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. 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 only work 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 is have to be motivated and helped to check (and document in their records) how well the individual patient has understood the problem and the information.

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BOOK REVIEWS

Voluntary Euthanasia and the Common Law


At first sight, this might not seem like the sort of book on 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. Otlowski argues that any examination of this subject matter necessarily involves “consideration of wider issues, including social change, as reflected in opinion polls and community attitudes for reform, the practice and attitudes of the medical profession, as well as considerations 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 these cases. Otlowski 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 do, in fact, help 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 arrived 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.

Edited by K O’Rourke, Georgetown University Press, 2000, £15.75; pp 323; ISBN 0878408029

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 coaching-oriented, so much so that the third of all issues, and thus, the most memorable, is the use of fetal tissue in research, physician assisted suicide, and many other issues, to early delivery of anencephalic infants. The diverse and individual cases, although necessarily brief, are always clear and well informed, and in general lay out the ethical issues and the various options fairly rather than being strongly directive, parodic, or one-sided.

The book has little to say about the philosophical and theological underpinning of bioethics; one must turn elsewhere for that. The book and all the authors adopt a middle ground from Roman Catholic stance. They rely on the “fourth way” of medicine, in its evolution from an “art” into a “science”, but also medical or bio-ethics, in its move to a pluralist ethic, which demands the application of universal, rational, objective rules to “cases”. Such a move results in some dissatisfaction with the medical focus, 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 pretesting and future doctors to be educated in the virtues? The sorts of institutional responses that authors argue 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, when the practical applications of virtue ethics—as she correctly points out—need greater ones.

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 philosophers too might welcome this often refreshing perspective.

R Huxtable

Extending the Boundaries of Care: Medical Ethics and Caring Practices

Edited by T Kohn and R McKechnie, Berg Press, 1999, £42.00 [cloth], £14.99 [pb], pp 206. ISBN 1-85973-141-4

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 disparate, covering diverse topics in a variety of ways. Subjects covered include a daughter’s story of her mother’s dying and death from undiagnosed Creutzfeldt-Jakob Disease; the problems for parents raising triplets; issues arising from the Depo-Provera contraceptive debate; the 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 is a focus demonstrating their own personal 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 thread in the book, which is perhaps why the particular title was chosen.
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 people in different situations involving care. This is no constructed consensus, rather authors struggle in a discussion that extends and refines the caring boundaries. In their view, the 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 among the issues that arise, and 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.

Care involves that which is overtly political, in this case, the rights of nurses to greater autonomy. With so many different viewpoints on show, the editors recognise “the apparent chaos created by fragmenting of old boundaries” (page 11). Yet, what might be irrevocable on paper, is certainly quite clear, even consensual, when care is needed in the reality of everyday life. Arguably, when you and I and our loved ones, whoever we are, from whichever ever gender, race, culture or society, have occasion to require “care”, we will know, as Okely does, exactly what it is that we are receiving, and whether it is as we expect to receive it; and we may find that the “old boundaries” are not so fragmented as the editors of this book might think.

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Confidentiality and Mental Health

Edited by C Cordess. Jessica Kingsley Publications, 2001, £15.95 (pb), £47.50 (hb), pp 201. ISBN 1853028592

The respect for confidentiality and the rhetoric about openness of information are in conflict in contemporary society, and the tone of the conflict is increasingly infiltrated. The sentence “the battlefield” is in turmoil from this social trend, as well as from the high profile technical developments in genetics, transplant surgery, and reproductive technology. But in addition mental health has always had its inherent problems over ethical practice since it has, to this day, inevitably retained some element of medical paternalism. This places practitioners in a position in which they have a responsibility for the care of their patient, but also a responsibility for the protection of society. The two positions often clash, and the tension in mental health often have deep moral implications, that do not exist in general medicine.

Chris Cordess has produced a timely book, in which he has written, with colleagues, the status and interaction of the mental health, psychotherapy, forensic psychiatry and legal fields, 13 chapters on the current status of confidentiality, its protection and erosion. The chapters originated in a conference in 1998 with the same title as the book, and they are arranged largely according to the impact of the conflict on specific disciplines, rather than particular themes. But themes do recur through the text: the protection of children and third parties; the research use of case studies in journals and other publications; interdisciplinary and interagency exchange of information; the commercial interests of patients and other organisations in the risk business; computer-stored records; disclosure in court and court reports, and so on.

“The book is concerned with the difficulties that are posed for practitioners and researchers by the social conflict over privacy and confidentiality. The professional consultation, not least in mental health, is aimed to be free of moral judgments with respect to not. Traversing this boundary is difficult, and means that more complexities intrude into the interpersonal encounter, which is quite difficult enough already. Practitioners might resent these burdens and find it suspicious that the book always hovers over these pages that professionals might view the call for openness as having less beneficent and more prurient motives behind it. Yet the reality is that the book is special pleading by incor- 

moded practitioners. Nevertheless, two chapters by lawyers are sympathetic to the problem, one advocating a “legally enforceable right of confidence for patients involved in legislation” (page 147). A thoughtful piece 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 risk of an ethicists’ paternalism, in which the claim that “the ethicist knows best” has taken over from “the doctor knows best”. The wishes of patients for confidentiality do in most instances coincide with the beliefs of doctors. The pressure to limit the doctor’s professional freedom of movement and to put his or her documents at the disposal of public scrutiny, negates the clinical alliance and partnership between doctor and patient. Rules and regulations derived from ethical principles need to be balanced. Because of the variety of different values, especially in mental health, between disciplines and cultures, principles need to be augmented by a focus-focused consideration of individual cases.

Medical ethics has always stood for values being a part of medical practice as well as sci- 

entific facts. This is no less the case in mental health; in fact it is more so since the battle lines are drawn. In my view, the “science” of psychiatry must operate. Such a reflective complexity may justify mental health as being in a category of its own within professional and medical ethics. The claim to be a special case is never very distant from this text, and should be listened to by ethicists; whilst all clinicians will find the important issues readily accessi- 

ble here.

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Informed Consent in Medical Research


Debates over research ethics have until recently revolved around two related questions: the voluntary, informed consent of subjects; the effect on care, gender roles in care, and the appropriate relationship between risk and benefit to subjects in the experiment. Recently more attention has been paid to the possible commercial exploitation of tissue samples in the international arena, and to issues of the scientific and financial probity of researchers. Yet these new foci augment rather than supplant the traditional focus on consent. Consequently “the rights and wellbeing of the subject take precedence over the interests of science and society”, as the Declaration of Helsinki (still) puts it.

Clinically the difficulties of obtaining the informed consent of subjects. One problem in research remain one of the more difficult barriers to research. Recently this issue has become more fraught in non-clinical research also, with complex debates over consent to the use and reuse of clinical information or stored tissue samples in epidemiological and genetic research. The trade-off between public interest in the development of epidemiological research and the rights of individuals to decline participation in such research remains precarious. The possibility that a surgeon might need to explain not only randomisation and equipoise between surgical procedures, but also the possible commercial exploitation of tissue samples extracted from surgical waste gives most thoughtful people pause at the difficulty of this process and the complex in which scientific, therapeutic, and commercial elements are entwined in it. The need for a general guidebook to the range of practical ethical problems in consent in research is profound, since most books and articles cover at most a small subgroup of research studies, usually from the points of view of research design or review, rather than from practice, patient, or consumer perspec-

In 1997 the BMJ published two studies in which the consent of subjects had not been obtained prospectively, and at the same time published critical commentaries on these papers. It then invited two debate papers to argue for and against the question of the BMJ’s role in research and refused to publish papers based on research where the informed consent of the participants had not been obtained, subject to some very stringent rules about exceptional cases. The two papers were written by Professors R D Hinshelwood and Jeffrey Tobias, respectively a Professor of medical ethics and a senior medical oncol-

ologist. There followed an unprecedentedly large correspondence on the issue. It was not accidental that 1997 was the 50th anniversary of the Nuremberg doctors’ trial and the famous code on human experimentation which was written in its wake.

This book reproduces the controversy from the pages of the BMJ in full, which in itself
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

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