The influence of the pharmaceutical industry on the off-label use of its medicines

Last year I described in this journal an unacceptable influence of a pharmaceutical company on the off-label use of one of its products. Now I would like to report on an acceptable and even praiseworthy initiative of a pharmaceutical manufacturer in monitoring the use of its drug. The devastating action of thalidomide on the human embryo caused its withdrawal from the market in the early 1960s. This teratogenic drug began, however, to be used again when it was found that it had a favourable effect on patients suffering from various diseases.1 One of the companies producing this drug was aware that it had a moral responsibility to prevent (accidental) abuse of its product. The scientists of this company have developed a number of criteria: STEPS, that is, a System for Thalidomide Education and Prescribing which includes a registry of all treated patients (under a code number). The authors show that they are aware of possible mishaps when they write: “Despite all the checks and balances in the STEPS programme, the system will work only if it makes intuitive sense to its participants and they adhere to program requirements.” An even more stringent attitude is taken by Bouvaros and Mueller when they write: “Given the ethical complexities of thalidomide use, we recommend that individuals planning to prescribe thalidomide consult with their hospital’s institutional review board and develop their own formal protocols, independent of the consent provided by the manufacturing company. Such a consent should include information about the efficacy in the condition being studied and review adverse effects of sedation, constipation, erythroderma, neuropathy, and teratogenicity.” Strangely enough none of the authors appear to have reserved a task for the governmental safety evaluation agencies. In my opinion they should be kept informed of all clinical trials with off-label administered drugs. These administrative authorities should be allowed to intervene, if necessary at all stages of the treatment.

Comment on: the influence of the pharmaceutical industry on the off-label use of its medicines

Gebhardt draws attention to an important issue. The responsibility for informing and warning patients about adverse effects and how to prevent them, or to recognise them early and minimise harm, is shared between the manufacturer, the national regulatory agency, the prescriber, and the pharmacist. The first two must ensure that prescribers and pharmacists are adequately equipped and helped to do their part. Any printed information needs to be tested on a sample of actual patients to demonstrate that over 90% can actually understand and use it. Beyond that, doctors and pharmacist, involved in the design and manufacture of thalidomide, have to be most-vated and helped to check (and document in their records) how well the individual patient has understood the problems and the information.

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References
1 Gebhardt DOE. Misoprostol in a topsy turvy world. Journal of Medical Ethics 2001;27:205
5 Zeidis J, Williams BA, Thomas SD. STEPS; a comprehensive program for controlling and monitoring access to Thalidomide. Clinical Therapeutics 1999;21:319–30

BOOK REVIEWS

Voluntary Euthanasia and the Common Law


At first sight, this might not seem like the sort of book in which an ethicist would be interested. Such fears are compounded when one reads in the introduction that the book is “primarily a legal analysis” of the issues (page 4). It is liberally sprinkled with footnotes, mainly legal in nature and surely we do not need another book about euthanasia? But we do, and this book is not only one ethicists can read, it is also one they should read. Oltowski argues that any examination of this subject matter necessarily involves “consideration of wider issues, including social change, as reflected in opinion polls and community agitation for reform, the practice and attitudes of the medical profession, as well as consideration of religious, moral, and ethical arguments” (page 4); and this is what the book provides. Thus, it is much more than a legal analysis, though everything in the book flows from this.

The main thesis presented is that the law does not in practice reflect or enforce the reality of doctor-patient contacts at the end of life. Rather, there exist “discrepancies” (page 128) between the theory and the practice of law, and an inherent “hypocrisy” (page 150) in what the law actually does when confronted with such cases. Oltowski argues that in practice criminalising voluntary euthanasia is counterproductive. She highlights two possible effects: first, medical decisions may not in practice be susceptible to evaluation by the courts, leading to a lack of regulation; and, second “there is a real risk of abuse if the law condones what is an unregulated practice” (page 151). The process through which these effects come about is simple, Oltowski claims. She shows how in selected countries, whilst voluntary euthanasia is illegal (this is the theory), there is evidence of an empirical nature that doctors are, in fact, helping their patients to die. Furthermore, the law, via such “legal fictions” and “unworkable distinctions” as those between “acts/omissions” and “killing/letting die”, is complicit in the deception. What is left, she argues, is a regulatory vacuum. Oltowski argues that there appears to be little interest in the law’s strict enforcement, the “most significant point to emerge from the . . . analysis is the scarcity of cases involving the prosecution of doctors . . .. This contrasts markedly with the available information regarding doctors’ practices” (page 147). This is of course not only a matter for the law, for if, as Oltowski claims, voluntary euthanasia is practised this raises important ethical questions.

The book continues by considering not only options for reform, but also the desire for it. We are treated to the results of opinion polls in various countries throughout the world, a “case study” of the Dutch experience, and more insight into the distinction between the theoretical and the real. It is here that the book is at its best, and of most help to ethicists; for what Oltowski attempts is to tear us away from the doctrinal and hypothetical, and push us towards an acceptance of reality. She mourns the repeal of the Rights of the Terminally Ill Act 1995 in the Northern Territory of Australia, as legalisation allows us the opportunity to “examine, over time, the impact of laws governing active voluntary euthanasia” (page xxv). Thus the message for
ethics is this: do not be bogged down in dogma; for that is how we arrive at the situation we are in now. Rather, our ethical response should be shaped by the reality of what works, so crossing the Rubicon from the hypothetical to the practical.

**J Miola**

**Primer for Health Care Ethics: Essays for a Pluralistic Society, 2nd edn.**


This is a thoroughly revised and expanded edition of a book originally published in 1994. It consists of a series of clear and thoughtful short essays, grounded in real cases in health care ethics. The range of coverage is extensive—from informed consent, through abortion, to assisted suicide, and many other issues, to early delivery of anencephalic infants. The decisions are often controversial, for example, in the United States implications of individuals' views, and in general lay out the ethical issues and the various options fairly rather than being strongly direct, partisan, or one-sided.

The book aims to say about the philosophical and theological underpinning of bioethics; one must turn elsewhere for that. The book and all the authors adopt a mainstream Roman Catholic stance. They rely on reason and nature in as much as they are human beings, and in the belief that the moral status of a human being rather than a potential human being. There are numerous impressive examples of the vigour and coherency of discussions within that tradition of bioethics; one must turn elsewhere for that.

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**D B Forrester**

**Death and Compassion: A Virtue-Based Approach to Euthanasia**

L van Zyl, Ashgate, 2000, £40.00 (hb), pp 230. ISBN 0-7546-1231-7

Can virtue ethics tell us what to do? And has principism had its day? These are two of the central questions concerning the care of the dying and death from undiagnosed Creutzfeldt-Jakob Disease; the problems for parents raising triplets; issues arising from incontinence, then referred to as the term of the moral status of a human being rather than a potential human being. There are numerous impressive examples of the vigour and coherency of discussions within that tradition of bioethics; one must turn elsewhere for that.

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**R Huxtable**

**Extending the Boundaries of Care: Medical Ethics and Caring Practices**


The title of this book embraces a subject that is very topical in the field of health care. It is a collection of papers most of which were initially presented at the Centre for Cross-Cultural Research on Women. All but one of the authors are women. The papers themselves are very diverse, covering topics in a variety of ways. Subjects covered include a daughter’s story of her father’s gradual decline leading to her father’s death and death from undiagnosed Creutzfeldt-Jakob Disease; the problems for parents raising triplets; issues arising from the Depo-Provera contraceptive debate; the human nature of human rights in relation to medical care: disease prevention; methods of research in relation to HIV and men who have sex with men, and nurses’ moral/political voices as expressions of care. Each writer’s subject of interest, even passion, within health or social care—hence their own deep concern or “care”. As a consequence it is difficult to find a unifying theme in the book, which is perhaps why the particular title was chosen.

**Van Zyl**

Van Zyl draws some tentative conclusions as to situations of justifiable euthanasia, she also accepts that there will be numerous cases that might not in fact constitute an alternative because, in suggesting, for example, in the closing chapter, that virtue ethics can nevertheless find some “rules”, Van Zyl arguably strays onto the principlist ground she is so keen to avoid. More generally, although Van Zyl’s criticisms are often well aimed, the principlist objection might stand, since it is not certain that virtue ethics alone will determine the morality of conduct. For example, would it fit with current professional and legal obligations? Similarly, how are both practising and future doctors to be educated in the virtues? The sorts of institutional responses that are currently being called for would almost certainly need to have some principlist component. It is perfectly plausible that virtue ethicists can and will answer such questions. It is a shame, however, given her useful reconsideration of a much discussed concrete topic, that the author uses most of her text to set out her stall, while the practical applications of virtue ethics—as she conceives them—need greater attention.

These points need not be laboured, however, since Van Zyl’s text is a vital corrective to much contemporary theorising. The book is therefore recommended, particularly to researchers and students, although practitioners too might welcome this often refreshing perspective.
In their introduction, the editors attempt to frame and explore what they consider the book’s common theme, “the way ‘care’ is conceptualised and practised”. They are keen to stress that the focus is not abstract ethical issues related to care but the real ways in which health and medical professionals grapple with situations involving care. This is no constructed consensus, rather authors struggle in a discussion that extends and refines the care-paradigm. In their view health and care models are socially constructed. Models of care, definitions of care, technology and its effect on care, gender roles in care, and the nature of care itself for the receiver, are amongst the issues that arise, are discussed and explored in the chapters. As the editors acknowledge, however, it is very difficult to define this abstract concept, “care,” and this difficulty is exemplified in the book. One of the central questions about the book is whether it does in fact achieve what it sets out to do in its title, notably to extend the idea of care, and relate it sufficiently to underlying ethical positions. The problem is that the concept of care now to come to hold a variety of meanings. Contrast the following two examples. The poignant and moving account given by a professor of anthropology (Judith Okely) of her mother’s illness, her dying and her death embodies, for the author, an idea of care as compassion and kindness. This she illustrates by practical examples, such as “a voice of warmth” (page 39): the unseen voice on the telephone of a matron of “a maternal ward” (sic) describing to the daughter the detail of the workings of her mother’s catheter. Equally moving is the description of the care assistant who cried as the daughter cut a lock of her dead mother’s hair as a memento. From Bill Fulford provides the introduction. He makes the point that medical ethics has gone too far in seeking ever more general principles to which doctors and therapists should conform in practice. Mostly these aim to restrict and exclude medical paternalism. However, he concludes bitterly that there is a claim that “the ethicist knows best” has taken and equipoise between surgical procedures, the consent of subjects had not been obtained prospectively, and at the same time the possibility that a surgeon always hovers over these pages that professionals might view the call for openness as having less beneficent and more prurient motives behind it. The concern is that the book is stuffe...
makes for a useful documentary casebook. What makes this book worthy of wide consideration is the wealth of additional material. Part 1 of the book reproduces the Nuremberg Code and the 1996 version of the Declaration of Helsinki, together with classic material by Henry Beecher and Maurice Pappworth on “human guinea pigs” and some valuable historical articles setting this material in context. Part 2 reproduces the articles and correspondence from the BMJ. Part 3 contains reviews of the “state of the art” on informed consent in research in a variety of contexts, including research with children, genetics research and access to patients’ records for research purposes. Part 4 reviews the moral role of informed consent and how better to achieve both consent and respect for its importance, in particular through education, consumer involvement and communications skills. The book concludes with closing remarks by the editors.

The reader interested in the complexities of current debates on consent in research will find this a very valuable guide. The chapters are rather brief, which make philosophical depth difficult to achieve. The cumulative effect of reading 32 short articles can be exhaustion and confusion. Taken individually, however, the articles are on the whole very well written and informative. The reader has a sense—unusually in a work of this kind—of an evolving debate and a growth in sensitivity of the contending parties to each others’ positions and the rationales underlying them. Some of the articles are likely to be classics in their own right, and all of them are stimulating. For this reason, the book transcends the “occasional” character of its source material, and is likely to have a long life in the reading lists and the libraries of researchers, doctors, and research ethics committees.

R Ashcroft

NOTICES

Ethics in health care

Oxford Brookes University and Oxford University have collaborated to develop a course which helps health professionals deal with difficult ethical decisions. The Ethics in Health Care course aims to give people practical skills that can be used in health care decision making. Course participants will increase their ability to analyse and assess arguments, apply ethical concepts to moral dilemmas, and articulate their own values and feelings.

It can be part of MSc programmes offered by both universities or a stand alone module and involves five days of lectures interspersed with workshops and student led seminars. It is based at the University Department for Continuing Education at Wellington Square, Oxford.

For more information please see the website at: http://www.conted.ox.ac.uk/health/htmlfiles/dentistry/dentfr.htm or contact Ms Phoebe Chen: Tel: +44 (0)1865 286947; fax: +44 (0)1865 286934; email: phoebe.chen@conted.ox.ac.uk

4th Asian Conference of Bioethics: call for papers

The 4th Asian Conference of Bioethics will be held from 22–25 November 2002 at Seoul National University, Seoul, Korea.

The sponsors are: the Asian Bioethics Association, The Korean Bioethics Association, The Korean Society for Medical Ethics Education, The Korean Association of Institutional Review Boards, the International Association of Bioethics, the Japan Association of Bioethics, the Chinese Society for Medical Ethics, the All India Bioethics Association, the Eubios Ethics Institute, and the Journal of Medical Ethics.


Deadline for Papers: 31 October. Format: Microsoft WORD 97 or higher. Language: English. Submissions to: ethics65@netsgo.com For further information please see: http://www.koreabioethics.org
The influence of the pharmaceutical industry on the off-label use of its medicines

D O E Gebhardt

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