Introduction

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SCENE 1

The 1997 announcement that researchers in Scotland had produced the first cloned mammal, a sheep named Dolly, gave rise to rampant discussions about the prospects of cloned human beings. Many scientists, bioethicists, and others weighed in to explore how we should respond—morally, politically, socially—to this new possibility. Public opinion surveys found that about 90 percent of respondents opposed the prospect of cloning as a form of human reproduction. But among those who supported it were some reproductive rights advocates, who were reluctant to endorse anything that might be construed as a limit on reproductive freedom.

In that context, Planned Parenthood Federation of America embarked on a process aimed at adopting an organizational position on human reproductive cloning, part of which involved bringing the issue to a 2001 meeting of board members and senior staff members. To gauge participants' sentiments, the senior Planned Parenthood staffer charged with facilitating the discussion, herself troubled by some of her colleagues' hesitation to oppose human reproductive cloning, prepared several hypothetical scenarios and presented them to breakout groups at the meeting. In one of these scenarios, titled "Happy Workers: Creation of a Free Market Empire,"

> a company [is] making a large profit with sales of a gadget for which consumer demand is inexhaustible. The owners face a challenge, however, because the final step in the manufacture of the gadget must be done manually, and "small, dexterous human hands are needed."
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> They identify a worker who is particularly skilled at this task, and propose to produce 1,000 clones of her. They approach her with an offer of $1 million now, and another $5 million after the clones are able to perform the job once they reach 16 years of age. The company will

> assume complete responsibility for rearing and caring for the clones. And "since the sole purpose of the clones will be to do the work in the last step of manufacture, they will be engineered to require little sleep and to have few ambitions other than performance of their work."[1]

Each discussion group was asked to decide whether it should be "permissible to produce clones for such a purpose." The scenarios' author later reported that although most participants found the situation disturbing, none of the breakout groups were willing to support legislation that would prohibit human reproductive cloning. All were persuaded by the counterargument that "the decision should be a matter of individual choice."

SCENE 2

In 2006, the Massachusetts Institute of Technology hosted a conference on a new drug called BiDil, which had recently been approved by the US Food and Drug Administration to treat heart failure. As Jonathan Kahn recounts in "Race in a Bottle," (part 9 of this volume), the FDA's action had triggered quite an uproar, because BiDil was the first drug ever to be approved for a particular racial group. The agency had given its blessing to BiDil with the stipulation that it would be indicated for black people—that is, sold with a label on the bottle that essentially said the drug was for black people only. To many observers, this governmental support for race-specific pharmaceuticals ratified the false idea that human races are biologically distinct and encouraged the conclusion that health disparities are caused by biological differences that can be resolved through race-specific medicines.

The MIT conference was convened to explore this new twist on the old tension between social and biological explanations for racial health disparities. Meeting organizers pointed out that the questions raised by BiDil's approval were especially pressing in light of new claims emerging from the field of human genetics about the ability to detect and speak to racial differences at a molecular level.

Legal scholar Dorothy Roberts, who explores these issues further in "The Problem with Race-Based Medicine" (part 9), presented a paper at the conference on the diversity of opinions within the black community about race-based medicines like BiDil. She explained that some black people are skeptical about BiDil because of the long history of medical exploitation of the community, while others see race-specific medicines as a form of atonement for years of neglect by medical researchers. Roberts's main point was that there was no unified perspective about BiDil in the black community. During the question-and-answer portion of the talk, Juan Cofield, president

of the NAACP's New England Area Conference, stood up and vociferously endorsed BiDil, declaring that "There is a consensus in the Black community that this drug is good for Black people." To which Roberts coolly responded, "There isn't a consensus among the black people *in this room*."[2]

SCENE 3

In 2015, the acronym "CRISPR" hit mainstream discussions. CRISPR is the latest of several recently developed techniques that allow scientists to "edit" segments of DNA and produce changes to the genetic code of any organism. In scientific and news reports, many researchers and others expressed particular excitement about the prospect of using CRISPR for *human* gene editing. Some focused on the potential of genetic modifications to treat diseases, including both inherited conditions such as Huntington's disease and beta thalassemia and pervasive illnesses like cancer.

Others spoke of a very different vision for CRISPR: using it to edit the genes of human embryos in order to control the traits of future children and generations. While these commentators typically focused on preventing the transmission of serious inherited diseases, they often ignored or downplayed the existence of safer alternatives for meeting the same objective, including embryo screening. And some jumped easily to enthusiasm for reproductive gene editing to create offspring with preferential traits—height, hair color, perhaps even intelligence—that would be permanent and heritable for all future generations.

This vision represents the most recent in a long line of proposals to alter the human germ line in perpetuity—that is, using science to engineer future generations according to current social preferences. Human germline engineering raises a host of thorny ethical questions. Who would decide which social or medical traits to insert into or weed out of the gene pool? Would it be solely up to parents? What could happen when individual preferences—for a particular kind of musculature, a certain eye color, or even skin color—align with historically fraught concepts about which children are more socially valuable and which groups should be marginalized?

These questions have been addressed in policy conversations, intellectual debates, and public deliberations around the world for the past several decades. Many have concluded that if human biotechnology can deliver the power and incentive to engineer enhancements and inequality into the germline, the potential for new forms of discrimination and social conflict is profound. As a result, dozens of countries have adopted legal prohibitions on human germline modification.

It is in this context that Nobel Prize–winning molecular biologist Craig Mello explored the implications of human gene editing during a radio interview on WBUR, Boston's public radio station. When asked about the ethics of altering the human germline and the potential for new forms of inequality, Mello replied, "If [gene editing technologies] were safe, and if we have the knowledge to make improvements in the human germline, then it might be unethical *not* to do so."[3]

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Medical ethics, a collection of professional norms designed to give guidance to doctors on how to manage health care dilemmas in a thoughtful and humane manner, dates back many centuries. Its most notable antecedent is the Hippocratic Oath, the modern version of which implores physicians to, in essence, "Do no harm." In the broadest sense, modern medical ethics has provided professional standards meant to guide physicians through the significant moral challenges that confront those engaged in the work of healing. Over the course of the nineteenth century and early to mid-twentieth century, medical ethics became, as Albert Jonsen states in his definitive work, *The Birth of Bioethics*, "almost synonymous with rules for professional cohesion and respectability."[4]

In other words, medical ethics organizes the private practice of medicine in a manner that aligns with the social virtues and preferences of Western thought as expressed through a mixture of religious, philosophical, and secular traditions. Key to this ideal is the notion that physicians and other medical practitioners, guided by these ethical norms, will typically make the right choices without any meaningful oversight beyond their peers or professional organizations.

To the extent that early twentieth-century medical ethics situated itself as a field that could rely largely on physician and researcher discretion to promote health and well-being, its limitations were grossly exposed in the wake of World War II and the Holocaust. The Nuremberg trials drew worldwide attention to the central role that physicians and researchers played in facilitating unconscionable human suffering in a twisted pursuit of advancing medical science. The role of medical doctors and researchers in concentration camps was nothing short of ghastly; people were subjected to inhumane experiments and purposefully given certain diseases and poisons just so researchers could study the precise mechanisms through which they suffered and died. While Nazi researchers received the bulk of the global criticism for these cruel practices, questionable research and exploitation of vulnerable populations were not unknown in other parts of the world, particularly the United States.

The Nuremberg trials began the process of raising questions about the wisdom of relying on professional norms to protect patients and research subjects from harmful practices. During this same postwar period, other scandals such as the Tuskegee syphilis experiments came to light, creating public pressure for physicians and researchers to be more thoughtful and accountable.[5] Amid these developments and questions came a unique set of deliberations that allowed a new scholarly field—bioethics—to emerge, and a new professional figure—the bioethicist—to claim expertise.

Thus, in many ways, "bioethics was born out the ashes of the Holocaust."[6] The field formalized in the latter half of the twentieth century with new technological developments, such as recombinant DNA, assisted reproduction, organ transplants, and life support mechanisms, that blurred the line between life and death. As public discussion of these developments increased, the field of bioethics evolved. It staked a claim to providing a detached, secular approach to these profound questions of life and death, one that could be endorsed by governments, private organizations (hospitals, professional associations, etc.), and practitioners regardless of religious affiliation or philosophical preference.

Notably, the principles set forth in the Belmont Report in the late 1970s and most famously explored in Tom Beauchamp and James Childress's 1979 book *Principles of Biomedical Ethics* (now in its 7th edition) have come to dominate bioethical thinking. Known as principlism, this modern approach, which is closely associated with Beauchamp and Childress, provides a common framework by embracing four principles as the foundation of bioethical deliberation: respect for autonomy (antipaternalism, or people should have agency in their decision making), nonmaleficence (do no harm), beneficence (help people), and justice (being thoughtful about the distribution of benefits and burdens).

In the context of the technological questions and demands for greater transparency that were rapidly occurring at the time, the professional field of bioethics that congealed was certainly an important step forward. Bioethics helped transition the manner in which medicine and scientific research handled ethical issues from a mostly private and individually contemplative endeavor largely hidden from public view to a more transparent, outward-facing set of principles that, in theory, could be applied across fields and topics to produce desirable and predictable outcomes for patients and research subjects. Moreover, as public awareness grew about startling new developments such as in vitro fertilization and artificial organs, bioethicists played an important role not only in helping practitioners think through their professional duties but also in assuring the public that an

independent party would be an important part of conversations and decisions about moving these new developments forward in an appropriate manner.

But bioethics as a field has at least three significant limitations. First, as John Evans discusses in "A Sociological Account of the Growth of Principlism" (part 2), the principlism that drives much of the conversation has an inherently individualist orientation. Principlism largely conceives of bioethical dilemmas as occurring in the relationships between doctors and patients, or researchers and human subjects. As an example, principlism offers a coherent way to determine the types of information that should be communicated in an informed consent procedure for a research study. But it provides a thin vision of how group and social dynamics might be crucial for a realistic understanding of "consent." For instance, it leaves much to be desired in terms of how and whether "informed consent" can be meaningful when recruiting subjects from vulnerable populations without access to basic medical care. While principlism's justice component offers a foothold for thinking through such issues, this approach has nevertheless proved inadequate for incorporating ethical values outside of individual relationships or transactions.

Second, as Carl Elliott describes in "The Ethicists" (part 2), the notion that bioethics provides a detached and independent assessment of the ethical issues surrounding science and medicine does not conform to on-the-ground bioethical practice. Bioethicists are often embedded in the same professional institutions and contexts as the very technologies and industries they are ostensibly overseeing. This can lead to situations in which financial or other professional incentives can obscure bioethicists' willingness or ability to consistently comport themselves in a manner that aligns with the public interest.

And lastly, while bioethics can provide a set of guidelines or professional norms, these principles or ideals are typically not translated into enforceable policy mechanisms. Bioethics can inform decision making by institutional review boards, help develop professional standards, and shape a handful of specific regulations such as those pertaining to human research protection. But without any broader regulatory mechanisms to implement these norms, bioethics is largely without teeth in dealing with the deeply profound and transformative social power of many new developments.

The departure point for this volume is to highlight how these limitations become fully exposed when bioethics' principlist approach is put in conversation with the social and policy challenges raised by new human genetic and assisted reproductive technologies. This suite of powerful tools

and practices carries social and political implications that go far beyond the limited parameters that can be addressed by autonomy, nonmaleficence, beneficence, and justice. The three vignettes at the beginning of this introduction highlight these limitations and tensions. None of the scenarios can be meaningfully assessed without guidance beyond principlism.

The "Happy Workers" scenario, for example, draws attention to the particular political context that underlay early responses to the prospect of human reproductive cloning. In an era of relentless attacks on abortion rights, people otherwise sympathetic to concerns about exploitation were perhaps understandably tempted to overlook it and double down on their commitment to "choice." Planned Parenthood's initial unwillingness to foreclose any avenue of reproduction—even one that involved producing "cloned insomniac slaves"[7]—fortunately did not persist. But this episode dramatizes the inadequacy of a principlist approach for a complex issue playing out on difficult social and political terrain.

Similarly, the dynamics surrounding race-based medicine cannot be meaningfully understood without considering the remarkably twisted (and at times brutal) history of race and medicine or taking into account the commercial imperatives leading to BiDil's development. Questions about, for example, autonomous decision making, or about "doing harm" versus "doing good" to individual patients, are tangential to the deeper social and political implications of the US government giving its stamp of approval to medicine premised on the dubious notion of biological race.

The gene-editing technologies at issue in the third vignette represent perhaps the most consequential of these new technologies—the ability to engineer and redesign human beings, and even humanity. Yet when faced with the prospect of the significant social and political challenges created by such developments, a leading scientist's ethical sensibilities leads him to ponder issues of individual safety to the exclusion of potentially great social harm.

In the mid-twentieth century, new technological advances and changing social contexts created the conditions for the private, inward-looking nature of medical ethics to be supplemented by a more public, outward-facing bioethical discourse. Similarly, in the late twentieth and now early twenty-first centuries, new human genetic and assisted reproductive technologies, coupled with the increasingly commercialized conditions of their development and deployment in addition to other social changes, are prompting new and far more public conversations about the proper relationships and negotiations between science and society. This approach places social justice, human rights, and the public interest at the center of its analysis. We call

this emerging field, which will inevitably remain in conversation with medical ethics and bioethics, the *new biopolitics.*

An entry for the term *biopolitics* in the *Encyclopedia of Bioethics* (coauthored by Darnovsky) asserts the following:

> The social and ethical challenges posed by human biotechnologies in the early twenty-first century encompass much broader issues, and capture much greater public attention, than was the case in the early days of the field of bioethics. Biopolitical controversies play out in social realms, including academia, news and online media, and popular culture, and on political stages including the courts, legislatures, and even national elections. And biopolitics is increasingly a focus for civil-society constituencies and public-interest organizations.
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> In contrast to bioethics, then, biopolitics focuses on broad social and political dynamics more than on encounters in institutional settings between doctors and patients or between researchers and human subjects. It emphasizes social values and policy proposals more than procedural recommendations and professional guidelines. Though bioethics and biopolitics are in constant conversation with each other, biopolitics is situated largely outside the organizational structures (such as academic departments, hospitals and clinics, institutional review boards, and corporate advisory boards) that are most closely associated with bioethics.[8]

The term *biopolitics* is used in a number of academic disciplines, including bioethics, sociology, anthropology, philosophy, and science and technology studies. It is most widely associated with the work of French philosopher Michel Foucault.[9] What we are calling the "new biopolitics" is distinct from these prior articulations yet remains a project in formation, with many of its contours and characteristics still blurry. But it is useful to sketch at least five particular concerns that further distinguish it from mainstream bioethical approaches:

- *Reckoning with the role of commerce and markets in biomedicine and biotechnology.* The new biopolitics is sensitive to the ways in which commercial pressures and market incentives can warp deliberations on the potential social impacts of new human genetic and assisted reproductive technologies. It also pays close attention to how science and medicine are not only healing endeavors but also profit-seeking enterprises that, like all market-oriented ventures, need regulation and oversight.
- *Understanding the human genome as part of the common heritage of humanity.* The new biopolitics takes seriously that if gene editing

or cloning were used for human reproductive purposes, either could alter basic understandings of what it means to be human in ways likely to have cascading effects for all subsequent generations. This approach also suggests greater humility and a precautionary approach in questioning whether we have the wisdom to understand the full range of social and biological consequences associated with, for example, inserting genetic enhancements or deleting genetic challenges from our gene pool. It appreciates statements by international bodies, including the United Nations Educational, Scientific and Cultural Organization; the World Medical Association; and the Human Genome Organization, Ethical, Legal, and Social Issues Committee (the international scientific coordinating body for the Human Genome Project), asserting that the human genome should be considered a symbol and a part of the common heritage of humanity.[10]

- *Avoiding technical developments and genetic narratives that embed social and political preferences at the molecular level.* The new biopolitics is sensitive to the discriminatory attitudes that may allow social preferences to guide the way human biotechnologies are implemented and to the deleterious impacts this can have on the preconditions for, and basic notions of, social justice. Human biotechnologies have the ability to reaffirm social preferences and lines of difference at a molecular level. As one example, race-specific medicines treat health disparities as a function of natural differences rather than as products of social inequality. As another example, using assisted reproductive technologies to identify and eliminate embryos that contain conditions many consider fully compatible with health and happiness effectively reinforces the view that bodies rather than social and political context are always the disabling factor. (See "Disability Equality and Prenatal Testing: Contradictory or Compatible?" by Adrienne Asch in part 8.)
- *Ensuring democratic oversight of powerful human biotechnologies.* The new biopolitics expresses skepticism about the ability of private companies or associations, professional bioethicists, or self-enforced rules to ensure that human biotechnologies truly serve the public interest. The choices being put in front of us by new human biotechnologies are profoundly political; they create winners and losers, shape our societies (and in some cases our very selves), and implicate society's deepest values about who we are and what we want to be. It would be remarkably unwise to hand such decision making to

any one group of experts or professionals and extremely reckless to leave it to "the market." Therefore, a new biopolitical approach not only promotes greater transparency but also much greater civic participation and inclusive democratic engagement in decisions about whether and how new human genetic and assisted reproductive technologies should be developed, deployed, and governed. It calls for "public engagement" and insists that this involve robust support for thoughtful and extended deliberations, so as to enable participation by civil society, public interest and faith-based organizations, community groups, labor unions, and others.

- *Steering clear of a new market-driven eugenics.* A central concern of the new biopolitics is that particular human genetic and assisted reproductive technologies may lead to a new form of eugenics. In contemplating this prospect, some observers argue that we no longer need to fear state involvement in citizens' reproductive choices or government efforts to weed out undesirable populations—that the sterilization laws, immigration restrictions, and outright genocides justified by eugenics are earmarks of a bygone (late nineteenth- and early twentieth-century) era. But a "new" eugenics, driven by market forces as opposed to state discrimination, could look eerily similar. Collective efforts to enhance future generations along the lines of socially acceptable aesthetic norms, or market dynamics that encourage using IVF-based screening technologies to avoid certain traits, may allow racist, sexist, and ableist norms to dictate who is an accepted member of society.

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Our ambition for this anthology is that it will crystallize and promote the growth of the new biopolitics as a field of public, policy, and scholarly concern. Though they focus on developments in the United States, the volume's essays and articles articulate a range of concerns and perspectives prompted by new human biotechnologies worldwide. They explore the troubling directions in which these technologies and associated ideologies can lead to without proper care, and offer an alternative vision for negotiating the power-laden fault lines among the life sciences, the biotechnologies they spawn, and society. The volume's specific focus—forgoing traditional bioethical topics[11] such as end-of-life care and organ transplants—stems from the particular dilemmas created for bioethics by contemporary financial and political conditions and by new and emerging technologies. Many

of the contributions also explore how these new dilemmas speak to the field's original core themes, like eugenics, the relationship of science and medicine to vulnerable populations, and the need for greater oversight of researchers and medical professionals.

The new biopolitical perspective this volume presents may provide useful insights for study and critique in other fields, such as environmental studies or urban planning, that involve social justice, human rights, and public interest values. We leave such extensions to future scholars, and focus here on the ways in which the profound challenges created by powerful new human biotechnologies call for a fresh framework of analysis and assessment. The new biopolitics doesn't provide definitive answers but guides us toward questions that prioritize social justice and human rights and suggests fruitful ways to explore them.

The articles in parts 1 through 10 are all reprinted or excerpted from previous publications. This heterogeneous collection exemplifies what has until now been a loosely aligned group of writings that focus on the shortcomings and limitations of mainstream bioethical approaches, in search of deeper inquiry into the intensely social and political nature of human biotechnologies. Not all contributors to this volume explicitly identify with this new biopolitical vision. As editors, our goal is to highlight the connections that some authors themselves may not immediately see but that, taken as a web of concerns, give birth to an alternative understanding of the appropriate relationship between science, medicine, and society. Inasmuch as multiple excerpts touch on a similar theme or topic, this book draws strength from demonstrating the many standpoints from which particular events can be understood, challenged, and critiqued. The original foreword by Troy Duster and original afterword by Patricia J. Williams are extraordinarily rich additions to this field-in-formation.

Part 1, "The Biopolitical Critique of Bioethics: Historical Context," and part 2, "Bioethics and Its Discontents," situate the new biopolitics in the contexts from which it emerges. The contributions in part 1 consider historical examples of techno-scientific abuses and begin to demonstrate the many linkages between past, present, and future. Part 2 collects articles that call attention to some of the limitations of mainstream bioethics.

The articles in part 3, "Emerging Biotechnologies, Extreme Ideologies: The Recent Past and Near Future," focus on the technological enthusiasts in the United States and elsewhere, who advocate the unfettered use of biotechnologies for extreme scenarios that include "designer babies" and "posthumans." Several contributors consider how such visions and ideologies threaten social justice, human equality, and the common good.

The next three sections examine the commercial context of biotechnological research and development. Contributors to part 4, "Markets, Property, and the Body," consider how powerful market forces affect researchers, doctors, patients, clinical trial participants, universities, institutional review boards, and the field of professional bioethics. Part 5, "Patients as Consumers in the Gene Age," takes a critical look at "precision medicine," "big genomics," and similar declarations of revolutions in health care, asking how we should weigh their promises against their perils, their possibilities against their opportunities, and other costs. In part 6, "Seeking Humanity in Human Subjects Research," contributors focus on problems in biomedical research involving human subjects, examining the economic, career, and other pressures and incentives that underlie them.

Part 7, "Baby-Making in the Biotech Age," and part 8, "Selecting Traits, Selecting Children," turn to assisted reproductive technologies. Contributors to part 7 look through a social justice lens at troubling aspects of the fertility industry, focusing on the United States and on cross border fertility arrangements. Part 8 explores the selection technologies currently in use in the context of assisted reproduction, including how they are changing the experience of pregnancy and the ethical and social challenges they pose.

Part 9, "Reinventing Race in the Gene Age," examines the scientific fallacies behind the resurgence of race as a biological concept and the dangerous social consequences this entails. In part 10, "Biopolitics and the Future," we look forward, exploring opportunities and mechanisms for incorporating new biopolitical ways of thinking into scientific discourses, policy debates, and public understandings of human biotechnologies and for fostering a new biopolitical imagination that is unafraid to confront the social and moral challenges they raise.

NOTES

1. Marcy Darnovsky, "Political Science," *Democracy* 13 (2009): 46.
2. Anne Pollock, "Medicating Race: Heart Disease and Durable Preoccupations with Difference" (PhD diss., MIT, 2007), 243.
3. "Re-engineering Human Embryos," *On Point*, WBUR 90.9, April 28, 2015, accessed November 17, 2016, www.wbur.org/onpoint/2015/04/28/human-embryo-genetic-engineering-china.
4. Albert R. Jonsen, *The Birth of Bioethics* (New York: Oxford University Press, 2003), 8.
5. Susan Reverby, *Examining Tuskegee: The Infamous Syphilis Study and Its Legacy* (Chapel Hill: University of North Carolina Press, 2009).
6. Arthur Caplan, quoted in George Annas, *American Bioethics: Crossing Human Rights and Health Law Boundaries* (Oxford: Oxford University Press, 2004), 161.

7. Darnovsky, "Political Science."

8. Marcy Darnovsky and Emily Beitiks, "Biopolitics," in *Bioethics*, 4th ed., ed. Bruce Jennings (Farmington Hills, MI: Gale Cengage Learning, 2014).

9. Michel Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–1979*, ed. Michel Senellart, trans. Graham Burchell (Basingstoke, UK: Palgrave Macmillan, 2008).

10. United Nations Educational, Scientific and Cultural Organization Declaration on the Human Genome and Human Rights, Article 1 (Paris: UNESCO, 1997); World Medical Association, "Declaration on the Human Genome Project (September 1992)," *Bulletin of Medical Ethics* 87 (1993): 9–10; Human Genome Organization, Ethical, Legal, and Social Issues Committee, "Statement on the Principled Conduct of Genetics Research" (1996), accessed on November 17, 2016, www.eubios.info/HUGO.htm.

11. Other anthologies on bioethics explore these traditional areas in more depth. See, for example, Vardit Ravitsky, Autumn Fiester, and Arthur L. Caplan, eds., *The Penn Center Guide to Bioethics* (New York: Springer, 2009); and Jessica Pierce and George Randels, *Contemporary Bioethics: A Reader with Cases* (Oxford: Oxford University Press, 2009).