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 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.

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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. 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 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 in conflict with 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
ethics is this: do not be bogged down in
dogma, for that is how we arrived at the situ-
ation 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
It consists of a series of clear and thoughtful
short essays, grounded in real cases in health
care ethics. The range of coverage is
cohesively consistent. Although some essays
are 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
theological writings on such matters as the
treatment of the elderly in the care 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 co-
gency 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 care, and by the invasion of health
care by the market: “the only way to solve the
emergency of discussions within that tradition of
bioethics; one must turn elsewhere for that.

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 explored in this book. Van Zyl
seeks to answer in the affirmative. Van Zyl wishes to encour-
age an approach to medical practice that
draws upon the requirements of virtue ethics,
in preference to principlist (primarily deonto-
logical and consequentialist) ethics. Her aim is
to count these themes to one
concrete realm of medical practice, decisions
taken at the end of life.

Van Zyl believes that the process of
moderisation has affected the practice of 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 applica-
tion of universal, rational, objective rules to
case”. Such a shift has led to some dissatis-
faction 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 address 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, virtue ethics and an Aristote-
lean approach to reintroduce three related
virtues: compassion, benevolence, and re-
spectfulness.

The virtue of compassion encourages an empathetic identification, and hence engage-
ment, with the patient and his or her
suffering. Benevolence encourages truly be-
necit, helpful actions, which will result from
this fuller understanding of the patient’s
condition. Finally, respectfulness encour-
ages 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) inclusion of “harm” and “benef-
efit”, 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 counter-
balance to the plethora of texts devoted to
principals accounts of morality, and the
morality of euthanasia in particular. More-
over, Van Zyl’s account may well be those who
despair at the limitations of the contemporary
focus on, and approach to, patient auton-
omy. On a more mundane note, the
argument is also well sustained and accessibly
presented.

Perhaps inevitably, however, a few vices
warrant note. Principally, 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
arguablystrays onto the principlist
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 profes-
sional and legal obligations? Similarly, how
are both practising and future doctors to be
educated in the virtues? The sorts of institu-
tional responses that are 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
cancrete 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 ones.

These points need not be laboured, how-
ever, since Van Zyl’s text is a vital corrective to
much contemporary theorising. The book is
therefore recommended, particularly to re-
searchers and students, although profes-
sors 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 them-
selves are very disparate, covering diverse top-
cics 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 inter-
est, 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.

www.jmedethics.com
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 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 among 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. If care involves that which is overtly political, it 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 is 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 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 professional freedom of movement and to put their ideas to the test in their daily work. 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 to which doctors and therapists should conform in practice. Mostly these aim to restrict and exclude medical paternalism. 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 the battle against that values are 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.
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