Caution One

Tip-Toe When Walking on the Bleeding Edge

Case 1  The Dangers of Creating Life in the Lab

Synthetic biology is receiving much attention in the media and in churches, schools and offices around the world. The issue is the creation of life in the laboratory. And the reactions range from excitement to ethical outrage to horror at the new potential for bioterrorism.

First, the scientists at The Institute for Genomic Research (TIGR) in Rockville, Md., published the details of their effort to isolate the minimum number of genes an organism needs to survive in *Science*. They reported on a project in which they aim to create a kind of life form by building each bit of the genetic code for a type of simple bacterium called mycoplasma in the laboratory, then stacking the bits together like toy blocks. At the end of the effort, the scientists can prove not only that the bits of genetic information they stack together can be artificially “animated” into acting just like any other bacterium, but also that the most important parts of bacteria and viruses can be synthesized at will in a laboratory.

But to build a virus with a minimum complement of genes that would allow it to perform the same tasks is not the same as making a more complex organism, even an amoeba. Let alone one that can self-replicate. That is what Craig Venter did.

Craig Venter set the scientific, religious, and political worlds on fire when he announced that he had created a new organism by synthesizing DNA from one bacteria and inserting it into another. This time the organism included not only the minimal number of genes for survival,
but also those required for self-replication. In doing so he created the first self-replicating synthetic bacteria.

And as a result of his research, even President Obama has been paid close attention to synthetic biology. Hijacking his own Presidential Commission’s agenda, he asked that group to report within 6 months about the ethical, social, and legal implications of Craig Venter’s research. That group concluded that “prudent vigilance” – a combination of Aristotelian notions of prudence combined with a eviscerated precautionary principle – is the approach that will allow science to flourish without running amok.

But in one sense there is a prior step: simply understanding what the current state of science can and cannot do. The creation of a self-replicating synthetic cell, while important scientifically, was not “playing God” or rearranging the natural order. Upon reflection, nearly every religious group – from the Vatican to Talmudic scholars – has come out in favor of the use of synthetic biology for its multitude of practical applications. In Venter’s case, he has argued that this technology would allow for using synthetic cells to create biofuels, and ultimately mitigating the effects of climate change.

And while there are legitimate concerns about the more unseemly sides of synthetic biology, building in protections to prevent those misuses of the technology while allowing science to flourish has been the magic sweet spot that regulators and policy makers have been trying to find.

### Outbreaks via e-mail?

The possible implications of synthetic biology can be downright terrifying. In little vials we see in movies like *Outbreak*, a few tiny bits of the most deadly viruses of our time are stored for research. Behind steel doors, frozen, with mighty ventilation and filtration systems, bits of anthrax, smallpox and countless biological variants of these viruses are kept for analysis at the US Centers for Disease Control and Prevention.

I’m really glad they sit there behind lock and key, and I bet you share my fear that the repository of viruses in the former Soviet Union is sometimes imperiled by fighting and political turmoil. Lots of folks would just as soon see our last bits of deadly virus eliminated.

Guess what? The synthetic biology research opens the door to a whole new problem: viral hacking. Who needs to find a tiny sample of smallpox, when you can synthesize it from scratch on a $1,000 iMac connected to a $10,000 gene synthesizer? If viruses can be manipulated and created, their
genetic codes can also be e-mailed around the world and built from innocuous lab materials using the same technology.

For ethicists and society, the puzzle is to identify how scientists should proceed, and for what reasons they might have to slow down. But this is not always an easy proposition.

And in some cases, ethicists are not the right people to puzzle about the problem. The problems of dual-use, the problem that scientific advances and new technologies, like synthetic biology, can be used for both good and bad outcomes is a problem that must include public health experts, national security consultants, experts in international law, scientists, and others. Synthetic biology opens a whole new world of biological terrorism and environmental restoration. We will have to think fast to stay ahead of the power synthetic biology puts in the hands of scientists and terrorists. There is reason to be cautious indeed.

**Case 2  Design: More Intelligent Every Day**

Thanks to a 2005 court decision, children in Kansas now learn that the fossil record of our planet holds evidence of “irreducibly complex” traits, biological wonders that seem too sophisticated to be products of natural selection. Advocates of intelligent design argue that such complexity of biological life reveals evidence of a designer.

A different sort of designer is working in the nascent field of synthetic biology. These scientists generate novel biological functions through the design and construction of living systems. Synthetic biologists manipulate the most complex biological interactions using the tools of engineering and computer science. It has borne fruit in the design of genomes, proteins, devices, integrated biological systems, and even cell-circuit hybrids. Synthetic biologists use evolution as a method. That seems pretty intelligent.

William Paley probably wasn’t imagining such researchers when he expounded on the form of the intelligent design theory that children will be learning in Kansas. In his publication in 1800, *Natural Theology*, in which he was the first to suggest the idea, he wrote that just as a watch requires a watchmaker, the unexplainable complexities of nature can only be explained by the work of an intelligent creator. A small army of contemporary disciples has advanced the claim that for a variety of reasons intelligent design is a necessary antecedent to the teaching of evolution in schools.
Intelligent design theory might well be inspirational to those in synthetic biology, whose job it is to use their own brains to make imaginative use of the raw materials and processes of creation. But the feeling would not be mutual. The Kansas school board spoke of its fear of evolutionists playing God. To an intelligent design proponent, synthetic biology is the blasphemous use of God’s erector set. If biology is the story of the sacrosanct plan of an omniscient being, rather than the vicissitudes of natural selection, humans have a hard time explaining why they are tinkering with the works.

According to a February 2011 Gallup poll only 40 percent of the US population believes in evolution. Of the 25 percent who say they absolutely reject the theory, it is many of these citizens who have gone to court and to the polls to push the ideas that intelligent design is an important scientific theory. They do so with religious zeal. A thousand miles away from Kansas in Dover, Pa., families who fired a school board that had insisted on teaching intelligent design are now in grave danger of incurring the wrath of God, according to televangelist Pat Robertson. “If you stick your finger in God’s eye too many times, maybe you should try praying to Darwin when the next disaster strikes.”

Some people working in synthetic biology wouldn’t mind sticking a finger in Pat Robertson’s eye. A leading synthetic biologist once said to me that she is working so hard on building and animating an artificial bacterium primarily so that she can prove to advocates of intelligent design that it doesn’t take a God to create life. I wish her luck, and Godspeed.

The real worry, though, is about the future of science. Children educated in a system in which untestable statements of faith are treated as privileged hypotheses are hardly prepared to face a world in which evolution is a fact of life. The next generation of scientists will face the rapid evolution of viruses and the implications of decreasing diversity in animals. We cannot afford to raise a generation of doctors who believe that drug-resistant bacteria are a punishment from God rather than an evolutionary process induced by the misuse of antibiotics. Whomever or whatever created the universe, let’s hope they wanted us to be intelligent, too.

**Case 3 “Shroom” Science: Safe and Effective?**

Are Ritalin and psilocybin equivalent in terms of effect and safety?

In the August 2006 issue of *Psychopharmacology*, Johns Hopkins researchers published a study in which some subjects were given...
psilocybin and then asked to relate their experiences. Francisco Moreno of the University of Arizona published in the November 2006 issue of the *Journal of Clinical Psychiatry* his patients’ reports that psilocybin helped them with migraine headaches. Harbor-UCLA Medical Center psychiatrist Charles Grob told the *Chronicle of Higher Education* that he is giving the compound to patients dying of cancer to see whether it eases pain by relieving anxiety.

The study of so-called magic mushrooms isn’t new; it could be argued that it is celebrating its 55th anniversary this year. It began, as best anyone can tell, when Wall Street banker R. Gordon Wasson documented his trip to a healer in Oaxaca, Mexico, whose brew, he claimed, enabled him to see the reality of ideas and concepts. His 1957 essay in *Life* magazine excited the imaginations of scientists around the world. Sandoz patented the two active chemicals in the mushrooms, calling the compounds psilocin and psilocybin. Chaos ensued as researchers struggled to do excellent scientific work using a family of substances whose effects – to put it mildly – were not easily measurable using the tools of the time.

The scientists who used psilocybin in their research in the 1960s poked at the nature of consciousness, but this particular compound just refused to be caged by ordinary scientific conventions. Paper after paper stabbed at descriptions of the effects and utility of psilocybin, but scalar measures of transcendence just could not capture its effects, or side effects. A few of the leading scientists engaged in its study, most notoriously Harvard psychologist Timothy Leary, simply abandoned the strictures of scientific research as insufficient to grasp the power of psilocybin.

By the time the FDA banned hallucinogenic drugs in 1970, the majority of those experimenting with mushrooms were not in universities. Hallucinogens became part of a counterculture that aged quickly. By the 1980s, the next counterculture devoted to brain modification was moving in a completely different direction, experimenting with highly addictive stimulants, such as cocaine, which assist in thinking faster, concentrating harder, and intensifying ordinary experiences.

Time passes, and what’s old becomes new again. In 2007 millions of people took legal stimulants and antidepressants. A decades-long quest for endless work capacity, unfettered concentration, and happiness on-demand has perhaps hastened the return of those who wonder whether the touch of transcendence could provide new insights into treating the maladies that have become rampant in our time. And indeed, new studies suggest that psilocybin may offer hope in treating a few of them, ranging from obsessive-compulsive disorder to rampant addiction.
With the dramatically enhanced ability of neural imaging to identify changes in brain state, and advances in the genetics of neuroscience, it is no wonder that some of those who researched psilocybin in the 1970s have begun to point again to the potential of that compound. Magic mushrooms are not addictive and have been around more than half a century. So should we really be worried about the potential that new research will lead a new generation to “turn on, tune in, and drop out”? Yes.

Ethics committees examining the research programs underway with hallucinogens need to be mindful that what sparked the widespread illegal use of psilocybin in the 1970s was not its mystical power but the reports of its safety and efficacy coming out of the leading institutions of higher learning in the United States. Scientists are acting with great care this time around, but let’s avoid a bad trip.

Hallucinogens have not been scientifically demonstrated to be either safe or effective enough to be used in the treatment of any disease. Studies of them should be undertaken only when investigators avoid sending subtle messages about the safety or delight of chewing on backyard mushrooms. For example, in the Hopkins study subjects were given either Ritalin or psilocybin, sending the terribly premature message that the two substances are in any sense equivalent in terms of effect or safety. It would have been much better to compare psilocybin with, well, anything other than a compound prescribed to tens of millions and often abused by those seeking better cognition.

Thankfully that study was all but ignored by the media. When it comes to hallucinogens, if the research sends the wrong message, drop it. Or rather, don’t.

Case 4 A Robot Code of Ethics

Should we require robot makers to program in a code of ethics?

The South Korean people really love robots. Industry in South Korea receives millions in government subsidies to develop them. Park Hye-Young, of the South Korean Ministry of Commerce, Industry, and Energy’s robot team, said in a statement to the French Press Agency that the Ministry hoped “to have a robot in every South Korean household between 2015 and 2020,” and predicted that these robots would develop “strong intelligence.” South Koreans are not the only ones embracing robots. Already iRobot, a company founded by Rodney Brooks, director of the MIT Artificial Intelligence Lab, has sold 6 million Roombas, a
little robotic vacuum cleaner. The promise of the robot vacuum and its
cousins is that the home robot will become faster, more reliable, and
more cost-effective than human domestic work. It has to get this “strong
intelligence” part down first. My Roomba is a one-trick pony, sucking
dirt while rolling in circles and slapping into the same walls every day as it
relearns a 12 in × 12 in room. This is not Rosie from The Jetsons. But the
more important issue regarding today’s domestic robots and the future is
not so much about intelligence as it is about ethics. If you ever watched
the Roomba-sized robots hack each other to bits on the aptly named
BBC-5 television program, Robot Wars, you know the fear that lives in the
souls of many who will never buy a domestic robot: that their Roomba
would one day awaken like the robots of The Terminator. A robot with
sinister intentions, without ethics, or adhering dispassionately to a code
of ethics where intuition and subtlety is required (remember RoboCop?)
has been the fuel of science fiction for decades. Should we require robot
makers to program in a code of ethics to domestic products?

Perhaps robots should be afraid of us too; whether or not they dream of
electric sheep, the robotic sex toys under development are purveyed as
better-than-real-life companions. But they are plastic and metal, not
human. As humans build robots that learn what their owners desire, the
dilemma of the robots of Blade Runner emerges: What do humans owe
“purpose-built” machines who begin to reach awareness, or to so resemble awareness that it becomes a selling point? Should laws be written to
protect robots from us, by requiring robot makers to stop short of, say,
robosexual devices that learn to be incredibly intimate with humans and
yet are owed nothing? If so, do we create such laws in the interest of robots,
or to preserve our own human dignity by choosing not to create a new kind
of slave, whether or not that slave is fully aware?

The South Korean government has taken a progressively minded step
by convening a committee to draw up an ethical code to prevent humans
from abusing robots and vice versa. The code draws in part on the work
of science-fiction writer Isaac Asimov, and specifically, according to
Park, on the three laws Asimov proposed for robot ethics in a 1942 story,
“Runaround.” They are: (1) A robot may not injure a human being or,
through inaction, allow a human being to come to harm; (2) A robot
must obey orders given it by human beings, except where such orders
would conflict with the first law; and (3) A robot must protect its own
existence as long as such protection does not conflict with the first or
second law.
Likewise, a committee of EURON, the European Robotics Research Network, met in Genoa, Italy, in June, 2006 and concluded that a code must be created to deal with the problems of hostility to and from robots, as well as how to avoid accidents, trace robots, ensure the secrecy of their data, and monitor the nature of their intelligence, which one member of the latter commission aptly described as “intelligence of an alien sort.”

It remains to be seen whether robots will become in some sense intelligent androids, capable of interacting as peers with humans and other parts of the world. In the meantime, we are much closer to making robots with “strong intelligence” than we are to creating a code of ethics to guide our stewardship of tin men, or to protecting humanity from misbegotten robotics. Either the effort to create a code of ethics to shape the evolution of robotics will be embraced, or we may reap the consequences.

It only remains to be seen who will wake up first.

Case 5  No More Periods, Period

For decades, fertility research has successfully decoupled sex from reproduction, forever altering women’s position and power in the developed world. Among all methods of contraception, none is as well known or influential as “the pill.” Now, its power has been kicked up a notch, and the pill is poised to do what some say will disrupt the very nature of the XX sex. This leaves us with one question: In the next step of the evolution of women’s contraception, should we eliminate the last major physical manifestation of the reproductive cycle, menstruation?

The birth control pill contains hormones that stop the release of an egg, which in turn prevents the buildup of the uterine lining. Bleeding occurs on traditional oral birth control (21 days of hormone pills, 7 days of placebo) only because of the interruption of the hormones during placebo days. A newer oral contraceptive, Seasonale, reduces the period still further, with only seven placebo days every three months. But the newest, continuous low-dose contraceptive, Lybrel, stops the period entirely.

No one disputes that eliminating menstruation could free women from a variety of uncomfortable or even dangerous symptoms, from severe pain and cramping to emotional swings. For some, these symptoms have a profound impact, but not necessarily one viewed as cause
to eliminate periods altogether, until recently. Now, the message is clear and direct to the consumer: In the twenty-first century, women who are not seeking pregnancy need not waste time and energy with menstruation.

What happens to human nature if the period comes to an end? In one example, Canadian researcher Christine Hitchcock told the *New York Times* she worries about products that “turn your body on and off like a tap.” Her concern was, in part, about the unknown consequences of stopping menstruation entirely, a concern shared by others who have asked whether the long-term side effects of such medication can really be predicted to any reliable degree. Other opponents of the end of the period argue vociferously that doing so is unnatural. Menstruation is not a “sickness,” they say – it gives woman a sense of identity, and eliminating menstruation in a mammal that does not show estrus will profoundly alter the very nature of human nature.

Paradoxically, the concept of “what’s natural” is one that supporters also use to justify the new contraceptives. On the Seasonale web site, Patricia Sulak, professor of obstetrics and gynecology at the Texas A&M University System Health Science Center – College of Medicine, argues that it’s not natural to have as many periods as modern women do, since previous generations had more children and breastfed longer. “Today we’re having hundreds of periods in our lifetime, whereas a century ago we were only having a few periods. One might say that that’s not natural; that’s not what we were designed to do.”

But these are preposterous arguments. The question is not whether stopping menstruation is natural. The question is: Is it safe? Menstruation isn’t what defines a woman, since women are still women after menopause, and menstruating women often live with ailments that stop their periods. Menstruation is something that happens to women, just like sweating and headaches; consequently, arguing that no-period contraceptives alter human nature is no different than saying the same about antiperspirants or analgesics.

It is a stretch to suggest that menstruation will be considered a disease, and it certainly makes sense to conduct research aimed at improving women’s quality of life. One could also note the billions of dollars spent on feminine hygiene products that serve no procreative purpose, or the environmental consequences of making and disposing of billions of pads and tampons. The real issue here is women’s right to make choices about their reproductive systems and sexuality, and even about what risks they are willing to take with either, just as when the FDA first approved the pill in 1960. Period.
Case 6  Search Me, Shape Me, Any Way You Want Me

In his April 2006 column, Jack Woodall suggested that we bring the “don’t be evil” technology of Google to the rapidly advancing field of brain-computer interfacing. It’d be dandy, he argued, to order the information in our brains in hierarchical fashion. In short, he wants to Google the brain.

But the more compelling argument, to me, is that a search engine-style filter would do for the brain what it does for academic research – find the good stuff fast. It’s a beautiful dream and it will probably come true within my lifetime. And as long as my brain doesn’t gain banner ads, spy ware, or pop-up windows, I’d probably sign up for the Woodall experiment.

Remembering is everything in the New World. Everything you have ever written can be stored: every e-mail, grant, paper, Power Point presentation, syllabus, recommendation letter, list of plans, and perhaps even your bad poetry and divorce decree. And if it can be stored, it can be accessed, filtered, and searched.

John Dewey, the philosopher most responsible for the development of the social sciences, wrote a large amount – by one estimation more than 13,000 pages of manuscript and perhaps a gigabyte of searchable correspondence. Historians of science in twenty years will find that even “B-list” scholars of today produce ten times that volume of information in the course of a decade, not including the vault of other people’s data we store in case we need it.

My most disorganized friends, or at least the smart ones, are steadily working their way toward scanning all the paper in their offices onto hard drives, turning piles of nomenclature and unfinished projects into a different kind of pile. Desks get cleaned, computers get filled. But the clutter is still there, it’s just hidden more effectively. Those who scan their worlds without clearing out the junk and learning to sort information just make their messes more intimate. I don’t need to remember a lot of what is stored around my office or in the corners of my mind.

There is something to be said for forgetting. Nietzsche argued that those who cannot forget are quickly driven to madness. The ultimate stoic, Epictetus, implored Roman soldiers to kiss everyone in their lives goodbye every time they walked out the door, pointing to the importance of focusing on the present. Beta-blockers such as Inderal can literally disconnect memories from their emotional impact; predictably, many victims of trauma are eager to kill the pain that data stored in the brain can cause.
Numerous studies on the most stressful activities in human life moving, divorce, and the death of a parent or child—suggest that the stress of a life change is mostly a matter of cognitive dissonance, the pain of remembering what is lost. Santayana, famous for his statement that those who forget the past are doomed to repeat it, wrote nonetheless: “I would I might forget that I am I, and break the heavy chain that binds me fast.”

The problem with hooking search engine technology up to my mind is that part of my identity, which I happen to like, has to do with my ability to really forget, to shape my own life. Perhaps a search engine could make that easier, perhaps I could block out things that are awful. But then again, Kierkegaard wrote: “Marry, and you will regret it. Do not marry, and you will also regret it.” And he didn’t even have a good memory.

Today’s search engine is no better than the myopic man behind the algorythmic curtain, and I am not sure what he’d make of the detritus in my brain.

Brains are great. Machines are great. Connecting them is great. But before the interface becomes my identity, I’d like it to be just a bit more refined.

Case 7 A Bloody Mess

From the moment of trauma, whether for wounded soldiers, victims of motor vehicle accidents, or children hit by bullets, the best solution to blood loss is, obviously, blood. But many ambulances don’t carry blood because it is extremely volatile. Paramedics can offer saline solution, sometimes even laced with nonblood “expanders,” but saline can’t ferry oxygen around the bloodstream to keep cells alive.

Enter Polyheme, an oxygen-carrying blood substitute that promised to revolutionize emergency medicine. Polyheme is made from a modified hemoglobin molecule, and it carries oxygen. It is more resilient than blood, with a much longer shelf life and better tolerance of the conditions at the scene of a trauma and in transport. It does not need to be matched to a patient’s blood type. And as a bonus, unlike an organ transplant or blood transfusion, there is no risk that a communicable disease will be passed in the process.

Oxygen-carrying blood substitutes have been tried for years on consenting research subjects with mixed results, but enough hope has existed that since 1970, no fewer than three companies have fixed their sights on
making one. Polyheme’s sponsor and manufacturer, Northfield Labs, sought approval for use on the battlefield or in a trauma helicopter near you. So with what could amount to a significant advance for trauma medicine being on the brink of approval, why were the airwaves, newspapers, academic journals, and magazines riddled with stories about whether research subjects in the trial are human guinea pigs?

The answer is that communities where this research has begun have been caught off guard. In Phase I and Phase II trials of Polyheme, all subjects were required to give informed consent. Eventually, Polyheme had to be tried on typical patients who would benefit from artificial blood: victims of trauma. Of course, the vast majority of trauma victims cannot give informed consent. Thus, regulations passed in the mid-1990s called the Final Rule allow such research, provided a list of precautions is followed, including something called “community consultation.” The idea is that while enrollees would be too ill to consent, investigators would have informed the community about the trial in advance; anyone who doesn’t want to participate can prospectively opt-out by, for example, wearing an armband.

The best laid plans

After Northfield Lab’s researchers informed the community about Polyheme, emergency medical technicians were to randomly administer either saline solution or Polyheme to trauma patients who are in hemorrhagic shock. The control group receives blood, the standard of care. Those randomized to Polyheme receive it for no more than 12 hours; part of that time may be in the hospital when they would otherwise be given blood.

The problem was that most people in the communities where Polyheme trials were going on, from Illinois to North Carolina to New York, didn’t seem to know a bit about it. Emergency medical research is a bloody mess right now because Polyheme, once unknown to potential subjects, suddenly came onto the public radar, but only because of concerns that include undisclosed or inappropriate risks to subjects in the in-hospital phase of the study, worries about whether the sponsor has withheld data from investigators, and criticisms from organizations such as the Senate Appropriations Committee and consumer advocacy groups.

It has become clear that patients worry about emergency research and that new methods for informing the community must be devised and
tested before proceeding with trials that have such potential to destroy public trust in research. We know some scientific facts: Saline solution doesn’t carry oxygen. Polyheme does. Therein lies the potential for a miracle. Polyheme, and other substances like it, are certain to end up on the Congressional black list because communities that do not trust researchers are not going to let them ride in ambulances.

Northfield goes on record about PolyHeme
You’d think that Northfield Labs (the sponsor/owner of PolyHeme) would have something thoughtful to say about how that company, in the middle of a tornado, will be dealing with the matter.

Nope. No committee, no ethics team, no refinement of materials, and still no answers of consequence to the charge that there was a cover up of material that should have been published. No comment of consequence even when the Johns Hopkins researcher the company had said would clear everything up was subsequently denied the data he needed to give that speech.

You’d think Northfield would want, in the face of all this controversy, to resolve any doubts that might otherwise need to be shared with the community. But instead the company seemed to have a zero ethics plan:

“Is this a good reg? Is it perfect? Can it be better? Can it be worse? Those are important policy questions that we feel we can and should address,” said Steven Gould, chief executive of Northfield Laboratories, the firm that makes and is studying PolyHeme. “To do research without prospective informed consent defies what we would all say is good ethical practices, so you have this conundrum.”

Yes. So you will be doing what? Asked by the American Journal of Bioethics to respond to an article written about the Polyheme trials, Northfield refused. Asked to participate in a discussion with principal investigators of the trial about how to refine community consultation so that communities can understand the ongoing issues that are in articles like this one, the company offered to consider the idea then didn’t reply. Asked whether they would like to try to convene an ethics review, board, study or to participate in any other review of the associated issues with others, there was no reply.

The conundrum was there, no question. But it wasn’t about the ethics of research without informed consent, or about failure to respond adequately (in the minds of many) to charges that their study was designed so that it intentionally requires that subjects receive Polyheme instead of blood even after they arrive in hospitals (and without consent), contrary to the standard of care.
No, the conundrum was how Northfield managed to avoid killing off resuscitation research entirely, while sitting in wait for a Senator who is mad as hops. Fortunately, the Polyheme trials were entirely stopped and Northfield disappeared from the research ethics radar screen. Doing significant damage to emergency research for years, the Polyheme study taught us that research regulations are there for a reason and failure to adhere to them can create one bloody mess indeed.

**Case 8 Stem Cells: The Goo of Life and the Debate of the Century**

Everyone is up in arms about stem cell research: adult versus embryonic, iPSCs, and parthenotes. And maybe not up in arms exactly. But certainly everyone has a champion, a favorite kind of stem cell, the cell on the verge of curing cancer, macular degeneration, or male pattern baldness.

*But don’t believe the hype*

Pluripotent stem cell research has the potential to revolutionize medicine, pluripotent cells seem to be the “goo of life,” a cellular biological discovery (by James Thompson and John Gearhardt) as revolutionary as the spiraling of DNA identified in 1953 by molecular biology pioneers James Watson and Francis Crick.

Once derived from an early-stage embryo, they may be directed to grow into virtually any kind of cell line. Liver cells, brain cells, bone cells, skin cells: If you need cells or tissue, we may soon be able to grow compatible, stem cell-derived cell lines to help.

But as we have now learned, pluripotent stem cells can be developed from more than just embryos. Induced pluripotent stem cells (iPSCs) uses a technique whereby pluripotent stem cells are created artificially from adult somatic cells. By using the correct growth factors and hormones, “the goo” transforms from adult skin cells, for example, to pluripotent cells with specific gene expression.

Then there is the so called “adult stem cell” camp, those who herald mesenchymal stem cells as the solution to all that ails the world. These multipotent stem cells have been successfully used to differentiate into bone, cartilage, fat, and pancreatic cells. The relative advantage of these
cells is, of course, once harvested from the human body and amplified, they can be injected right back into the patients they came from without any need to change the cell’s potency.

Many could benefit

A few of the diseases for which stem cells, whether embryonic, iPSC, or mesenchymal, might offer therapies or cures: Parkinson’s disease, Alzheimer’s disease, diabetes, heart disease, stroke, arthritis, birth defects, osteoporosis, spinal cord injuries, and burns made the list, as well as most cancers. That accounts for more than half of all Americans, and Patient’s Cure estimates that 148 million Americans will be candidates for stem cell therapy. That is once stem cells can be used as therapies.

On the other hand, you could scarcely imagine a more controversial field of research. While opinion polls suggest that the majority of Americans support the use of very early embryonic cells for this research, most Americans are both vehemently opposed to abortion and frightened to death by what they hear about a few outlying infertility clinics and practices in the United States.

Catholic bioethicist Richard Dorflinger has argued that embryos should not be used under any circumstances, even if the embryo is discarded in freezers at fertility clinics. It is difficult to imagine, other pro-life groups have argued, a bigger destruction of human life than that entailed by a massive stem cell research campaign.

Existing Federal law (the Dickey–Wicker Amendment) prohibits the destruction of embryos for research, but NIH has made a distinction between the destruction of embryos, which the agency cannot fund, and research on resultant stem cell lines, which it can. Pro-life scholars counter that federal funding of pluripotent stem cell research is the same as funding abortions.

The abortion debate is certainly one of the greatest failures of American democracy to empower and civilize public discourse. Lives are lost, careers and esteem destroyed, and religion made to serve as a political football.

We have needed to separate stem cell research from the abortion debate for more than a decade and we still keep failing to do so. The creation of iPSCs and advances with mesenchymal stem cells can help skirt some of these debates, but they do nothing to resolve them and do little to differentiate how people think about “stem cell
research” writ large. The critical issues here are tough, and they require us all to do some deep thinking about how we want to understand human life and dignity and about how we want our social institutions to work.

The issues

First, what is an embryo? In the short term we may see human embryonic tissue derived from excess embryos in IVF clinics, but if the political debate becomes too toxic the researchers will turn to other ways to make stem cell tissue.

For example, a researcher at the University of Massachusetts made an embryo-like thing by merging DNA from his cheek cells with a cow egg. He found what looked like stem cells in the resulting organism. Is that an embryo? Is it a chimera? Is it a clone? Is it human?

Second, what is the best way to regulate ethically difficult research? The answer clearly is not to play ostrich. Take infertility: Totally unregulated, research in infertility sometimes does not even require animal studies, and there are few rules about any of the important questions in the field.

Even with federal funding restored for stem cell research (after a hiatus during the Bush presidency), many argue that stem cell research still is hampered by existing federal regulations. With federal funding, the field is being controlled and the results carefully monitored. But some argue too carefully. This is why a significant portion of stem cell research in the United States is funded by the states – mainly California, New York, and Massachusetts.

Third, what is the right balance between respect for embryos and respect for the suffering patient? Sick Americans wait for the outcome of a debate about whether suffering ill, our parents and children, should be denied therapy when all that is required is that embryonic tissue is used in research rather than thrown away. This debate began in the late 1990s and continues to this day.

There isn’t a debate here, there is the beginning of a critical conversation about the most important new technology of the millennium.