

Presumptions of Scientific Knowledge in the Evolution of Ethical Policies for Nascent Individuals

James L. Sherley

The Adult Stem Cell Technology Center, P.O. Box 301179, Boston, MA 02130; jlsherley@gmail.com

ABSTRACT: There is a common belief that the best available scientific knowledge at the time played a significant role in informing the complex social ethics that guide and govern present-day medical practice and biomedical research involving nascent individuals like human embryos and fetuses. Herein, the validity of this prevalent view is considered from the perspective that it is a misplaced notion. The complexities and complications of medical and biomedical ethics and their integration into clinical and biomedical research practice are managed well by the local deliberations of hospital and university institutional review boards (IRBs), which comprise participants from diverse professional, educational, and socioeconomic backgrounds, including medical and biomedical ethicists. Yet despite this richness of experience, expertise, motivation, and counsel in the local review and approval process for human subjects research protocols and clinical trials, external state and federal agencies and the acts of different branches of government ultimately dictate the policies that are applied. In particular, IRBs must adhere to the regulations, policies, and laws set down and enforced by administering agencies like the National Institutes of Health and all 3 branches of the federal government. When current scientific knowledge is excluded—most often at the government level—a vertical misalignment can occur between the bioethics reasoning of IRBs and the government agency bioethics regulations they must follow, which creates seemingly inexplicable contradictory situations. This is the current state of affairs for the entwined vexing social issues of abortion rights and human embryo research, which can be explained as the consequences of a misinformed presumption that up-to-date scientific knowledge guides government decisions on the treatment of nascent individuals.

KEY WORDS: nascent individuals, human embryo, human fetus, abortion, human embryonic stem cell research, institutional review board, *Roe v. Wade*, *Sherley v. Sebelius*, U.S. Supreme Court, National Institutes of Health

I. INTRODUCTION

It is widely acknowledged that the most divisive social, ethical, moral and political issue in modern US society is the question of abortion rights.^{1,2} Even though 40 years have passed since the US Supreme Court handed down its now landmark decision in *Roe v. Wade* that legalized elective abortions, socially and politically the matter is still far from settled. Antiabortion and pro-abortion groups continue to face off both in person via public and civic forums and through their elective representatives in federal and state legislatures. Many elected officials and candidates for office warily avoid this political hot button issues, and legislative bills devised to revise or extend the law according to *Roe* are brought to a vote on a regular basis, sometimes (but rarely) with success. Even

in families and among friends, the topic is often taboo, with the personal views of others being presumed but only rarely discussed openly.

In the current state of widespread disagreement on the constitutionality of abortion rights in the United States, 2 dominant questions in the minds of many Americans on either side of the issue are, “Could *Roe* be overturned?” and, if so, “What would be the tipping point?”^{3,4} However, before these questions can be reasonably entertained from either perspective, a look at how the current state of things came into being is instructive. As will be described later, many would be surprised to learn that the decision in *Roe* did not incorporate the relevant scientific knowledge of the day on the nature of nascent human beings. Such surprise would suggest a lack of understanding or underappreciation that the exact legal issue addressed by the court in *Roe* was the authority of governing states to intervene in the private medical affairs of pregnant women with their physicians to meet states’ interests and responsibilities in protecting the lives and quality of life of all their citizens, including both pregnant women and their unborn children. Yet *Roe* is widely thought to have addressed, in particular, the now iconic question, “When life begins?” (*sic*) That being said, it is difficult not to contemplate how the decision might have ended differently if scientific knowledge had played a role in the court’s deliberations.

Recent decisions in court cases adjudicating the legality of federal funding of human embryonic stem cell (hESC) research (specifically, *Sherley v. Sebelius I–VII*,^{5–11} in which the author was among the plaintiffs) have a similar widely misperceived focus and exclude relevant scientific knowledge. Whereas the general public’s impression may be that scientific considerations were weighed in these decisions, the actual rulings were based on legal principles that precluded arguments grounded in current scientific knowledge of the biological nature of the earliest nascent forms of human beings: embryos. Again, it is instructive for future medical ethics and bioethics policymaking to consider this disconnection between what is actually found in these court decisions and the general public’s expectation and impression that “Science” would necessarily be an integral factor in the decision making.

Because scientific knowledge is generally reputed to have a unique and ideal character of not only being produced by dispassionate observation, experimentation, and systematic reason but also being falsified by independent experimentation, it stands apart from all other forms of human intellectual creation in the likelihood that it will be mistaken as unprejudiced and infallible. Unfortunately, because social and political adversaries often are equally unequipped to tell the difference, as a result of this accorded preeminence, the invocation of Science in public and political discourse on any topic garners sometimes excessive homage, including begrudging acquiescence, whether it is represented accurately or inaccurately. The side that plays the “science card” first often gains the entirety of whatever advantage can be had from the public’s general regard for scientific information. The common tendency of those who are not scientists or experts to represent, accept, and treat scientific information as objectively pure and often as irrefutable makes its accuracy essential for it to insure valid outcomes in the resolution of important societal and political controversies and debates such as the ethical regard for nascent human beings.

The problems in the translation of scientific information to the public are well appreciated.^{12,13} However, in the present perspective, a more subtle problem, which is proposed as responsible for continuing adverse consequences in the communication of scientific knowledge regarding the nature of nascent human beings, is examined. Worse than spreading inaccurate and misinformed pronouncements of crucial scientific knowledge would be promulgating an impression that the policy outcome of a contentious social, political, and ethics discourse was the result of a deliberative process that included the observant weighing of sound scientific input when, in fact, it did not. This is the case with both past and recent legal and governmental regulations and policies on abortion rights and hESC research. Although institutional review boards (IRBs) may have exercised good ethical principles that were informed by current and relevant scientific knowledge, such good practice has been laid low before laws, regulations, and policies handed down by government agencies and branches that operated without the inclusion of crucial scientific knowledge. Whereas the intent of such exclusions can only be speculated, their consequences are quite devastating to the validity of the ongoing arguments and debates. Social, political, legal, and ethical attitudes about the medical and research treatment of nascent individuals are ill-founded because of the mistaken presumption that decisions on acceptable medical and research practices were based on the best scientific information available at the time, and the public, which includes many physicians and scientists themselves, is puzzled by why physicians and scientists on both sides of the issues are still arguing with their peers.

II. THE SCIENTIFIC KNOWLEDGE OF NASCENT HUMAN LIFE

Given the long-standing scientific knowledge of the detailed cellular and even molecular nature of human development, the persistence of the pervasive question, “When life begins?” (i.e., an individual human life) should be enigmatic in our times, but it is not. In fact, the average US citizen thinks that this question remains unresolved, after *Roe* as before *Roe*. So, other factors must be at play that undermine dissemination of and education about this basic knowledge, for which there is a large volume of rather exacting scientific evidence.

What is the scientific evidence that the life of human beings begins with fertilization? The elementary lesson for understanding that *biologically* a human life begins with fertilization is recognizing that essentially all vertebrates on Earth, which include humans, begin their biological existence in this manner. More generally, the event is defined by the activation of a largely diploid human genome for human organismal development by the molecular factors that constitute a fertilized human egg.¹⁴ This biologically exact but general definition also encompasses the initiation of living human beings by *in vitro* techniques such as parthenogenesis and somatic cell nuclear transplantation. In parthenogenesis, duplication of the half complement of the human genome carried by natural human oocytes is induced; in nuclear transplantation, a cell nucleus with a complete diploid human genome is transferred into an oocyte whose nucleus, equivalent to a half genome, has been removed. There are many experiments in animal models showing

that the developmental life of mammalian organisms, like humans beings, begins with the establishment of their species-unique complete genomes in the environment of their eggs at fertilization. The successful development of human *in vitro* fertilization (IVF) technology in Britain in 1978 demonstrated that the same is true for human beings. The molecular changes that spontaneously initiate when the haploid genomic complement of the human sperm joins that of the human oocyte to establish a diploid fertilized egg are the biological beginnings of a living human individual.

Although evidence for the start of a human life with IVF was not available at the time of *Roe*, its unavailability was not responsible for the court's suggestion of the view that when human life begins might be unknowable. As will be discussed in greater depth later, this minor attribution is because the question "When life begins?" although posed in *Roe*, was in fact irrelevant to the legal focus of that case. However, this question has been reanimated by the 12 years of more recent public debate and court actions to end federal funding of hESC research. In the case of ongoing social, legal, and ethical arguments about hESC research, the subversion of the fundamental scientific knowledge that even the first single zygotic cell formed by fertilization is a living human being has been particularly effective in fostering supportive laws and policies that influence public attitudes on not only hESC research but also abortion rights.

To be sure, the scholarly academic ideas represented in the *Roe* decision became the pattern for the mystery cast around the "When life begins?" issue. The court invoked many nonscientific ideological, theological, and sociological perspectives on the nature the start of human life from ancient times to modern times.¹⁵ Its review was presented without evaluative content or prioritization and served instead to illustrate the far-ranging scope of human thought, culture, and practice around the issue. Even though the court did not provide an assessment of the merit of these ideas, many of them were recognizably obsolete. However, as will be discussed with more focus in the next section, the court did not base its legal argument on either this exposé of the question or the question itself. More powerfully, it left the whole issue as *uncertain*. Uncertainty for a crucial question in a legal argument is not a neutral aspect in the law. In fact, as will be seen in both the *Roe* and *Sherley I–VII* decisions, this characterization of key aspects of the pertinent science precluded the need for considering existing scientific knowledge that could have been a significant factor in the reasoning, logic, and outcome of the legal arguments in contention. Compound this legal practice with the public's mistaken presumption that sound scientific knowledge was an important part of the court decisions on the regard and treatment of nascent individuals, and suddenly ethical medical and research practices could be suspended *legally*.

III. THE PRESUMPTION OF SCIENTIFIC KNOWLEDGE IN THE ROE V. WADE DECISION

Throughout human history, the question of what acts are permissible when addressing an unwanted human pregnancy has posed a vexing moral, ethical, political, and societal dilemma. In the past century, discourse on this deeply dividing question moved from

secrecy and privacy into widespread public debate. In the United States, the Supreme Court's 1973 decision in *Roe v. Wade*,¹⁵ which legalized elective abortion, instituted a legal resolution. However, the court's ruling fell far short of settling the broader societal discord and public and political debates. Americans remain significantly separated on the question^{1,2}; *Roe* has become a flag to be upheld or brought down by opposing positions.^{3,4} Underlying this ongoing moral and ethical battle is a current belief by many that science has been weighed as uncertain and unable to offer an objective basis for mitigation. Actually, nothing could be farther from reality. Misperceptions born of *Roe* continue to sustain this state of affairs.

For the treatment herein, the remarkable aspect of *Roe* is that its decision ultimately rests on the argument of biological uncertainty without supporting evidence based in the science of human biology. The Supreme Court ruled that the degree of religious, cultural, theological, historical, and societal disagreement about when human life begins made it unlikely that first-trimester abortions would destroy a human life as it has been defined over the ages. In this way, the court recast the unborn human dilemma as the "When life begins?" question. It did this in the same instance of disavowing any expertise to render, and thereby any responsibility to render, an opinion as to the likely answer to the question. The court wrote, "When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus [on the question of when life begins], the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer."¹⁵ The court acknowledged, "Some of the argument for this justification rests on the theory that a new human life is present from the moment of conception."¹⁵ However, this "theory" was attributed to reference n45, which was a citation of a law review in the amicus brief submitted by the National Right to Life Committee.¹⁵ However, the word *science* does not appear in the court's decision, and *scientific* and *biological* each appear only once: the former in reference to "Physicians and their *scientific* [emphasis added] colleagues have regarded that event [i.e., quickening] with less interest and have tended to focus either upon conception, upon live birth, or upon the interim point at which the fetus becomes 'viable,' that is, potentially able to live outside the mother's womb, albeit with artificial aid" (section IX.B) and the latter in, "State regulation protective of fetal life after viability thus has both logical and *biological* [emphasis added] justifications"(section X).¹⁵ Although the decision contains an academic litany of cultural, theological, medical, and historical perspectives on human development, it presents little from the literature then available, the many dusty volumes of scientific reports and treatises on the developmental biology of how life begins for many different mammals, which humans are.

Remarkably, the court's reframing of the unborn humans dilemma as one of societal uncertainty instead of societal ethics has clouded the issue for 40 years, despite informative animal model evidence existing at the time of *Roe* and widely publicized definitive human evidence becoming available a few years later after the successful IVF and birth of human babies in 1978. The court did not represent science as being ineffective in the discourse. Instead, it simply ignored the available science. Given the primary focus of the court's deliberation, a good argument could be made that it had to dispatch the issue

of the humanity of nascent individuals as conveniently as possible so that it could move on to addressing the more troubling question, “When is it permissible for a pregnant woman to abort a fetus, whose humanity is not in dispute?”

“When” for the abortion rights question encompassed both, “Under what medical conditions?” and “When during human fetal development?” It is the latter question that preoccupied the justices in *Roe*. However, this question was not explored from the perspective of the personal interests of nascent individuals—fetuses in this case. The affirming justices framed their charge as deciding when during human development the interests of states to protect human life outweighed the constitutional privacy of women to decide the course of their pregnancy in consultation with their physicians. The court ruled that the critical point in development was the time at which extrauterine viability was attained. This was not a scientific measure. It was a medical metric based on the approximate time when newborns could survive on their own without medical assistance.

Although the decided balancing point immediately caused new distressing moral and ethical dilemmas, it has survived mostly intact for 4 decades. With the rapidly advancing coincident innovation in technology for critical care for premature infants, the wake of *Roe* immediately caused many obstetrical caregivers to face ethical dilemmas regarding the treatment and disposal of aborted fetuses, which might survive if instead they were provided intensive medical care or might live only for agonizing periods of time if they were not.¹⁶ Interestingly, although the socially problematic medical situations continued (as seen in the controversy over “partial birth” abortions¹⁷), the local medical ethics dilemmas have largely evaporated. Both conscientious recusal by objecting health care providers and the widespread segregation of abortion practice into dedicated clinics,¹⁸ which are staffed by medical personnel who do not object to the destruction of human fetuses, have effected an apparent dissolution of the previously widespread ethical dissonance in US medicine over the maltreatment of aborted human fetuses. As will be seen, the development of hESCs by Science popped the top off this managed ethical jack-in-the-box because it put the question of ethical treatment of unborn human beings back before the a general public more broadly than just right-to-life groups.

The court invoked legal and constitutional arguments to keep the interests of the fetus off the scales of the simpler balance between the interests of states and the interests of pregnant women seeking elective abortions. Its legacy remains active today. The writers of the US Constitution did not anticipate modern questions regarding the rights of individuals in their unborn nascent forms. The court took the tack of considering whether the fetus had the rights of born “persons” “before the point of extrauterine viability. More specifically, it evaluated whether unborn individuals were legal “persons” per the Constitution. The language developed around this argument in the court’s decision continues to constrain current discourse on the topic by relegating unborn individuals as having only “potential life” and, per the Fourteenth Amendment of the Constitution, not included among “persons.” The court acknowledged that the constitution “does not define ‘person’ in so many words,” but it based its future critical precedent on phrasing from the Fourteenth Amendment that “...first, in defining ‘citizens,’ speaks of ‘persons born or naturalized in the United States’” (section IX).¹⁵

If well-established scientific knowledge of the nature of human development had been included and considered in the *Roe* decision, one can but wonder whether the precedent now in place would be somehow different. As it was, in reality, science had no recorded role in informing the court's thinking on the unborn individual dilemma, which clearly complicated the court's deliberation on the balance between personal privacy interests and states' regulation interests. Despite whether it was a strategy devised to reduce an unsolvable legal "three body problem" to a more manageable "two body problem," the court's approach to resolution defined the nature of the human beginning as uncertain and unknowable for the next 3 decades, until the hESC debate erupted. It did so by essentially ignoring the available scientific knowledge while passively leaving the presumption that science had been consulted. Amazingly, even after IVF technology broadcast to the world the human-specific scientific evidence that the life of human individuals begins with fertilization, the uncertainty precedent set by the court in *Roe* remains intact in many sectors of society. As will be seen in the next section, the survival of this invalid perspective is due to complex causes that include not only the courts, but the legislative and executive branches of government as well, and even scientists themselves. However, a common feature threading through these misrepresentations to the public is a false impression of responsible consultation with "good science."

IV. THE PRESUMPTION OF SCIENTIFIC KNOWLEDGE IN THE *SHERLEY V. SEBELIUS* COURT CASES

Much of the societal angst and uneasiness about the legalization of abortion subsided as elective abortions became a muted, though broad, band of color in the fabric of American life. Although religious groups and right-to-life groups continued to advocate on behalf of the personal rights of unborn individuals, their efforts were largely washed over in the wake of *Roe*. The emergent "choice" versus "life" debate joined the ranks of other ebbing and flowing chronic issues that make up the American sociopolitical scene. Advocates for life and advocates for choice settled in for a long ground war of electing representatives who might work to overturn *Roe* or work to preserve it, respectively. However, most of the country watched from the sidelines without much interest or awareness when skirmishes erupted. A whole new generation of Americans matured with little awareness of the lingering ethical and legal questions about the personal rights of nascent individuals. Then, scientific advances brought these questions back to the top of the consciousness of American society again.

Ultimately, it was the debate over federal funding of hESC research that most galvanized renewed discourse on the bioethical considerations for the social regard of nascent individuals. Yet the core principles at issue in the hESC funding debate predated the scientific discovery of the technology used to produce hESCs by 2 full years. The legal embodiment of this important precedent was the Dickey-Wicker Amendment ratified by Congress in 1996. This act of Congress is now a rider on the yearly congressional budget appropriations bill (Omnibus Appropriations Act). Dickey-Wicker was written by Congress to address ethical concerns about public funding for research conducted

with human embryos, which IVF could make available on demand. The enactment of this regulation occurred on the heels of concerns about proposals for the use of human fetal tissue, initially in federally funded research projects and thereafter potentially as treatments for disorders like Parkinson's disease.¹⁹ Existing government regulations administered by the National Institutes of Health (NIH) and other government research sponsors adequately dealt with political worries that newly proposed treatment research and therapies requiring fetal tissues might incentivize elective abortions at the expense of taxpayers who disagreed about abortion itself, even as a private matter, and who would certainly object to sourcing treatments from aborted fetuses as a public matter. Although, by extension, the same concerns could materialize for human embryo research, no preventions were in place. So, Dickey-Wicker, in essence, extended the existing "protective" regulation for human fetal research to human embryo research. Although human "embryos" and "embryological data" are mentioned in *Roe*, it clouded the humanity of embryos under the "When life begins?" question. In Dickey-Wicker, the humanity of human embryos is both implicit and as broadly defined as the scientific knowledge of the day supported.

The amendment is found in section 509 of the Omnibus Appropriations Act, reapproved by Congress each year since, and reads as follows:

*"SEC. 509. (a) None of the funds made available in this Act may be used for— (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."*²⁰

The language of Dickey-Wicker guarantees the youngest nascent individuals, embryos, the same ethical research protections as more mature individuals, even if they are not in utero, thereby removing the requirement of "birth" to be considered a human research subject. Moreover, the last sentence of Dickey-Wicker indicates the scientific thought that went into the law's development. Several of the stated ways in which mammalian life can be initiated were anticipated but not yet performed for humans at the time. However, Dickey-Wicker did not anticipate the use of human embryos to produce hESCs. This shortcoming, unanticipated by the writers at the time, would become the key mask over scientific knowledge later in this history.

The report²¹ of the production of hESCs at the University of Wisconsin-Madison in 1998 revitalized public interest in nascent human individuals in a new way and occurred with surprising events in bioethics. Unlike in *Roe*, where the personal rights of nascent individuals were removed from the legal equation, the questions raised by hESC research addressed the human rights of human embryos expressly. The ethical problem

posed by the facts that human embryos necessarily died during the derivation of hESCs, precluding any benefit for themselves, and that any benefits of their death would instead accrue to other individuals, was evident to expert bioethicists and laypersons alike. This point of reference produced a new turbulent debate, which initially occurred without any reference to *Roe*.

The new right-to-life debate had a very different tone than the discourse provoked by *Roe* because it originated in scientific advances, and scientific considerations became unexpectedly complex because scientists were not uniform in their views on the matter. Unlike their background placement in *Roe*, embryos and their human rights were now in one pan of the scale weighed against, not private rights, but instead the public good in the form of potential new medical treatments. The controversy also was confused by the fact that Dickey-Wicker only prohibited the use of *public* funds for hESC research. The very same use of human embryos was not restricted if *privately* funded. Layered in was fast-moving science coming up with new ways to produce hESCs with artificially produced embryos instead of IVF embryos. The most widely publicized and argued of these methods was “therapeutic cloning.” For this procedure, the full complement of human genomic DNA was isolated from mature human cells and injected into human eggs whose genomic DNA had been removed. Though it never became sufficiently effective for routine use, the cloning procedure was planned for producing human embryos from which hESCs might be derived in large quantities. A major motivation driving development of scientific approaches such as cloning was attempts to find strategies to evade the regulations of Dickey-Wicker. This effort resurfaced the question of “When life begins?” as “Are cloned embryos human persons?” This was the beginning of an erosion of the responsible use of science to inform the ethical questions facing the public regarding fair treatment of nascent individuals.

Roe taught very clearly that nascent individuals, embryo, fetus, or anyone before birth, were not legal “persons” according to the law. Changing this legal precedent would require an act of Congress or a constitutional amendment. However, as implied earlier, nascent individuals hold a definite status as research subjects, as codified by laws governing the use of federal funds for scientific and medical research. These incongruent ethics between legal issues relating to personal privacy and those relating to protection of human research subjects continue to confound public views on supporting hESC research. After all, if elective abortions, in which the humanity of unborn infants is not disputed, are legal in the United States, what is all the fuss over cloned or natural embryos that even some scientists describe as “just a ball of cells”?

Most recently, the US courts were petitioned in 2009 by a partnership of right-to-life groups and conscientious objector scientists (*Sherley I–VII*)^{5–11} to preside over a legal challenge to restarting federal funding of hESC research. Unlike the course of the debate described earlier, in which scientific considerations played a prominent role, the courts, in their legal judiciary role, regressed public views to a mistaken presumption of responsible incorporation of scientific knowledge in their deliberations. However, this regression of scientific knowledge already had been set into motion by earlier events before the courts were asked to weigh in again.

As a result of an executive statement issued by President George W. Bush in 2001,²² federal funding was prohibited for any research that involved hESCs produced after a designated set of 60 existing hESC lines. Many scientists wishing to pursue hESC research complained that the allowed hESC lines were inadequate for the best research that might be done. Some of these investigators obtained private funds to continue hESC research projects, and new hESC lines were developed by private companies. The ensuing years witnessed some hESC research scientists suggesting publicly that physicians and scientists were actually still uncertain about when a human life began²³; such statements and attitudes revived public confusion and uncertainty about the biological nature of nascent human beings, although scientifically this issue was resolved and closed more than 2 decades earlier. To be fair, in science, the time scale for the complete curing of new scientific discoveries, concepts, and principles can be centuries, and even then, new knowledge can disrupt old dogma. That is the nature of scientific discovery and progress. However, this was not the situation with scientists and physicians who detracted from the established biology of nascent human life. Instead, by simply equivocating when asked to provide expert input on the issue, a few widely respected scientists and physicians cast into the public consciousness doubt and uncertainty about the nature of nascent individuals, undoing 2 decades of progress.

The Bush ban was rescinded in 2009 with the issue of an executive order by newly elected President Barack Obama. In addition to revoking the Bush resolution that limited federal funding to research employing only certain allowed hESC lines, the new order authorized “the Secretary of Health and Human Services (Secretary), through the Director of NIH, [to] support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by the law.”²⁴ The NIH developed and issued *Guidelines on Human Stem Cell Research*²⁵ soon thereafter. The series of court actions against the government that followed (*Sherley I–VII*)^{5–11} challenged whether the NIH had met the requirements of the Obama executive order. Plaintiffs challenged that, based on ethics principles, hESC research was not “responsible”; based on scientific grounds, it was not “scientifically worthy human stem cell research”; and based on the legal precedent of *Dickey-Wicker*, it was not “permitted by the law.” In addition, they argued that the NIH had not followed proper procedural rules in the manner in which it established the new guidelines.

Because of the 3 challenges announced by the plaintiffs in *Sherley I–VII*, scientific considerations might be expected to have been an integral factor in the presiding courts’ deliberation. However, as in *Roe*, and as should be expected in all cases before district, circuit, and supreme courts, legal issues and precedents dominated to the exclusion of issues of science. The main thesis of this perspective is that, despite this common reality, the public presumption is that since scientific issues motivated the legal action they were also an important consideration in the legal decision and, as a result, societal views on the ethical regard for nascent individuals is not only underinformed, but it is also misinformed. In *Sherley III*, the District of Columbia District Court issued a preliminary injunction that suspended federal funding of hESC research.⁷ After an initial successful petition for a stay of the injunction, allowing hESC research funding to resume while the

court case continued, in *Sherley IV* the government was successful in obtaining a grant of appeal.⁸ The basis for this decision was the decision of the District of Columbia Court of Appeals that the language of Dickey-Wicker was “ambiguous.” This argument arose out of the government’s contention that the phrasing “research in which” did not apply to funding research that used hESC lines produced with nonfederal funding. By this decision, the court authorized funding of research projects that used hESC lines derived from the deaths of nascent individuals by state-, private-, or foreign-funded agencies. Not only did this judgment not involve any scientific knowledge of human embryos or their nature, it also set a new legal precedent for compartmentalizing scientific research itself into arbitrary and separable units. *Sherley V* and *VI* dealt strictly with case law issues^{9,10}; *Sherley VII* was a denied petition for a hearing before the Supreme Court. The petition focused on the case law issues, which had dominated the course of the court action.¹¹

The lesson of how *Sherley I–VII* proceeded and ended may be that the US court system is an intrinsically inappropriate setting for scientific knowledge to inform ethics discourse on the personal rights of nascent individuals and the societal responsibility of the government to safeguard them from exploitation, injury, and death, whether in private life or as subjects of research, in all spheres of American enterprise, public or private. Such a lesson raises the question, “What, then, is the right setting?” The answer may ultimately be Congress, in its function as the elected representatives of the public. However, in the specific case of human subjects research, the incorporation of scientific considerations is certainly occurring daily in IRB forums. Many IRB members must find themselves in conflict between their personal and professional ethical perspectives on respecting the humanity of human embryo research subjects and their new charge from the NIH and courts to approve research that requires the ongoing demise of these nascent individuals. This dissonance may occur even though IRBs have been released legally from the long standard requirement of ensuring the ethical conduct of the research not only in their own institution, but also that occurring at partner institutions that contribute subjects and/or tissues for human research. Now, although IRBs must continue to evaluate whether extramurally supplied mature human tissues were procured according to ethical procedures, no matter what their source, they are charged to ignore the fact that hESCs supplied were the direct consequence of the destruction of nascent individuals elsewhere. Such contradictions in logic and reason often manifest ethical missteps.

The crucial scientific knowledge that is conspicuously absent from the NIH *Guidelines*²⁵ is the fact that embryos are living human beings.¹⁴ By omitting this most relevant biological and social character of embryos, the *Guidelines* obfuscate the humanity of embryos from the public and offer conflicted IRB members the justification of deference to a higher authority. In this way, the NIH promotes a mistaken presumption of reliance on relevant scientific knowledge. The NIH is the pinnacle of biomedical research in the country and has the current president’s blessing; only rare members of the public would think that good sound science had, in reality, only played a role in the current outcome by being excluded. This practice undermines the quality and validity of the continuing social, political, and ethical discourse on hESC research and the rights of the nascent individuals who are exploited and killed by this research.

V. CONCLUSIONS

It is generally well understood by laypersons and professional experts that medical ethics and bioethics are essential codes of conduct in medicine and life science research, with the purposes of safeguarding the welfare of human patients and research subjects; protecting them from undue risk of or experience of stress, pain, injury, suffering, or death; honestly informing them of what adverse events might occur and with what likelihood; obtaining their informed consent or that of a responsible advocate; and applying the most scientifically rigorous practice to ensure that treatments and studies are as scientifically sound and appropriate as the existing state of scientific knowledge allows. What many overlook, though, is the deeper understanding that ethical practice in medicine and human research is not just for the patients and research subjects. It is also for the humane edification of the investigators and the greater good of human society, of which they are members. A society that embraces and fosters ethical practices toward its members creates a humane atmosphere in which members are valued and respected at a high level. The idealized thought experiment here is, Would the general quality of life and happiness in American society improve (1) if the abortion rate were replaced by a balance of reduced unwanted pregnancy and increased adoption, and (2) if human embryo research was guided by the same bioethics policies that are applied to more mature human research subjects? Like all scientific experiments, the potential outcomes of this thought experiment can be imagined, guessed, projected, estimated, modeled, and argued, but they can be known only by doing the actual experiment—and doing it well.

The past 12 years of deliberation, discussion, and debate on whether the use of human embryos for hESC research is an ethically acceptable and allowable societal pursuit are likely to be only the beginning of a very protracted human experience and sociopolitical discourse. Certainly, if the example of abortion, the predecessor of the moral and ethical issues of hESC research, is any indication, this first decade is only the start of a centuries-long path to resolution. This prospect makes better integration of relevant scientific knowledge into future dialogues even more crucial to accelerate better ethical solutions, especially since scientific advances are often major causes of sudden dilemmas in medical ethics and bioethics.

On the basis of the past experience related here, moving beyond the mistaken presumption of the inclusion of scientific knowledge to the actual practice of routine reliance on it may be much easier to suggest than to accomplish. As seen in the courts, some essential components of society may have an inherent structure in which scientific considerations have little relevance. In other situations, when exact scientific knowledge might lead to societal prohibition of particular lines of research desired by significant societal factions, many forces may conspire to confound and/or exclude it. Whereas physicians, scientists, engineers, and other medical and science professionals may themselves sabotage the full and exact disclosure of scientific knowledge when their self-interest is in conflict, as a group they are best suited to ensure active inclusion of science in societal and ethical discourse with the intent of benefiting the public good. In general, this group has been trained at the expense of the public, and the public supports their

livelihood with research grants. Although trained research professionals may be the best suited to meet this increasingly important societal need, current formal science education neither instills in students the suggested scientific and ethical values nor prepares young scientists with the skills required to exercise and foster these values effectively. Putting more resources into correcting these deficiencies in the way scientists are trained might allow societies to advance beyond their present state of unnecessarily confused, unknowingly misinformed or underinformed and unproductive arguments and debates. Finally, with the achievement of scientifically well-informed discourse, societies would be better able to move forward to constructive conversations to bring societal regard for nascent individuals in line with a valid scientific understanding of the nature of human life. Whatever the outcome of such an alignment of thought and reason, it would have to be better than what we experience now, which some have become resigned to accept.

ACKNOWLEDGMENT

The author was supported by a grant from the Lee Iacocca Family Foundation.

REFERENCES

1. Joffe C. *Roe v. Wade* and beyond: forty years of legal abortion in the United States. *Dissent*. 2013;60:54–9.
2. Hoffman JP, Johnson SM. Attitudes toward abortion among religious traditions in the United States: change or continuity? *Sociol Relig*. 2005;66:161–82.
3. Manninen BA. Rethinking *Roe v. Wade*: defending the abortion right in the face of contemporary opposition. *Am J Bioethics*. 2010;10:33–46.
4. Allegrucci LJ, Kunz PE. The future of *Roe v. Wade* in the Supreme Court: devolution of the right to abortion and resurgence of state control. *J Civil Rights Econom Dev*. 1991;7:295–328.
5. *Sherley v. Sebelius I*, 686 F. Supp. 2d 1 (D.C. 2009).
6. *Sherley v. Sebelius II*, 610 F.3d 69 (D.C. Cir. 2010).
7. *Sherley v. Sebelius III*, 704 F. Supp. 2d 63 (D.C. 2010).
8. *Sherley v. Sebelius IV*, 644 F.3d 388 (D.C. Cir. 2011).
9. *Sherley v. Sebelius V*, 776 F. Supp. 2d 1 (D.C. 2011).
10. *Sherley v. Sebelius VI*, No. 11-5241 (D.C. Cir. Aug. 24, 2012).
11. *Sherley v. Sebelius VII*, No. 12-454 (U.S. Jan. 7, 2013).
12. Nisbet MC. Framing science: a new paradigm in public engagement. In: Kahlor L, Stout P, editors. *New agendas in science communication*. New York; Taylor & Francis; 2009. p. 40–67. Available from: <http://ion.uwinnipeg.ca/~clark/teach/3480/nisbetframingscience.pdf>.
13. Osmond DL, Nadkarni NM, Driscoll CT, Andrews E, Gold AJ, Allred SRB, Berkowitz AR, Klemens MW, Loecke TL, McGarry MA, Schwarz K, Washington ML, Groffman PM. The role of interface organizations in science communication and understanding. *Front Ecol Environ*. 2010;8:306–13.

14. Sherley JL. The importance of valid disclosures in the human embryonic stem cell research debate. *Cell Prolif.* 2008;41(Suppl 1):57–64.
15. *Roe v. Wade*, 410 U.S. 113, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973).
16. Grimes DA. Second-trimester abortions in the United States. *Fam Plann Perspect.* 1984;16:260–6.
17. Sprang ML, Neerhof MG. Rationale for banning abortions late in pregnancy. *JAMA.* 1998;280:744–7.
18. *An overview of abortion in the United States [presentation on the Internet]. 2011 Aug [cited 2013 April 24]. New York: Guttmacher Institute. Available from: www.guttmacher.org/presentations/abort_slides.pdf.*
19. Coutts MC. Fetal tissue research. *Kennedy Inst Ethics J.* 1993;3:81–101.
20. Available from: <http://beta.congress.gov/bill/111th-congress/house-bill/1105/text?q=%22omnibus%20appropriation%22>.
21. Thomson JA, Itskovitz-Eldor J, Shapiro SS, Waknitz MA, Swiergiel JJ, Marshall VS, Jones JM. Embryonic stem cell lines derived from human blastocysts. *Science.* 1998;282:1145–7.
22. President George W. Bush's address on stem cell research. 2001 Aug 9 [cited 2013 April 24]. Available from: http://articles.cnn.com/2001-08-09/politics/bush.transcript_1_adult-cells-cell-lines-cell-research?_s=PM:ALLPOLITICS.
23. New frontier of human cloning [podcast on the Internet]. Boston: 90.9 WBUR. Available from: <http://onpoint.wbur.org/2005/05/19/new-frontier-of-human-cloning/player>.
24. Office of the Press Secretary. Executive order. Removing barriers to possible scientific research involving human stem cells. 2009 March 9 [cited 2013 April 24]. Washington, DC: The White House. Available from: <http://www.whitehouse.gov/the-press-office/removing-barriers-responsible-scientific-research-involving-human-stem-cells>.
25. 2009 Guidelines on human stem cell research [webpage on the Internet]. c2011 [cited 2013 April 24]. Bethesda, MD: National Institutes of Health, US Department of Health and Human Services. Available from: <http://stemcells.nih.gov/policy/pages/2009guidelines.aspx>.