The international context of the last fifty years of modern bioethics have been significant in establishing health-care ethics or bioethics as a common parlance—an ideology of our times, achieving near universal acceptance, with little dissent. Most international health organizations have developed important declarations that have become the credo of their daily practice and long-term commitments. However, in the last decade in particular, bioethicists and other health-care practitioners and scholars have worried about the persistence of health-care inequities and the inadequate realization of bioethics, particularly in low-to-middle income countries. Global bioethics, now well into the new millennium, has entered a regulatory crisis: it needs to confront not just global bioethical commitments around major scientific revolutions such as genomics, but further, a regulatory crisis about the persisting national public law silences and health inequities, especially in low-to-middle income countries.

Many questions remain unanswered in these silences of national regulation of genomics. What is required to assure global commitments to genomic ethics? How will the numerous ethical treatises produced by international organizations stimulate regulatory responses in low-to-middle income countries? Moreover, how do international commitments on ethical, legal, and social issues (ELSI) genetics provide low-to-middle income countries the tools to develop their own regulatory mechanisms and confront moral complexities and pluralism in their own countries? What difference will these international commitments make for empowering low-to-middle income countries to undertake health policy initiatives in ELSI genomics? In what manner do low-to-middle income countries feel “ownership” over genomic ELSI international instruments? How will scholars and international organizations respond to the challenges of ELSI genomics as an evolving field embedded in cultural, social, and political diversity? How can we develop regulatory resources that move beyond texts to contexts, making ELSI genomics realizable for low-to-middle income countries and eth-

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ically diverse societies. If we cannot achieve these goals, is ELSI genomics destined to confront its own philosophical and methodological crisis in coming decades?

These are some of the genomic and health-care ethics challenges that the World Health Organization (WHO) has been struggling with over the last decade. A WHO meeting on “Ethical Issues in Medical Genetics” was held in Geneva in 1997. As a result, the Proposed International Guidelines on Ethical Issues in Medical Genetics and Statement of WHO Expert Advisory Group on Ethical Issues in Medical Genetics were discussed and issued (1998). To meet these ethics challenges, the World Health Organization commissioned an informal report in 1999 on the implications of medical genetics and biotechnology on public health, co-authored by Professor Abdallah S. Daar and Professor J.F. Mattei. The foundational 1999 report was the catalyst for revisiting the Human Genetics Programme’s (WHO) priorities in ELSI. At the WHO’s former Director General’s request, the Advisory Committee on Health Research (ACHR) prepared a report entitled, Genomics and World Health (2002). Member States emphasized the importance of genomics for world health, and the significance of the attending to ethical, legal, and social issues, especially surrounding genomics, including intellectual property.

Anticipating the need for the further development and specification of the ACHR report’s recommendations, HGN convened an expert meeting in Toronto in 2002 hosted by the Joint Centre of Bioethics (JCB), University of Toronto, to formulate a WHO strategy which would promote genetic services and collaboration with national centers. At this time the JCB was formally established as a WHO Collaborating Centre. To implement some of the recommendations, WHO and the Centre co-sponsored the inaugural Post-Doctoral Fellowship/Ethics Officer to lead ELSI activities in the Human Genetics Programme.

The collaboration initiated a series of ELSI developments including the ELSI ReD, a regulatory database of documents and resources produced around the world on major topics in ELSI genetics and a regulatory framework developed as a resource for low-to-middle income countries. The database is available at the Human Genetics Programme’s online Genomic Resource Centre (GRC), which was also catalyzed through the Programme’s partnership with the Joint Centre of Bioethics at the University of Toronto. The GRC was publicly introduced in December 2003 (see http://www.who.int/genomics/en/).

In this paper, we discuss the ELSI Genetics Resource Kit that is being developed by the Human Genetics Programme (HGN), WHO in partnership with the Joint Centre of Bioethics (JCB), University of Toronto. The Resource Kit provides one solution to the problem of inadequate national ELSI genomics regulation, particularly in low-to-middle income countries, because it functions as a resource tool for policymakers to develop their own regulation in ELSI genetics. It includes an introduction that comparatively discusses selected topics in ELSI genetics, a regulatory framework, and two relevant databases including a regulatory database. It builds upon important research resources such as HumGen and the United Nations Educational, Scientific and Cultural Organization’s (UNESCO’s) Bioethics Database. By contrast to the UNESCO Bioethics Database, ELSI ReD is a dedicated database that specializes in ELSI genomics with a current specific focus on legislative and regulatory information and documents concerning genetic testing and screening, pharmacogenetics, genetic patenting, and genetic databanks. Moreover, the Resource Kit regulatory project aimed at developing a practical implementation tool that policymakers in low-to-middle income countries could adapt to their country-specific needs. Further, the ELSI Resource Kit is distinctive from other codes and guidelines, because rather than developing a regulatory framework through a series of in-person consultations, we created two specialized databases, and combined comparative methodology and ethical analysis to develop a tool for policymakers. In this paper, we explain the need for such a regulatory resource, survey the resources provided by the Kit, overview regulation around the world, and highlight some “best practices” in ELSI regulation around the world. Given that one objective of the Resource Kit is to comparatively discuss different regulatory approaches to key issues in ELSI genetics, we do not duplicate that analysis here; rather, we recommend that the reader examine the “Introduction” to the Resource Kit for this analysis.

The Contribution of an ELSI Genetics Resource Kit

Global health ethics regulation, as a set of international norms and national commitments, is urgently needed to support genome research with ethical results and
processes. In October 2003, President Jacques Chirac called upon UNESCO to respond to the challenges of global ethics law by developing an international convention. He said that there is an urgent need to develop principles of bioethics in international public law, “clear ethical standards that are universally recognized to serve humankind and civilization” that would allow science to flourish with better ethical assurances. How should nations respond to the call for international health policy and regulation of genomics? One issue that has become clear is that international consensus and enforcement of international public health law depend upon national action in individual countries including low-to-middle income countries.

In this context of ethical, legal and social issues of human genomics, national regulatory frameworks and tools are gaining importance. While genetic research is producing important technologies and approaches for the benefit of public health, regulatory frameworks are still needed in many countries to safeguard human health, safety, dignity, state interests, and health for all. Some countries discussed below have exercised leadership through regulatory developments, or ad hoc commission analyses in the ethical, legal and social issues (ELSI) of human genetics.

The ELSI Resource Kit is inspired by the intuition that a distilled, comparative analysis of these existing regulatory models can provide a practical, easy-to-use tool for policymakers in low-to-middle income countries (see the overview of the Resource Kit below). In particular, it includes a regulatory framework which is the product of our comparative and evaluative research. The regulatory framework is a policy framework for regulating selected topics in ELSI genomics. The key issues that the regulatory framework addresses are the ethical, legal, and social implications of genetic testing and screening, preimplantation genetic diagnosis, genetic counseling, gene therapy and genetic research. Below, we distinguish the regulatory framework from an “ideal policy model” and we explain its innovation.

However, while the need for normative resources is compelling, there are some ethical and pragmatic complexities in developing global, normative recommendations or a “distilled, regulatory framework” for ELSI of genomics only, given that (1) genomic research and development is evolving rapidly and (2) countries, and groups within countries, differ in their cultural, social, and moral approach to both genomics and ethics. The complexities of pluralism can, in some cases, pose difficulties in international norm setting. For example, a number of international organization initiatives demonstrate the difficulty of developing international principles: UNESCO’s recent five year review of the “implementation status” of the Universal Declaration on the Human Genome and Human Rights suggested, at best, mixed results; the UN Sixth Committee on Human Cloning’s inability to achieve consensus thus far on a treaty on reproductive cloning through repeated meetings; and the contemporary challenging process of achieving agreement on the International Bioethics Committee of UNESCO’s proposed declaration on genetic databanks. Consensus on ELSI of genomics is hard fought.

In producing the ELSI Resource Kit we aimed to move beyond establishing a set of moral principles to developing an effective tool for policymakers in low-to-middle income countries. The tool responds to the generalized lack of ELSI genetics regulatory frameworks in low-to-middle income countries. Many states, particularly in low-to-middle income countries, with a few salient exceptions such as in India, have not established ELSI regulatory frameworks for genomics despite the fact that genomics promise to change the face of healthcare and it has enormous potential for developing countries. The Resource Kit also draws attention to regulatory accomplishments in low-to-middle income countries, and thereby, it provides practical models of regulatory frameworks that have been successfully implemented in developing countries.

Why produce a consolidated regulatory resource kit that addresses multiple issues in human genomics, rather than the approach favored by many large nation states such as the United States, in which each issue in human genomics is addressed with considered depth and analysis? First, many nation states and international organizations have produced single-topic documents. However, very few resources exist that consolidate, compare and analyze competing ideologies and regulatory approaches on these issues. Second, low-to-middle income countries do not usually have extensive resources to devote to global research and regulatory analysis; a consolidated regulatory Resource Kit affords a useful starting point and a concise information tool for regulatory initiatives.

The ELSI Genetics Regulatory Resource Kit: An Overview

Understanding the complexities of ELSI genomics regulation, the Human Genetics Programme of WHO in partnership with the Joint Centre for Bioethics at the University of Toronto, WHO Collaborating Centre, utilized an alternative methodology to produce a tool for ELSI in human genetics policy making.

The Resource Kit is designed mainly in service of low-to-middle income economy countries. While low-to-middle income countries vary dramatically in their scientific and technological capacity, they confront eth-
Introduction: Explains the research methodology and provides an extensive comparative analysis of the selected topics and how the elements of the regulatory framework were developed. It compares and contrasts regulatory practices in diverse nation states, outlining their strengths and limitations for application to developing countries.

Regulatory Framework: The policy framework designed for developing countries that is the product of our comparative and evaluative research as explained in the introduction.

Appendix One: Regulatory database which consolidates our country and international organization research into the ELSI Genetics Regulatory Database: a series of five tables listing regulation (policy, ethics guidelines, codes of conducts, specialized ELSI analyses by commissions or stakeholders, and information documents) in different regions and countries. Each table focuses on the priority areas: genetic testing, pharmacogenetics, and genetic databases. The fifth table overviews all of the tables.

Appendix Two is an ELSI genetics bibliographic database that catalogues several interdisciplinary academic articles written on the subject of human genetics according to the four subject areas.
According to the four priority areas specified above. Since the ELSI ReD database is continually updated, the appendices in the ELSI Genetics Regulatory Resource Kit will be current at the time of publication. The ELSI Genetics Regulatory Resource Kit will be jointly published by the Human Genetics Programme and the Joint Centre of Bioethics, University of Toronto.

The regulatory project required a one year process of research, analysis, and evaluation. The first phase of the regulatory project entailed creating the two databases (discussed above): the regulatory database and an ethics bibliography. The regulatory database, created in collaboration with WHO regional and country offices, records main regulatory documents received from these sources and through internet searches (totaling approximately 140), including guidelines and recommendations produced in countries and international organizations available in the English language.

In the second phase, we comparatively evaluated existing regulatory advice, legal frameworks, and ethical guidelines to identify “best practices.” By “best practice” we do not necessarily mean a universal ideal practice. Generally, for our purposes, a “best practice” identifies a common or representative regulatory practice that anticipates genomic changes in public health and captures the complexity of ELSI of human genetics including gender effects. The detailed criteria used to determine a “best practice” and the research methodology are explained in the Resource Kit.

The notion of “best practices” even for the issues where there is substantial multi-regional consensus may be misleading, because a specific practice may not be a “best practice” or “ideal” for all settings; even within regions, there can be substantial diversity between and within countries. In some cases, the “best practices” may conflict with other state (moral) commitments. Accordingly, the “best practices” that we discuss here should be viewed as commonly accepted policy options, that need to be adapted, revised and reviewed, according to the needs of a particular country and its diverse interests in order to be effective as a regulatory device. We suggest that states explore their needs and interests in inclusive dialogue with their civil society to identify best practices that can be effectively implemented and supported by their diverse people, using the ELSI Genetics Regulatory Resource Kit as a starting point for discussion. The Resource Kit, thereby, is intended to provide information for policy-makers in low-to-middle income countries and to stimulate ELSI regulatory initiatives within countries, even where they have not begun already.

These best practices were, then, coherently edited into a basic regulatory framework and the specific provisions of the framework generally derive from globally available regulatory sources. The framework is a component of the ELSI Resource Kit which we aim to have available through the Genomic Resource Centre and as a joint JCB/WHO publication by 2005; the GRC will provide current information on this project’s development. By ensuring that the provisions made the best fit with the guiding principles and the precepts of the regulatory framework as a whole, we aimed for coherence in the overall framework. By guiding principles, we mean moral commitments that guide, rather than determine solutions to moral problems; they provide ways of understanding the moral crux of ELSI genetics, rather than determining a single inflexible truth about the matter that may be incongruent with the fact of ethical pluralism in the world. We discuss the derivation and theory behind these guiding principles in the Resource Kit itself.

**The Innovative Methodology of the ELSI Resource Kit: An Alternative Methodology for Developing Tools for Low-to-middle Income Countries**

International and regional organizations usually develop ELSI resources by organizing a group of experts to consult on a contemporary issue to develop the agenda, priorities, and central problems or questions. Oftentimes, these groups make some effort to include “other” participants from industry, civil society and other international or regional organizations, which do not always have participant rather than observer status. Then, the consultation is usually followed by a more intensive study, usually through additional consultations or a series of consultations of the most critical or significant questions according to the mandate of the organization with the aim of producing guidelines, recommendations or international standards on practice. The Human Genetics Programme has conducted such consultations and commissioned work to academic experts, all leading to recommendations for genetic testing/screening and genetic health services. These sorts of consultations can be valuable tools for norm setting in a regional or international context.

Since the major topics of the regulatory framework have been studied in every world region by states, foundations, international organizations, NGOs, and others, we chose to build upon those analyses utilizing an alternative methodology for ELSI product development. Rather than developing the regulatory framework through a series of in-person consultations, we created two databases and combined comparative methodology and ethical analysis to develop a tool for which policymakers could adapt for their own needs. The introduction and the regulatory framework were, then, reviewed and revised through consultation with academic ex-
erts, civil society groups and WHO professional staff. In particular, experts from both high income and low-to-middle income countries were asked to review the regulatory framework.

The distinguishing feature of our ELSI resource methodology is that we began from a base-line of multi-regional, internationally representative ideas (as expressed through country regulatory documents) to develop a tool for policymakers, particularly for those in low-to-middle income countries. Furthermore, the tool, unlike other sorts of guidelines and ELSI studies, is a resource kit that consolidates information from a multi-regional array of sources. While this approach may diminish the normative status of the framework as a “model” of ideal ELSI policymaking, the framework has the advantage of being flexible and adaptable to country-specific needs, highlights areas of multi-regional or global consensus, consolidates global resources in one policymaking resource, and illustrates an innovative methodology for regulatory ethics that balances consensus and moral theory.

The ELSI in human genetics regulatory framework is a framework, rather than an ideal model, in so far as it is a basic resource that can be adapted to the needs and interests of countries. The insight of the comparative methodology is that no “one-size” regulatory model that will fit all countries’ needs and interests, as diversity and ethical pluralism characterize world countries and global cooperation. Certainly, an important aspect of adapting the regulatory framework will be a process of inclusive public engagement in states – including citizens, advocacy groups for marginalized groups, clinicians, industry, and other stakeholders – to produce nationally endorsed ethical safeguards in human genetic research and genetic health services.

The framework, thereby, lays groundwork for ELSI genetics policy making, providing guidance where there is considerable multi-regional consensus (mainly among high income countries), and providing consolidated resources (the two databases) for further study and investigation. Where insufficient consensus has been achieved, the framework resists providing detailed guidance, but rather, hones in on the key issues to be resolved within countries for regulation. That is, at several points, the framework highlights the need for national guidelines on a particular issue to be developed through a proposed national Human Genetics Commission, especially on complex or evolving issues. However, such oversight bodies are hotly contested – an issue that is discussed in further detail in the introduction to the Resource Kit. For this reason, we suggest that a supervisory body is not the only means for resolving these sorts of issues; rather, countries must decide for themselves whether a national genetics com-

mission is an appropriate mechanism for overseeing ELSI genetics in all countries.

The significance of the combined comparative and ethical analysis for developing the ELSI Genetics Regulatory Resource Kit is that it recognizes that effective, global ELSI cooperation requires a balance between consensus and moral reasoning. As Aristotle recognized, the challenge for the just ‘ruler’ is exercising practical wisdom (phronēsis), deliberating well and toward the good in a manner that balances public consensus and virtue. The enduring insight of practical wisdom is that while policymakers may in some cases wish to regulate ethics – express concern or develop safeguards for universal human goods – they must, in doing so, recognize the contingencies of practice and the realities of context for which regulation must be designed: “for [practical wisdom] is practical, and practice is concerned with particulars.” ELSI resources should be developed in a manner that makes regulation effective, rather than esoteric. “Practical wisdom is concerned with action.”

**Significant Genomic Regulatory Accomplishments in Comparative Perspective**

In the context of our research, we identified some significant regulatory accomplishments around the world which we briefly outlined here. Such accomplishments are discussed in greater detail and breadth in the introduction to the Resource Kit. There are many excellent examples of human genetics regulation in different world regions, each with their own particular or distinctive contribution. By no means is this intended to be an exhaustive list or an “ideal list” of only the best (for example, significant developments in France, Germany, and most international organizations are not discussed below). Rather, in this context, we discuss a diverse range of significant examples that particularly informed the ELSI Genetics Regulatory Resource Kit or key resources which have been instrumental in the advance of regulation in various countries.

**1. United Kingdom**

The British government adopted the Warnock Report recommendations and drafted the Human Fertilization and Embryology Act 1990 which established a national oversight body, the Human Fertilization and Embryology Authority (HFEA). One strength of the legislation is that it was drafted in sufficiently broad terms such that the British Parliament has been able to expand the scope of purposes of the Authority as technology advances and changes without having to amend the legislation or invent new supervisory agencies. The legislation has been a paradigm law for many countries that subsequently drafted legislation in this area, including Canada, Australia, and France.
Further, the Human Genetics Commission is an advisory body established by the United Kingdom government at the end of 1999. Its work programme focused initially on the ethics of personal genetic information and after a series of consultations, it produced *Inside Information*, a report released in May 2002 on “balancing interests in the use of personal genetic data.” The report examines the ethics of personal information in a variety of contexts from clinical practice to medical research to forensic to parentage testing. Furthermore, the Nuffield Council on Bioethics situated in the United Kingdom has been prominent and prolific in developing a series of reports that engage seriously in a range of issues in the ethics of human genetics, ranging from genetic screening to, more recently, intellectual property issues in genetics. Overall, the United Kingdom has made foundational and important contributions to human genetics regulation.

2. South Africa
The Medical Research Council revised the third edition of its 1993 ethical guidelines for reproductive biology and genetic research. The revisions were prompted by major socio-political changes in South Africa since 1993 including (1) changes to the South African Constitution which entrenches probably the world’s most progressive bill of rights; (2) the Human Genome Project revolution; and (3) the intensifying of the HIV/AIDS epidemic sweeping sub-Saharan Africa. Thus a central dimension of thinking about genomics is its role in the epidemic and the major health concerns of the nation.

In this context, the South African MRC, in the current 4th edition revisions, split the original third edition volume into a 5-book series: general principles; reproductive biology and genetic research; use of animals in research; use of biohazards and radiation; and HIV Vaccine Trials. In particular, book 2 on reproductive biology and genetic research, discusses a range of topics including *in vitro* fertilization, gamete donation, embryo research, sex selection, gene therapy, genetic screening and testing, neonatal screening, privacy and data protection, genetic registers, insurance, cloning, safety, a oversight body, and intellectual property rights. The document makes a series of policy recommendations and it references central ethical research documents from around the world. A particular strength of the document is its ability to address a wide range of issues and build upon existing ethical research and analysis around the world. At the same time, the document is specifically tailored to South African needs.

3. India
India has undertaken a number of regulatory initiatives in genomics which balance scientific advances in human genomics and India’s particular history and concerns. The Department of Biotechnology, Ministry of Science and Technology, Government of India, has drafted a document entitled, “Ethical Policies on the Human Genome, Genetic Research & Services” which identifies the membership of the National Bioethics Committee, central principles and policy considerations and outlines specific research and services recommendations and guidelines. The scope of topics range from genetic privacy and discrimination to DNA and cell-line banking through to intellectual property rights and benefit sharing.

Similarly, the Indian Council for Medical Research (ICMR) has produced a “Statement of Specific Principles for Human Genetics Research,” and it has produced an Intellectual Property Rights Policy statement. The particular strength of the Indian initiatives is their swift response to the regulatory issues at stake and its development of consolidated, clear guidelines and policy positions that address a range of problems while protecting India’s particular social, health and economic interests.

4. Australia and HUGO
In 2002, the Australian Law Reform Commission published a more than 1,000-page document on the protection of human genetic information in relation to human genetic research, human genetic databases, health professional services, genetic registers, genetic counseling and medical education, insurance, DNA parentage testing, aboriginal identity, employment, and law enforcement and evidence.

While the document is carefully informed throughout by ethical, legal, and social dimensions, it has some distinctive features that distinguish it from many other national documents of its kind. Specifically, given that the Australian report is produced by its Law Reform Commission, it is particularly strong in addressing the comprehensive legal implications of genetics information and the multiple dimensions that need to be considered in law reform in particular. As well, the document is ahead of its time in engaging substantially with issues surrounding genetic databases and forensic evidence. Further, the Australian report is one of the few documents in the world that even begins to consider specific ethical issues with respect to genetics and aboriginal communities within its own borders.

One of the few other noteworthy documents among international organizations on genomic databases is the HUGO Ethics Committee *Statement on Human Genomic Databases, 2002*. A key feature of the HUGO Statement is its explicit recognition, even in the preamble of the document, that genomic research produces global public goods.

5. United States
The United States has invested the most resources to
bioethics through its multi-billion dollar Human Genome Project which began in 1990 as a 13-year effort coordinated by the US Department of Energy and the National Institutes of Health; three per cent of the project budget was reserved for the ELSI Program. The ELSI program funds and manages studies related to the ethical, legal and social implications of genetic and genomic research, and it supports workshops, research consortia and policy conferences related to these topics. While the ELSI program is the largest supporter in the United States of ELSI research, a plethora of research occurs in the United States through independent centers, other academic research, and the President’s Commission for Bioethics, all of which reflect a diversity of US constituencies and perspectives. However, given the resistance to adopt a supervisory body in the United States, the breadth of research and commentaries lack a coherent and consolidated voice that can form the basis of legislative initiative by the US Congress. The ELSI database that we have produced helps bring us closer to the goal of consolidation by cataloging some of the major US ELSI documents on selected topics in human genetics.

6. Mexico/Latin America
At the first Latin American Meeting on Bioethics and the Human Genome, convened in Manzanillo, Mexico, a satellite meeting of the Mexican Association of Genetics was convened. At this meeting, the “Declaration of Manzanillo” was drafted. The Declaration supports the application of ethical guidelines to the Human Genome Project. In principle, it supports UNESCO’s declaration on the Human Genome and Human Rights; however, it goes further to include other principles integral to Mexican culture and values, and the particular concerns of a developing nation. Further, it discusses the application of these principles to the clinical setting. The Declaration is also significant because it establishes a regional Ibero-American Network on Bioethics and Genetics for the purpose of exchanging information and collaborative research on social, ethical, and legal issues related to the human genome.

7. Canada
The Canadian policy experience overseeing human reproductive and genetic technologies has followed a rather tortured path, recently leading to Canadian House of Commons passing An Act Respecting Assisted Human Reproduction, a reproductive and genetic technologies act, following numerous long debated attempts at consensus and public engagement. As a precursor to the current act, the Royal Commission on New Reproductive Technologies produced a two-volume report in 1993 with fifteen volumes of supporting material and discussion which enumerated recommendations that form the basis of policy changes and the current Act.17

The report is distinctive and exemplary in its practical application of ethical theory to bioethical problems. The entire methodology and analysis of the report is organized by applying the “ethics of care.” The report is significant, further, because it is the first of its kind to employ ethics of care theory, rather than a few commonly accepted bioethical principles, or the formal theory of “principlism.” Since ethics of care identifies moral obligations that inhere in central relationships, an important dimension of the report is its extensive public engagement: more than 40,000 Canadians were directly involved in the Commission’s public consultation process, and importantly, these perspectives were incorporated into the policy analysis.

Conclusion
In contemporary times, bioethics in international public law confronts the enormous challenge of finding inclusive responses that attend to diverse moral commitments, vast global health inequities, conflicting interests, human rights, and health for all. Inadequate national regulation of the ELSI human genetics marks a regulatory crisis. That is, we need to find ways to move toward national commitments and action that affirm genomic benefits for individual countries while responding to national responses that close the gap between high income countries/international organizations and regulation in low-to-middle income countries. The silences of regulation are serious, given the enormous potential of genomics and the nature of its influence. The ELSI Genetics Regulatory Resource Kit illustrates an innovative way of meeting these challenges, particularly to meet policymaking needs of developing countries.

Specifically, the Resource Kit aims to meet this challenge by:
- providing ELSI tools to low-to-middle income countries which may be adapted to particular needs, cultures and values;
- stimulating effective, efficient, and productive ELSI regulation in human genetics; and
- combining comparative multi-regional insights and best practices, including the perspectives of low-to-middle income countries into ELSI resources.

The significance of the Resource Kit is that it consolidates and highlights regulatory accomplishments in diverse countries. As a whole, the Resource Kit promises better opportunities for the future of bioethical regulation in genomics. At the same time, the Resource Kit encourages low-to-middle income countries to take ownership of their genomic policy making, integrating
integrating their own distinctive regulatory approaches and concerns. In this way, policymakers in developing countries are better positioned, through their own recognition and initiatives, to lead their countries out of the regulatory crisis of international public health law in genomics.

References
3. WHO, Collaborations in Medical Genetics, report, Toronto, Canada, 9-10 April, 2002 (WHO/HGN/WG/02.2).
5. A.S. Daar and P.A. Singer, eds., Top Ten Biotechnologies for Developing Countries (Toronto: Joint Centre of Bioethics, University of Toronto, 2002).
7. Ibid.
PART 4: PRIVACY

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Challenging Themes in American Health Information Privacy and the Public’s Health: Historical and Modern Assessments
James G. Hodge, Jr. and Kieran G. Gostin

This article discusses the premise of balancing and the device of informed consent as featured in the HIPAA Privacy Rule, assessing the perpetual difficulties underlying these concepts for public health authorities. Like many health information privacy laws, the Privacy Rule does not once more need to respect individual autonomous control of personal health information while attempting to balance commercial goods in the collection and dissemination of health information. We suggest rebalancing individual and communal interests in identifiable health data to demphasize notions of informed consent for disclosures for public health purposes.

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The Changing Legal and Conceptual Shape of Health Care Privacy
Roger S. Magnusson

This paper reviews the changing conceptual nature of challenges to health information privacy. It argues that the debate about the legal protection of health privacy is best understood in terms of a series of shifts or transitions. The evolution of health privacy law demonstrates not only that the law’s oversight of clinical medicine is becoming more pervasive, but that, as the state asserts its role as broker for information flows within healthcare settings, public law is assuming greater prominence within health law.

PART 5: LAW AND MEDICINE

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The ELSI Genetics Regulatory Resource Kit: A Tool for Policymakers in Developing Countries
Zara Merali, Victor Bouhyjenkow, Peter A. Singer, and Abdullah S. Daar

We discuss the University of Toronto/WHO ELSI Genetics Resource Kit. The Resource Kit functions as a tool to help policy makers and, thereby, provides one solution to the problem of inadequate national ELSI genomics regulation, particularly in developing countries.

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Disputes about the Withdrawal of Treatment: The Role of the Courts
Loane Skene

Can patients and their families use the court process to gain access to extratreatment that clinicians think is futile or unduly burdensome? Although courts have been reluctant to intervene in medical decisions, they have done so in some recent cases described in this paper.

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An Appraisal of Abortion Laws in Southern Africa from a Reproductive Health Rights Perspective
Charles Ngcesa

The article evaluates the abortion laws of Southern African countries from a reproductive health rights perspective. It is submitted that, despite the rhetoric of commitment to equality and the realization of reproductive rights for women, the majority of Southern African countries have been slow, if not averse, to liberalizing abortion laws.

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Law and Clinical Research – From Rights to Regulation? An English Perspective
J.V. McHale

Post Nuremberg and the Helsinki Declaration there has been a growth in the regulation of clinical research both nationally and internationally. Focusing on England and Wales this article explores the relationship between rights and regulation in relation to two case studies: the inclusion of persons without mental capacity in clinical research and the use of human material. Both are illustrations of areas where new/proposed new legislation will regulate the research process. The article critically examines the extent to which enhanced regulation necessarily safeguards the rights of the research participants.

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Commentary: Social-Ethical Values Issues in the Political Public Square: Principles vs. Packages
Margaret A. Somerville

The use of social-ethical values issues for political ends is now a major election strategy in countries such as Canada and the United States. Such issues include same-sex marriage, abortion, human embryo stem cell research, capital punishment, engaging in armed conflict, euthanasia, legalizing marijuana and access to health care. This article explores the role these issues, and their manipulation by politicians and the media, played in influencing Canadians' voting decisions in the recent Federal election.

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