

PostScript

LETTERS

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

Last year I described in this journal¹ 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.²⁻⁴ One of the companies producing this drug was aware that it had a moral responsibility to prevent (accidental) abuse of its product.⁵ 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".⁵ An even more stringent attitude is taken by Bousvaros and Mueller⁶ 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.

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The editors will decide as before whether to also publish it in a future paper issue.

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

A Herxheimer

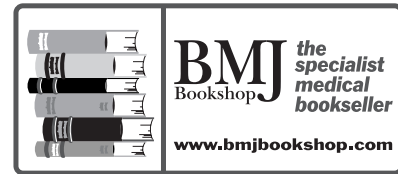
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BOOK REVIEWS

Voluntary Euthanasia and the Common Law

M Otlowski. Oxford University Press, 2000, £25, pp 564. ISBN 0-19-829868-4

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. 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 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 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, Otlowski 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.

Otlowski 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 Otlowski 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 Otlowski 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 xxiv). Thus the message for

ethicists 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 extensive—from informed consent, through futile therapy, genetic testing, organ donation, the use of fetal tissue in research, physician assisted suicide, and many other issues, to early delivery of anencephalic infants. The discussions of 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, partisan, 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 mainstream Roman Catholic stance. They rely, they say, "on a very definite concept of the human person and some precise values and goals of the healing relationship that we believe have brought out the best in people in the health care professions over the centuries" (page xii). Their arguments, they believe, are founded on reason and natural law as well as on faith. At key points recent Roman Catholic teaching on such matters as the evil of abortion in virtually all circumstances, even rape, is affirmed, as is the conviction that an embryo from the moment of conception has the status of a human being rather than a potential human being. There are numerous impressive examples of the vigour and cogency of discussions within that tradition of the ethical acceptability of specific forms of treatment.

The book directly addresses the injustices generated by the fact that in the United States some four million people do not have proper medical cover, and by the invasion of health care by the market: "the only way to solve the health care problems in our society is to insist continually that we must have universal health care coverage. Until that goal is accomplished, we are fighting bush fires and ignoring the major conflagration" (page 256). This is also a reminder, however, that to a certain extent this book addresses specifically American issues, or matters which are treated in a rather different way in the United States from elsewhere because of legislation and court decisions. But for the most part the problems with which it wrestles are common to the major industrial societies.

Two final comments. First, the book claims to be "essays for a pluralistic society". It may fairly be regarded as a very useful and irenic Roman Catholic contribution to a very complex and confusing debate about how we can agree on the principles and practices of health care in societies which are deeply fragmented

morally. This book does not wrestle with the underlying problem of ethical pluralism, but its tone is constructive and positive rather than hectoring, arrogant, or aggressive. Secondly, the book presents itself as a "primer", but denies that it is intended to be a textbook. Probably its real value is as a resource and a stimulus for conscientious and reflective practitioners, and for students of ethics who are anxious to ground their studies in real situations.

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 principlism had its day? These are two of the questions that van Zyl's text seeks to answer in the affirmative. Van Zyl wishes to encourage an approach to medical practice that draws upon the requirements of virtue ethics, in preference to principlist (primarily deontological and consequentialist) ethics. Her account then relates these twin themes to one concrete realm of medical practice, decisions taken at the end of life.

Van Zyl believes that the process of modernisation has not only affected medicine, in its evolution from an "art" into a "science", but also medical or bio-ethics, in its move to a principlist ethic, which demands the application of universal, rational, objective rules to "cases". Such shifts account for some dissatisfaction with the medical focus, since it is just that, while the patient's wider "suffering" passes unnoticed. Virtue ethics—that is, the approach that might account for such suffering, meanwhile, has been relegated to—at best—a "place on the sideline". In contrast to such popular, but bare and impersonal, principles as beneficence, non-maleficence, and autonomy, the author employs an Aristotelian approach to reintroduce three related virtues: compassion, benevolence, and respectfulness.

The virtue of compassion encourages an empathetic identification, and hence engagement, with the patient and his or her suffering. Benevolence encourages truly beneficent, helpful actions, which will result from this fuller understanding of the patient's predicament. Finally, respectfulness encourages full respect for the patient as a self-realising individual. A dialogue conducted in accordance with this virtue will result in shared decision making, as opposed to the doctor or patient-directed approaches presumed by, respectively, paternalistic and autonomy-based models.

In line with the expanded (patient-directed) conceptions of "harm" and "benefit", the goal of medicine is conceived in terms of promoting patient welfare. Applying her thesis to euthanasia, Van Zyl contends that where this goal cannot be achieved, and where continued life might even be harmful, euthanasia might be permissible, in either an active or a passive sense. Euthanasia, as a last resort, can therefore be justifiable as a compassionate, benevolent, and respectful response to a patient's suffering. Although Van Zyl draws some tentative conclusions as to situations of justifiable euthanasia, she also accepts that there will be numerous cases that are not so amenable to resolution; in these the process of interaction between physicians,

patients and patients' families might be more important than the actual decision reached.

To get the inevitable pun out of the way, this work certainly has its virtues. Principally, the book succeeds in offering a useful counterbalance to the plethora of texts devoted to principlist accounts of morality, and the morality of euthanasia in particular. Moreover, Van Zyl's account might cheer those who despair at the limitations of the contemporary focus on, and/or approach to, patient autonomy. On a more mundane note, the argument is also well sustained and accessibly presented.

Perhaps inevitably, however, a few vices warrant note. Primarily, Van Zyl's argument 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. How, 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 probably required 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 concedes—need greater development.

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.

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 of focus demonstrates 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 individuals and groups grapple with situations involving care. This is no constructed consensus, rather authors struggle in a discussion that extends and refines the caring boundaries. In their view health 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, 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. Indeed, the central question 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", has now 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 geriatric 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 remembrance. For another writer (Jan Savage), the focus is on the caregivers, how nurses understand "closeness". This gives rise to the author's argument that the moral basis of 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 irreconcilable 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 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 inflamed. The senior professions are the battleground. Medical ethics 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 particular problems 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 in 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 insurance companies and other organisations in the risk business; computer-stored records; disclosure in court and court reports, and so on.

The book is stuffed 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; whilst public life is 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 burdening intrusions; the suspicion always hovers over these pages that professionals might view the call for openness as having less beneficent and more prurient motives behind it. And this raises the concern that the book is special pleading by incomed 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, neglects the clinical alliance and partnership between doctor and patient. Rules and regulations deriving 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 process-focused consideration of individual cases.

Medical ethics has always stood for values being a part of medical practice as well as scientific facts. This is no less the case in mental health; in fact it is more so since one could argue that values are themselves the raw material on which 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 accessible here.

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Informed Consent in Medical Research

Edited by L Doyal, J S Tobias. BMJ Books, 2001, £50.00 (hb), pp 336. ISBN 0-7279-1486-3

Debates over research ethics have until recently revolved around two related questions: the voluntary, informed consent of subjects, and the appropriate relationship between risk and benefit to subjects in the experiment. Recently more attention has been paid to issues of justice in research studies, especially 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, since arguably "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 to participation 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 way in which scientific, therapeutic, and commercial elements are entwined in it willy nilly. 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 perspectives.

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 the question of whether the *BMJ* should refuse 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 Len Doyal and Jeffrey Tobias, respectively a Professor of medical ethics and a senior medical oncologist. 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.

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Proposed paper themes: 1) Bioethics and Asian Cultures; 2) Research Ethics and Protection of Research Subjects; 3) Bioethics and Commercialization; 4) Law and Policies—for example, National Bioethics Commission; 5) Ethical Issues in Assisted Reproduction; 6) Women’s Health and Bioethics; 7) Genetics and Human Dignity; 8) Bioethics and Religion; 9) Organ Transplantation and Organ Selling; 10) Environmental Ethics; 11) Death and Dying; 12) Bioethics Education; 13) Prenatal Sex Selection, and 14) Ethics of Stem Cell Research.

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>