

Forthcoming in: F Thiele et al (eds). *Bioethics in a Small World*. Springer: Berlin 2004

Bioethics and (Public) Policy Advice

Udo Schuklenk
University of the Witwatersrand
Faculty of Health Sciences
Division of Bioethics
Johannesburg 2193
South Africa
udo@udo-schuklenk.org

Jason P. Lott
University of Oxford
Brasenose College
Oxford, OX14AJ
United Kingdom
lott@imap.cc

Abstract

Bioethics, more so than any other field of applied ethics, has been historically defined by government commissions in English speaking countries such as the United States, United Kingdom, and Australia. Governments, non-governmental organizations and international institutions increasingly call upon bioethicists to provide advice and assistance in the creation of targeted ethical guidelines, indicating an ever-growing importance of professional bioethicists in shaping public policy.

Professional bioethical analysis has evolved from its modest beginnings as a purely academic exercise rooted in philosophy to emerge today as an influential force behind government regulation and legislation. Such influence is most clearly expressed by the unprecedented sums of money currently provided for bioethical analyses associated with particular public initiatives (for example, the Human Genome Project). Likewise, private firms and other commercial organizations, especially within the pharmaceutical and insurance sectors, maintain a growing interest in bioethicists, sponsoring professional positions in bioethics, entire research projects, and even whole bioethics institutes.

We argue that the consequences of these developments have been ambivalent from a professional point of view. On the one hand they have led to an appreciation of professional bioethical advice and its utility in the process of developing public policy. On the other hand they have engendered very serious conflicts of interest with the potential of negatively impacting bioethicists' professional activities and professional standing. Disentangling and understanding the practical roles bioethicists play in policy making is thus necessary for any positive movement promoting impartiality in ethical discussion and subsequent professional advice.

In the last part of this article we propose various solutions addressing the problems of bias and conflict of interest by means of changing the ways in which bioethicists engage themselves qua

professionals in policy development. We conclude that without such reforms, the credibility of professional bioethics may soon be lost, leaving the ethical foundations of public policy weakened if not thoroughly dismantled.

I. Introduction

“No academic field has been defined more by these government commissions than bioethics, beginning with the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.”

Jonathan Moreno

Bioethicists currently serve in many countries' national bioethics commissions as advisors on matters of bioethics. Similarly, large international organizations, such as the World Health Organization (WHO), as well as smaller international groups, such as the Council for International Organizations of Medical Sciences (CIOMS), frequently call upon bioethicists to advise professionally across a wide range of problems, from resource allocation decisions to intellectual property rights, ethical research guidelines, and many other issues. Bioethicists also serve on local, regional and national research ethics committees, as well as on numerous bioethics advisory boards within small and large commercial organizations, particularly those involved in the biotechnological and pharmaceutical industries.

As the influence of professional bioethicists has become more pervasive, so has their status of ethical advisors become more questionable. Consider, for example, United States President George Bush's decision to re-align his country's national bioethics commission by appointing bioethicists who publicly support the conservative ideologies maintained by his administration. Worse, it has been observed that such “commission stacking” practices are not limited only to the sphere of bioethics but indeed extend to the work of many US federal agencies.¹

Arguably this violates the United States Federal Advisory Committee Act requiring committees to insure balance among represented views. As Levendosky points out, “the act also requires that advice and recommendations ‘not be inappropriately influenced by the appointing authority or by any special interest.’”² Clearly the method of appointment to the US national bioethics commission fails to meet the demands of this act and thus stands as the most glaring example yet of politically motivated attempts to consciously manipulate the outcomes of professional bioethical advice.

Other questionable appointments have been less obvious. For example, since 1997 acrimonious international debate has ensued over what constitutes ethically appropriate standards of care in clinical trials undertaken in developing countries.³ A group of well-financed bioethicists located in the Department of Clinical Bioethics of the US National Institutes of Health toured the world teaching ‘research ethics seminars’ in developing countries, partly to ensure that their point of view was not lost on developing world-based clinical researchers, policy makers and bioethicists. When CIOMS invited participants from all over the world to attend their final Geneva-based discussions on research ethics guidelines, the organization was unable to finance the attendance of developing world-based delegates. By virtue of this only certain bioethicists were able to attend, namely those who, like the bioethicists supported by the US NIH, had access to significant external financial support. Arguably this affected the outcome of the CIOMS deliberations in a manner similar to President Bush's hand-picking of certain bioethics experts for his national commission.

These examples illustrate a significant risk for bioethics—that the activity of the professional enterprise itself could be undermined. The wider public might well begin to see a given national bioethics commission no longer as a group of professionals discharging their professional obligations in an unbiased manner, but instead as a group selected by the power of the day to conveniently serve an already pre-determined ideological agenda. It seems the prominence currently

enjoyed by bioethics in the public eye may in fact be coming at a significant price as it is increasingly utilized by powerful interest groups to coerce public debate and decision making.

In this paper we describe why bioethics inherently lends itself to these sorts of manipulations and propose how professional bioethicists, finding themselves 'roped in' to serve certain ideological agendas, should respond to this challenge.

II. The Problem

Bioethics understood as a discipline of applied philosophy offers professional expertise in response to varied normative problems. Insofar as a virtual catalogue of distinct normative problem-solving approaches is available to bioethicists, it is not surprising that one professional's bioethical advice is often exclusive (and incompatible with) another's. Recognizing this fact, the responses of bioethicists to a particular ethical problem posed by a sponsoring agency will be largely determined by their ideological convictions, rather than any consensus-generating motive. This in itself is not problematic, provided such ideological approaches are balanced with other views and positions expressed in the committee.

The problem is, of course, that sponsors are not entirely unlikely to choose their bioethics experts based on the types of response they seek to elicit from their funded panel, as the selection of ethics projects pertaining to the Human Genome Project suggests. Not a single bioethicist opposed to mapping the genome received funding from the Human Genome Project to further her or his research agenda (though those unopposed were funded from a significant percentage of the project's budget earmarked for ethical analysis). In turn, such academics were less likely to publish in professional journals, because they were busier fulfilling university teaching obligations than their moneyed counterparts, who were more likely to attend the international conference circuits and build their professional careers.

It seems reasonable to claim that bioethicists whose research agendas did not conform with those of potential funders are placed at a significant disadvantage to colleagues whose research activities match funders' ideological needs. Primarily, the 'conformers' research output is more likely to be larger than their 'non-conformer' colleagues, serving not only the implicit goals of the funders—they, after all, want their project to secure "approval"—but also providing an easy way for conformist-friendly bioethicists to rapidly advance their careers.

III. Bioethicists and Committees

Scientific progress has fostered many, if not most, of the bioethical issues faced by society today. More recent examples include human embryonic stem cell therapies, genetically modified organisms, life-sustaining medical protocols, advanced pharmacological medicine, etc., which have forced society to reconsider both practical allocations of limited resources (particularly money and time) and fundamental views on the nature of life itself (e.g., does a human embryo have moral rights? does genetic modification somehow violate basic moral principles? are artificial life support patients best considered alive or dead, and do they have any moral rights?). A proliferation of committees/ commissions/boards has arisen in response to these problems, which are typically populated with bioethicists who are supposed to have professional expertise in analyzing these issues. These committees exist at the local, national, and international levels and serve either public or private entities.

Public policy committees tackling bioethical problems are of particular interest, since their influence extends well beyond any private firm's internal decisions and can produce widespread social effects. Such committees can generally be broken down into two categories: (1) those that produce legally binding regulations (usually statutory bodies), and (2) those that produce policy documents influencing public debate but which do not carry the force of law.⁴ Given the sheer

prevalence of the latter, bioethicists are more likely to find themselves serving on committees producing guidelines, recommendations, and non-binding decrees/opinions, thereby assisting governments and the wider public in approaching a given issue, who in turn make legal decisions.

(a) conflicts of interest

Sponsorship of public committees by corporations or governments means a number of potential problems for member bioethicists, particularly for those at the beginning of their careers, the foremost of which are conflicts of interest. These conflicts of interest reside at different problematic levels and may affect public committees of any size and audience.

- *Bioethicists aiming to advance their own careers tempted by calls for (research) proposals serving particular ideological needs of funders*

As discussed above, new bioethicists avidly seeking career advancement may find it easiest, if not sometimes necessary, to pursue sponsored research projects, if only because this affords them opportunities to publish, attend conferences, build professional contacts, etc. that would otherwise be retarded (if not made impossible) in the absence of sponsor funding.

- *Bioethicists, like other scientists, having to frequently decide between true research needs (i.e. obvious research priorities) and calls for (project) proposals that are not congruent with these research priorities.*

Ongoing research ethics projects all over the developing world are a case in point. Clearly there are more pressing bioethical research and policy developmental needs in developing countries than research ethics, yet funding agencies in the North America, continental Europe and the United Kingdom have made funding of these projects a priority.⁵

The developing world has subsequently been flooded with research ethics training programs, promoted by illustrious incentive packages such as all-expense-paid trips to North America. It is particularly ironic that many developing countries in fact have the capacity to teach their own researchers and ethics committee members about research ethics (without the developed world's help), yet funders, of a seemingly neocolonialist/paternalistic bent, insist on training developing world-based scientists about research ethics in, for example, the United States. Given the recent large-scale failures of institutional review boards in the US, coupled with the relentless research ethics breaches of US and other developed country researchers working in developing countries, this in itself is quite remarkable.⁶

- *Bioethicists fundamentally orienting themselves towards ethical positions which support prevalently-funded ideologies*

The most basic sort of conflict of interest, the infrastructure of bioethics as a field could be altered by the presence of heavily sponsored universities and other instructional institutions who present a distorted, even one-sided view of ethical positions on certain issues or even entire debates. New bioethicists may be "pre-ordained" (via skewed instruction) to support ideologies in harmony with those of sponsors affiliated with their college or university.

We recognize that this sponsorship effect on instruction is, in principle, difficult to prove. For example, a dedicatedly conservative bioethicist who preaches against stem cell research to his students may in fact be only coincidentally affiliated with an educational sponsor who holds the same views. But it also does not seem unreasonable to assume

that *some* formal bioethical instruction may be a direct dictate of who pulls the purse strings, placing the integrity of bioethics as an academic field at serious risk.

These are only some of the important conflicts of interest which have, to date, remained essentially unaddressed by professional bioethicists, many of whom are likely to encounter these and other relevant conflicts routinely in committee work. Such conflicts (and potential for conflicts) will no doubt persist unless deliberate steps are taken to remove them from the professional bioethics community.

(b) impartiality and consensus generation

Eliminating potential sources of conflicts of interest from public policy committees does not imply, however, that bioethicists should strive for impartiality. There is no 'right' ethical theory to be embraced by all professional bioethicists. A properly conceived role of professional bioethicists recognizes that distinct philosophical approaches to bioethical problem solving (e.g. strict utilitarianism versus social contract theories versus classical Kantianism) preclude impartiality for individual bioethicists, who should not be expected to favor the same philosophical theory. As mentioned previously, bioethicists serving on the same committee and analyzing the same problem may nonetheless hold differing opinions and frequently issue non-overlapping (or entirely opposed) professional recommendations.

A lack of impartiality among individual bioethicists is important for properly contested committee deliberations—essential if a given bioethical problem is to receive thorough analysis. It is relatively easy to see how public policy committees may be corrupted by sponsors even when funding-related or other conflicts of interest are not immediately present. Committee sponsors can easily manipulate deliberations by appointing only like-minded bioethicists who are likely to make recommendations desired by the sponsor, generating predictable consensus before the committee even sits down to meet. The bioethics committee sponsored by the Human Genome Project for example, had no members opposed to critical of the mapping endeavor, allowing seamless execution of the project. Nor have many been surprised by the bioethical policy advice from President Bush's National Bioethics Advisory Council, which has mainly echoed the voices of Leon Kass, Francis Fukuyama, and other conservative committee members.

Across the Atlantic, similar concerns have been raised about the 2001 establishment of a second German bioethics advisory commission—the German National Ethics Council (Nationaler Ethikrat)—which, as Friele notes, “was suspected of producing predictable outcomes.”⁷ Its government sponsor, the German Chancellor Gerhard Schröder, “was accused of gathering experts, well known for their position, to back his own position against the recommendations produced by the first committee (the German Enquête Commission),” which has been making policy recommendations on the same bioethical issues since March 2000, but clearly not to the liking of Chancellor Schröder.⁸ Tellingly, a *Die Zeit* commentator has noted, “Der Kanzler ist ein Meister in der Erfindung von Nebenparlamenten, die er unter wohlthätiger Berücksichtigung eigener Ziele auswählt und unter Einschaltung von SPD-Hausphilosophen auf Vordermann bringt—wie beim Nationalen Ethikrat.”⁹

Private sector sponsorship of bioethics committees/institutions is more troublesome, since funding-related conflicts of interest become increasingly probable. Carl Elliott has recently emphasized the growing “coziness” between corporate money and academic bioethics centers.¹⁰ The University of Pennsylvania Center for Bioethics, for example, receives substantial funding from such pharmaceutical companies as Monsanto, de Code Genetics, Millenium Pharmaceuticals, Geron Corporation, Pfizer, AztraZeneca Pharmaceuticals, Human Genome Sciences, and others; Stanford University's Center for Biomedical Ethics has received a one million US dollar donation from the SmithKline Beecham Corporation, while Merck has “financed a string of international ethics centers in cities from Ankara, Turkey to Pretoria, South Africa.”¹¹ Another notable example is the Midwest Bioethics Center located in Kansas City, Missouri, which has received nearly six

hundred thousand US dollars from the Aventis Pharmaceuticals Foundation to issue policy statements on research ethics under the newly-founded Research Integrity Project.

Sponsorship has not been limited to health-related industries. The University of Toronto Joint Center for Bioethics, for example, has received over a million dollars from the Sun Life Corporation (a large Canadian insurance firm) to establish the Sun Life Chair in Bioethics. Though not strictly an issue in bioethics, it is perhaps remarkable that few (if any) bioethicists at the joint center have published extensively on the questionable insurance activities associated with the Sun Life Corporation since endowing the Toronto chair in 1996.¹²

It remains unclear how these examples of public bioethics committees and institutes have secured impartiality among their individual members to issue credible policy advice in the face powerful, behind-the-scenes political and financial interests. Certainly the aim of these third parties is to guarantee ethical consensus, and yet that is entirely the *opposite* of what should occur in those committees serving in an advisory capacity. Advisory committees enjoy impartiality only insofar as the partialities of individual members are representative of important bioethical positions which are balanced against each other.

Committee consensus is generally only valuable to policy-making committees, who must concur in the end for committee-centric policy formation to be practical, which even then must be free from irrelevant, biasing motivation from sponsors that could artificially impose agreement. It is of course debatable whether policy-making/statutory committees have any valuable function in societies that promote democratic governance, which (almost by definition) exclude appointed committees bypassing standard election procedures. A strong argument can be made that bioethical statutory committees operating under optimal conditions (whose member bioethicists collectively hold a plurality of ethical positions and are free from conflicts of interest) remain illegitimate as policy-making institutions because, importantly, they fail to meet minimum standards of democratic representation (absent of both direct and indirect electoral representation). Accordingly, we believe that professional bioethicists serving or invited to serve on such committees might do well to avoid them altogether, placing a higher premium instead on more basic democratic political procedures.

(c) transparency

Transparency is critical for public policy committees to maintain and establish integrity and produce reputable results. Transparency can assuage fears of conflicts of interest and reveal whether committee impartiality is truly genuine or merely imposed from above. In these ways, transparency can act as an external constraint promoting discipline among member bioethicists.

Unfortunately most public bioethics committees do choose to meet behind closed doors and forgo transparency, creating suspicion among other professional bioethicists and the rest of the public, even when in fact there may be no justifiable grounds for believing something to be amiss. It is quite easy to imagine a well balanced, representative bioethical committee comprised of members individually lacking any conflicts of interest nonetheless raising various eyebrows because they decide to meet and deliberate in private, publishing conclusive recommendations *ex nihilo*. Bioethical advice administered without transparency ushers in uncertainty, which must be dispelled with knowledge of the previous considerations leading to the committee's final results.

Consider, for example, the development of the CIOMS research ethics guidelines.¹³ It is not obvious how or by whom members of the authoring committee were selected. Nor is it obvious how the deliberations were determined or if they were guided by a pre-defined operating procedure. There was also no clear consultation of those potentially affected by the guidelines, i.e. it is unknown how those affected by the guidelines were approached for comments/consultation, and how these responses were subsequently handled and integrated into further committee deliberations. Erecting an almost complete barrier between itself and the public, the CIOMS Research

Ethics Committee did not even allow public access to the public's own comments received by the committee.

More generally, consider the sorts of numerous corporations providing support for many bioethics think-tanks, or the lack of justification behind the appointments of committee members by governments and other international bodies. In no instance has the public been explicitly consulted or involved in the selection or deliberation of these committees. At best, the public discovers private-sector affiliations and political motivations after the process of policy advising and creation has already occurred and are, in effect, removed entirely from the laws that eventually govern them. Lack of transparency in committee appointment and deliberation thereby marginalizes a fundamental pillar of democratic rule—participatory government.

Bioethicists serving committees often weakly justify their opaque proceedings and deliberations by citing a need for freedom of expression and debate that is simply unattainable when under the scrutiny of the general public, which often carries certain expectations regarding consistency in opinions and time-efficient results. It is argued that committee members could be unduly scrutinized for altering their position on an issue if all aspects of deliberations were entirely open, or criticized for admitting ignorance, or pressured to end debate prematurely—each of which detracts from the quality of committee work.¹⁴

Unfortunately this response misses the mark: committees ultimately answer to the public they serve, which must be fully informed of their activities in order to meet the bare requirements of democratic rule. The propensity of non-member laypersons to encourage inefficiencies during open committee deliberations reflects more a poorly selected committee unable to publicly justify their deliberative thoughts than an incorrigible public intent on disrupting and side-tracking important policy debate. Such democratic principles, coupled with the heightened ability of committee bioethicists to more easily hide conflicts of interest and sources of partiality in private than in public spheres, presents a strong case for complete transparency throughout the bioethical advisory process—beginning with committee selection and ending with full disclosure of all materials related to policy advice.

IV. Solutions

The problems of conflicts of interest, impartiality, and transparency discussed above immediately suggest ways of reinforcing the integrity of professional bioethical advice. Genuine deliberation occurs only when conflicts of interest are (to the greatest possible extent) minimized, when bioethical advisory committees are impartial by virtue of a plurality of representative bioethical views, and when deliberations are best described as fully transparent, hiding nothing from the public.

We believe that promising reforms (to help achieve, at least partially, the requirements above) begin with the basic functioning of bioethics advisory committees. First, the role professional bioethicists on such committees should be reconceived. Bioethicists should be consulted to (a) give the committee some idea of the landscape of ethical positions relevant to the issue in question and (b) establish the parameters/boundaries within which committee deliberations should subsequently proceed. Recognizing the latter as a constraint on both the committee deliberations and the influence of member bioethicists highlights the true purpose of professional bioethical advice. Again, Friele puts the point nicely:

“In contrast to widespread belief, ethicists neither rely on mere moral intuitions nor do they have to be able to give final answers on legitimacy or any other questions to fulfill their task, which is to analyze different moral stances, etc. Rather, they can already provide a valuable contribution to deliberative processes by testing the various types of arguments used with respect to their usefulness as a means of discursive argumentation.”¹⁵

Bioethicists thus assist committee deliberations by putting forth various ethical theories to consider and then helping the rest of the committee avoid contradictions and inconsistencies during

the debate that follows. Notice how this conception of committee debate further diminishes the impact of lingering conflicts of interest by limiting the perlocutionary role of the bioethicist.

Second, the debates of bioethical advisory committees should be open. Committee meetings and proceedings should not only be easily accessible to the public as they take place, enabling the public can have some idea about the current and future direction of committee deliberations, but also, at the end of debate, the committee should formally publish and issue to the public a representative compendium of the positions discussed during deliberations. This could, for example, take the form of an edited volume of collected papers offering various committee member views on the debated issue, which would then be widely distributed to the public for review.

Third, the committee should encourage the public to provide feedback (opinions, comments, suggestions) on the published deliberations, which would then be combined with the original committee positions and presented both again to the public (to make individual responses available to all) *and* to the appropriate representative governing body (e.g. a country's parliament). The governing body could then consult the work of the committee as well as the public response to that work, thereby informing consequent debate of elected officials who in turn issue the appropriate legislation.

We believe these three reforms could substantially improve upon the workings characteristic of most bioethical advisory committees, assisting bioethicists in maintaining their professional integrity and more deeply involving the public on issues of great societal concern. The fact that a similar model of the bioethical advisory committee process has been implemented by the Swiss government with great success and sustained public advocacy is, we believe, proof of its viability.

V. Conclusion

Professional bioethicists must continue to remain cautious over the explosion of public policy committees seeking their assistance. Certainly bioethicists voice important insights on bioethical matters, but their voice should neither reflect the underlying interests of financially or ideologically motivated sponsors nor drown out the voice of the public. Recognizing that conflicts of interest, sources of partiality, and lack of transparency persist within public advisory committee deliberations is necessary to commence with much-needed improvements. To that end, we have suggested a few modest changes in the committee process which we hope will secure the future credibility of both professional bioethicists as public policy advisors as well as bioethical advisory committees as democratically consistent institutions.

¹ Minority Staff Special Investigations Division of the House Committee on Government Reform. 2003. *Politics and Science in the Bush Administration*. (Accessed on August 18, 2003 at <http://www.reform.house.gov/min>)

² Levendosky, Charles. The White House distorts science for political ends. *International Herald Tribune* August 20, 2003, p.6.

³ Schuklenk, Udo, Ashcroft, Richard E. *International Research Ethics*. *Bioethics* 2000; 14: 158-172.

⁴ Examples of the former include the United Kingdom Human Fertilization and Embryology Authority, the New Zealand National Ethics Committee on Assisted Reproduction, and the Australian Health Ethics

Committee. The latter includes the aforementioned United States National Bioethics Advisory Council, the National Council on Ethics in Human Research of Canada, the Finnish Advisory Board on Health Care Ethics, and the Belgian Advisory Committee on Bioethics.

⁵ Chadwick Ruth F., Schuklenk Udo. The Ethics of Research Funding. *Bioethics* 2003; 17(2): iii-v.

⁶ Editorial. Dying for a Cure. *US News and World Report* October 11, 1999. See also Schuklenk, Udo. Protecting the vulnerable: Testing Times for Clinical Research Ethics. *Social Science and Medicine* 2000; 51: 969-977.

⁷ Friele, Minou. "Do Committees Ru(i)n the Bio-political Culture? On the Democratic Legitimacy of Bioethics Committees." *Bioethics* 2003; 17: 303.

⁸ Ibid., 302-303.

⁹ Assheur, Th. "Defekte Demokratie." *Die Zeit*; 15:2002

¹⁰ Elliot, Carl. "Pharma Buys a Conscience." *American Prospect*; 12:17 (accessed on August 31, 2003 at <http://www.prospect.org/print-friendly/print/V12/17/elliott-c.html>)

¹¹ Ibid.

¹² Concerning the pension sales irregularities made by Sun Life in the United Kingdom, prompting review by the UK House of Commons Treasury Select Committee in 1999. The year-long Scotland Yard investigation into Sun Life was reported by the *Globe and Mail*, May 8, 1998.

¹³ *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization, Geneva, 2002.

¹⁴ Friele, 311-312.

¹⁵ Ibid., 314.