amount of popular and academic literature regarding the relationship between industry and the production and publication of research in the United States for the last decade, there is much less information about another vital player in development of research and research protocols: the Institutional Review Board (IRB). Much of the debate regarding industry's influence has translated into significant reform at many academic medical centers throughout the country. And despite the publication of new recommendations (from the Association of American Medical Colleges and the Association of America Universities) regarding routine reporting of financial interests from all IRB members and policies for reporting conflicts of interest (COI) among IRB members (there are no federal policies or procedures regarding these types of disclosures currently), no significant investigation has

Cambridge Quarterly of Healthcare Ethics (2010), **19**, 154–156.

doi:10.1017/S0963180109990363

been previously undertaken to determine if these guidelines have been incorporated and utilized by many of the major medical institutions across the country. This study attempts to partially remedy this situation by investigating current practices among IRBs at various institutions, both academic and private.

This study surveyed IRB chairs from the institutions representing medical schools and independent hospitals receiving the most funding from the National Institutes of Health in 2003. The completely anonymous survey (developed as a tool for this specific study) was mailed out in fall 2005, with a total of 316 IRB chairs included in the final sample. Of these, 211 responded, though 36 were excluded because they were no longer serving as chairmen of their IRB, and 58 ''alternative chairmen'' were excluded to avoid duplicative responses, leaving 107 active chairmen whose data were analyzed. From the data received, some interesting trends emerged. First, though three fourths (74.5%) of the IRB chairs indicated their institution has a policy regarding IRB member disclosure of financial and other industry relationships and two thirds (66.0%) of those chairs reported voting members were required to disclose relationships with industry, about one quarter (25.5%) of respondents indicated there were no such policies in place at their institutions. Additionally, 62.1% of respondents said IRB members with industry ties reported these relationships to the IRB chairs, whereas 75.9% made these disclosures to the entire IRB. Interestingly, though 68.2% of IRB chairs indicated their institutions have a written policy (and of those, 90.3% felt the written policy was either ''very clear'' or ''clear enough'') for defining COIs, almost one third (31.7%) do not know if there is a policy or have no defined policy for COIs.

This study illustrates a high degree of variability across academic medical centers regarding their IRB membership and the requirements of those individuals sitting on these important committees. The authors of this work also point out that ''failure to address the issues raised could call into question the ability of medical school IRB's to appropriately manage their members' industry relationships and appropriately identify COI's,'' possibly leading to ''confusing inconsistencies and their potentially damaging consequences.''

Romano ME, Wahlander SB, Lang BH, Li G, Prager KM. Mandatory ethics consultation policy. *Mayo Clinic Proceedings* 200984(7): 581–5.

Voluntary ethics consultations have traditionally been used to avoid the appearance that they are legal proceedings. Although mandatory ethics consultations have long been discussed, they have rarely been employed. *New York state law and the healthcare lawyers who interpret it for institutions have pushed mandatory ethics consultations into reality, requiring that a patient who lacks decisionmaking capacity may only have life support removed if he or she has a written advance directive, a legal healthcare proxy, or prior ''clear and convincing'' evidence that the patient requested such an action.* This law has generated an enormous increase in ethics consultations–100% over 7 years–which is the only positive statement that these authors can make about the law–or their subsequent consultations.

This paper describes the results of 168 adult ethics consultations in the Columbia University Medical Center's intensive care unit during a single year. Because the hospital's protocol requires an ethics consultation in any case involving withholding or withdrawing life support, 64% of the consults were mandatory. Usually, only one consultant was involved in each of these cases.

It is unclear how useful these consultations were, what ethics background consultants other than their director have, how substantive the quality control is over these consultations, or how these results apply to ethics consultation systems in other institutions. Also troubling is the lack of description of how to deal with cases involving ''legal–ethical interface'' (7% of cases) or ''spiritual–cultural issues'' (2% of cases). This paper raises more questions than it provides answers to, but the questions should stimulate significant discussion among those involved in clinical ethics.

Barnett DJ, Taylor HA, Hodge JG, Links JM. Resource allocation on the frontlines of public health preparedness and response: Report of a summit on legal and ethical issues. *Public Health Reports* 2009;124:295–303.

Public health leaders confronted with a range of disasters from weather, epidemics, and terrorism need legal and ethical principles to assist them in making decisions about scarce resources. In addressing

these public health emergencies, public health leaders must emphasize a balance between individual and communal considerations. Legal flexibility during public health emergencies is crucial. Laws in various jurisdictions are being reformed to achieve greater flexibility guided by the Model State Emergency Health Powers Act and other legal tools. However, this flexibility can lead to confusion and could potentially inhibit public health interventions. Several existing ethical theories regarding resource allocations provide a framework for decisionmaking. Unfortunately, theories such as Emanuel and Wertheimer's ''lifecycle'' principle, which states that ''each person should have an opportunity to live through all the stages of life,'' and Kinlaw and Levin's social worth assessment may result in contradictory determinations.

To date there has been little effort expended to develop general legal and ethical principles that could guide decisionmaking during disasters. To address this need, the authors put in place a summit planning team consisting of faculty and staff from the Johns Hopkins Center for Public Health Preparedness, the Johns Hopkins Berman Institute of Bioethics, and the Centers for Law and the Public's Health at Johns Hopkins and Georgetown Universities. A series of planning meetings resulted in the selection of 20 participants and eight observers. Almost half (45%) of the participants were from academia and the rest were from nonacademic leadership, policy, and practice settings. In advance of the summit participants were provided a series of relevant legal and ethical articles to review. During the summit there were two brief presentations on legal and ethical principles of resource allocation in emergencies followed by a ''tabletop scenario'' entitled ''Trouble in River City.'' At the conclusion of the exercise a draft list of 34 principles was produced. The results could be conceptualized as substantive and procedural as follows, ''Substantive principles supported by Summit participants included that allocation decisions should be (*1*) driven and supported by good data, (*2*) nondiscriminatory and sensitive to the needs of vulnerable populations, and (*3*) revisable. Procedural principles included the need for (*1*) transparency to all stakeholders, (*2*) public participation to the greatest extent possible, and (*3*) accountability.'' The authors ultimately analyzed the data and produced 10 principles to legally and ethically guide management of scarce resources in public health emergencies. The 10 summit-derived principles were distributed among three categories: (1) obligations to community, (2) balancing personal autonomy and community well-being/benefit, and (3) good preparedness practice. Each of the 10 principles is listed in the paper with narrative summaries describing them in greater detail. *Although the varying nature of public health emergencies cannot be addressed by a rigid set of guidelines, the authors contend that an established list of principles based on ethical and legal considerations to determine allocation decisions involving scarce resources in public health emergencies may serve as a useful framework and launching point for future research into this critical subject.*

These Abstracts of Note were compiled by
Aimee Kaempf, Steven Herron, Kenneth Iserson, Chelsea Shih, and Barry Morenz.