

BOOK REVIEWS, NOTES AND COMMENTS

Edited by

Federica Napolitani Cheyne**SPUNTI PER UNA SANITÀ MIGLIORE**

Girolamo Sirchia.
Padova: Piccin Editore; 2010.
p. 183.
ISBN: 978-88-299-2103-4.
€ 25,00.

A primary need of biomedicine in Western countries is to render the general public cultured enough to make convenient decisions. Italian citizens so far lack some basic scientific background, due to the overwhelming relevance of the humanities in the Italian tradition. Science has been introduced in teenager curricula at national level in 1962. Therefore, most of the population, particularly senior people, has no great knowledge of biomedical issues. Painfully, a rather recent OECD-Pisa screening of scientific (logic) capabilities of early adolescence revealed scarce capabilities, despite very wide variations due to geographical distribution and/or social-economical background of their families.

Patients need to be educated to interact with the public and private health systems. Professor Girolamo Sirchia, fellow of the Royal College of Physicians of Edinburgh, covered for over 40 years relevant roles in the Italian biomedical system up to being the Ministry of Health between 1999 and 2001. He is a recognized hematologist, particularly interested in promoting healthy lifestyles, having contributed to some recent regulations at European level.

This handsome booklet is intended for the general public, but it is particularly important for local decision makers interested in having a quick look at the main changes which occurred in contemporary medical care systems. It covers a wide range of topics, ranging from smoking, alcohol, drug abuse to the delicate emerging issue of obesity. We found chapter 4, dealing with the aging of the Italian population and related necessities, particularly cogent. The senior patient is viewed in a modern way, and a selected series of strategic directions useful for local or national decision

makers is addressed in this chapter. We refrain from doing more than opening a discussion about the final consideration (chapter 9): the same Prof. Sirchia's point of view is a robust starting point, though his depiction of contemporary medicine (p. 127-128) and of professionals dealing with the delicate and often costly decisions touches ethical, deontological and practical considerations.

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**IL MALATO IMMAGINATO**
I rischi di una medicina senza limiti

Marco Bobbio.
Torino: Giulio Einaudi editore;
2010. 217 p.
ISBN 978-88-06-20298-9.
€ 18,00.

"Italians either suffer from a liver disease, or believe that they suffer from a liver disease, or expect to suffer sometimes in the future from a liver disease". Thus wrote a well-known French journalist about 50 years ago, when Italians were consuming *à go go* liver extracts and other pseudodrugs, often dangerous ones (an intravenous calcium injection could kill). Subsequent studies showed that both Italians and their French "Latin brothers", constantly concerned about the quality of their food and the regularity of their digestion, were heavy consumers of gastrointestinal and liver drugs and pseudodrugs. By contrast Germans, influenced by their romantic traditions and therefore highly sensitive to the slightest vagaries of their tender hearts, were found to be insatiable consumers of cardiovascular drugs and pseudodrugs.

Since then a lot of water has passed under the bridge: and today, *mutatis mutandis*, Marco Bobbio

– whose excellent work on conflicts of interest in the medical sciences has already been reviewed here (*Ann Ist Super Sanità* 2004;40(4):517-529) – provides us with a rigorous confrontation between the real and the less real progresses of medicine; then goes on explaining the many ways by which healthy subjects can be transformed into sick subjects (*disease mongering*) and therefore induced to do something to recover their health, be it a drug treatment or other.

In the “Introduction”, and more extensively in one of the last chapters, “The paradox of medicine” is thoroughly illustrated. As medical advances proliferate, the expectations for medicine’s omnipotency increase even faster; therefore, failures cause an ever increasing level of unhappiness (the only certitude in our vale of tears is death, which can be postponed but not avoided, as Bobbio repeatedly underlines in front of the fact that quite a few people seem to have forgotten this *vérité de La Palice* or *Lapalisse*). Failures are mainly of two types: firstly, quite a few pathological conditions are still poorly understood and/or not curable, at least in the majority of cases; secondly, some of the subjects with curable diseases are either resistant to therapies or victims of errors. These exceptions cause in the unlucky ones and their relatives and friends an increasing level of unhappiness, frustration, or even rage; a feeling of being the victims of a hideous injustice. At the same time, the mistrust towards the doctor(s) in charge increases, due to the confounding between avoidable and unavoidable failures (we will not deal here with the financial and other consequences of “defensive medicine” triggered by the fear of legal actions).

Medicine, in short, has not yet succeeded to harmonize the more and more sophisticated statistical reasoning on *patients’ groups* and the dialogue with *individual subjects*, which basically follows a binomial mode: healthy/ill, improved/turned for the worse, cured/incurable, alive/dead. The acceleration of scientific progress, without a parallel growth of the socio-psycho-anthropological knowledge needed to manage such progress, not only enhances suffering, which is a function of frustrated expectancies, but also escalates the financial costs. According to WHO, 20-40% of medical expenses are unjustified, while hundreds of millions lack even the most elementary measures of medical care. In addition, this gap paves the way to the disease mongering which is powered by financial and corporative interests.

Before going on, let us give a very recent example not mentioned in Bobbio’s book (see the article by Lisa Cosgrove in the last 2010 issue of *Academe*, the journal of the American Association of University Professors www.aaup.org/AAUP/pubsres/academe/). The next fifth edition (DSM V) of the Diagnostic and Statistical Manual of the American Psychiatric Association proposes the diagnosis “Premenstrual Dysphoric [*sic*, not the

more usual *dysphoric*] Disorder” (PMDD). This diagnosis applies to women in their premenstrual days, often exhausted because of their long working hours both in a factory or office and at home, who act out with a shrill voice in the face of some difficulty. One of the pharmaceutical firms is particularly interested in PMDD: in fact, since the patent of its antidepressant is about to expire, an entirely new indication could maintain a high level of sales of the drug under a new trade mark, since the same indication could not be used for the drug sold as a generic. One of the most widely run TV ads for this “new” drug shows a frustrated and irritated woman outside a supermarket trying to pull a stuck shopping cart out of its lineup. And the author notes that up to 70% of the members of the DSM V expert panels have ties with the pharmaceutical industry.

The following chapters provide a clear illustration of the various aspects of the question. “The induction of need” draws a distinction between appropriate and inappropriate uses of the increasing knowledge on risk factors (*risk factorology* is the *ad hoc* ironical neologism). Specifically, a frequent confounding occurs between *chance associations* (Bobbio gives several picturesque examples, except the one which has been standard since the 19th century: the statistically significant correlation between the number of arrivals of storks and the number of births), *indirect associations* (e.g., between yellowish fingers and lung cancer), and *causal associations*. In addition it is seldom made clear that the latter are not the equivalent of genuine causes, but factors (independent variables) that may modify the probability of given events (dependent variables). An intervention on such factors – not unfrequently by methods which are far from having been adequately tested – may result in a zero sum game, or even produce more damages than benefits. Bobbio places here considerable emphasis on narrative, subjective and contextual aspects of physicians’ exchanges with patients, which should weigh at least as much as the strictly medical-scientific aspects – except of course in those situations (mostly acute ones) in which the patient should be promptly and frankly informed about the urgent need of a specific intervention.

In “The conditioned research” chapter, Bobbio updates the information more extensively analysed in his previous work on conflicts of interest; as shown by the PMDD example, this is a bubble which continues to expand with an unpredictable explosion deadline. The author being a well-known and respected clinical investigator, his critical and self-critical confrontation between the advantages and limits of Evidence Based Medicine (EBM) is strikingly courageous. Bobbio, for example, makes it clear that we are far away from finding an appropriate solution for the problems of patients (mostly ageing ones) with a steadily increasing number of chronic ailments. According to the more reliable guidelines,

many of them cumulate prescriptions for up to 10, 15, or more medicines, some of them to be taken two or more times a day. Besides the toxicological risk and the costs, it is unavoidable that quite a few of these patients will start dropping some of their drugs, mostly on a random basis; therefore, omissions often concern the more vital medications.

The chapter “The interpretation of scientific data” emphasizes the contrast between the increasing quality and quantity of valid data and the increasing difficulty of identifying the more effective solution for the individual patient. For example, there is often a considerable difference between the marked reduction of *relative* risk after the adoption of a given regime by asymptomatic subjects and the much smaller reduction of *absolute* risk: hence the question “How many subjects must we treat – for, say, ten or more years – in order to prevent one severe adverse event or one death?”. When an asymptomatic subject is enrolled in a prevention project, the probability is high that he will embark on a “disease career”, which often interferes with his normal life activities or even becomes pathogenic *per se*; not to speak of the possible adverse effects of treatments with powerful medicines such as antihypertensives and statins (the author being a cardiologist, most of the examples come from his discipline; but much more severe problems occur in areas where the etiopathogenetic *know* and the therapeutical *know-how* are even more controversial, such as psychiatry). The physician does not have a crystal ball to foresee which patients (generally a minority) will have a substantial benefit after entering a prevention program and which ones (generally a majority) will have minimal or no benefits, while facing the toxicological risk and the adverse consequences of medicalisation. Moreover, powerful interests tend to blur the distinction between high-risk subjects, who have a substantial probability of benefiting from a given intervention, and the much larger number of lower-risk subjects, for whom the risk-benefit and the cost-benefit ratios are much higher.

The chapter “The lowering of thresholds” analyses the consequences both of repeated reductions of optimal values – of blood pressure levels, of total and LDL cholesterol levels, etc. – and proliferation of screening methods. Again, methods of little or no value, or even potentially harmful ones, are often mixed in the same bag with methods of proven value. Wild promotion of the former is one of the effective tools used for disease mongering, whose various aspects are illustrated in a series of chapters – “The creation of new diseases”, “The non-diseases”, “The interested advice”. In several instances, the author uses as starting point a well chosen real case which illustrates, for example, how the launching of a new drug leads to the invention of a new disease (or at least a new illness, or an “inadequacy” of the subject to meet the expectations of performance in his or her work, family,

and social life); or how the problems of health and disease are handled more and more frequently like those of the fashion market; or how the publicity campaigns through the media make a bold use of a mix of scientific and nonscientific data. Changes of strategy in this area are often quite rapid: for example, Bobbio does not deal with the very recent escalation of hidden publicity through the web, non only via web sites, which are subject to a minimum a control, but more and more often through fraudulent intrusions in blogs and Facebook (see the article by Linda Grilli and Gianna Milano in *Tuttoscienze/La Stampa*, 29 December 2010, p. 28, www3.lastampa.it/tuttoscienze/sezioni/edicola/articolo/1stp/45491/).

Once in a while, of course, something goes wrong; for example, a new “miracle” drug and potential blockbuster must be quickly withdrawn because of unforeseen and severe adverse effects. The usual remedy is the recourse to some kind of “oblivion machine” in order to cancel the traces of previous bombastic claims. At the same time, however, attempts are sometimes made to recover the investments by redirecting the campaign towards an apparently different goal (see, e.g., on p. 102-109, the case of a campaign against the “lazy bowel” redirected against hemorrhoids after the withdrawal of the drug tegaserol due to cardiovascular accidents). Too much curiosity sometimes kills the cat – but most of the times only apparently: a recent note in the *British Medical Journal* (www.bmj.com/content/341/bmj.c7360.extract/) indicates that over the past five years pharmaceutical firms paid in the US huge fines for civil and criminal violations, a relatively small penalty, according to market experts, in the face of the companies’ revenues.

In this analysis, which is not devoid of potential risks, the author never yields to a destructive nihilism. He recognizes, for example, that it may be legitimate to treat a “non-disease” which creates serious problems, such as “king-size” flap ears. He remarks, however, that concessions in this direction often pave the way to uncontrollable escalations. Examples are the inappropriate use of growth hormone in subjects of low stature not due to pituitary deficits; treatments with the psychostimulant methylphenidate – a drug which anyway should be used in conjunction with appropriate social and psychopedagogical interventions – not only in the more severe cases of Attention Deficit Hyperactivity Disorder (ADHD), but in an increasingly large number of “misfit” children with turbulent reactions to the constraints of their family and/or school environments (in the US, diagnoses of ADHD have gone up in a few years from 5 to 67 per 100 000).

Quite clear – and also quite useful from a didactic viewpoint – is the classification of self-referring (*autoreferenziale*) medical advice: *inappropriate advice*, the proposed intervention to be carried out by the same physician who gives the advice, which makes it difficult to understand whether it is a right

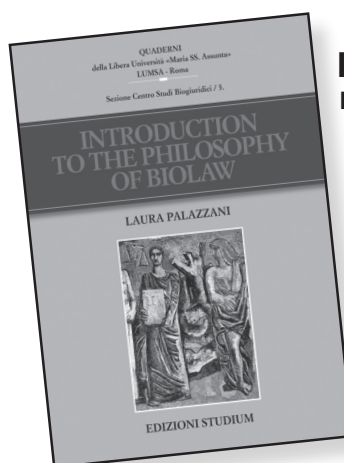
or wrong choice, due to conflict of interest; *misleading advice*, the undue emphasis on the severity of the ailment and urgent need of intervention, aimed at persuading a patient to skip a long waiting line in the public services (*Servizio sanitario nazionale*, SSN) by the recourse to a private service; *“disinterested” advice*, by which the intervention proposed is not rerouted to a different service, but increases the physician’s credentials and bonuses which depend on the business volume of the service (a phenomenon which has been repeatedly documented in private services financed with SSN funds); and at a more subtle level, *technical advice*. In a condition of uncertainty, instead of discussing with the patient the *pro’s* and *contra’s* of different management approaches as a joint function of the ailment and the preferred lifestyle, each subspecialist strongly recommends the intervention of his/her competence. For example, in the case of an obese, diabetic and hypertensive patient with coronary trouble, the medical cardiologist will suggest an attempt to adopt a healthier life style, plus the appropriate drug treatment, before making recourse to a more invasive intervention if necessary; the hemodynamist will recommend the immediate insertion of a medicated stent, the heart surgeon the performance of a bypass.

The author then proceeds to analyse the factors which make medical interventions so variable in front of equivalent disease profiles: large and small area variation; variation due to socio-economic conditions and other patient and/or physician characteristics; etc. He gives significant examples – sometimes surprising ones – showing how even in severe pathological conditions the performance or omission of a given intervention of proven efficacy may not modify the outcome; or how compliance versus non-compliance to a given drug treatment may result in the same difference in outcome as compliance *versus* non-compliance to a corresponding placebo treatment. And after the “Epilogue”, a useful “Afterword” by an expert internist, Luigi Pagliaro, gives a concise picture of the “unknown patient”: unknown in the diagnosis process, in the treatment procedures, in his/her autonomy, in the relation with the physician.

Last, but not least, the reader should not delude himself that the perusal of a review as extensive as the present one can be a substitute of an attentive reading of the original work; in fact, the latter contains much significant information not even mentioned here. Bibliographic notes are exhaustive, appropriate and updated; but the lack of an index unfortunately detracts from the value of this otherwise excellent work, particularly for purposes of consultation after cover-to-cover reading.

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INTRODUCTION TO THE PHILOSOPHY OF BIOLAW

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Edizioni Studium
(Quaderni della Libera Università
Maria SS.ma Assunta,
LUMSA, n. 5).
Roma: LUMSA; 2010. 136 p.
ISBN: 978-88-382-4091-1.
€ 16,00.

The relationship between bioethics, a relatively young field, and law, a very ancient discipline, is twofold. One side can be described as “law in bioethics”, and consists in applying legal norms to bioethics: law receives, assess and use bioethics. The other side can be described as “bioethics in law”, and involves experts, ethics committees, institutional review boards, bioethics commissions that furnish important inputs to the legal system. Legal scholarship on these issues have flourished in many universities.

As the variety of subjects discussed in the book testifies, bioethicists need to face continuously new developments, from embryo research to ascertainment of death, from cloning to genetic engineering. The search for common rules for different communities in these and other fields of biolaw is peculiar for several reasons. Among these reasons there are: the need to face also cultural aspects, which stay behind the choices; the need to confront with public opinion; the existential choices which are frequently at stake. Often it is not easy to confront with all these needs.

If bioethics and law are to collaborate more effectively, each will need a solid understanding of both the fundamental principles and of methods to translate them into practical criteria. Opinions, determinations, documents by ethics committees and commissions will continue to be relied on if they do not contravene core legal norms. At the same time, determinations will continue to be rejected or used as negative examples if they override ethical values and human rights. Moreover, this interaction has also judicial outcomes: even if the grounds on which judges and the Courts respond to bioethics will continue to be legal, not bioethical, judges and the Courts will incrementally make use of bioethical norms.

The goal is not to bring bioethics reasoning in line with legal reasoning and vice versa. Legal and bioethics reasoning need to remain distinct. However, they need to operate alongside and to influence each other. The objective is to avoid direct clashes between bioethics and legal norms.

According to a “Policy Forum” published in *Science*, “Daubert initiated a scientific revolution in the law”, in this interaction between bioethics and law science plays an essential role. The author refers to the landmark

opinion in *Daubert vs Merrell Dow Pharmaceuticals, Inc.*, in which the Supreme Court held that trial court judges must ensure, as gatekeepers, that proffered scientific evidence is valid and reliable: biolaw needs to be grounded on sound science.

As the title suggests, the book aims to be an introduction to the complex field of biolaw taking into account its “twofold structure”: the theoretical and practical side. This is surely the most precious contribution of the book: avoiding the reduction of biolaw to “proceduralism”, that is to a simple and mechanical application of rules to particular cases, without explaining the theoretical framework assumed by that rules, so that the result is often a false objectivity and neutrality.

On the contrary, the first part of the book, titled “From bioethics to biolaw”, is an in-depth examination of the birth and the development of biolaw as a new theoretical approach to ethical and legal questions arising from the relationship between human life and technoscience (assumed in the broad meaning as science married to technology): what is the role of law in a time when biology is often assumed as the main category to define humankind? How can biolaw prevent or correct such a reductionist perspective?

From the first part of the book emerges a vision of biolaw as an intriguing field, reflecting the complexity of contemporary society, claiming the necessity to well know “different reasons” in order to understand and dialogue with them. We can surely affirm the present book is a relevant example of this urgent methodology.

All the main theoretical perspective in contemporary biolaw discussion are well described: first of all the liberal-libertarian standpoint, one of the most reclaimed and common, especially in the western society, with its presupposed non-cognitivism (there are not objective good and bad, or at least we can’t know them). Another widespread theoretical category is the utilitarianism, according to which the only ethical criteria is to maximizing utility (pleasure, preference satisfaction, etc.) or minimizing negative utility as summed among all sentient beings. The book clearly shows the “structure” of the utilitarianism, result of the sum of consequentialism, welfarism, collective-equalitarianism. The premise of this general framework in an empirical conception of human person, according to which priority is given to sensation in order to define what is right and what is wrong from an ethical and legal point of view. Thus an utilitarian approach promotes a functionalist conception of the person, according to which its defining properties are the ability to feel pleasure and pain, the ability to prefer pleasure, the ability to be autonomous. The result of this reasoning is the centrality of sensitivism: the condition to be morally and juridical relevant is the ability of “having interests”.

The book points out that this thesis, which divides human being and person (not all humans are persons and not all persons are humans) is counter-intuitive,

while more useful in order to assess biojuridical and bioethical questions is a personalistic approach, according to which the human being is characterized by an intrinsic dignity. The separationist approach to person starts from a confusion between ontology and phenomenology, and at the end it is not so easy to retain the human rights doctrine if we assumed such a conception.

This is an example of the highly complex context in which biolaw has to work, and the book clearly and rightly shows that this complexity is first of all a theoretical one. The main risk for contemporary biolaw is “to arrive too late”, that is to think about contemporary technoscience after its possible negative consequences. This is a critical point: ethical reasoning seems to be slower than technology and science, so that today ethics is always a *post-factum* assessment. But what about law? Can we reduce it to a simple *post-factum* judgment? How can it prevent negative consequences within a society grounded on human rights’ doctrine, taken as the minimal requirement for a really civil society?

The different conceptions of the relationship between law and life sciences, so well analyzed in the book, can be divided into two main approaches: the movement known as “HIL”, “highly inappropriate legislation” (e.g., formal or soft law: abstensionism, libertarianism, liberal model, formalistic model, procedural model, contextual model, sociological-factual model), and a conception of the law promoting coexistence and inter-subjective relationship which starting from the human rights doctrine states the need to defend human life.

The second part of the book, titled “Questions of biolaw at the edges of human life”, is a case-by-case analysis (status of the embryo, reproduction technologies, genetics, reproductive and therapeutic cloning, end-of-life, organ transplantation, allocation of health resources) which gives at the same time an example of dialogue between different views and a clear affirmation of what we could generally define a “personalistic approach”.

In conclusion this book is a helpful analysis, on a case by case basis, of these interactions and a useful tool to tackle the challenges that rise at the boundaries where bioethics and law meet one another. The book has the big merit to show the urgency to reflect about biolaw as development of new categories to assess technoscience-human life relationship. This “meta-biolaw” has the urgent task to clear the difference between legality and legitimacy, between human rights and human dignity, and this will be possible only through the dialogue with (bio)ethics, both as “law in bioethics” and “bioethics in law”.

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