THE RISE OF THE BIOCRATS

From stem cell research to HPV vaccinations, healthcare policy to genetic modification, bioethics increasingly provides the framework for weighing the costs and benefits of scientific progress. Long a leader in the field, the University is moving to make Penn *the* place where such work happens, and where the next generation of bioethicists will be minted.

BY TREY POPP

Whether it goes down in history books as a chapter heading or a footnote, the Republican presidential debate of September 12, 2011 was a remarkable event. The first such contest ever to be sponsored by the Tea Party addressed issues ranging from Herman Cain's "9-9-9" tax-reform plan to whether Federal Reserve chairman Ben Bernanke should be strung up for treason. But the most memorable exchange turned out to be a dust-up over cancer prevention.

It pitted two candidates widely considered by pundits to be the political equivalent of twins: Texas Governor Rick Perry and Minnesota Congressswoman Michele Bachmann. Both candidates were courting social conservatives and Tea Party voters. Following some debate over the appropriate use of executive orders, Perry was asked to answer for one he had signed in 2007, requiring that 11- and 12-year-old girls in Texas be vaccinated against human papillomavirus, or HPV, a sexually transmitted infection known to cause cervical cancer.

Perry professed regret about using an executive order to enact the policy, but defended the HPV-vaccine mandate as a life-saving measure. "Cervical cancer is a horrible way to die," he said. "What we were trying to do was to clearly send a message that we're going to give moms and dads the opportunity to make that decision, with parental opt-out."

Bachmann pounced on her competitor. "I'm a mom of three children," she declared. "And to have innocent little 12-year-old girls be forced to have a government injection through an executive order is just flat-out wrong ... It's a violation of a liberty interest."

A few moments later, former Pennsylvania Senator Rick Santorum jumped into the fray. He declared executive orders to be beside the point; the HPV vaccine should not be administered, period. "There is no government purpose served for having little girls inoculated at the force and compulsion of the government," he said.

For bioethicist Jonathan Moreno, a David and Lyn Silfen University Professor in the history and sociology of science, this tussle was emblematic of something deeper than the tactical imperative of likeminded candidates to distinguish themselves from one another. It was just the latest example of how "when the politics of biology rears its head, all bets are off."

In the debate's aftermath, Perry found his 2007 decision supported by women's health advocates—a contingent more typically given to calling the governor "abysmal" or even "a Texas-sized threat" to women's health. Yet that was cold comfort, for Bachmann and Santorum had clearly scored a rhetorical victory.

"The fact that Perry followed the medical advice of experts on public health provided him no shelter in this debate," Moreno noted in a *Huffington Post* opinion piece at the time. Indeed, so powerfully did Bachmann disagree with those medical experts that for her the issue seemed to trump the business-friendly posture virtually all Republican politicians take pains to project; she accused Perry of mandating the vaccine to reward the drug company—and Perry campaign contributor—that markets it.

"We are in the midst of a new biopolitics," Moreno wrote on the *Huffington Post*, "in which the power of science confounds the usual left-right spectrum of public policy, one that by no means favors one side or the other."

The politicization of the HPV vaccine may be his favorite example from the current political season, but it is by no means the only one. Nor, of course, is it the first. Stem cell research has been a contentious issue for the last decade. So have the agricultural use of genetically modified organisms, the patenting of genes, and the creation of hybrid organisms or human/non-human chimera in laboratory research—to mention just a few that Moreno discusses in his new book, *The Body Politic: The Battle Over Science in America*. But Moreno senses that the bioethics debates of recent years are just the advance ripples of a wave system that has the potential to disturb our politics more profoundly.

"After the economy, biopolitics might just be the item that most challenges the 2012 candidates' policy prescriptions," he predicted in another of his frequent essays on the *Huffington Post*. Yet even that formulation misses the full thrust of Moreno's argument (as he would grant), because biopolitics is increasingly inextricable from economic policy.

By way of example, Moreno pointed toward a less-commented-upon issue from the campaign trail during a January conversation in his Cohen Hall office.

"Santorum presents himself as somebody who wants to invest in reindustrializing America," he observed. "So what do you do about biotechnology?"

Which is to say: Do you leave any techniques that involve, say, creating pigs whose arteries pump human blood (as Mayo Clinic researchers have done to study the transmission of viruses from animals to humans) to pharmaceutical

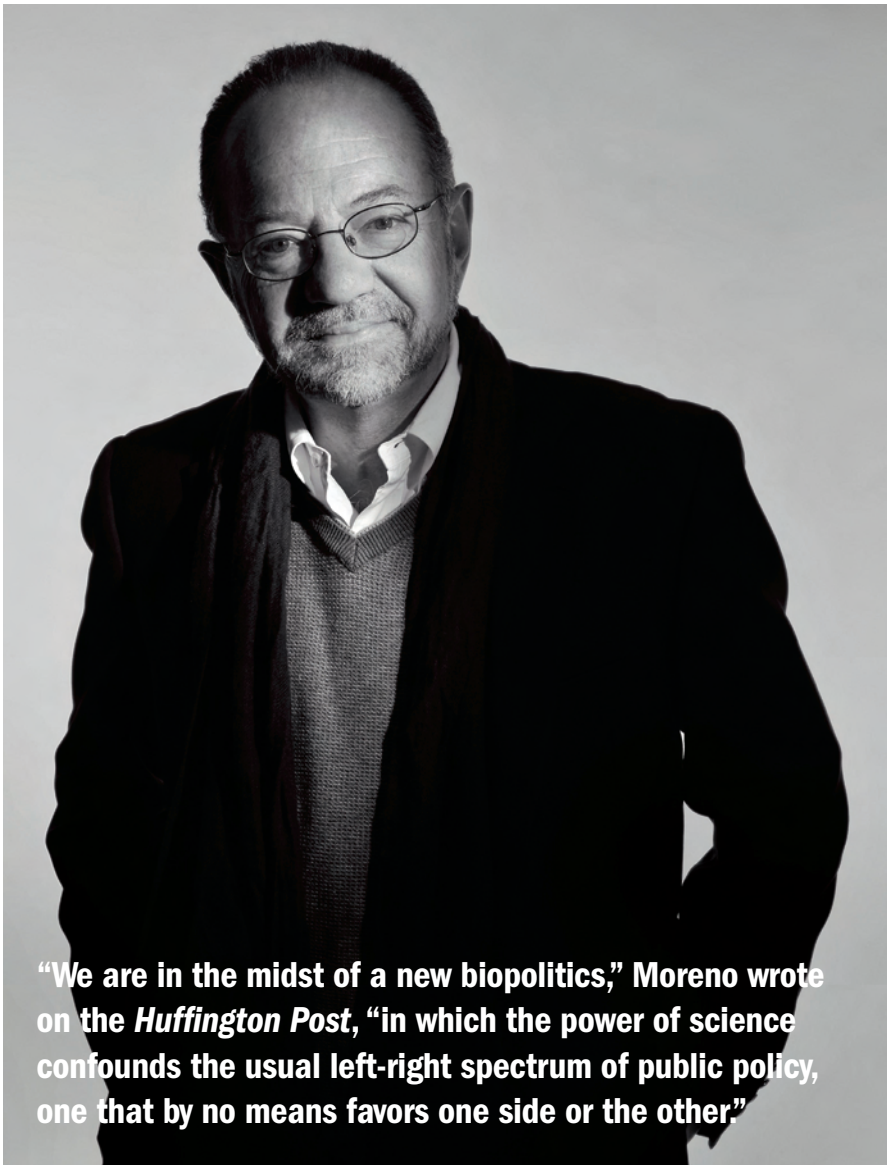
ILLUSTRATION BY THE HEADS OF STATE | PHOTOGRAPHY BY CANDACE DICARLO

companies in Singapore and universities in Denmark? Or do you permit that, but bar scientists from injecting human-brain stem cells into the brains of mice—as has been done to study neurodegenerative diseases? Judging from the trends of the last 20 or 30 years, the industrial infrastructure of tomorrow is likely to look more and more like the cutting-edge labs of today. As Moreno remarked to a business publication some years ago, in a story about a patent lawsuit over a four-color automated DNA sequencer in which hundreds of millions of dollars were at stake: "These machines are the ancestors of the kind of equipment that will be available for your children in doctors' offices and pharmacies to design drugs for you ... Once the machine is more understood, it's going to be one of the 21st century's equivalents of the light bulb or the Model T."

When you start drilling down, *What do you do?* is a question that pops up anew with every twist of the bit into the next layer of bedrock. What do you do when some novel technique seems promising enough to test on human subjects? That's a question with a ready answer: informed consent. But what constitutes informed consent for someone who'd be getting an experimental treatment for a traumatic injury that has rendered him comatose? And does informed consent look the same in Boston as it does in Botswana, should a drug company based in the former find it advantageous to run clinical trials in the latter?

Or suppose the Boston company's research hinges on the donation of human eggs for stem cells, and it's having trouble finding donors. Can it offer them financial compensation? Not if it plans to use federal funding, at the present time. But it could consider moving to New York, where a state advisory board on stem cell bioethics decided in 2009 to permit financial compensation of donors out of state research funds. (Moral quandaries aside, score a victory for job creation—and tax receipts—in the Empire State.)

Many of these questions deal with small-bore issues. Some broach policy dilemmas provocative enough to attract demagogues. But all of them require answers—or at least a framework for working toward answers: gathering evidence, comprehending fine-grained technical distinctions, squaring policy proposals with legislation and case-law precedents, and even subjecting conventional wisdom to experimental scrutiny.



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"The complexity of modern technology means that these advances [in science, medicine, and technology] cannot be well understood or fully considered by a single field or just a few fields," says Penn President Amy Gutmann, who earlier this year was reappointed as chair of President Obama's Commission for the Study of Bioethical Issues. "Bioethics joins the perspectives of multiple disciplines—medicine, nursing, law, ethics, philosophy, religion, engineering, and beyond—to consider the opportunities and challenges raised by scientific progress."

It happens that all of the examples above are issues faculty or alumni of Penn's bioethics program have tackled, in professional capacities ranging from the design of clinical trials in emergency-medicine settings to advising the state of New York's commissioner of health on stem cell research ethics.

Lately, University administrators have moved to make Penn *the* place where such work happens, and where the next generation of bioethicists will be minted.

The story of bioethics at the University begins with Art Caplan, who recently announced he would depart in July to head a new medical ethics division at New York University, but for 18 years has been the highly visible face of bioethics at Penn as the Emmanuel and Robert Hart Director of the Center for Bioethics and the Sydney D. Caplan Professor of Bioethics. Caplan played a pivotal role in building bioethics into

an area of conspicuous strength at the University, and leaves behind an important legacy.

But in recent years Penn has added more heavy hitters to its bioethics lineup. Moreno, who came here as one of the first PIK professors in 2006 ["Proof of Concept," Sept|Oct 2008] and was recently named to UNESCO's International Bioethics Committee, is one key player in the University's push to become a world-premier hub of bioethics scholarship and training. And with the recent hiring of Ezekiel Emanuel ["Gazetteer," Nov|Dec 2011], who ran the bioethics department at the Clinical Center of the National Institutes of Health before becoming a special advisor on health policy to the Obama administration, the University has a new general manager, so to speak, in the clubhouse.

And one bent on acquisition. Emanuel plans to "double" the faculty in his department—the Perelman School of Medicine's recently formed Department of Medical Ethics and Health Policy—over the next three years. (He also chairs the Wharton-based Department of Health Care Management, and is the Diane v.S. Levy and Robert M. Levy University Professor and vice provost of global initiatives.) Additionally, he is spearheading the creation of a second bioethics master's program at Penn—one designed to groom the Caplans, Morenos, and Emanuels of tomorrow.

As is the case whenever a university pushes a large pile of chips into a new pot, it bears asking what exactly lies behind Penn's aims. How many bioethicists does the world need, anyway? What has the field accomplished so far, and what has it left to achieve? Is politics warping bioethics, or the other way around? What can people actually do with a bioethics degree? And how does Penn hope to impact the world by minting more of them?

Caplan, Moreno, and Emanuel have differing perspectives on the trajectory of bioethics at Penn, and in the world more generally. But those perspectives overlap with the experiences of alumni of the University's 15-year-old master's of bioethics program to paint a picture of a field in transition, and one that promises to have a growing influence on society and its management.

THE AMATEURS

Caplan jokes that he is frequently (albeit erroneously) "accused of being the founder of the field," but while bioethics may have existed before him, there wasn't much evidence of it at the University when he arrived in 1994. "There wasn't any bioethics program, or center, or anything," he recalls.

Given the prominence of medical research at Penn, and the growing dominance of health care and pharmaceutical enterprises in Philadelphia's regional economy, it made sense for the University to develop a bioethics backbone. That became particularly clear in 1999, when a clinical trial for gene therapy at Penn resulted in the death of an 18-year-old named Jesse Gelsinger. An investigation by the Food and Drug Administration concluded that the scientists conducting the trial had fallen short in their informed-consent process, and failed to notify the agency or stop the study when two other patients suffered toxic reactions to the therapeutic agent ["Gazetteer," Mar|Apr 2000]. Gelsinger's family sued the University for wrongful death, assault, battery, lack of informed consent, and fraud. The parties reached an out-of-court settlement in November 2000.

"I hate to put it this way," Caplan says now, "but scandal is often bioethics' best friend." In the fallout of the Gelsinger case, he remembers, "there was a commitment to fix oversight of research. Well, it dragged bioethics along."

Penn's trustees approved a cross-disciplinary master's of bioethics program (MBE) in 1997. It was designed to be a supplementary degree, serving students enrolled in other graduate programs—primarily medicine and law—as well as mid-career professionals like healthcare providers and administrators.

"We didn't intend you to become an academic bioethicist," Caplan explains. "We were always saying: We're going to train the next generation of doctors who are interested in bioethics, or lawyers who are interested—or Indian chiefs who are interested, whatever they are."

This was a natural approach given the state of the field at the time.

"When bioethics began, it was an amateur's delight," Caplan recalls, referring roughly to the 1970s and '80s. "You could come from any field," he explains. "There was no notion of a discipline. There was no notion of a profession. And to talk academic-ese, there wasn't a canon."

The field had matured enough by the 1990s that a handful of people could make a full-time career out of it. But Penn's aim was basically to bring more amateurs into the fold. That's what it has done over the past 15 years, and to a far greater degree than comparable programs at other universities.

"We get 50 or 60 new students a year. The next largest program probably takes in 20 to 25," says Autumn Fiester Gr'02, who currently directs the master's program. "And students also take our courses as electives," she adds. "So we do about 650 enrollments a year—far more than the number of people matriculated into the program."

One measure of the MBE program's success is its alumni. Among them are directors of state and national bioethics commissions, chairs of medical departments and academic programs, general counsels of major hospitals, and a vice president for policy at Johnson & Johnson. [See p. 36.]

Over the MBE program's lifespan, bioethics as a discipline has come into its own in ways its progenitors probably never imagined it would. Even Caplan, who played a seminal role in bringing bioethical debate out of the ivory tower (first through a syndicated column and nowadays as every beat reporter's go-to source for an eminently quotable expert opinion), has been surprised.

"I thought it might turn into something that people would chat about and kick around the water cooler, and kind of maybe take into their Kiwanis Club or talk about at the church supper," he says. "I've been amazed, personally, [that bioethics has gone] from this sort of amateur-hour field that I came into as a graduate student, all the way out to seeing people like Bill Frist talk about Terri Schiavo in Congress and lose his presidential ambition over a bioethical biopolitics issue. I've been amazed to see George Bush sit in the Rose Garden before 9/11 and give his first speech on embryonic stem cell research, as his kickoff. Pretty impressive. I have been amazed to be asked to chair this United Nations taskforce on organ trafficking—an ethicist would get to be the chair! ... And it's been interesting to see Zeke have such a role, as an ethics person, in the health-reform effort."

A few things happened to transform bioethics from water-cooler chitchat into what Caplan calls "a real discipline that has established methods and techniques." The most crucial, in his estimation, was a shift away from the overtly religious language that characterized bioethical discussion in its early days, when people like Catholic moral theologian Richard McCormick, and Christian ethicists Paul Ramsey and James Gustafson, numbered among its most outspoken contributors.

"There was a critical moment at which bioethics almost didn't make it past its early, amateur, sort of carnival days, because if you speak explicitly in religious terms you tune out people who don't buy into your religious perspective," Caplan says. "The philosophers arrived and said, 'We can secularize that language.' This is not secularism—it's a secularization of the ways to talk. That's when I showed up, just as part of that shift. And religious voices got tamped down. They didn't disappear. There are plenty of them. But bioethics managed to evolve a discourse that let it talk without privileging any book, authority, divine being, or outlook. That was crucial to its success. It has now become the way the culture talks about its most important problems ... We don't have a lot of ways to get past American pluralism, but bioethics is a common-ground area."

FROM CARNIVAL BARKERS TO POLICY WONKS

Coming of age amidst revolutions in molecular biology, genetics, organ transplantation, in-vitro fertilization, neuroscience, robotics—it's hard to think of an area of engineering or the life sciences that couldn't be added to this list—bioethics was and probably always will be fertile territory for mind-bending water-cooler chitchat. Who *isn't* fascinated by debating the ethical status of (to take an example Amy Gutmann threw out to an undergraduate bioethics class last year) elective surgery to replace a perfectly healthy arm with a super-capable bionic one? Yet the field's spadework is increasingly shifting toward peer-reviewed journals and the policymaking arena.

Gutmann's work on Obama's presidential bioethics commission is emblematic. During the 2000s, George Bush's Council on Bioethics was known for producing reports that were long on philosophy, with a primary focus on concepts like human dignity. Obama, by contrast, charged his commission with offering "practical policy options."

Judging from the new commission's reports and public meetings, that is precisely the spirit in which Gutmann has taken her assignment. Whereas the Bush-era Council on Bioethics tackled subjects like "Human Cloning and Human Dignity" and "Biotechnology and the Pursuit of Happiness," its successor has let its wonk flag fly. Its latest report reviewed regulations governing federally sponsored research involving human volunteers, and recommended 14 changes to current practices. Another report focused on "research across borders," surveying varying norms of human-subjects research around the world and making recommendations such as the implementation of a US system to compensate subjects for research-related injuries. A report titled "New Directions: The Ethics of Synthetic Biology and Emerging Technologies" recommended the incorporation of "suicide genes" into synthetic organisms to limit their lifespan, and the evaluation of regulatory requirements to ensure that "risks to communities and the environment should not be unfairly distributed" among different groups in the population—and went all 192 pages without uttering the phrase *human dignity* (which, as was noted in a Bush bioethics council report that deployed it repeatedly, is "absent ... as an explicit concept in American law").

Ezekiel Emanuel personifies the growing influence of bioethicists on policymaking. Aside from being the brother of Rahm (the current mayor of Chicago) and Ari (a high-powered Hollywood talent agent who inspired the character played by actor Jeremy Piven on the HBO series *Entourage*), Emanuel is perhaps best known for his views on euthanasia. Though his writing on the subject has been misrepresented to the point of absurdity—if not well past that point—by Republican opponents of national healthcare reform, some of whom accused him of paving the way for so-called "death panels," Emanuel's work on physician-assisted suicide is an example of what one might call evidence-based bioethics.

"The analogy I like to make is to physics," he explains. "We've got to have a group which does theoretical physics and a group which does experimental physics. And it's basically the same in bioethics. You need people who do theory and think about the right resolution, but you also need people who do empirical work and test out, do those theories work in the real world? What is the real world—how are they solving the problems, or how are they seeing the dilemmas? Does it match up with theory? Do we need to modify them?

"One of the things I've become quite skeptical of is conventional wisdom," Emanuel goes on. "When people say, 'Oh, for sure, people think this,' [my response is], 'Yeah? You got any data?' Because you don't know. And the public can surprise you."

With respect to physician-assisted suicide, the common argument in the 1990s was that those likeliest to request it would be dying patients in the grips of unremitting pain. This assumption was even central in federal court rulings, such as a Ninth Circuit Court of Appeals decision in 1996 that struck down a state law prohibiting physician-assisted suicide. Emanuel, whose colleagues once commemorated his spirit of "combative collegiality" by presenting him with a hefty chef's knife (mounted safely in a glass case)—led a study testing this assumption by interviewing cancer patients.

"Then we actually interviewed patients close to the end of life, as confirmed by their doctor," he recalls. "And one of the things you find out is, what motivates people who might be interested in assisted suicide or euthanasia is not pain. It turns out to be other things. It turned out to be depression. They have a much higher rate of depression.

"And once you think about euthanasia in the context of depression being the main motivator," he adds, "then it looks less like euthanasia and a 'good death,' and much more like suicide."

Partly on the basis of that research, Emanuel argued at length against the legalization of physician-assisted suicide (which many contemporary bioethicists supported) in, among other venues, *The Atlantic*. Soon thereafter, the US Supreme Court came down on his side of the issue,

unanimously finding no constitutional right to die with the help of a physician. Later, Emanuel expanded his argument in the *New England Journal of Medicine*, analyzing available data to estimate the potential cost savings from physician-assisted suicide—another line of argument often cited by advocates of legalization. He (and a co-author who took a different position on the overall issue) concluded that it amounted to "less than 0.1 percent of total health care spending in the United States."

As an advisor to the Obama administration, Emanuel helped to shape the Patient Protection and Affordable Care Act in ways that drew upon both his bioethics background and his related expertise on resource allocation and cost-effectiveness.

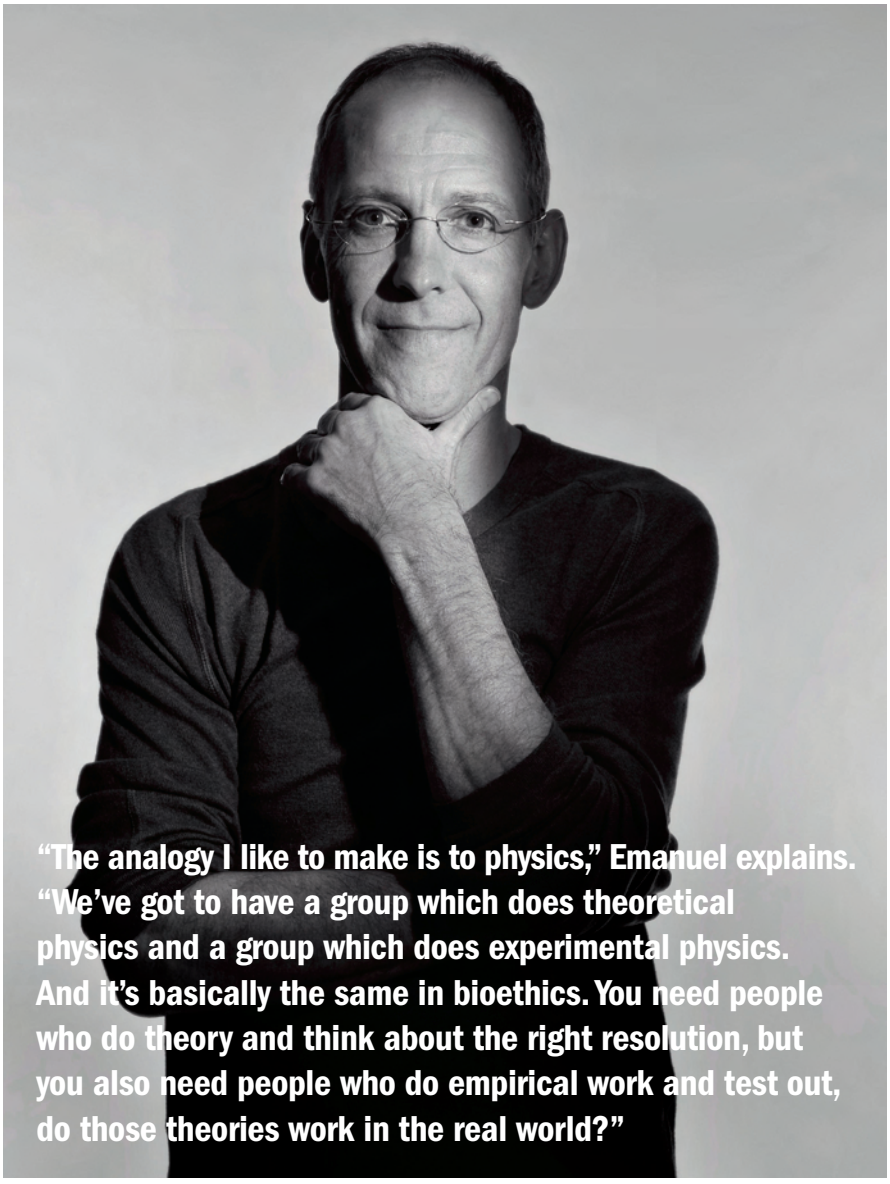
"For example, we spent a long time negotiating some elements around the comparative-effectiveness work to make sure [we addressed] some of the ethical concerns of religious groups about not biasing some of the results against people who wanted to have end-of-life care," he says. "That negotiation was clearly ethical, involved a lot of ethical choices and discussions."

Though it's less directly an extension of his bioethics work, he also takes credit for incorporating administrative simplification, particularly as related to health care billing, into the law.

"I can say very confidently, had I not pushed that, it would not have been in the bill," he says. "Because Congress was not interested in it. Most of the administration didn't see its importance. It's worth $30-$40 billion a year, mostly to the private sector. Hospitals will save money. Doctor offices will save money. Insurance companies will save money. But it wasn't going to happen without the government setting standards."

Around the time he came to Penn, Emanuel began writing occasional columns for *The New York Times* exploring where the biggest potential cost savings are—and aren't—in the US health care system.

In one of them, he took dead aim at the "medical arms race" to build proton-beam treatment facilities—like the Roberts Proton Therapy Center at Penn ["Inside the Cancer-Cell Smasher," Mar|Apr 2009]. Citing the lack of evidence that proton-beam therapy is more effective than cheaper treatment options, he called the rush to build new centers "crazy medicine and unsustainable public policy." (Combative collegiality indeed.) In that article, he also examined a few ideas for how to deal with the situation—each of which has bioethical dimensions. Medicare could simply refuse to pay for the treatment except where it has been proven clinically superior. Or, since clinical trials depend on some level of reimbursement for the treatment under scrutiny, Medicare could pay for the treatment—but only for patients who are enrolled in a randomized trial comparing their treatment outcomes to those of other methods. Or hospitals could just charge willing (i.e. wealthy) patients a premium for proton-beam therapy over less expensive, more conventional options.



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"When is two-tier medicine ethical, and when is it not ethical?" Emanuel mused one morning in his College Hall office. "I think that is another deep kind of allocation question that we need to look at ... I'm very confident that there are times when a two-tiered system is perfectly ethical. And so I think we need to understand that a little better. And part of the question is: Does the public understand that also?"

Public enlightenment has been Art Caplan's mission for as long as he's been at Penn.

"I thought, there's no point in doing bioethics if you can't engage the public," he says. "Because part of what's going on here is giving them things to think about, almost a prophetic role of saying there's a problem coming that you should pay attention to."

A LAWYER, A DOCTOR, AND A CORPORATE CONVERT: THE CAREER PATHS OF THREE MBE ALUMNI

The story of how David Sontag L'03 G'03 ended up in the master's of bioethics (MBE) program should resonate with anyone who's ever been bitten by the bioethics bug.

"I'd taken an undergrad class in medical ethics and was fascinated by it. I thought that's what I wanted to do in life," he says. "My mom, ever the pragmatist, said, 'Well, who's going to pay you to do that?'"

She was by no means the first parent to ask such a question about a grown child's passion. (As anyone who's footed the bill for a theater arts degree can attest.) But Sontag's career path is one example of how bioethics has matured into a discipline with myriad professional outlets.

After deciding to go to law school, Sontag narrowed his choices down to programs that offered the possibility of pursuing additional education in bioethics or public health. Penn emerged as the best option. According to Law School Dean Michael Fitts, between seven and 10 law students a year now get a bioethics degree in conjunction with their law education.

"It attracts a lot of students to us," says Fitts. "If you think about bioethics, it's substantively, economically, and philosophically one of the most important areas in the world and in our economy. It raises almost every fundamental issue in society: ethical issues about our bodies, personal questions, economic issues, everything. And that's what great about law. Lawyers and the law faculty spend their time thinking about problems that are large and interrelated. So on our faculty, we probably have five or six people—which given our size is a lot of people—who focus in that area."

For Sontag the attraction was more intellectual than professional. "Whether it will help me get a job or not, I didn't so much care," he recalls. "Bioethics teaches you how to think about problems in a different way. It's not so much a substantive education as it is a philosophical one."

After graduating from the Law School, Sontag clerked for a federal judge in the Eastern District of Pennsylvania, then worked at firms in Philadelphia and Boston, focusing on health law.

"A lot of my practice was based on financial transactions—deal-related work that involved some private equity firm buying one health-care-related company over another," he says. "But part of the practice was advising hospitals and other health care providers on how they should be acting—whether to comply with the law, or, from a moral and ethical standpoint, how they should be reacting to certain situations that come up in everyday provider lives. I realized that's the part I liked the most, because there was sometimes an intersection with bioethics.

"Sometimes there are black-and-white answers in the law that say you have to do X, Y, or Z," he elaborates. "But there are plenty—and probably more—areas of gray, where you can justify doing it this way, or that way … so how should we do it? Sometimes those are bioethical questions. So I tried to find a position where I could do that if not all the time, then at least more often."

Last June he found one, as associate general counsel for Beth Israel Deaconess Medical Center in Boston. His new job lets him delve into patient-care-related issues at a more "granular level," working through issues like health care proxies, medical guardianship, and informed consent. "Nowadays I do use more of the bioethics in that way," he says.

"I liked my jobs in the past," he adds. "I love this job."

Jill Baren G'02 enrolled in the MBE program as a mid-career professional, seeking to bolster her teaching in the medical school, where she is a professor of emergency medicine.

"Even though I was a health-services researcher and doing some clinical-trials work, the things I got tremendous enjoyment out of were the humanistic aspects of medicine," she says. "For example, I was a doctoring instructor in the medical school. I enjoyed lecturing and teaching on end-of-life care. I was always getting involved in any kind of initiatives that had to do with professionalism and the patient experience. These were a little tangential to my research, but they were professional activities that gave me a lot of pleasure.

"I wanted to really enhance my teaching of my specialty—how to weave in ethical issues and how to construct appropriate ethical arguments and understanding the theory behind bioethics," she adds. "So one of the reasons I wanted to undertake the formal training was to have credibility around those issues."

But once she got going, new goals emerged.

"The way I went into the program was very different from the way I emerged," Baren says. "I recognized that there was a tremendous need in my specialty of emergency medicine for learning better how to conduct clinical trials within an ethical framework in the emergency setting.

"In order to study conditions which affect critically ill and injured patients," she explains, "we're dealing with patients who are incapacitated, so they're are not able to provide informed consent. Someone in cardiac arrest, someone who has traumatic brain injury, someone who is in septic shock, someone who has exsanguinating hemorrhage from trauma: if we're going to study those conditions—how we can intervene in those conditions, or how we can construct clinical algorithms around treating those conditions—we can't obtain consent from the patient … If we don't, for example, intervene within the first five minutes of a patient who has status epilepticus, we may miss the opportunity to test the efficacy of the drug. So if one thinks about a valid informed consent process that's robust and meaningful, that can't be accomplished in five minutes."

There is a special set of federal regulations governing research undertaken without prospective informed consent, and Baren became "somewhat of an expert" on applying them in an emergency setting.

"Because we are foregoing prospective informed consent, we must do certain activities before the trial in order to demonstrate the acceptability of the trial in the community in which it is conducted," Baren says. "So we do community consultation, we do public disclosure, we go through an exercise where we look at the scientific trial design in and of itself and put that forward to the IRB [institutional review board] so they can see how the scientific and ethical issues interrelate. Essentially, it's a much longer and different process that you put forward as an investigator, in contrast to, say, a cancer trial."

Determining who makes up "the community" in the context of something like a trauma-care trial is challenging. "The federal regulations talk about two kinds of communities: geographical, and the community of individuals who are likely to be affected by the disorder being studied," says Baren, who now consults on such trials. "I help people strategize and develop methods to satisfy the requirements for community consultation."

Her interest in the patient experience remains strong, and she believes bioethics mentoring has a key role to play in improving the way medical providers deal with thorny dilemmas at the bedside.

"We're very good at teaching in the medical system how to work through a problem in a clinical sense, but we're not always good at teaching how to work through a problem in an ethical sense," she says. "And I think as we get better at that, the improvement that really will come out of the patient-provider relationship will be substantial.

"A perfect example is having a policy on the books at the University of Pennsylvania that talks about withdrawal of life-sustaining therapy in patients with persistent vegetative states," she elaborates.

"[It's a] well-constructed policy, [with] thoughtful information provided by experts, very grounded in ethical principles, supported by legal counsel … But if we have myriad patients in the hospital who don't have providers who can execute those conversations with families, then we have a big problem on our hands. We have the continued creation of suspicion and mistrust when information isn't being given, when the issues aren't framed properly for the family at the bedside.

"Having the policy is wonderful," she concludes. "But teaching people how to apply it, how to have those conversations, that I think really makes the difference."

Sheldon Sloan G'08 was another mid-career matriculant in the MBE program—but he enrolled at a turning point in his second career. Sloan was a gastroenterologist in academic practice, specializing in gastroesophageal reflux disease, until he made the leap to industry in 1997 by joining Johnson & Johnson in a clinical-research role.

In the years that followed, he slowly found himself assuming roles that were more managerial in nature.

"In 2004, I began a new role in the Johnson & Johnson corporate office of science and technology, administering programs to help scientific collaboration across the corporation," he says. "I was also responsible for issues related to our research enterprise that might need corporate oversight or input. One activity was the preclinical aspect of our research engine, which got me involved in animal welfare issues—not only helping to internally shape our guidance and policies, but also to represent J&J on non-profit boards, which allowed us to share best practices and discuss common issues."

Soon thereafter, he started shopping around for formal bioethics training, initially considering distance-learning programs like one run by Loyola University in Chicago. One day at work Sloan found himself at Centacor, a J&J company that has since been renamed Janssen Bioetech, where Art Caplan was giving a talk about the history and ethics of human-subjects research. Afterward, Caplan talked Sloan into applying to Penn.

Caplan sees the corporate employment of bioethicists as an incipient trend. "You can see them just starting to hire that way a little bit," he says. "Law firms, too. It sort of gives you a little leg up now when you say, 'Oh, I do bioethics.'"

Sloan's experience attests to that. "I grew personally and professionally, expanding myself and stretching myself," he says. The company also footed his tuition bill.

"By having a diverse curriculum, the program allowed me to explore several aspects of how bioethics is practically applied," Sloan elaborates. "One course in particular, 'Bioethics Goes to Washington,' heightened my interest in policy. Coming from a corporate perspective, I wanted to understand how some of these policies get generated, discussed, and implemented, which is important on the professional side.

"Research ethics was also a core course for me," he adds, while animal-welfare ethics proved to be "key in understanding all sides of a very complex issue" for his work at Johnson & Johnson.

Now he's applying what he learned in the Penn MBE program at J&J.

"I got more involved in bioethics policies" after graduating from the MBE program, Sloan says. "I got much more comfortable tackling them for the corporation.

"My current job is overseeing a portfolio of products—primarily gastrointestinal products—which involves human-subjects research. Bioethics principles and dilemmas are part and parcel in overseeing human-subjects research. Beyond my role as a portfolio leader, I am also on a newly formed Johnson & Johnson ethics team—having been a graduate of the Penn bioethics master's program allowed me to be considered as a candidate."

Sloan adds a point that other MBE alumni echo, which is that his relationship with Penn's bioethics program didn't end at graduation. Through colloquia and other events, many MBE alumni stay connected.

"Another benefit of being a Penn bioethics graduate is my familiarity with the Penn faculty," Sloan says. "They are a body of experts that I know and feel comfortable to call upon. We've consulted with Penn faculty, and part of that was my experience knowing their strengths."

Going forward, those prophets are likely to be addressing emerging dilemmas around vaccination research and policy, organ and tissue transplantation, and neuroethics—and "you're going to have to be certified to do it," Caplan says. "I suspect the master's degree is minimal, and the advanced master's degree is going to be what you need to teach it."

Which is where Emanuel's plans for a master's of science in bioethics program (MSc) come in. While the MBE program did end up generating a crop of professional academic bioethicists, it did so from the ranks of its junior faculty, not—as was never the aim—its students. (Paul Root Wolpe C'78 now runs a bioethics program at Emory; David Magnus runs one at Stanford.)

"There is, as in many areas of medicine, a pipeline problem," says Emanuel. "There are only a few sites around the country where you can get suitable training. And so part of the plan is to make Penn the best place in the world to train to become a bioethicist."

Notwithstanding the MBE program's success in spreading bioethical modes of analysis to health providers, clinical researchers, lawyers, and the like, he adds: "What Penn hasn't, in my opinion, been at the forefront of—and where we're moving to—is in the scholarly work around bioethics. And that's not to say it hasn't been there. It hasn't been No. 1 in the world, and my plan is to make it No. 1 in the world."

Logistically, that means growing the Department of Medical Ethics and Health Policy from four standing faculty members to 11 over the next few years, to permit a one-to-one ratio between faculty mentors and MSc students.

"You have to have a certain critical mass of faculty to do this kind of mentoring," explains Autumn Fiester. "Helping a student get from concept of research all the way through [the regulatory process and implementation] requires an enormous quantity of personnel and depth of mentoring.

"Zeke has an extraordinary track record of creating a pipeline and actually placing students at the end of their training," she adds. "The NIH has one of the most formidable bioethics training programs in the country, and he's been running that program for a long time."

DAWN OF THE BIOCRATS

"Bioethics," says Art Caplan, "is a little bit like geology. There are shifts going on, but you have to really watch them over time to see them."

In the 40-odd years since the term *bioethics* was coined, the field has shaped the practice of medicine in some substantial ways.

"Truth-telling was a big issue when I first got into this," Caplan recalls. "Do you tell the patient the truth about their diagnosis? Nobody argues about that anymore ... The default shifted from tell[ing] a few elite people that we think could understand, to: you will be given full, complete information on your miserable disease and your fatal future, unless you say, *I don't really want to know that.* So truthfulness between doctor and patient shifted enormously.

"The ability to stop care," he continues, is another sea change. "So DNR [do-not-resuscitate orders], do-not-treat, the willingness to write a living will and pay attention to it, the willingness to listen to a surrogate and stop—that wouldn't have happened 30 years ago.

"Part of the reason bioethics has grown is that bioethics has succeeded," Caplan says. "It delivered on the challenge to solve certain problems."

On the whole, solving those problems has entailed minimal controversy. (In hindsight, the case of Terri Schiavo represents the exception that proves the rule.) But consensus has its limits, especially in a country where adding one shot to the childhood-inoculation schedule is enough to touch off a new skirmish in the culture wars.

Caplan thinks Moreno is right in his observation that "a new biopolitics is emerging and has been doing so for some time." He believes that it is in fact bioethics' "rare success in finding some way to talk cross-culturally" that accounts for that emergence.

"Bioethics, *because* it is a way to talk across the aisle, has evolved into a lot of biopolitics," Caplan reckons. "The experts can have opinions or try to shape the debate. I do. But it's ultimately politics where bioethics gets settled."

Does that mean that the Zeke Emanuels of the world are destined to be supplanted by the Bachmanns and Santorums? On the contrary, there's every reason to believe that the influence of bioethicists will grow.

One of the clearest statements of that case comes from a commentator who does not exactly welcome their influence, the conservative *New York Times* columnist Ross Douthat.

"There are three broad camps in contemporary debates over bioethics," Douthat wrote in 2011. "In the name of human rights and human dignity, 'bio-conservatives' tend to support restricting, regulating and stigmatizing the technologies that allow us to create, manipulate and destroy embryonic life. In the name of scientific progress and human freedom, 'bio-libertarians' tend to oppose any restrictions on what individuals, doctors and researchers are allowed to do. Then somewhere in between are the anguished liberals, who are uncomfortable with what they see as the absolutism of both sides, and who tend to argue that society needs to decide where to draw its bioethical lines not based on some general ideal (like 'life' or 'choice'), but rather case by case by case."

Moreno might hasten to add that those three camps don't map neatly onto the American political spectrum. "'Green' progressives harbor deep doubts about the implications of science for social justice, often striking a distinctly bioconservative tone," he points out in *The Body Politic*. Meanwhile, there's a natural affinity between traditional business conservatives and the bioprogressives who, in Douthat's telling, always "find reasons to embrace each new technological leap while promising to resist the next one."

But Moreno would agree with—and endorse—Douthat's emphasis on the evolution of mainstream bioethics into a discipline driven by a case-by-case approach. After all, merely identifying the ethical fault lines of practices like "human-mouse bone marrow transplants" (which, lest you mistake them for science fiction, "have been performed since the 1980s and have been part of studies of AIDS and leukemia") requires a level of technical mastery to which broad Presidential or Congressional edicts are ill suited.

As Caplan puts it: "We don't have a Taliban or a Sanhedrin or the Pope to say, 'Well, this is how we are going to do this.'"

And as long as we don't, bioethicists will likely occupy a growing role as enlightened bureaucrats. Indeed, when asked how the University aims to impact society by expanding its bioethics footprint, President Gutmann highlighted faculty and alumni who have served in government-advisory capacities.

"True to Penn's strong commitment to public service," she said, "our strength in bioethics is represented by no fewer than eight Penn students, alumni, and faculty who have served as high-level staff on the Presidential Commission for the Study of Bioethics, and six Penn faculty members publicly testifying for the Bioethics Commission on topics as diverse as synthetic biology, neuroethics, and protections for human volunteers in research studies."

They, and the generation Penn aims to train in their footsteps, will face an ever-more-complicated set of challenges.

"The first intellectual who really talked about biopolitics," Moreno reflects, "was Michel Foucault, who died in 1984—probably the first famous person to die of HIV/AIDS. Foucault talked about biopolitics in terms of the control over bodies and populations. And he said that one of the things that happened in Renaissance Europe was that you had this clustering of populations, especially during and after the Black Plague. And what the plague taught people was that when you start putting a lot of bodies together in a small place, interacting, that a lot of funky things can happen, not only crime and violence, but disease.

"So Foucault's general argument is political systems develop to try to control the interactions of bodies," Moreno goes on, getting to the crux of it. "If Foucault had lived, he would have seen that the next step for biopolitics is not only control over bodies and populations, but also over the parts of bodies that provide new sources of wealth and knowledge and power—and that's cells, tissues, organs, genes."

Those terms are foreign to the common-sense intuitions our species has developed over millennia to help us pursue the greatest good. The men and women who develop and refine supplementary modes of thought have a weighty task.

"The ways we respond to the implications of modern biology," Moreno puts it in *The Body Politic*, "are of great importance for the country at many levels: for the future of our economy, our place in international technological innovation, our sense of national purpose, the social and ethical choices that await us, and our self-understanding as a people."◆