Contents

Introduction iii
Contributors iv

Moral Disagreement, Moral Realism, and Vagueness 1
Thomas ADAJIAN

Well-being, Desire, and the Problem of ‘Miswanting’:
Rethinking the Philosophical Theories of Well-being and
the Practice of Informed Consent in View of Psychological Studies 13
Makoto SUZUKI

Moral Realism and Moral Disagreement: An Alternative Account 23
Laura SPECKER

Responsible Research? 33
Carwyn Rhys HOOPER

Human Enhancement and Human Nature 40
Takeshi SATO

The Relationship between Neuro-Intervention of Memory and
Moral Responsibility 53
Wanning CHOU

Biocentrism and Synthetic Biology 62
Sune HOLM

“Society in Science”: the DelPGenesis Project and the Democratization of
Health Policy Strategies through Public Deliberation 75
Claudio CORRADOETTI, Gillian BARTLETT-ESQUILANT

Moral Obligations of States 86
Anne SCHWENKENBECHER

Honor in the Military and the Possible Implication for
the Traditional Separation of Jus Ad Bellum and Jus In Bello 94
Jacob BLAIR
Introduction

This collection of essays is the final summation of the Fifth International Conference on Applied Ethics held at Hokkaido University on November 5-7, 2010. The conference was organised by the Center for Applied Ethics and Philosophy, Graduate School of Letters, Hokkaido University (Sapporo, Japan).

The purpose of this collection is to bring together the wide-ranging papers on various fields of applied ethics presented at the conference.

It is our hope that this collection will contribute to further developments in research on applied ethics and promote our Center’s mission, which is to bridge the gap between theory and practice.

May 2011

Center for Applied Ethics and Philosophy
Hokkaido University
Sapporo, Japan
"Society in Science": the DePGx Project and the Democratization of Health Policy Strategies through Public Deliberation

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1. Science, Truth and Society: the Relevance of Deliberative Consultations

With the ever rapid development of scientific and technological research in the 19th century, the power growth of scientific institutions and their specific influence have expanded incredibly due to the results they have achieved in several areas. In view of the enormous occurrence of scientific discoveries in everyday life, state allocation of public funding has consequently been devoted to the promotion of certain promising subjects. The process of control and the setting of the agenda for health policies has only rarely been established in accordance with shared priorities of public concern. Indeed too often, governments have subordinated resource allocations to "health technicians" who, in their turn, have prioritized only one narrow perspective over the complexities involved. So far, therefore, the public management of scientific research has been kept isolated from a multiperspective assessment grounded in public understanding. It is believed that the widespread prejudice preventing the involvement of public sectors of society into the decision making processes, consists in an old-fashioned idea of "scientific truth" as "correspondence" which can only provide a form of self-legitimization to science itself. The understanding according to which scientific research is capable of providing a form of truth "exempted" from competing arguments is not only a naïve view of science, but also a misplaced reconstruction of how science proceeds. Indeed, scientific explanatory accuracy of physical phenomena proceeds through an assessment of contrasting empirical counter-evidences in the light of what Popper has presented as the principle of "falsifiability". The question being referred to here is very complex and indeed, it cannot be adequately addressed at this time. For the present purposes, it suffices to say that Popper's central tenet for scientific statements claims that systems of statements - namely scientific theories - can be defined as scientifically relevant only if they can be falsified on the basis of empirical counter-evidences. This point helps us introduce the reasons in support of a more articulated scheme of what counts as truth in science, as well as to advance a more articulated model on why different stakeholders should be involved in the process of scientific decision-making. The question can be put as follows: as scientific truth per se is characterized by competing theories exhibiting a falsifiability status and gaining credibility in accordance to their expiatory force, then, different actors must be allowed to provide their say in order to contribute to the falsifiability process of truth construction. The type of argument proposed makes reference to a sort of analogy-model between scientific truth and truth in the public domain. Nevertheless, while in the former falsifiability proceeds on the basis of empirical counter-evidences, in
the latter it proceeds through argumentative confrontation. In this second case, facts can only be interpreted as either supporting or countering against a certain position. What the two domains share, though, is a polyarchical model of truth pointing to a structural continuum between scientific truth and its public accountability.¹

As just referred, parallel to the process of epistemological reformulation of the paradigm of “truth” in science, is today’s process of internal revision of health policy strategies (Hassenteufel et al, 2010). Indeed, more and more countries are introducing forms of public inclusion through stakeholders’ involvement into health policy planning and decision making. What is happening is a structural transformation where interest representatives of health care bodies (research or clinical), are asked to take part into the same process of policy programs formulations. In addition, health care systems are facing profound changes. At the one hand so called “universal health care systems” are exposed to deep economic crisis and, thus, are introducing partial private health care elements; at the other hand, classical private health care systems are undergoing attempts at transformations pushing towards the consideration of health as a “public good” and therefore as a good to be supported by the state. What in both cases governments are aiming at is efficiency in the delivery and cost reduction of national state health care expenditure. Nevertheless, within normal democratic interplay, it seems not possible to introduce major changes without countervailing efficiency with justice and thus with citizens’ mechanisms of legitimation. If democracy can be said to be a form of government springing “from” the citizens and directed “to” the citizens, then any political step regarding the “common good”, such as in the case of health care provision, should be legitimized by public consensus. The latter, should permeate large sectors of health service administration, from National Health Ministries to Bioethical Councils, or from the public sector to private enterprise.

These preliminary points amount to the following: the search of higher efficiency and cost reductions in the delivery of health care services cannot be obtained outside a process of public consultation; but whereas periodical elections are held in order to let citizens choose major political goals in the long period, further forms of political legitimation must be sought for the protection of the “common goods”. Such goods are inalienable by the citizens, and therefore cannot enter into any form of political compromise or exchange. In order to cope with the above mentioned difficulties, along the following essay we will present the case of deliberative consultations concerning the ethical assessment of pharmacogenomic research, alias, the DePGX project. Deliberative consultations represent an instrument for the overcoming of “legitimation crises” in the field of health care service provisions. They not only make public some of the most pressing concerns springing from the same beneficiaries, but they also rationalize public concerns through discussion and exchange of arguments. Public deliberation, therefore, is not only aimed at introducing and making manifest those preoccupations arising from those same people having an actual or potential interest as beneficiaries to

¹ On the necessity to maintain a unified notion of validity between the epistemic and practical sphere, see J. Habermas (2003).
provokes an institutional setting oriented to a progressive clarification of the reasons leading to the prioritization of a certain health research objective over another. Transparency in decision making is thus achieved on the basis of a convergence of different epistemic frameworks of understanding that force to the institutionalization of institutional and non-institutional channels of discussion with the goal of achieving “order” within potentially conflicting perspectives/interests. Finally, as far as the third point is concerned, the process of legitimization of public policies is due to a democratic and fully transparent process of decision making. In modern democracies, to obtain legitimate policies, means to be publicly accountable and to be able to defend those public reasons that have contributed to the formulation of specific health policies. The deliberative model we have realized, is primarily aimed at providing orientation policy guidelines for health state agencies.

How does this occur? Let us turn to the dynamics activated by the process of deliberation. The idea here is that of a limited number of people holding differentiated epistemic backgrounds and gathering under the supervision of a deliberative coordinator. Discussion is conducted on a set of predefined questions whose method of selection is based upon an in-depth consideration by the analysis of widely shared ethical concerns showing public relevance. The detection of relevant topics to discuss arises from the analysis of experts’ roundtables, consultation with stakeholders and from the evaluation of the research level achieved in pharmacogenomics. What characterizes the type of discussion conducted in deliberative polls is the search for a unanimous agreement on deliberative outcomes. The general orientation of the participants towards a common objective is precisely what differentiates this model of deliberation from other sorts of deliberative models or discussion groups. Whereas in the latter there is no need to be oriented towards a common agreed result, in the former, the deliberation is conducted by keeping in mind a reasonable outcome to be shared by each participant. At this stage, one might wonder why there should be a specific attention to deliberation as a form of ethical assessment of publicly relevant health issues. The answer to this question lies in the added value that deliberation bears in comparison to other forms of ethical assessment, as well as with the functions it plays.

First of all, deliberation exhibits an epistemic function, that is, it provides a privileged tool for the exchange of different reasons and the improvement of the quality of the arguments grounding certain outcomes; secondly, by raising the ethical issues involved, deliberation provides a democratic legitimization to pharmacogenomics (as is the example in this case). This is due to the dynamics of its same functioning; that is, to its capacity to be all-inclusive of several perspectives, as well as to be capable of providing a qualitative improvement of the complexities of the rationales involved. Finally, the democratic legitimization of scientific research through deliberation, allows for both an internal and an external structuring of research policies on the basis of the organizing activities conducted by research institutes and local and national authorities. The functions just introduced apply generally and unconditionally to deliberative activities, granting certain properties to the outcomes involved.

2. Methodology of the DePGx Project

Moving to the presentation of the deliberative experiment on the ethical assessment of pharmacogenomics, it is important to consider that the primary aim the project has met, consisted in delivering guidance and indication to public policy makers, for future investments in this field of research. As already introduced, the DePGx Project is a project funded by the Canadian Institutes of Health Research in a joint cooperation between the Department of Family Medicine of McGill University, Montreal, Canada, and the Institute of Generic Medicine of the European Academy, Bolzano, Italy. Through the setting up of a certain number of deliberative polls, the project has achieved interesting results culminating in the proposal of a future draft of a Charter of Ethics and Pharmacogenomics as an instrument of policy self-regulation. First of all, deliberative sessions were organized into two steps and included three polls during the first phase and a final poll composed by first-stage group representatives. Each session lasted 1.5 hours. Groups were organized as including patients representatives, primary care physicians and stakeholders from genomic associations and health ministries. As far as the number of participants, according to the specific proposed methodology, it has been prioritized qualitative confrontation to quantitative participation. This has resulted in an “easy to manage” set of deliberative polls which has in parallel maximized qualitative outcomes. Among the patients group, four female and one male were included with an average age of 69 years. All were retired and educated. As far as the family physician session is concerned, two sessions were held on two different dates, with a total of two men and four females participants. Among them, four were family physicians and two were primary care researchers with an average age of 55 years. Finally, in the stakeholder deliberative forum, six stakeholders were evenly split between females and males with an average age of 38 years. They represented a genome policy centre, a national public health agency, an academic centre on personalized medicine and a national pharmacists association and a non-profit genome research centre.

Participants were selected on the basis of the epistemic differences of their knowledge. The criterion of epistemic difference has been considered as “the” crucial factor, among other traditional criteria (such as gender, age, race), for the construction of the polls. Accordingly, participants have been grouped first in view of a criterion of “variability within similarity” of their epistemic backgrounds, and then representatives of each poll have been rejoined into a final deliberative poll. Along the first phase, participants were grouped around three main polls representing respectively: general practitioners, lay-people, stakeholders (policy makers and interest groups). While in the first round, the idea was that of provoking a “critical clash” among the different epistemological narratives within the same deliberative groups themselves, in the second stage the aim has been that of provoking an inter-epistemic clash among the representatives of each group. From each deliberative poll it was expected a precise outcome, that is, it was expected a deliberative result upon which each group-participant would have finally agreed upon. The second stage of deliberation, indeed, was aimed at provoking the same “critical clash"
by increasing the level of specificity of the argument produced for or against certain specific identified issues. These issues were submitted for consideration to the participants by the moderator on the basis of the analysis of the outcomes of the first-round polls. Due to the peculiar methodological properties adopted, namely the epistemically differentiation of participants, the outcomes produced by deliberation have produced new findings and opened new roads for understanding the ethical concerns in pharmacogenomics. Indeed, it is from the disagreement of the participants that new and fair solutions have been sought both during the first and the second stage of deliberation.

The DePGx project was conceived in order to provide two frames of discussion focusing respectively 1) on basic ethical concerns raised by pharmacogenomics and 2) on the ethical implications raised by primary care pharmacogenomic interactions, as for instance a possible rethinking of informed consent forms. For the first point, participants were provided with two sets of basic issues to be assessed. The first provided a brief scenario where personalized medicine was presented as developing in view of specific population/race/territorial diseases emergencies and genetic reactions. The foreseeable consequence suggested was that those groups showing a lower genetic capacity for reaction to certain sets of medical treatments would be excluded from personalized medical treatment and pharmaceutical research. This position has been considered as raising a serious ethical threat from ethically unchecked policy for pharmacogenomic research and drug development. Indeed, an implication was the issue regarding the terms of individual interest maximization in respect to the group. This cross cutting issue virtually intersects the above-mentioned macro topic since it involves resource investments into specific diseases affecting a small number of people against the totality, as well as the interest of corporate groups, such as insurance or pharmaceutical companies coming into possession of personal data.

All considered, the issues addressed dealt with the risk-benefit assessment, their ethical implications and the actual promise of pharmacogenomic research. One of the most discussed points was whether there are enough convincing reasons to invest future research attempts into the pharmacogenomic sector, and on which specific grounds should public authorities invest into this sector. The evaluation of such points has been considered to explicate what is to be the public policy function that deliberative activities target, that is, the added advantage that a plurality of discussing actors would provide to the ethical assessment of pharmacogenomic research.

For the second area of application, the project wished to highlight possible ethical issues within the domain of informed consent. The question to be answered by participants regarded whether, in accordance to the existing state and international parameters on informed consent, personalized medicine may possibly worsen the condition of privacy or data protection. Indeed, even if health risks in taking part into genetic testing are excluded from consideration, the range and number of problems involved in such an analysis are wide and reflect all the usual security measures of anonymization of data involved into an ordinary system of privacy protection as well as sensitivity of the health information revealed. Patients were recruited on the basis of the circulation of an electronic information notice through the network of patients associations affiliated to McGill University Family Care Department and the McGill University Hospital Centre. As far as the recruitment of family physicians was concerned, the invitation was circulated through the associations of family physicians in Montreal. Stakeholders were identified through an earlier workshop that involved interested parties for genomic research in primary care.

3. Deliberative Results

Along the first round of deliberative consultations, each deliberative group addressed specific issues running from cost-benefit analysis to racial implications, privacy issues and the proposal of a National Charter or an Act regulating pharmacogenomics. As far as the importance of a cost-benefit analysis in the assessment of pharmacogenomics is concerned, stakeholders' participants reached a general understanding and agreement on the fact that this cannot be taken as the only perspective for measuring the advantages or the disadvantages of pharmacogenomics. Furthermore, none believed that pharmacogenomics provides a complete "solution" to many of the issues with prescription medication. Pharmacogenomics has been rather perceived as a method that should be "integrated" to supplement the already existing best practice strategies to optimize patient treatment. Contrary to what might be expected, stakeholders group focused on the fact that pharmacogenomics, besides certain possible negative and discriminatory effects, can further the study and the understanding of treatment for rare diseases. It has been noticed that the tendency, as in the USA for instance, is that of creating special categories for rare diseases. A distinction has been suggested separating the relevance of rare diseases and the rarity, not fully corresponding, of genotypes. It was thought that it is rather in the latter sense that ethical issues may arise due to possible low profits that such groups would provide. A similar line of reasoning has been followed among patients' deliberations. In this case, the discussion immediately addressed the costs of pharmacogenomics research, as well as the role that the federal government should play within the entire process. Some of the proposed ideas, concerned the fact that the government should be allowed to buy at a convenient price the required drugs in order to avoid patient discrimination and pharmaceutical speculations. It has been noticed that since the health system in Canada is public, it currently runs into several difficulties due to burdensome costs. Indeed, reservations were expressed in case research on pharmacogenomics would cut into the provision of services in other relevant sectors. Also for patients, genome testing was perceived as not being "the only solution" for treating diseases, so that carefulness has been suggested in communicating the realistic advantages of this research sector. Common consensus has been expressed on the following points: at present there are not sufficient reasons and evidences for investing money on pharmacogenomics research. Nevertheless, it was believed that if no investment were made in this field, then we will never know what advantages
could be obtained. Participants all agreed that money can be invested in genomic research only upon the condition that the government is involved in regulating costs, possibly by restricting the profit margin on drugs patented by the pharmaceutical companies. Also, a general agreement was achieved on the constraining role that the government should play towards pharmaceutical companies. This consisted in not letting them manipulate genomic research and consequently the health care system with only a profit motivation. Connected to the relevance and the limits represented by the cost-benefit analysis is a second bulk of issues addressed in particular by family physicians and the stakeholders. Whereas public stakeholders noticed how pharmacogenomic research could be extremely beneficial in reducing medical costs in developing countries, the former highlighted, on the contrary, the risk of group-stratification that pharmacogenomics can give place to. A specific set of ethical preoccupations regarded family physicians’ agreements on the ethical concerns raised by a scenario characterized by a lack of medical care for orphan populations and diseases. Indeed, participants established an interesting point of interconnection between population group/racial implications and pharmacogenomics by focusing on the case of a lack of medical care as a consequence of a genetic profiling. The point of concern regarded how should family physicians behave in the case a genetic screening would tell the person is not able to respond to the currently available drugs. This was considered to have very serious ethical implications and produced conflicting feelings in the perception of pharmacogenomics. Indeed, it was considered that if, in the first instance, personalized medicine produced many positive feelings, the possibility for a physician to inform a patient of the lack of care might cause several negative feelings. One further problem taken into consideration and being extensively connected with this issue were people’s expectations. What was considered as fundamentally important was the relevance of a large public information campaign in order to cope with people’s expectations. This touched upon a further aspect that was also debated, that of the perceived effects of a genetic test in accordance to the result it might provide. Indeed, it has been said that it must be considered the possible effects on depression arising from not being able to provide an effective drug as a consequence of the test. Finally, a general agreement by the participants has been expressed on the fact that pharmacogenomics promises to reduce the “poisoning” and the side-effects of general drugs used nowadays, even if a concern was expressed on the timing in obtaining the profiling results as well as on the necessity of an alternative system of management between all the interested sectors (family physicians, hospital laboratories, etc.).

A third point addressed more extensively later along the discussion occurred in the final mixed session, touched upon the need or the opportunity of enacting a Non-Discriminatory Genetic Act in order to protect information from insurance companies and employers. Even if ways for obtaining personal health information through family history tools were detected, genetic information was perceived as extremely sensitive issue in need of high protection. This does not amount, though, to consider such form of information as requiring a special type of protection besides the implementation of more sophisticated systems of informed consent. As it emerged also from the deliberative outcome derived from family physicians,

it was felt that personalized medicine does not raise special issues that are not yet part of the current practices for informed consent, but that actual informed consents are so informal nowadays that they need to be reformed. While a general agreement was obtained in considering genetic information on a par with normal medical information; no general agreement was achieved on the utility of legal acts in regulating the field or in protecting information. Indeed, some participants thought that the use of an Act, rather than a non-legally binding Charter, would rather prevent future modifications by blocking the process of updating policies as scientific/genetic research improves.

Overall, general support was expressed for pharmacogenomics. Nevertheless, the worry that this information may eventually be related to genetic disease prediction was mentioned. It was hypothesized that in as far as pharmacogenomics is supposed to present itself as an extension of the family history; then, no specific ethical problem would arise. The worry, as already mentioned, was perceived more as relying in the “mechanical” procedure that all this new approach would imply as well as in the privacy of the data that should be granted and in the delay in providing answers to patients. Finally, a concern was expressed in the role that pharmaceutical companies will play within this process. A unanimous agreement has been expressed in keeping pharmaceutical companies outside the process of genetic profiling in order to guarantee as much as possible independence and privacy of data. Even if it is easy to foresee that pharmaceutical companies would offer to pay the genetic screening, which currently runs from hundreds to thousands of dollars, a general understanding was reached in considering that money for screening can be progressively taken from the cutting off of the costs of hospitalization as well as in the progressive reduction of the costs of the tests.

As already introduced, after the first round of deliberative sessions, the project rationale has considered the development of a second polling session with the representatives of all deliberative groups. This second round of deliberative consultation, has served a duplicity of functions: 1) a refinement of the ethical issues involved in the ethical assessment of pharmacogenomics and 2) the proposal of new strands of solition for the observed difficulties. Nevertheless, before moving to further topics, participants spent time in discussing the problem of patenting, either as test patenting, or as gene patenting etc. as well as the more general issue of intellectual property rights. The discussion turned then to the question of who should regulate the process of pharmacogenomic research and drugs commercialization. Some initial thought was expressed regarding the opportunity for medical physicians to obtain a stronger role in health policy, even if after discussion, agreement was obtained in giving highest representation and power to patients. It has been claimed that patients’ psycho-social insights deserve to be taken more seriously within ethical committee and governing bodies and that they should be given a higher decision-making role. With only one exception, participants finally agreed on the non-opportunity of a yet another regulatory agency, suggesting rather the necessity of reforms for the already existing ones, in accordance to the improvement of patient representation and empowerment. A participant confirmed that Genome Quebec is actually thinking of including patients representatives within its body and that
this issue is becoming more pressing. Nevertheless, perplexities were advanced on
who is going to select patient representatives, since a wide range of perspectives
should be taken into account. The proposal has been made of including a high
range of patient participants within governing bodies with the aim of restricting the
possibility of voting only to a limited number. A second suggestion focusing more
on the regulatory scope, addressed the issue of providing health bodies with a more
extensive powers to regulate what pharmaceutical companies can and cannot do
with samples. While aware of the significance of several existing policy statements,
participants agreed unanimously in the draft of a charter document on the ethical
principles guiding pharmacogenomic research and clinical treatment. The scope
of the charter was suggested to be national and to be adopted as a standard for the
ethical approval of clinical and research projects.

Conclusions

From the above mentioned deliberative findings, a picture emerges where
pharmacogenomic research is seen as a very promising field of investment for the
reduction of costs of hospitalization, as well as for the production of more efficient
drugs. Nevertheless, the promise of a paradigm shift in medical and pharmaceutical
research is perceived by all involved groups as determining a wide range of ethical
concerns in need of a regulatory enterprise. The proposal of a national charter
on pharmacogenomic research has been thought, therefore, to be the most appropriate
initial step to be taken before future investments by the government and private
companies are made. In the light of such indication, it is therefore our hope that
governmental bodies will take all the appropriate steps in order to facilitate the
promulgation of such a regulatory tool.

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