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The New Biology and International Sharing - Lessons from the Life and Works of George P. Smith, II (Inaugural Lecture: George P. Smith, II, Distinguished Visiting Professorship-Chair of Law)

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The New Biology and International Sharing—Lessons From the Life and Work of George P. Smith, II

THE HONORABLE JUSTICE MICHAEL KIRBY, AC CMG*

[The George P. Smith, II, Distinguished Visiting Professorship—Chair of Law and Legal Research endowment was established by George P. Smith to broaden students' exposure to scholars and judges of national and international reputation and to allow distinguished visiting scholars the opportunity to do research at Indiana University and share their ideas with the faculty and students of the Indiana University School of Law and Indiana University. George P. Smith, an Indiana native, received his B.S. degree in business, economics, and public policy in 1961 from Indiana University and his J.D. from the Indiana University School of Law in 1964. He was awarded an LL.M. from Columbia University in 1975 and an Honorary Degree from Indiana University in 1998. George P. Smith has been a professor of law at The Catholic University of America, in Washington, D.C., since 1977.]

To inaugurate this endowment, the Honorable Michael D. Kirby of the High Court of Australia delivered the following lecture on January 26, 2000. Justice Kirby received his B.A., LL.M., and BEc from Sydney University and is internationally recognized for his work in bio-ethics, human rights, and international law. In 1991, Justice Kirby was awarded the Australian Human Rights Medal. He currently serves as the president of the International Commission of Jurists.]

* Justice of the High Court of Australia. One-time Chairman of the Australian Law Reform Commission and member of the World Health Organization (WHO) Global Commission on Acquired Immuno Deficiency Syndrome (AIDS). Member of the International Bio-ethics Committee of UNESCO. Member of the Ethics Committee of the Human Genome Organization.

I. PRESCIENT PROPHET OF THE NEW BIOLOGY¹

Professor George Smith is a devoted alumnus of Indiana University. In his name, the University has conferred on him the degree of Doctor of Laws *honoris causa*.² Now it has established a Chair of Law and Legal Research that bears his name. I have come from the other side of the world to give this lecture to help inaugurate the new chair.

I have done so because of two decades of friendship with Professor Smith and respect for his “truly awesome” writings.³ But I have also taken this long journey to make it clear that this native of Wabash and graduate of Indiana University is honored far away, as well as close to home. He is, as Balfour said of Joseph Chamberlain, “no mere man of the hour. He is a man of tomorrow and the day after tomorrow.” As his students at the Catholic University of America wrote in the *Journal of Contemporary Health Law and Policy*,⁴ in a volume dedicated to his name, Professor Smith exhibits an “indefatigable spirit and sense of total commitment”⁵ to “high standards of professionalism and his unstinting devotion to his students.”⁶ Indiana University, honoring him with the Distinguished Alumni Award as long ago as 1985, extolled his prodigious energy and uncompromising principles, saying, “his inquisitive mind is constantly searching to expand his horizons and those of the legal community” by “his unstinting labors.”⁷

George Smith’s fellow citizens in Indiana have done well to celebrate the work of this remarkable legal professor and scholar. Astonishingly enough, he has maintained his prodigious output since the days of his youth, and there is no hint of a decline in his energy. One colleague commented that a day in George Smith’s life was not the same if he did not write three thousand words in final form.⁸ On a good day (i.e., one that is cloudy, overcast, or raining) he has been known to write as many as eight thousand words. What irritates mere mortals of hesitant disposition is the amazing way in which George Smith combines the highest of scholarly rigor with deliberate intellectual provocation, the exploration of dark corners of present and possible future scientific

1. See Raymond C. O’Brien, *The World of Law, Science and Medicine According to George P. Smith, II*, 8 J. CONTEMP. HEALTH L. & POL’Y 163, 181 (1992).

2. Conferred May 9, 1998.

3. See O’Brien, *supra* note 1, at 182.

4. The *Journal of Contemporary Health Law and Policy* was established by George Smith, II.

5. O’Brien, *supra* note 1, at 1.

6. *Id.*

7. *Id.* at 2.

8. *Id.* at 165.

developments, and the quest for solutions in the law that will be necessary if we are to cope adequately with the dilemmas of contemporary science and technology.⁹

It is now well established that, in recent years, there has been a decline in published essays and speeches by U.S. judges. However, there are some exceptions. For example, Chief Judge Richard Posner (whose output gives even Professor Smith a challenge) seems partly intent upon single-handedly filling the void occasioned by the reticence of others.¹⁰ The usual explanation for this reticence is the concern felt by some individuals with an eye on a Supreme Court vacancy that their writings will affect their nomination (arising from the political analysis of the extra-judicial writings of Judge Bork which ultimately led to the rejection of his nomination to the highest court).¹¹ In my view, the real explanation is that few judges could rival the engaging titles chosen by contemporary academics for their law review contributions.

Fewer still could challenge George Smith in this connection. The titles of his essays are obviously designed to capture attention and to challenge the reader to read further. A few illustrations will be sufficient to make this point. Take, for example, the following titles: *Stop, in the Name of Love!*;¹² *From Cutlass to Cat-O-Nine Tails*;¹³ *Patient Dumping: Implications for the Elderly*;¹⁴ *Reviving the Swan, Extending the Curse of Methuselah*;¹⁵ *Murder She Wrote, Or Was it Merely Selective Non-Treatment?*;¹⁶ *All's Well That Ends Well: Toward a Policy of Assisted Rational Suicide*;¹⁷ *Lost Horizons, Captains Courageous and Disabled Newborns*;¹⁸ *Intimations of Immortality*;¹⁹ *The Ice Person Cometh: Cryonics and the*

9. *Id.* at 181.

10. See, e.g., Richard Posner, *An Affair of State*, 1999 reviewed *ABA Journal*, Nov. 1999, at 98.

11. See S. Scott Gaille, *Publishing by United States Court of Appeals Judges: Before and After the Bork Hearings*, 26 J. LEGAL STUD. 371 (1997).

12. 19 ANGLO-AM. L. REV. 55 (1990).

13. *From Cutlass to Cat-O-Nine Tails: The Case for International Jurisdiction of Mutiny on the High Seas*, 10 MICH. J. INT'L L. 277 (1989).

14. 6 ELDER L. J. 165 (1998).

15. *Reviving the Swan, Extending the Curse of Methuselah, or Adhering to the Kevorkian Ethic?*, 2 CAMBRIDGE Q. HEALTHCARE ETHICS 49 (1993).

16. *Murder, She Wrote or Was it Merely Selective Nontreatment?*, 8 J. CONTEMP. HEALTH L. & POL'Y. 49 (1992).

17. *All's Well That Ends Well: Toward a Policy of Assisted Rational Suicide or Merely Enlightened Self-Determination?*, 22 U.C. DAVIS L. REV. 275 (1989).

18. 1 *Reports Seventh World Congress on Medical Law* 75 (1985).

19. (1983) 6 U. N.S.W. L.J. 119.

Law;²⁰ *The Razor's Edge of Human Bonding*;²¹ *For Unto Us a Child is Born—Legally*;²² and *Through a Test Tube Darkly*.²³ These works are but a few; there are dozens more. They display the author's love of literature and poetry and his utter rejection of quiet orthodoxy and temperate understatement. Readers know from the headline that this is, as his students have averred, a dramatic communicator²⁴ who rejects the studied understatement of most disciples of the law. Whereas he has learned lessons from the banners of the tabloids, the content of his writings into which we are so provocatively drawn is rigorous and scholarly. Yet, it never forsakes readability or a challenge to a lively intellect.

A review of the legal writings of George Smith over the last thirty years bears witness to several recurring themes—many of them on black letter topics that would gladden the hearts of the most conservative of jurists. For example, one of his monographs is on environmental control in Arkansas.²⁵ Environmental law, land use, and associated legal themes of nuisance law make up his scholarly collection. So do his essays on the law of remedies, with their examination of the mollifying impact of equity upon the common law derived from the legal traditions of England's Court of Chancery in the United States and Australia. George Smith has written much on property law,²⁶ and has also contributed to the literature on civil liberties, sexuality, and jurisprudence.

However, it is in the field of health law, and in the special realm of bioethics and the law, that George Smith has become a world-recognized scholar of the first rank. He is much in demand as a Visiting Fellow at universities everywhere. This demand has taken him not only to the great

20. 1 CRYONICS, L. & MED. 23 (1983).

21. *The Razor's Edge of Human Bonding: Artificial Fathers and Surrogate Mothers*, 5 W. NEW ENG. L. REV. 639 (1983).

22. 56 A.B.A. J. 43 (1970).

23. *Through a Test Tube Darkly: Artificial Insemination and the Law*, 67 MICH. L. REV. 127 (1968).

24. 2 J. CONTEMP. HEALTH L. & POL'Y 1-2 (1986). A bibliography of the writings of Professor Smith from 1964-1989 may be found at 6 J. CONTEMP. HEALTH L. & POL'Y 483-93 (1990).

25. (1970).

26. See George P. Smith, II, *The Right to Property Law in American Constitutional Law* (Apr. 1986) (paper submitted for Konrad Adenauer Foundation, Conference on German and American Constitutional Law, Notre Dame University). See also George P. Smith, II & Griffin W. Fernandez, *The Price of Beauty: An Economic Approach to Aesthetic Nuisance*, 15 HARV. ENVTL. L. REV. 53 (1991); George P. Smith, II, *Nuisance Law: The Morphogenesis of an Historical Revisionist Theory of Economic Jurisprudence*, 74 NEB. L. REV. 658 (1995).

universities of his own country, but also to their counterparts in England, Germany, Italy, Scandinavia, the Netherlands, and my own country, Australia.

George Smith and I first met in 1982 when he lectured for the first time at the University of New South Wales in Sydney, Australia. He has since returned there on many occasions. At the time of our first meeting, I was the inaugural chairman of the Australian Law Reform Commission. That Commission had then recently concluded a report on human tissue transplantation.²⁷ Professor Smith's own growing interest in the law and bioethics, and my new-found acquaintance with its mysteries, brought us together. Since then, we have met on every occasion that he has returned to Australia. I have watched with fascination and admiration his remarkable career and virtually unequalled scholarly output. He did not choose a safe area of the law with perimeters chartered in the *Year Books* and dilemmas that had been scrutinized for centuries. Instead, his inquisitive mind took him into the most puzzling interface of law and modern technology; he simply could not leave the topics alone. He cogitated, analyzed, lectured, and wrote. All the time, the scientific and technological foundation for his studies was shifting dramatically.

Professor Smith's first entry into law reform occurred as long ago as 1969. In that year he served as a consultant to the New York Assembly (and later served in the same capacity for the Pennsylvania State legislature in 1976). The New York Assembly, with the help of Professor Smith, developed model legislative drafting proposals concerned with what was then considered an important issue of law and bioethics—artificial insemination donors.²⁸ The mere mention of this topic indicates the dynamics of scientific and technological developments that have accompanied Professor Smith in his journey through bioethics and the law. The “artificial insemination husband” had given way to the “artificial insemination donor.” The law reviews were full of the exploration of these themes. Soon they were overtaken by human tissue transplants. And then this was displaced by *in vitro* fertilization. Soon this too was replaced by new dilemmas of artificial reproduction. Now we have seen the creation, by reproductive cloning, of the sheep, Dolly.²⁹ Today, it seems, we are on the brink of reproductive cloning of the human species.³⁰

27. AUSTRALIAN LAW REFORM COMMISSION, HUMAN TISSUE TRANSPLANTS (1976).

28. See O'Brien, *supra* note 1, at 181 n.132.

29. See George P. Smith, II, *Judicial Decisionmaking in the Age of Biotechnology*, 13 NOTRE DAME J. L. ETHICS & PUB. POL'Y 93, 112-16 (1999).

30. See *id.* at 114-15. See also LAW AND HUMAN GENETICS: REGULATING A REVOLUTION 1 (Roger Brownsword et al. eds., 1998) [hereinafter LAW AND HUMAN GENETICS].

In the space of the years of our friendship—fewer than twenty years—the technological revolution in biology and genomics has presented problems of ever greater magnitude and at a seemingly unstoppable pace in both number and difficulty. How easy it would be to surrender to the pageant of truly difficult dilemmas for ethics and the law which it presents. Most mere mortals would do so. A law professor or a judge would turn his or her attention to simpler and safer fields—such as taxation, legislation, or (if they were venturesome) the law of restitution. But George Smith responded with an energy atypical of the law and more typical of the scientific imagination presenting the problems in the first place. He has kept pace with the most puzzling challenges of our time. Not content with these, he has looked searchingly into the future for other difficult problems that are just around the corner—such as the problems associated with acid rain³¹ and the potentiality of cryonics to give Elizabeth Taylor (and eventually the rest of us) the hope of palpable immortality.³² For those who laugh at these issues and call them science fiction, not science, it is necessary to reflect upon all that has happened in the past decades. Scientific achievement often grows out of scientific imagination. Someone in the law should be keeping pace. More often than not, that someone is George Smith.

With thanks for his many contributions to legal scholarship and education in Australia and in acknowledgment of his extraordinary work over such a sustained period, I have come to the place of his origin to help inaugurate the Chair of Law and Legal Research, which is named for him. I am proud to have that honor. It will be a daunting chair for its incumbents. A minimum of 8,000 words a day will be expected, and they will need to be addressed to cutting edge issues, not to the safe backwaters of the law.

II. SEARCHING FOR A PRINCIPLE

It is one thing to recognize the dilemmas of bioethics and law and another to contribute to the scholarly and practical ways of elucidating the choices that must be made. The methodology of the common law encourages a mode of thinking which responds to each practical problem as it arises. This pragmatic methodology encourages the decisionmaker to move from precedent to

31. See George P. Smith, II, *Acid Rain: Transnational Perspectives*, 4 N.Y.L.SCH. J. INT'L & COMP. L. 459 (1983).

32. See George P. Smith, II, *Intimations of Immortality: Clones, Cryons and the Law*, 6 U.N.S.W. L. J. 119 (1983).

precedent, as Lord Tennyson said, applying a past decision by analogous reasoning when confronted with a new dilemma.

The difficulty with this methodology is nowhere more evident than in the field of bioethics. Here, lawyers, and other policymakers, are confronted by a number of acute and special problems. The lay observer will not always understand, or understand fully, the scientific development that has occurred and the technological applications that have sprung from that development. Looking back on the twentieth century, we can perceive at least three main scientific advances that have changed the face of our planet, namely nuclear fission, informatics, and biogenetics. Somewhere, awaiting discovery, is a grand theory that will explain the interconnections of all of these scientific discoveries. It is easy enough to conceive the connections between informatics and genetics. Unraveling the secrets of the human genome would be impossible without the assistance of computers to perform the essential analysis of the data. But as that data is presented and takes the scientist and the technologist into even more dramatic developments, the lawyer and the ethicist tend to be left behind. For the most part, like laymen, lawyers cannot truly comprehend the detail of science and much less where it is leading. They cannot keep pace with the rate of change. They cannot foresee the leaps of scientific imagination that occur in a propulsion of ideas, and not by linear development. Above all, they lack a general methodology which will offer a consistent approach to the way in which the law should respond to such new dilemmas.

Some individuals urge resort to religious dogma to solve the conundrum. But so extraordinarily varied are the puzzles that we must now confront that dogma is often unhelpful to the specificities of contemporary problems. Professor Smith, himself a religious man, writes:

If the Church is largely ignored today it is not because science has finally won its age-old battle with religion, but because it has so radically re-oriented our society that the biblical perspective of the world now seems largely irrelevant. As one television cynic recently remarked, few of our neighbours possess an ox or an ass for us to covet. The deep questions of existence are approached differently by science and religion. While science is based on both careful observation and experimentation which in turn allow for theories to be constructed connecting different experiences,

religion asserts unalterable truths which cannot be modified to accommodate changing ideas. Accordingly, the true believer stands by his faith regardless of whether evidence may be deduced against its efficacy. Yet for the scientist, if scientific irregularities prove a theory to be fallacious, it will be abandoned and a new approach adopted.³³

This conclusion leads George Smith to the opinion that traditional religions “often appear to be lacking in modern relevance in resolving both personal and social problems.”³⁴ Unless the law is to turn a blind eye and have nothing to say to science, it is essential that tools must be found to provide just, efficient, and realistic solutions to the many new problems that we must confront and solve. No one would subscribe to a theory providing a total, universal solution to such problems. The old common law found comfort in notions of fairness or reasonableness. Economic rationalists will insist upon maximizing economic freedom. Philosophers may search for ideas inherent in our very humanity. But even this will be inadequate as the Human Genome Project presents our species with the potential to redefine humanity and to alter the genetic makeup of future human beings.

Searching for his own solution, Professor Smith has suggested that a basic idea which may help us to answer the dilemmas of bioethics is the force of human love. He regards this as the driving force of the conscious life of the human being which makes the individual, in the words of Dr. Joseph Fletcher of the University of Virginia, grow “in love of God and neighbor.”³⁵ This is how George Smith expresses his fundamental principle:

Since the binding force of life is love, then it can be argued that [humans] should endeavour to maximise a response to love in whatever situations [they find themselves.] If an act renders more harm than good to the individual concerned, and to those around him, the act would properly be reviewed as unloving. The crucial point of understanding is that a basic cost/benefit analysis is almost always undertaken—consciously or unconsciously. Of course the methodology utilised in this

33. Smith, *supra* note 29, at 100.

34. *Id.*

35. George P. Smith, II, *Quality of Life, Sanctity of Creation: Palliative or Apotheosis?*, 63 NEB. L. REV. 709, 732 (1984). See also O'Brien, *supra* note 1, at 178.

assessment would be situational and incapable of absolute determination. Of necessity, the basic norm or standard to be used will be love.³⁶

These words resonate with the thirteenth chapter of St. Paul's first letter to the Corinthians. In words so familiar to people of all religions, and of no religion, the writer of that letter explains the dilemmas which bioethicist, lawyer, and philosopher must face and how none of us is excused from the obligation to face them:

Love never faileth: but whether there be prophecies, they shall fail; whether there be tongues, they shall cease; whether there be knowledge, it shall vanish away. For we know in part, and we prophesy in part. But when that which is perfect is come, then that which is in part shall be done away. When I was a child, I spake as a child, I understood as a child, I thought as a child: but when I became a man I put away childish things. For now I see through a glass, darkly; but then face to face: now I know in part; but then shall I know even as also I am known. And now abideth faith, hope and love, these three; but the greatest of these is love.³⁷

In an age when there is so much pressure to solve problems by reference solely to economic criteria (and selfish ones at that) it is surely important to have voices suggesting that difficult quandaries can be solved by reaching into our capacity for love and respect for other human beings and other species. Those we love may include human beings outside our nuclear family—those whom we do not even know and/or those whom we know and do not fully understand. Respect for fundamental human rights and human dignity is one of the key movements that has grown out of the catastrophic disasters of the twentieth century. On an otherwise dark landscape, the achievements in the field of human rights represent bright beacons of hope as we enter a new century. Despite some critics (many of them autocrats) who doubt the

36. O'Brien, *supra* note 1, at 177-78.

37. 1 *Corinthians* 13:8.

universality of human rights and urge a multitude of cultural exceptions, it is important to recognize that it is the overwhelming genetic commonality of the human species that stamps upon the discourse of human rights its search for universal principles. Like Professor Smith, I have always thought that the foundational idea behind respect for the human rights of family and strangers, indeed of every other member of our species and beyond, is a love that we potentially feel for them as creatures whose lives are overwhelmingly similar to or shared with our own.

To bring these generalities to an element of specificity, I now turn to two highly practical and somewhat urgent dilemmas of a bioethical character, both of which have potentially legal implications. Each of them illustrates the inadequacy of economics as a universal principle to provide solutions to the world's health problems. In a highly diverse world of international problems, each illustrates the impossibility of offering solutions by reference to the dogmas of particular religions. In a world of diverse religions, and of no religion at all, it is increasingly impossible to impose worldwide solutions that reflect the values and beliefs of one religious tradition alone. Each dilemma also illustrates the quandary of sharing. How do we share the benefits and burdens of important technological advances potentially affecting the health and well-being of our species? What are the principles of distributive justice that will help us to find the solutions for the laws and policies we should adopt?

III. THE DILEMMA OF HIV VACCINES

The fastest spreading new pathogen threatening life in the human species today is the Human Immunodeficiency Virus (HIV) which ordinarily progresses to Acquired Immuno Deficiency Syndrome (AIDS).³⁸ In the absence of readily available therapeutic drugs or effective vaccines, the only remedy accessible to most societies is behavior modification. As any lawyer can tell, from millennia of experience with the law, changing the behavior of people in conduct that is pleasurable and important to identity (including sexual and drug use), is most imperfect. If change occurs at all, it is extremely slow and intermittent. For any degree of effectiveness, it is necessary, in the case of HIV, to challenge entrenched religious, moral, social, and other sources of resistance. Nevertheless, because it is estimated that every day 16,000 new HIV infections occur, there is enormous pressure to secure an effective

38. See *Despite Necessity of Behavioral Research, Vaccines Only Real Hope*, *AIDS Official Says*, *AIDS POL'Y & L.*, Sept. 30, 1994, at 1.

vaccine, particularly in developing countries devastated by the virus. This is said to be, in most developing countries, the only “realistic” way to deal with the epidemic.³⁹ It is why in recent years there has been a renewed commitment by government leaders, including in the United States, for the development of HIV vaccines.⁴⁰ One health minister from a developing nation afflicted by the epidemic observed: “If you don’t get on with this soon . . . there will be no one left to protect.”⁴¹ Even a low efficacy, limited-impact vaccine (in places where the spread of HIV is rapid) protecting some of the individuals at primary risk to the spread of the virus would, according to mathematical population models, have a huge impact on the spread of HIV.⁴²

HIV/AIDS presents particular challenges to vaccine development. It has been exactly 200 years since Edward Jenner released his study on the first vaccine known to humanity, that against smallpox.⁴³ One by one, other conditions have responded to immunization: yellow fever, plague, polio, diphtheria, tetanus, typhoid, whooping cough, rabies, and measles. Most of these conditions are produced by bacteria (such as typhoid) or by a comparatively stable virus (such as smallpox). The challenges of HIV/AIDS stem from the mutations of HIV, the multiple strains in which the virus manifests itself, and the social context in which those affected have to live and work.

George Smith’s principle of love requires us to face squarely this bioethical dilemma. It necessitates recognition of the fact that *not* to act is often to make an ethical decision. Not to invest in HIV vaccines, but to do so in genetic cures for wrinkles because that would be more profitable, is to make an ethical choice. Not to press on with medical testing and trials for fear of the legal risks they may involve is to make such a choice. To conduct the trials only in developing countries may seem a sensible course because of political pressure, strong governmental support, the ease of securing local participants, and the unlikelihood of legal proceedings if things go wrong; but, this too involves an ethical election.

Trials of HIV vaccines in the United States have been discontinued because everyone knows that legal liability for mishaps would be scrupulously

39. *Id.* at 1 (quoting Dr. William Paul, Director of the Office of AIDS Research, National Institutes of Health).

40. KEITH ALCORN, AIDS REFERENCE MANUAL 280 (1998-99).

41. Christine Grady, *HIV Preventive Vaccine Research*, 19 J. MED. & PHIL. 595, 599 (1994).

42. See ALCORN, *supra* note 40, at 284.

43. See EDWARD JENNER, AN INQUIRY INTO THE CAUSES AND EFFECTS OF THE VARIOLEA VACCINAE (1798).

enforced in the courts.⁴⁴ Yet, the shift of trials to developing countries where such risks are minimal presents new problems.⁴⁵ These arise, in part, from the fact that the market for HIV vaccines that would render the investment profitable is largely in the developed world where strains of the virus may be different. Furthermore, there is an increasing recognition that the conduct of such trials in developing countries must allow the people who take part in them, and the nations that facilitate them, to reap a just return—"the vaccine dividend"—if the trial goes ahead and later a commercially viable vaccine emerges as a result.

Three principles should govern the conduct of prophylactic or therapeutic research into HIV involving human beings. Those principles include: (1) respect for the persons involved, their autonomy in decisionmaking, and self-determination; (2) beneficence—maximizing benefits and minimizing harms to such persons; and (3) distributive justice—equitable distribution of both the burdens and benefits of participation in research.⁴⁶ In common law countries we are quite familiar with the first two principles. We protect the individual. We insist upon beneficence. We do so in the decisions of the courts which demand that patient consent be truly informed and that the only justification for medical intervention (which would otherwise be an assault or trespass upon the person) is the purpose of those involved to secure the best interests of the patient.⁴⁷

It is the principle of distributive justice that makes the ethical decisions in a field such as the development of HIV vaccines somewhat different from the ordinary ethical choices the law enforces. In this dilemma, the ultimate question is: What is in it for the people of Uganda or Thailand who are submitted to an HIV vaccine trial that we do not conduct upon people in the

44. See U.S. Code of Federal Regulations 45 CFR 46.116(4) ("the subject must be 'informed of appropriate alternative procedures or course of treatment if any that may be advantageous to the subject'") and 45 CFR 46.111(2) ("the risks to subjects [must be] reasonable in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result"). See also Grady, *supra* note 41, at 607.

45. U. Schqklenk, *The Ethics of Clinical AIDS Vaccine Trials in Developing Countries—A Critical Commentary*, 13 MONASH BIOETHICS REV. 13 (1994) (criticizing N. Christakis, *The Ethical Design of an AIDS Vaccine Trial in Africa* 18(3) HASTINGS CENTER REPORT 31 (1988)).

46. See Joe Thomas, *Ethical Challenges of HIV Clinical Trials in Developing Countries*, 12 BIOETHICS 320, 322 (1998).

47. B. N. Dickens, *Legal Approaches to Healthcare Ethics and the Four Principles*, in PRINCIPLES OF HEALTHCARE ETHICS 305, 308 (R. Gillon ed., 1994), referring to *Kruzan v. Director, Missouri Department of Health* 110 S. Ct. 2841 (1990); *Sidaway v. Bethlem Royal Hospital* [1985] 1 AC 871. See also *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125 (1914); *Canterbury v. Spence*, 464 F.2d 772 (1972), *cert. denied*, 409 U.S. 1064 (1972).

developed world whose pharmaceutical companies have developed the vaccine? In addition, what can, and should, law and policymakers in developed countries do to address the issues of distributive justice which the trial of HIV vaccines necessarily raises?

Past experience with the conduct of trials for medical purposes has taught the need for great vigilance. The Tuskegee study in the United States denied newly developed penicillin to indigenous victims of syphilis even after that drug was widely available throughout the country.⁴⁸ Subsequent revelations also showed how human subjects were radiated without their awareness of the dangerous risks to which they were being exposed.⁴⁹ In the case of HIV, there is a possibility (I put it no higher) that, because of its high volatility, the virus may “unattenuate.” An attenuated strain involving dead virus might come back to life to threaten a person vaccinated with it.⁵⁰ Although, in accordance with standard procedures, clinical trials on animal subjects must first be exhausted,⁵¹ the point is reached when it becomes scientifically essential to conduct a clinical trial on human subjects. At this point, risks must be measured. These trials must be taken with a clear appreciation of the urgency that faces humanity in relationship to this disease. It is also necessary to ensure that there is a sharing of benefits and burdens. In short, people in far-away developing countries should not be reduced to the status of objects. It is the ethical, and should be the legal, duty of individuals and corporations in developed countries to make sure that scientists and entrepreneurs proceed in a way that respects the basic human rights and human dignity of the trial group and the communities in which such trials take place.

Ethical principles require that those who participate in an HIV vaccine trial must be alerted, counseled, and reinforced in the lessons of behavior modification. At the moment, this represents the only certain means of preventing sero-conversion. Trial subjects must not put their faith in the vaccine with which they are being tested. Whether they receive the experimental product or a placebo, they must be constantly reminded about self-protection. Yet paradoxically, the effectiveness of any HIV trial will only be proved if some of the participants do not receive, or ignore, such messages and become infected.⁵² In this sense, those involved in HIV vaccine trials

48. See David B. Resnik, *The Ethics of HIV Research in Developing Nations*, 12 *BIOETHICS* 286, 301 (1998).

49. *Id.* at 306.

50. See *Vaccine for AIDS*, *ECONOMIST*, July 4-10, 1998, at 81.

51. See Grady, *supra* note 41, at 598.

52. S. Kippax and J. Crawford, *Prophylactic Vaccine Trials: What is Different About HIV?*, 8

have, potentially, an operational interest in the sero-conversion of some of those receiving the placebo. They also have an operational interest in the exposure to risk of those who do receive the vaccine product. I do not, of course, suggest a *desire* that others become infected or a cold indifference to that possibility. Instead, I merely call to notice the operational necessities of any drug or vaccine trial.

In vaccine trials that are not life threatening (mumps, measles, and so on),⁵³ such potential conflicts of interest and duty may be tolerable. Where HIV/AIDS is concerned, the highest possible vigilance and strict scrutiny of the trial is required. The World Bank and international initiatives of the United Nations interagency, Joint United Nations Program on AIDS (UNAIDS), are addressing these truly global dilemmas. Because HIV is a virus of the human species and because it is spread rapidly by a movement of people to every part of the world, very few communities are completely immune from its devastation. In providing a response, it is not enough for the law to attempt to impose barriers at the frontier—they will not work. Law, to be ethical, should support vaccine trials and the international efforts to conduct them. Yet, if such trials are to take place, potentially for the benefit of people in other lands, distributive justice suggests the need to protect those who take part in the trial, to defend them if the trial fails, and to reward them if the trial produces a commercially viable vaccine.

These principles can be stated in general terms. George Smith would doubtless explain that they have their ultimate foundation in the love and respect that we should share for every creature who partakes of the humanity that is also our own. Legal regulation should not be so onerous as to discourage still further the investment in vaccine development, trials, and marketing that are essential to any effective and global scientific response to the AIDS epidemic. Yet, distributive justice requires that attention be given to individuals who submit to trials in other lands. If, ultimately, there are successful HIV vaccines, they will represent a commercial bonanza. In that event, what is the reward that will be shared with those whose risk-taking made it possible? Has the law a role to ensure that these individuals benefit directly from their contribution?

VENEREOLGY 178, 179 (1995).

53. See Grady, *supra* note 41, at 598-608.

IV. THE GENOME AND BENEFIT SHARING

The Human Genome Project (Project) is the largest cooperative scientific enterprise in history. It involves the mapping of the human genome comprising approximately 100,000 genes that determine the genetic makeup of each human being. The Project, which is ahead of schedule, is expected to be completed in the year 2003. Even when the location of the genes in the structure of the human DNA is known, the function of most of them will, for the time being, remain unknown.⁵⁴ Scientists will have a great mass of data. It has been likened to "a very large encyclopedia written in an unknown language."⁵⁵ The hope of this Project is that the functions of all of the genes will eventually provide knowledge that will help medical science to treat more than 4,000 genetic diseases, which presently afflict humanity, as well as many other diseases in which genetic predisposition plays an important role.

It is not my present purpose to identify even the main ethical and legal quandaries that the Human Genome Project presents.⁵⁶ The United Nations Educational Scientific and Cultural Organization (UNESCO) Universal Declaration on Human Rights and the Human Genome⁵⁷ bases its approach upon the requirement of defending human dignity and the common heritage of humanity. These objectives are sometimes explained by reference to Immanuel Kant's second formulation of the categorical imperative.⁵⁸ This formulation instructs that one should "act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means but always at the same time as an end."

Mutations or variations in the human genome may be important to the discovery of therapies that will be developed from the scientific research. They may result in drugs that have the potential to be highly profitable. Take two examples, not wholly theoretical:

54. See Lee Rowen et al., *Sequencing the Human Genome*, SCIENCE, Oct. 24, 1997, at 605; G. D. Schuler et al., *A Gene Map of the Human Genome*, SCIENCE, Oct. 25, 1996, at 540. See also J. Kinderlerer & D. Longley, *Human Genetics: The New Panacea?*, 16 *Mod. L. Rev.* 603 (1998).

55. See Kinderlerer & Longley, *supra* note 54, at 604.

56. See LAW AND HUMAN GENETICS, *supra* note 30; George P. Smith, II, *Harnessing the Human Genome Through Legislative Constraint*, 5 *EUR. J. HEALTH L.* 53 (1998); George P. Smith, II & Thaddeus Burns, *Genetic Determinism or Genetic Discrimination?*, 11 *J. CONTEMP. HEALTH L. & POL'Y* 23 (1994).

57. UNESCO Universal Declaration on Human Rights and the Human Genome, Nov. 11, 1997, (visited Feb. 24, 2000) <<http://www.unesco.org/ibc/uk/genome/project/index.html>>.

58. IMMANUEL KANT, *THE METAPHYSICS OF MORALS* 209 (Mary Gregor ed. & trans., Cambridge Univ. Press 1996) (1797). See also D. Beylveid and R. Brownsword, *Human Dignity, Human Rights and Human Genetics*, 61 *MOD. L. REV.* 661, 665-67 (1998).

- (1) Research on prostate enlargement has led to a study of particular families, many of them in developing countries, which have manifested an apparent immunity resulting in the natural development of an inhibitor against prostate enlargement. If the development of the steroid appearing in this group of human beings could be isolated, it could ultimately be of great benefit in the treatment of prostate enlargement in the general population of many countries. This is a common human ailment. If pharmaceutical companies, seeking to protect large investments in the research and development that may produce medications for such treatment seek the protection of patents over their discovery, should such protection be available to them? If so, for how long? Should rewards be paid in the event that a medication results in large profits to the pharmaceutical company? If so, to whom should the rewards be paid? To the individual from whose genetic particularity the treatment was refined? At least in developing countries, to the village of such donors or to their tribe or social group? Or to their nation so that it can be ploughed back into the medical treatment of others for both prostate enlargement and other conditions?⁵⁹
- (2) Researchers from a developed country, studying the genetics of nicotine dependence take samples from patients in an isolated village in China. As a condition for the award of a research grant, they bank their samples permanently. The researchers make them available, on request, without charge to other researchers, including commercial entities. They do not provide the names of the individual donors. The researchers find several promising genetic markers for nicotine dependence in the samples. Later, a pharmaceutical company using the samples discovers a gene associated with these markers. After many years of research and development, the company produces an immensely profitable drug to combat nicotine addiction in the human species. Does the company owe anything in these circumstances to the original donors in China if they could be found? To the original researchers? To the village or ethnic

59. ETHICS COMMITTEE, HUMAN GENOME ORGANIZATION, GENOME-BENEFIT SHARING, para. 6 (forthcoming 2000) [hereinafter HUGO ETHICS COMMITTEE].

group of the donors? To China as a country? Does any principle of benefit sharing require the provision of benefits to these individuals, groups, or nations? If so, is it provided for reasons of justice? Or possibly for reasons of prudence to avoid political, economic, or other opposition? Or as charity, out of the pocket of the rich into the pocket of the poor?⁶⁰

These are the questions being examined by the Ethics Committee of the Human Genome Organization. The answers given will not be found in the teachings of any particular religion. These questions are addressed to the whole world, with its multitude of religions, philosophies, and beliefs. The answers will draw upon the international guidelines that have been developed by the World Health Organization⁶¹ (WHO) and other bodies. As in all bioethical reflections, it is necessary to approach the quandaries from a thorough understanding of the practical environment in which they arise.

Some human diseases such as river blindness and sleeping sickness appear virtually exclusively in poor developing countries. The WHO estimates that more than fifty-six billion U.S. dollars is spent globally each year on health research. However, less than ten percent of that sum concerns diseases which afflict ninety percent of the world's population. Multinational pharmaceutical corporations do not ordinarily invest in new products unless they offer the promise of large and preferably prompt returns.

Turning a gleam in a researcher's eye into a handful of useful pills is an expensive and time-consuming business: on average, it costs \$300 million and takes more than a decade. Between 1975 and 1997, an impressive 1,223 new [medical] compounds were launched on the market. But . . . only 11 of them were designed for tropical diseases.⁶²

Already, particular national groups have begun to negotiate arrangements by which there is a trade-off between the group participating in a genetic trial

60. *Id.*

61. See HUMAN GENETICS PROGRAMME, WORLD HEALTH ORGANIZATION, PROPOSED INTERNATIONAL GUIDELINES ON ETHICAL ISSUES IN MEDICAL GENETICS AND GENETIC SERVICES (1998). See also WORLD HEALTH ORGANIZATION, *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services* (visited Feb. 27, 2000) <<http://www.who.org/ned/hgn/hgnethic.htm>>.

62. *Balms for the Poor*, ECONOMIST, Aug. 14, 1999, at 71.

and the pharmaceutical company conducting it. In February, 1998, Hoffman-La Roche, Switzerland, agreed to an arrangement for a contribution to the government of Iceland of 200 million U.S. dollars over five years. During that time, the company will study the genes and alleles (or mutations) that predispose Icelandic people to the development of up to twelve common diseases. These diseases include four cardiovascular diseases, four psychiatric-neurologic diseases, and four metabolic diseases. The project is called "deCode." It has been described by its supporters as "the first example of recognition of the patient population contribution to the drug discovery by a pharmaceutical company." Under deCode, Icelanders "will receive medications developed for their contribution free of charge."

Although there has been some opposition within Iceland and elsewhere to the scheme, the project has been fully developed in the Icelandic community and decided in the democratically-elected Parliament of Iceland. Decisions have been made by the community through its legislature to accept the bargain with the pharmaceutical company. Its supporters present deCode as a modern example of benefit sharing.⁶³ There are similar developments in other countries. However, for the most part, developing countries and the governments, tribes, villages, and individuals in them who participate in such trials are less well-positioned than the representatives and people of Iceland to insist that they should share the benefit of research and gain the "genomic dividend" if the study of their mutations produces therapeutic or prophylactic medicines, which are of benefit to human health and profitable to the companies that market them.

In a partial response to these developments, the World Bank and WHO, together with a number of donor countries and philanthropic organizations, have formed the Global Alliance for Vaccines and Immunization. The object of this body is to improve access to existing vaccines in developing countries and to support the development of new vaccines.⁶⁴ The program envisages "contingent lending" by which donors in developed countries will afford capital on the basis that needy countries will agree to purchase the vaccine if and when a useful one appears. Since December, 1998, the Gates Foundation has

63. See, e.g., Ragnheidur Haraldsdottir, Letter to the Editor, *Iceland's Central Database of Health Records*, 283 SCIENCE 487 (1999) (Haraldsdottir is the Deputy Permanent Secretary, Ministry of Health and Social Security, Reykjavik, Iceland.); Michael Specter, *Decoding Iceland*, NEW YORKER, Jan. 18, 1999, at 40-42. For recommendations of the Human Genome Organisation (HUGO) Ethics Committee, see *Statement on the Principled Conduct of Genetics Research* (last modified Sept. 23, 1998) <<http://www.gene.ucl.ac.uk/hugo/conduct.htm>>.

64. *Balms for the Poor*, *supra* note 62, at 71.

provided fifty million U.S. dollars for malaria vaccine development, twenty-five million U.S. dollars for HIV/AIDS vaccine research programs, and 100 million U.S. dollars for global children's vaccine programs. The children's vaccine programs aim to improve access to expensive new vaccines against hepatitis B and the influenza virus. International developments of these kinds, both within global institutions and by private bodies, assist in sharing the benefits of international medical research, including that derived from the Human Genome Project.⁶⁵ The law is not irrelevant to these developments. The reform of intellectual property law (encompassing patents and copyright) and the enactment of legislation which ensures that domestic corporations, subject to local law, conform to basic norms of individual and distributive justice, represent ways by which George Smith's principle of love for fellow human beings, wherever they are, may be reflected in the ethical decisions to which such laws give effect.

CONCLUSION

George Smith has frequently made the point that, at least in common law countries, there is always a potential legal decisionmaker who will solve dilemmas and provide binding norms. Where a problem is presented involving serious disagreement, there is never a legal gap. Although the legislative and executive branches of government may fail or run away from such dilemmas, this is not a privilege open to judges in a properly constituted suit. Judges must find a solution, even if this involves making new law by analogical reasoning from past judicial decisions. In a recent essay, Professor Smith quoted Professor Roger Dworkin to explain the limitations inherent in judge-made solutions:⁶⁶

Common law judges have no power to issue advisory opinions or proffer generalised codes of conduct. They have no power to rule for the future even about problems that seem certain to arise. This means that for the common law to deal with technology the technology must exist and have operated in a way that angered someone enough for that person to have claimed injury and sought legal redress. Thus, to the

65. See HUGO ETHICS COMMITTEE, *supra* note 59, para. 32.

66. ROGER B. DWORKIN, LIMITS: THE ROLE OF THE LAW IN BIOETHICAL DECISION MAKING 9 (1996), *noted in* Smith, *supra* note 29, at 99.

extent that a rapid response or response in advance of a bio-social development is important, the common law cannot provide it. Common law is reactive, not proactive.

Dilemmas of bioethics can sometimes elicit solutions to complex problems from distracted and nervous lawmakers. In 1997, President Clinton banned the use of federal funds for human cloning.⁶⁷ Subsequently, he settled on a five-year moratorium.⁶⁸ Later still, the National Bioethics Advisory Commission of the United States recommended federal legislation be enacted to allow a limited number of scientists to create cloned human embryos for a limited time for further scientific research aimed to benefit humanity. The Commission suggested that the use of such embryos for human reproduction be prohibited.⁶⁹

Ultimately, one could imagine cases coming before the courts in which many of the dilemmas presented by genetic and genomic science have to be solved. An individual or group affected in a foreign country may sue a local corporation for breach of proper standards in the conduct of an HIV trial. Individuals concerned may seek redress for the use without authority of their genetic materials in the development of a therapy or vaccine. Claims to distributive justice, as well as individual entitlements, may come to engage the judiciary in the future. Certainly, these claims will require the attention, and properly so, of the legislative and the executive branches. When this occurs, it will be important for decisionmakers to have guidance from those who have thought deeply about these issues, identified the scope and nature of the questions, and explored some of the answers. At this time, it is certain that the

67. See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1. Bills S. 368 and H.R. 922 of the 105th Congress seek a permanent ban of federal funding for human cloning. But H.R. 923 seeks to impose an outright ban on human cloning. See Smith, *supra* note 29, at 115-16.

68. See Guy Gugliotta, *United Against Human Cloning, Hill Leaders Differ on Specifics*, WASH. POST, Feb. 4, 1998, at A4.

69. See Rick Weiss, *Panel Backs Some Human Clone Work*, WASH. POST, June 4, 1997, at A1. In 1997, California became the first state in the United States to legislate a prohibition on reproductive cloning of a human being. See CAL. HEALTH & SAFETY CODE § 24185 (West Supp. 2000). A five-year moratorium was imposed on human experimentation in cloning, and heavy civil penalties were imposed for violation. See *id.* §§ 24185, 24187, 24189.

writings of Professor Smith, as a “prescient prophet of the New Biology,”⁷⁰ will be in the forefront of the thinking of the decisionmaker.

George Smith holds up the light of his scholarship to the rest of us. He sheds light into dark and mysterious places, where the darkness threatens to encircle us and the mysteries deepen and multiply into a gloom.⁷¹ For this we must be grateful. To say so, I have crossed the world to express the gratitude of many outside the United States. Professor Smith should continue to cajole, stimulate, irritate, and aggravate us. He should continue to seize our attention and to present us with the great puzzles of our time. Given the changes that have come about in the thirty years of scholarship and the acceleration of change we have witnessed, we will need him and others like him to apply human intelligence to great issues as we enter this new century where the dilemmas will only become more difficult.

Can our democratic law-making institutions survive these challenges? Or will our institutions remain as often-irrelevant relics of an earlier, simpler age? That is the fundamental question which bioethics presents to the law. Professor George Smith, son of Indiana University, is not content to walk away from such questions. He shows the obligation, and the means, to respond. But will we have the imagination and the courage to follow?

70. Harold A. Buetow, *Book Review*, 2 J. CONTEMP. HEALTH L. & POL'Y 173 (1986), cited in O'Brien, *supra* note 1, at 181. See generally GEORGE P. SMITH, II, *BIOETHICS AND THE LAW* (1993); GEORGE P. SMITH, II, *ETHICAL, LEGAL AND SOCIAL CHALLENGES TO A BRAVE NEW WORLD* (1982); GEORGE P. SMITH, II, *FAMILY VALUES AND THE NEW SOCIETY: DILEMMAS OF THE 21ST CENTURY* (1998); GEORGE P. SMITH, II, *FINAL CHOICES: AUTONOMY IN HEALTH CARE DECISIONS* (1989); GEORGE P. SMITH, II, *GENETICS, ETHICS AND THE LAW* (1981); GEORGE P. SMITH, II, *LEGAL AND HEALTHCARE ETHICS FOR THE ELDERLY* (1996); GEORGE P. SMITH, II, *MEDICAL-LEGAL ASPECTS OF CRYONICS: PROSPECTS FOR IMMORTALITY* (1983); GEORGE P. SMITH, II, *THE NEW BIOLOGY LAW, ETHICS AND BIOTECHNOLOGY* (1989).

71. See Letter from Guido Calabresi to Paul D. Carrington, in “*Of Law and the River*,” and of *Nihilism and Academic Freedom*, 35 J. LEGAL EDUC. 1, 23 (1985), cited in O'Brien, *supra* note 1, at 182.

