

CONTENTS

Page

Articles

| | | |
|---|------------------------|---|
| RATIONALIZING RISK ASSESSMENT IN HUMAN SUBJECT RESEARCH..... | <i>Carl H. Coleman</i> | 1 |
|---|------------------------|---|

Our system of protecting human subjects in medical research faces an unprecedented crisis. In addition to a few highly publicized scandals in which previously healthy individuals died during the course of clinical trials, a series of government investigations has documented widespread deficiencies in the system's capacity to ensure compliance with federal regulations governing human subject protection. There is widespread consensus that any effective reform program must do something to improve the existing system of institutional review boards ("IRBs"), the committees within research institutions that decide which protocols can go forward and under what conditions. However, most of the current discussion about IRB reform has focused on questions about the basic structure of the IRB system, ignoring important process-oriented questions about how IRBs actually decide which protocols to accept, reject, or revise. To fill this gap, Professor Coleman takes a critical look at the process IRBs use to review research protocols, focusing specifically on risk assessment, one of the most important, and least understood, elements of protocol review. He argues that IRBs' current approach to risk assessment closely mirrors the deliberative process used by common law juries, and that in both juries and IRBs this process suffers from considerable flaws. After examining the limitations of a jury approach to risk assessment determinations, Professor Coleman explains why our willingness to tolerate these limitations in the context of jury deliberations does not mean they also should be accepted in IRB review. He argues that, in place of the ill-fitting model of the common law jury, IRBs should incorporate decision-making mechanisms used by judges and administrative agencies, including reasoning by analogy, written opinions, appellate review and precedent, and notice-and-comment rulemaking. He shows how adopting these strategies could improve the quality of IRB risk assessments, and examines the practical considerations such changes are likely to raise.

| | | |
|--|--------------------------|----|
| ENRON, PENSION POLICY, AND SOCIAL SECURITY PRIVATIZATION..... | <i>Richard L. Kaplan</i> | 53 |
|--|--------------------------|----|

This Article analyzes current U.S. pension law and policy in light of the Enron implosion and considers the implications of this analysis for privatizing Social Security. The Article begins by addressing the

major shift in retirement funding risk from professionally managed plans to ordinary workers, beginning with the substitution of defined contribution plans for defined benefit plans, and continuing with the growing predominance of 401(k) plans. The Article then examines the central problem of the Enron catastrophe: the heavy concentration of 401(k) plans in employer stock. From this context, the Article then considers the essential premise of Social Security privatization—namely, that individuals should control their own retirement assets. The Article concludes with policy recommendations based on this analysis to prevent the sort of financial devastation that Enron (and others) has brought.

| | | |
|---|-----------------------------|----|
| POSTMORTEM CONCEPTION AND A FATHER'S LAST WILL | <i>Kristine S. Knaplund</i> | 91 |
|---|-----------------------------|----|

In the past decade, thousands of men have frozen their sperm for their own use in case surgery, exposure to chemicals or biological hazards, or various injuries cause them to have difficulty conceiving later. If the man dies and his widow or partner uses his frozen sperm to conceive a child, what legal issues are posed for construing the man's will? If the will leaves a devise to the testator's "children," should we hold his estate open for years in case a child is later born? If the will makes no mention of the testator's children, should a postmortem child inherit as a pretermitted heir? The increasing number of requests to obtain frozen sperm after men have died, plus at least eleven claims filed with the Social Security Administration on behalf of children born years after their fathers' deaths using frozen sperm, indicate that the phenomenon of postmortem children is real. Four recent court cases have grappled with the issue of whether a child conceived postmortem can inherit in intestacy, but so far no court has dealt with the problem of construing the dead father's will. This Article proposes a new framework for resolving these disputes, using common law concepts dating back to ancient Egypt, Greece and Rome to try to resolve the issue without legislation.

Notes

| | | |
|--|-----------------------|-----|
| EMPLOYMENT REFERENCES: SHOULD EMPLOYERS HAVE AN AFFIRMATIVE DUTY TO REPORT EMPLOYEE MISCONDUCT TO INQUIRING PROSPECTIVE EMPLOYERS? | <i>John Ashby</i> | 117 |
| <i>ZELMAN, DAVEY, AND THE CASE FOR MANDATORY GOVERNMENT FUNDING FOR RELIGIOUS EDUCATION.....</i> | <i>Joshua Edelman</i> | 151 |

Arizona Case Notes

| | | |
|--|------------------------|-----|
| <i>GUNNELL V. ARIZONA PUBLIC SERVICE COMPANY</i> | <i>J. Blake Mayes</i> | 179 |
| <i>MAY V. MCNALLY</i> | <i>Candice Pitcher</i> | 185 |