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# **Bioethics and Self-Governance: The Lessons of the Universal Declaration on Bioethics and Human Rights**

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*The following article analyzes the process of conception, elaboration, and adoption of the Universal Declaration of Bioethics and Human Rights, and reflects on the lessons it might hold for public bioethics on the international level. The author was involved in the process at a variety of levels: he provided advice to the IBC on behalf of the President's Council of Bioethics; he served as the U.S. representative to UNESCO's Intergovernmental Bioethics Committee; and led the U.S. Delegation in the multilateral negotiation of Government experts that culminated in the adoption of the declaration in its final form. The author is currently serving a 4-year term as a member of UNESCO's International Bioethics Committee.*

## I. INTRODUCTION

As advances in biomedical science and biotechnology continue to confer vast new powers to subdue nature for “the relief of man’s estate,” vexed moral and ethical questions inevitably arise about the use of such capacities (Bacon, 2000, 32). To what ends should they be applied? How might they be abused? Are they safe? What is the human meaning of such new powers? Might their use threaten human dignity? What does scientific freedom demand? What does justice require? Who should have access to the fruits of such scientific advances? In democratic regimes, these questions do not long remain the subject of mere academic reflection or private rumination. Because we must govern ourselves, such issues are debated in the public square and are thus transformed into political and, perhaps ultimately, legal matters. As the public square expands beyond national borders, matters of bioethical

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import increasingly become the focus of intergovernmental deliberations. Indeed, there is a long history of international instruments intended to provide guidance and even establish binding norms for the conduct of scientific research and the practice of medicine.<sup>1</sup> United Nations Educational, Scientific, and Cultural Organization (UNESCO's) Universal Declaration on Bioethics and Human Rights represents the most recent effort in this vein.

As is evident from its title, it is an extraordinarily ambitious document of potentially massive scope. A full and fair appraisal of its content and significance would require many pages. The scope of this article, however, is far narrower, namely, to analyze the process of the instrument's elaboration and adoption and to reflect briefly on what lessons this might hold regarding the wisdom and possibility of the international governance of science and medicine according to ethical principles.

To that end, the article will proceed in the following way. Part II provides a brief overview of UNESCO's role with respect to bioethics. Part III gives a short account of the origins and aspirations of the Declaration. Part IV analyzes the process of the elaboration of the Declaration (including the preliminary drafting by a UNESCO committee of experts and the subsequent negotiation among member states). Part V offers a brief reflection on what lessons the negotiation and acceptance of the Declaration might hold regarding global bioethical governance.

## II. BIOETHICS AT UNESCO

### The UNESCO Framework

In 1993, UNESCO established its Bioethics Program, which is part of UNESCO's Division of the Ethics and Science and Technology in the Social and Human Sciences Sector. The Bioethics Program has two advisory bodies, the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC), which collaborate to produce recommendations (often in the form of proposed declarations or conventions) for the consideration of UNESCO's governing branches (e.g., the Director-General, Executive Board, and ultimately the General Conference).

The IBC is composed of thirty-six experts who are, in principle, independent of the member states from which they hail. The IBC distinguishes itself as the only advisory body within the United Nations (UN) framework mandated to engage in reflection on the ethical implications of advances in the life sciences. The IBC is responsible for the initial drafting of recommendations (including declarations and conventions).

The IGBC is a thirty-six-member body drawn from UNESCO's member states, whose role is to advise the IBC on its various activities. In particular, the IGBC is called on to provide comments and advice on IBC drafts of bioethics instruments. As will be discussed below, the IBC is not procedurally

bound to accept any of the IGBC's comments or suggestions. Once the IBC has completed its draft instrument (ostensibly in consultation with the IGBC), the draft is submitted to the member states themselves, at a session (or series of sessions) where government-appointed policy experts negotiate, debate, discuss, revise, and, in principle, come to consensus on the instrument's final form. At the conclusion of this negotiation, the revised version of the instrument is submitted to the Executive Board and later to the General Conference for formal adoption or rejection. This is the process that has yielded UNESCO's three bioethics declarations: the Universal Declaration on the Genome and Human Rights, the International Declaration on Human Genetic Data, and the Universal Declaration on Bioethics and Human Rights.

This, in effect, is the road map for the adoption of bioethics instruments at UNESCO. A body of independent experts (the IBC) drafts the instrument with nonbinding advice and comment from government-appointed officials (the IGBC). The draft is then subject to negotiation and revision by government-appointed policy experts, after which it is ultimately submitted for acceptance or rejection by the General Conference itself. Throughout the process, the procedural standard of acceptance is consensus. Voting is strongly disapproved, and even the suggestion of a vote is deemed uncollegial and in very bad taste. This is not to say that member states (and the Secretariat itself) eschew applying pressure to the minority during negotiations. UNESCO observers have reported that enormous social pressure is sometimes applied to such holdouts; they are strongly criticized and hectorated by the majority as "blocking consensus" and refusing to "act in solidarity" with the majority. Seasoned UNESCO observers note that such tactics are highly successful at achieving "consensus."

### UNESCO and the United States

To fully appreciate the dynamic of the negotiation of the Universal Declaration on Bioethics and Human Rights, it is necessary to understand the historical relationship between UNESCO and the United States. The United States (along with the United Kingdom) withdrew its membership from UNESCO in 1984, citing excessive politicization of the body (especially in matters relating to the Cold War), an institutional bias toward statist solutions to problems under consideration and general ineptitude and incompetence in the management of UNESCO. The U.S. decision to withdraw was bipartisan and was widely praised by the editorial pages of *The New York Times*, *The Washington Post*, and *The Wall Street Journal*.

In September 2002, President Bush announced that the United States would rejoin UNESCO, noting that the problems that prompted the U.S. departure had been largely addressed in a satisfactory way. It soon became clear that a chief priority of newly appointed Ambassador Louise Oliver was to demonstrate that the United States is an active, supportive, and fully

engaged member of UNESCO. It was in this spirit that the United States entered the process of elaboration of the Universal Declaration.

### III. ORIGINS AND ASPIRATIONS OF THE DECLARATION

In October 2001, at its thirty-first session, the General Conference of UNESCO requested that the Director-General investigate the possibility of elaborating an instrument that would articulate “universal norms of bioethics.” Thereafter, the Director-General instructed the IBC to draft a report on the feasibility of such a project. In June 2003, the IBC finalized its report, which affirmed both the need for and the feasibility of elaborating an instrument that would set forth universal norms of bioethics. Moreover, the IBC’s final report made it clear that it regarded UNESCO to be the appropriate forum to undertake to produce the instrument, given its unique mission to articulate and disseminate international standards in the field of social and human sciences. At its meeting in October 2003, the General Conference declared that it was “opportune and desirable to set universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics” (UNESCO, 2003, 47). The General Conference instructed the Director-General to set in motion the formal process of elaboration.

### IV. THE PROCESS OF ELABORATION

#### The Questionnaire and “Consultation”

As a first step in the elaboration process, the Secretariat solicited comments from the member states about the potential scope and substance of the instrument. It did so by circulating in January 2004 a very short questionnaire to all 191 member states. The questionnaire itself was quite spare and provided very little context or explanation of its procedural or substantive questions. For example, the questionnaire asked procedural questions like “Should the Declaration include a preamble?” (98% of respondents voted “yes”); “Should the Declaration be organized into Sections?” (98% of respondents voted “yes”—one wonders what a declaration without sections would look like); and “If so, which sections could be included? General provisions? Scientific research? International cooperation? Promotion and implementation?” There was no background provided, nor a discussion of the possible virtues or drawbacks of a preamble and its contents, nor was there any elaboration on the content or significance, or even definition of the proposed sections. Moreover, the only possible answers permitted were a binary “yes” or “no.”

The questions as to potential substantive content were similarly formulated. Respondents were invited to provide a simple “yes,” “no,” or “no preference” answer to questions such as “Which fundamental principles should

be reaffirmed in the Declaration? Autonomy? (82% of respondents voted “yes”). Benefit sharing? (80% voted “yes”). Confidentiality? (95% voted “yes”). Equality? (90% voted “yes”). Freedom of research? (82% voted “yes”). Informed and free consent? (98% voted “yes”). Integrity of research? (92% voted “yes”). Justice? (90% voted “yes”). Nondiscrimination? (99% voted “yes”). Respect for human dignity? (100% voted “yes”). Respect for privacy? (98% voted “yes”). Solidarity? (82% voted “yes”). Transparency? (96% voted “yes”). Truth telling? (89% voted “yes”). None of the principles was defined, explained, or elaborated. Nor was there any explanation in the questionnaire as to how the principles related to one another or how conflicts among the principles might be resolved.

It is difficult to see how such questions formulated in the abstract and lacking any context or explanation could provide meaningful guidance to the Secretariat. Compounding this difficulty was the very low percentage of completed questionnaires returned to the Secretariat. Only sixty-seven of UNESCO’s 191 member states responded. Moreover, among those member states that did provide responses, there was a marked disparity in the regions represented. For example, the ratio of North American and European responses to those from Latin America and the Caribbean was five to one (thirty-one responses compared with six). The ratio of North American and European responses to those returned from African member states was three to one (thirty-one responses compared with eleven).

In April 2004, the IBC convened an Extraordinary Session to discuss the elaboration process. At this session, the IBC reviewed the results of the questionnaire and received advice and comment from invitees, including representatives from various member states’ national bioethics committees, officials from relevant intergovernmental bodies and international agencies (such as the World Health Organization [WHO]), and an assortment of nongovernmental organizations.

### The IBC Drafting Committee

Immediately following the conclusion of the April 2004 Extraordinary Session of the IBC, a drafting committee was selected to begin work on the Declaration. Justice Michael Kirby of the High Court of Australia was chosen to chair the IBC drafting committee. The timetable for the drafting committee set by the Executive Board was quite compressed: they were to meet only seven times between April 2004 and January 2005, after which the preliminary IBC draft was to be submitted to the member states, whose government policy experts would then conduct negotiations in two rounds, to be held in April and June 2005. This timetable provoked widespread criticism and concern, particularly in light of the extraordinary aspirations and ambitions for the Declaration itself; the IBC drafting committee had only seven meetings over nine months to articulate and elaborate the universal norms of bioethics.

The meetings of the IBC drafting committee were closed, and the substance of the deliberations was a jealously guarded secret. There was a report issued following each meeting that reflected the agreed-on version of drafts produced at each meeting but did not provide insight into the process or substance of the deliberations that yielded the text itself.

The active membership of the drafting committee seemed to fluctuate from session to session (as evidenced by the different signatories to the reports that followed each meeting). It would appear from the signatory pages, as well as from the nature and frequency of interventions made at the various IBC meetings from April 2004 until January 2005, that there was a small core of committee members who regularly attended drafting committee meetings and who were most actively involved in its work. This core group included Justice Kirby, Leonardo De Castro (a philosopher from the Philippines), Héctor Gros Espiell (a professor of international law from Uruguay), Nouzha Guessous-Idrissi (a professor of parasitology-mycology from Morocco), Michèle Jean (chair of the IBC and vice president of the administrative council of the Fonds de la Recherche en Santé du Québec), Judge Patrick Robinson (judge at the international criminal tribunal for the former Yugoslavia, originally from Jamaica), Hans Galjaard (emeritus professor of genetics from the Netherlands), and Edmund Pellegrino (emeritus professor of medicine and bioethics from Georgetown University and one of the most important figures in bioethics in United States). The drafting committee was, by virtue of its core membership (and its leadership under Justice Kirby), strongly oriented toward international law and human rights rather than “bioethics” as such. Only two members of this group were academic bioethicists (Pellegrino and de Castro). The remaining members were lawyers, researchers, or public officials.

#### “Consultations” with the IGBC

The IBC released a “First Outline of a Text” in June 2004. It was clear from this outline that the drafting committee had decided to limit the scope of the instrument primarily to those issues affecting human beings, although recognizing that there were additional important issues (such as stewardship of the biosphere and other environmental concerns) that would be acknowledged. This was a decision consistent with preferences expressed by those member states who returned the questionnaire (in response to the question “Should the Declaration be limited to human beings?” to which 66% of respondents answered “yes” and 34% replied “no”).

The outline also suggested that the drafting committee had decided to articulate principles of general applicability rather than wade into the thorny questions that would arise from efforts to flesh out how such principles might be applied to actual problems in concrete contexts. For example, the first outline included a list of principles such as “Human Dignity, Human Rights, and Justice,” “Diversity and Tolerance,” and “Solidarity, Equity, and

Cooperation,” but did not elaborate on how these principles might be applied in practice in the context of human cloning, research involving human embryos, or end-of-life matters. This approach seemed to reflect the reasonable worry that consensus on these sorts of vexed questions would prove impossible and doom the entire project. One especially noteworthy feature of the first outline, however, was the inclusion, in the “Aims” section of the draft, of a provision that declared one of the objectives of the instrument to be the promotion of “respect for life in all its diversity and in particular respect for human life.”

Shortly after the release of the first outline, the Secretariat convened an “Information Meeting” with the IGBC to advise that body of the IBC’s progress. At this meeting, the first contours of the concerns of member states began to emerge. In response to Justice Kirby’s progress report, IGBC representatives from Latin America (Brazil in particular) raised very strong objections to the outline, arguing that it did not go far enough to condemn what it called “biopiracy,” a pejorative expression for the practice whereby commercial interests acquire and appropriate the traditional medical and pharmacological knowledge of indigenous people in developing countries, without compensating such people in return.

Other delegations, such as the United States, Canada, and Germany, expressed the worry that many of the provisions of the draft were formulated in a manner not appropriate to a declaration in that they used binding language (such as “shall”) rather than hortatory language (such as “should”). These delegations urged that because a declaration is an aspirational expression of principle, rather than a legally binding document (such a treaty or a convention), the hortatory “should” is more appropriate. These delegations (*pace* Brazil) also expressed the worry that the first outline did not sufficiently confine the scope of the instrument to matters relating to human beings; the inclusion, for example, of “Ecological Responsibility” as the first “Principle” was cited as an overbroad expansion of the Declaration’s scope. The U.S. delegation offered praise to the IBC drafting committee for the positive emphasis accorded to human dignity and the respect for human life.

Over the next five months (from July 2004 to January 2005), the IBC drafting committee met four times and circulated a newly revised draft following each meeting. Additionally, in October 2004, the committee solicited written comment from member states. By December, they had received replies from twenty-seven member states and one permanent observer, which the committee read in advance of preparing the “Fourth Outline of a Text.”

From January 24 to 28, 2005, the IBC and IGBC convened a joint session to discuss the Fourth Outline, line by line. The criticisms of the new draft leveled by IGBC members were largely the same as they had been in the June 2004 meeting (in response to the prior draft). That is, the developing world (in particular, Latin America, represented chiefly by Brazil’s delegation) argued strongly that the draft did not go far enough to protect the property rights of

indigenous peoples in their traditional knowledge and was not emphatic enough in asserting the right to health and essential medicines. The industrialized nations, represented chiefly by IGBC members from Canada, Germany, Japan and, to a lesser extent, the United States, renewed their previous worries that the Declaration's binding language was not consistent with the logic of a declaration, that intellectual property rights might be undermined by some of the provisions, and that the draft's definition of bioethics was overbroad and encompassed literally every social concern under the sun.

The U.S. IGBC representatives objected strenuously to the excision of the provision in the Aims section that asserted that a central purpose of the document was to promote respect for human life. Specifically, the U.S. representatives argued that respect for human life was so foundational as a general principle that any instrument purporting to articulate universal norms of bioethics that failed to affirm this concept would (and should) not be taken seriously. An intervention from the IBC drafting committee member from the Netherlands illuminated the rationale for this excision: the drafting committee, he said, struck the phrase "respect for human life" from the draft because it might be construed as a restriction on practices exploitative or destructive of fetal or embryonic human life, such as embryonic stem cell research, human cloning, or abortion—activities that a majority of the drafting committee did not wish to be heard to oppose.<sup>2</sup> The United States responded that this objection was unintelligible in light of the logic of the Declaration itself. By design, the instrument was a statement of general principles that clearly remained silent as to their concrete application. The IBC was not persuaded, and the provision was not returned to the text.

The United States also strongly objected to the inclusion of a provision that declared that progress in science and technology should contribute to "access to quality health care, including reproductive and sexual health." The United States argued that it was unseemly and peculiar to single out these branches of medicine for emphasis and that this appeared to be an inappropriate endorsement of abortion rights. An intervention from a Dutch member of the IBC drafting committee confirmed the U.S. worries. He observed that the drafters did, in fact, have abortion in mind as part of "reproductive health."<sup>3</sup> The U.S. delegation renewed its opposition, noting that such inclusion was contrary to the spirit of the document (as an articulation of general principle rather than concrete application), and would make consensus impossible. The U.S. arguments fell on deaf ears in the IBC, however, and the provision remained intact. The United States concluded its final intervention by noting its puzzlement and difficulty in reconciling the drafting committee's concerns about the implications of a generic phrase such as respect for human life with its utter absence of concern about an explicit approving reference to the highly controversial (and conspicuously specific) notion of reproductive health.

### The IBC's Final Draft

Less than two weeks after the conclusion of the IGBC/IBC meeting, the IBC approved the work of the drafting committee and released its final version, titled "Preliminary Draft Declaration on Universal Norms on Bioethics." Although there were some cosmetic alterations to the Fourth Outline, it was substantively the same in all important respects. The drafting committee had not taken seriously the objections and concerns of any of the members of the IGBC. The principal concerns raised by the developing world had not been addressed. The worries of the industrialized world were ignored. And the particular concerns of the United States had been disregarded. Indeed, the final draft not only lacked any reference to the respect for human life (from the first version) but also included a provision that stated that it was an aim of the Declaration to "recognize the importance of ... the responsibilities of human beings toward *other* forms of life" (emphasis added). Thus, the final draft included an anomaly (galling to the United States) in the form of the moral injunction to mankind to pay due regard for all forms of life except human life.

The final draft was presented with much fanfare. The drafting committee chairman, Justice Kirby, reprised a speech that he had delivered at the outset of the IGBC/IBC meeting, outlining what he regarded as the "Twelve Achievements" of the IBC's draft (Kirby, 2005). Justice Kirby proudly cited what he regarded as the draft's primary contributions to the governance of bioethics on the global level. First, the draft was completed in the time frame provided by the Executive Board—in nine months the group produced a draft instrument of breathtaking scope, novelty, and import. Second, Justice Kirby declared that the committee had drafted an "inspirational" document whose rhetoric amply reflected its subject matter, for, in Justice Kirby's words, "at stake is the future of humanity and all other living things in the biosphere." Justice Kirby likewise noted the "rigorous drafting" as the third laudable achievement of his committee. Specifically, he cited the recurring formulation "any decision or practice," which established the circumstances to which each principle applied. In crafting this language, the committee intended to assert that the Declaration offered guidance to all relevant actors at every relevant stage of decision making. Fourth, Justice Kirby celebrated the provision that noted that the provisions were "interrelated and complementary." Fifth, he praised his committee's product for rooting its provisions in the tradition of human rights law. Sixth, Justice Kirby praised his committee for expanding the scope of bioethics to encompass pressing social concerns (such as poverty, illiteracy, and the like). Seventh, Justice Kirby congratulated his committee for its organization of the principles. Eighth, he noted approvingly the committee's handling of the matter of the "precautionary principle," a particularly vexed matter in Europe about the standards and burdens for risk assessment in the environmental context.<sup>4</sup> Kirby offered his opinion that the committee

had formulated a novel provision that was distinct from either of the competing models that would “sufficiently reflect concerns about risks whilst avoiding the divisive international debates about the so-called precautionary principle.” Ninth, Justice Kirby expressed his pride at the procedural “Implementation” provisions of the Declaration, which were meant to promote the values of honesty, integrity, transparency, and the like, in making decisions within the scope of the Declaration. Tenth, Kirby noted approvingly that the Declaration expressed the importance of man’s duty to the biosphere. Eleventh, he praised his committee’s inclusion (over the objection of many delegations) of mandatory and binding language such as “shall” for all provisions except for those explicitly addressed to states (which used the word “should”). Twelfth, and last, Kirby expressed admiration for his committee’s provisions relating to follow-up and monitoring by relevant UNESCO bodies.

### The Government Expert Negotiation

Approximately two months after the completion of the IBC’s work and the release of its final draft, government-appointed policy experts met to begin negotiations on behalf of their member states. Although it was clear from the outset that consensus would be difficult to reach, there was consensus that the IBC draft was entirely inadequate and would require radical revision if the Declaration were to be salvaged. Despite the strong substantive disagreement among various delegations (and coalitions of delegations), there was surprising uniformity of opinion that the IBC had not engaged in meaningful consultation with member states or other relevant parties. The questionnaire in particular was subject to withering criticism by member states. There was a widespread view that advice from member states in the IGBC had been roundly ignored by the IBC. Member states were in broad agreement that the drafting process lacked transparency and some went as far as to call it inappropriately secretive. Member states criticized the compressed time line. Some member states (notably from the developing world) expressed their disgust that the drafting committee itself was insufficiently diverse. Still other member states questioned the institutional competence of UNESCO generally (and the IBC specifically) to elaborate a document focused on bioethics. Indeed, the complaints about the IBC were so widespread and severe that there was a suggestion to pointedly omit any reference to the IBC in the Declaration’s final version and to strip from it any role in promoting the Declaration.

Despite the uniformly held view that the IBC’s draft was profoundly flawed and that the process that produced it was defective, there was little substantive agreement at the outset. Several different agendas emerged, the seeds of which had been evident in the IGBC meetings (as many of the government policy experts appointed to participate in the negotiations had previously represented their member states at the IGBC sessions). Most obviously, there was a very strong “development agenda” supported by the Group of 77

(G-77), the largest coalition of developing countries in the UN, who agreed to vote together for purposes of this negotiation. The most outspoken representative of this group was the delegation from Brazil, who argued strenuously that the Declaration should condemn biopiracy and include provisions more strongly affirming the importance of access to quality health care and essential medicines, as well as the proper stewardship of the biosphere.

In addition to the development agenda, there emerged what might be termed “the industrialized nations’ agenda.” This group was composed principally of Germany, Canada, Japan, and the United States. Concerns raised by this coalition included worries about the language of legal obligation (i.e., “shall”) in a declaration that was meant to be hortatory, worries about an overbroad definition of “bioethics” that included every thing or event that might present a matter of social concern, and worries about potential threats to intellectual property rights arising from some of the provisions relating to benefit sharing.

There also emerged what one might call “the embryo research agenda,” championed principally by the United Kingdom, South Korea, Japan, and the Netherlands. This coalition sought to excise any language from the Declaration that might be construed to limit the prerogative to engage in research requiring the use and destruction of human embryos. For example, delegates from these member states vigorously opposed the restoration of the respect for human life as an explicit aim of the instrument. Moreover, they sought to introduce the global use of the word “person” rather than the broader term “human being” throughout the instrument so as to avoid a construction of the Declaration that might lend support to member states wishing to limit practices requiring the destruction of embryonic or fetal human life. Delegations committed to this agenda were particularly sensitive to such limitations, as they had just been handed a highly publicized defeat at the UN, which had issued a Declaration that deemed all forms of human cloning “incompatible with human dignity and the protection of human life.” Relatedly, it seemed as a general matter during the elaboration process that the Secretariat at UNESCO was eager to assert itself as the primary seat of bioethics policy making in the UN system.

Another agenda evident at the government policy expert negotiations might be named the “Nucleus of Future Conventions” agenda. The chief proponent of this agenda was France (and the Secretariat itself), whose interventions reflected a desire to use binding language (such as “shall” and, in the instrument’s title, “norms”) throughout the document so as to facilitate an easy transition in the future from a hortatory declaration into a binding treaty. Moreover, the French delegation was eager to minimize sometimes profound differences of opinion and declare consensus where none, in fact, existed. They were quite open in their hopes that this instrument was merely a “first step” or “nucleus” of what would become a vast constellation of legally binding instruments on the subject of bioethics.

Finally, there was the “Human Dignity and Respect for Human Life” agenda. At the outset the most vocal proponents of this view were the

United States, Costa Rica (which, at the time, held the presidency of the G-77), and the Holy See (a UNESCO observer). Interventions by these delegations reflected a concern that human dignity should receive pride of place among the Declaration's principles, as it was the font from which all human rights flow. Moreover, they argued, if the Declaration was to be understood as anchored in human rights law, it should not eschew the explicit principle stated in Article 3 of the Universal Declaration of Human Rights (cited approvingly in the preamble of the draft Declaration itself) that "everyone has the right to life, liberty, and security of person." Finally, these delegations reprised the argument that, formulated as a general principle, respect for human life was neither controversial nor objectionable. To the contrary, these delegations argued that a declaration on bioethics that failed to include a general approving reference to the respect for human life would utterly lack moral authority and could not be taken seriously.

As the negotiations unfolded over two sessions (in April and June 2005), it appeared that these various competing agendas were intractably opposed. To be sure, virtually all of the IBC draft had been dismantled; indeed, few if any of Justice Kirby's twelve achievements were left standing. The word "shall" had been globally replaced by "should" or a variation of it (e.g., "the fundamental equality of all human beings ... shall be respected" was replaced by "the fundamental equality of all human beings ... is to be respected"). The IBC's effort to define "bioethics" was rejected entirely. The member states agreed that there should be no such definition in the instrument. The ubiquitous phrase "any decision or practice" that expanded the scope of application of virtually every principle in the IBC draft was globally excised. The IBC compromise language regarding the "precautionary principle" was completely removed. The section titled "Conditions for Implementation" in the IBC draft was renamed "Application of the Principles" and was entirely rewritten. The relationship between the Declaration and preexisting domestic and international law as conceived by the IBC was completely overhauled and modified by new preambular language. The section titled "Implementation and Promotion of the Declaration" by the IBC draft was renamed "Promotion of the Declaration," and its provisions were dramatically changed to minimize the role of the IBC in promoting the Declaration (indeed, the IGBC was intentionally listed before the IBC as a resource for UNESCO for purposes of such follow-up activities.).

Despite the agreement reached on these provisions, the more vexed matter of the inclusion of respect for human life continued to be a source of difficulty. Similarly, the issue of whether and to what extent the concerns of developing nations should be addressed in the Declaration persistently divided the member states. Finally, no agreement had been reached regarding the worries of the industrialized countries that the Declaration was inadequately protective of intellectual property rights.

The United States found itself in an especially difficult position given that it agreed with aspects of both the industrialized and developing world's agendas. It shared a commitment to the respect for life and human dignity echoed in the interventions of many of the developing nations (particularly by the delegations from Latin America and Africa) and found a natural affinity with their delegations for this reason. However, the United States did not share the view held by these member states that the scope of bioethics includes any social and economic matter of concern to developing nations (such as illiteracy). In short, the United States tended to agree with the industrialized countries that although the concerns of the developing nations had merit and required a comprehensive and sustained response, they were not appropriately addressed in a declaration purporting to articulate universal principles of bioethics. Despite this point of agreement between the United States and the group of industrialized countries, the latter coalition did not share the U.S. commitment to the inclusion of respect for human life as an explicit aim of the Declaration. Indeed, as their formal interventions made clear, some of the more influential member states in this coalition seemed implacably opposed to such language. Those remaining delegations in the coalition that were not unshakably resistant to the language nevertheless failed to offer interventions supportive of the U.S. position.

On the fourth morning of the second round of member state negotiations (June 23, 2004), the United States requested the privilege of the day's first intervention. Ambassador Pablo Sader of Uruguay (the able chair of the member state negotiations) granted the request. The United States began by explaining to the assembly that it had come into the negotiations with a very settled understanding of the scope of bioethics as a discipline and with grave concerns about including provisions in the Declaration that were outside of that scope. However, the United States explained, over the course of the negotiation it came to realize that the instrument was not rightly understood as an academic or scholarly treatise on bioethics (indeed, following the revision of the IBC draft, the instrument did not attempt to offer a definition of bioethics), but rather was a more comprehensive document that was meant to express and acknowledge matters of human concern that arose at the nexus of science, medicine, and technology. Certainly, the Declaration would contain certain principles of bioethics that should provide guidance for the actions of states and other relevant institutions and individuals, but it could also recognize the importance of other serious matters that arise in the same context.

Animated by this new understanding of the Declaration, the United States offered revised language (borrowed directly from the World Health Organization's Constitution) that it hoped would address the concerns of the developing world. The United States offered a substantial rewrite of the IBC's draft Article 14 that would provide in relevant part:

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.
2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:
  - (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered a social and human good;
  - (b) access to adequate nutrition and water;
  - (c) improvement of living conditions and the environment;
  - (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;
  - (e) reduction of poverty and illiteracy.

The proposed language by the United States differed substantially from the IBC's draft language. Unlike the IBC draft, it neither did formally expand the scope of "bioethics" to encompass any and all worthy social concerns nor did enunciate "new" rights. The U.S. proposal did, however, explicitly take note of the descriptive fact that the promotion of health and social development is a central animating function and aspiration of government and society. Moreover, it reprised, verbatim, the language of the WHO Constitution that framed the enjoyment of the highest attainable standard of health as a fundamental right of every human being without invidious distinction. At the same time, it excised the reference in the IBC draft to ensuring access to "reproductive and sexual health" in the original provision and replaced it with the stronger and broader phrase "access to quality health care and essential medicines, especially for the health of women and children."

At the conclusion of the U.S. intervention, it became clear that the G-77 were completely taken by surprise by the willingness of the United States to listen carefully to and formally acknowledge the developing world's concerns.<sup>5</sup> There followed a dizzying sequence of interventions by members of the G-77 affirming and accepting the U.S. language. Ambassador Sader canvassed the room and declared that there was consensus as to this provision, and it was adopted as proposed by the United States.

The United States and the influential Latin-American delegations next turned their attention to the matter of respect for human life. The United States and the most outspoken delegations from the G-77 made it clear that the language in question should be reinserted. Those nations previously opposing the inclusion of this phrase asked permission to contact their capitals for instructions. Ambassador Sader granted this request and adjourned the session. When negotiations resumed, several delegations previously hostile

to the inclusion of respect for human life as an explicit aim of the Declaration signaled a new willingness to compromise in the interests of consensus. As a result, the following language was formally suggested for Article 2 (Aims) of the Declaration:

The aims of this Declaration are:

(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law.

Ambassador Sader surveyed the room for objections. Delegations previously opposed to the language realized that they were vastly outnumbered and remained silent so as not to be seen as blocking consensus. Hearing no objections, the chair banged the gavel and declared the provision to be formally adopted. With consensus achieved on the most vexed aspects of the Declaration (e.g., the development agenda, the excision of the reference to “access to reproductive and sexual health,” and the inclusion of “respect for the life of human beings”) and with the IBC draft almost entirely rewritten, the remainder of the negotiation was more or less harmonious.

Four months later, at the Thirty-third Session of the General Conference, the revised draft was adopted formally under the heading “The Universal Declaration of Bioethics and Human Rights.”

## V. LESSONS OF THE DECLARATION?

What, if any, lessons can be drawn from the elaboration and adoption of the Declaration regarding the wisdom or mechanisms of the international governance of science and medicine according to bioethical principles? A useful point of departure is the General Conference’s original aspiration for the document, namely, “to set universal standards in the field of bioethics.” This aim presupposes that bioethical issues—matters about which there is vexed (seemingly intractable) moral disagreement—are the proper subject of political deliberation. Is this a sound premise? Or are these questions better left to those with expertise in the relevant fields of life science, medicine, and ethics? For self-governing peoples, the answer to this question seems obvious. Of course bioethical questions are properly framed as political (and in some cases, by extension, legal) questions. The issues presented are normative, *human* questions not resolvable by any scientific methodology (though sound science must obviously inform the decision makers). What is owed to the suffering, and how this obligation stands in relation to our duties toward human beings at the earliest stage of development is not a scientific question. What treatment is fitting for those nearing the end of their lives or for those who live in a permanent cognitively diminished state is also not, finally, a

scientific or medical question. How to allocate scarce resources such as essential medicines and health care among the world's population is likewise, at bottom, a deep moral question. The techniques of science and medicine cannot reveal the proper ends to which such powers should be directed. Again, these are human questions in which every person has a stake, not merely experts in the fields of science, medicine, or ethics. And in democratic regimes, these questions can and must be debated in the political sphere. It would be highly corrosive of freedom and democracy to do otherwise. Thus, the General Conference's aspiration to invite its member states to articulate certain hortatory bioethical principles seems perfectly appropriate and even laudable (assuming one accepts the premise that it is appropriate for UNESCO to take up issues of geopolitical significance as a general matter).

That being said, the foregoing discussion of the Declaration's elaboration and adoption reveals some cautionary lessons for similar efforts in the future. As with all such political endeavors, the chief aim is *legitimacy* (both real and perceived). Legitimacy (and the perception thereof) is directly linked to the process of elaboration and adoption itself. The weaknesses of the process that produced the Declaration are thus instructive. Such weaknesses include the institutional relationship between IBC and IGBC, the composition of the IBC drafting committee, the process of consultation that was meant to inform the work of the drafters, aspects of the drafting committee's work, and the procedural standards for acceptance of the Declaration by member state delegations.

First, the institutional relationship between IBC and IGBC raised serious difficulties. As a body of independent experts, the IBC was responsible for the initial drafting of the document. This is sensible as a matter of division of labor—it would be unworkable for government policy experts from 191 member states to collaborate on a draft document. Moreover, such an arrangement would increase the risks of political agendas hijacking the process at the outset (though it would certainly be naive to imagine that the members of the IBC were free of political agendas). Whereas the structure of the relationship was sound, the execution (particularly on the part of the IBC) was defective. The IBC drafting committee did not seem to take seriously its responsibility to draft an instrument that would be acceptable to member states. By persistently ignoring the express concerns of IGBC members, the IBC laid the foundation for its own failure. It left the government experts no choice but to systematically dismantle and replace virtually every key provision of the IBC draft.

The composition of the IBC drafting committee raised concerns for legitimacy as well. Representatives from developing countries complained about lack of regional diversity. To this one might add that the drafting committee lacked ideological diversity. There was also arguably an overrepresentation of human rights lawyers on the drafting committee. There is certainly a place for such individuals, given that matters of bioethical import necessarily touch

and concern human rights. But in the main, these individuals lack familiarity with many of the philosophical concepts and principles central to bioethics. As a result, the philosophical rigor of the document was wanting in many respects (a fact that has not been lost on several commentators). It might have been useful to have more voices such as Dr. Pellegrino or Alex Capron (then-Director of WHO's Ethics, Trade, Human Rights, and Health Law Committee), namely, those who are able to translate the sometimes complex language of applied moral philosophy into political and legal terms. The high concentration of international lawyers on the drafting committee seems to have been responsible for a profusion of "rights talk" in the IBC draft. Standing alone, such language fails to capture the nuances of bioethical problems. As Carl Schneider (himself a very fine legal mind) has noted, framing bioethical conflicts solely in terms of "rights" seems to privilege autonomy above all competing values and, in so doing, loses sight of the unique context of mutual dependency and human vulnerability that characterize the human relationships in which these issues arise. Such a single-minded focus on autonomy opens the door to the peril of "abandoning people to their rights" precisely at the moment when we should take seriously their vulnerability and neediness (Schneider, 1994, 16–22).

A third problem with the process of elaboration for the Declaration was the lack of meaningful consultation at the outset with member states. As discussed above, the initial questionnaire was not helpful in this regard. This placed the IBC drafting committee in a difficult position in conducting its work. Relatedly, the compressed timeline for the elaboration process was far too short for a full treatment of the matters within the scope of the Declaration.

Fourth, the work of the IBC drafting committee would have been received more favorably if it had observed greater transparency. IGBC members and member states were not privy to the discussions that produced the draft and were suspicious as a result. Had the IBC published transcripts of the meeting, or indeed released comprehensive minutes, this would have ameliorated this concern.

It is worth noting that many of the flaws in the process of elaboration resulting from the work of the IBC drafting committee were (painstakingly) corrected by the subsequent negotiation and drafting sessions of the Government Experts. It has been reported that the IBC is going to produce a series of commentaries ostensibly meant to elucidate the meaning of the Declaration's various provisions. This project is potentially worrisome in that it empowers those whose drafting efforts were roundly repudiated to produce what could come to be regarded as the authoritative interpretation of the revised text (given that it will be a UNESCO publication). The temptation for such commentators will be to "rehabilitate" the new text in a manner that preserves what the member states self-consciously rejected. Needless to say if this happens, such texts will be entirely illegitimate as guides to the

meaning of the Declaration. UNESCO will need to be vigilant in guarding against this possibility.

Finally, it is worth reflecting briefly on UNESCO's rule of consensus, which deeply affected the negotiation of this instrument. Much has been written about the validity of consensus as a procedural standard for public policy deliberations involving bioethics. Jonathan Moreno's *Deciding Together* makes a powerful and elegant case for consensus. H. Tristram Engelhardt and Griffin Trotter, among others, have authored potent rejoinders.<sup>6</sup> It is unnecessary to rehearse that rich debate here. For present purposes, it suffices to note that the rule of consensus in this negotiation produced a Declaration whose principles are framed at a very high level of abstraction. This has implications for both the utility and legitimacy of the Declaration. Some commentators, such as Engelhardt, have criticized the instrument as being simply void for vagueness (to borrow a phrase from American Constitutional law). There is surely something to this critique, but any concrete elaboration of the principles would have precluded consensus—recall, the inclusion of “respect for the life of human beings” as an explicit aim of the Declaration required a Herculean effort. A competing approach was on display during the roughly contemporaneous negotiation at the UN General Assembly on human cloning. That process involved a vote of member states resulting in a declaration calling for the prohibition of all forms of human cloning (both to produce children as well as for biomedical research). The measure passed 84-34. In the wake of its passage, supporters celebrated and opponents resolved that it would have no effect on their conduct. Which model produces more useful and legitimate results? There are powerful arguments on both sides, and this vexed matter is beyond the scope of this essay. Nevertheless, UNESCO would do well to reflect on this question in the future.

## VI. CONCLUSION

UNESCO's aspiration to produce an instrument that provides guidance on bioethical questions was entirely appropriate, and indeed laudable. A commitment to self-governance most richly understood requires that such questions be subject to political deliberation. The process itself was imperfect, but careful reflection on the problems themselves points to clear remedies: a more collaborative relationship between IGBC and IBC, more diversity (regional, disciplinary, and ideological), meaningful consultation, greater transparency, and perhaps a shift from a rule of consensus to procedures for voting (though this is a difficult question). All of these steps would go far in the direction of conferring legitimacy—the touchstone of all political activity in a self-governing regime or in an intergovernmental forum of such regimes—on such endeavors in the future.

## NOTES

1. See, for example, the World Medical Association's "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects" (adopted in 1964 and amended in 1975, 1983, 1989, 1996, and 2000); the Council for International Organizations of Medical Sciences' "International Ethical Guidelines for Biomedical Research Involving Human Subjects" (adopted in 1982 and amended in 1993 and 2002); the "Council of Europe's Convention on Human Rights and Biomedicine" (adopted in 1997, with Additional Protocols enacted thereafter); and the UN's "Declaration on Human Cloning" (adopted in 2005).

2. It was clear from his interventions at the various IBC sessions open to the public that Dr. Pellegrino objected strongly to the exclusion of the phrase "respect for human life" but had apparently been overruled by the remaining members of the drafting committee.

3. It later came to light that Dr. Pellegrino had previously sent a letter to the chair of the IBC drafting committee formally expressing his strong disagreement with both the excision of "the respect for life" and the conspicuous inclusion of "access to ... reproductive health[care]." His concerns were ignored by the committee.

4. The version of the principle that is most often cited is from Article 15 of the 1992 Rio Declaration on Environment and Development: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." UN General Assembly, Special Session. *Report of the U.N. Conference on Environment and Development (Rio de Janeiro, 3–14 June 1992)* (A/CONF.151/26). Declaration.

5. The United States also suggested language for the articles relating to the sharing of benefits (Article 15) and the protection of the environment, the biosphere, and biodiversity (Article 17), as well as preambular language signaling a special concern for "developing countries, indigenous communities and vulnerable populations" that spoke to the concerns of the developing world in a manner different from the IBC draft. This show of good faith further promoted good will and solidarity between the United States and the G-77.

6. In his piece "Bioethics and healthcare reform: A Whig response to weak consensus" (2002), Griffin Trotter argues for a compromise-oriented approach to bioethics, which he finds both less coercive and more effective at appropriating moral commitments than consensus models. Similarly, in his book *Global bioethics: The collapse of consensus* (2006), H. Tristram Engelhardt has put together a collection of essays that discuss the various causes and effects of what he sees as the failure, and ultimate impossibility, of building wide consensus on bioethical issues.

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