

# Bioethics and Populism: *How Should Our Field Respond?*

BY MILDRED Z. SOLOMON AND BRUCE JENNINGS

Across the world, an authoritarian and exclusionary form of populism is gaining political traction. Historically, some populist movements have been democratic and based on a sense of inclusive justice and the common good.<sup>1</sup> But the populism on the rise at present speaks and acts otherwise. It is challenging constitutional democracies.<sup>2</sup>

By “constitutional democracy,” we mean a form of government that is broadly responsive to the will of a majority and to the greatest good of the greatest number while carefully preserving a rule of law and protecting the liberties and interests of individuals, including minorities. Constitutional democracy is compatible with, and creates the very conditions necessary for, discussion and debate across the political spectrum, including differences of opinion about the relative merits of private-market mechanisms and governmental regulation. However, the polarization seen in *authoritarian* populism goes beyond the familiar left-right political spectrum and generates disturbing forms of extremism, including the so-called alternative right in the United States and similar ethnic and nationalistic political movements in other countries. The field of bioethics—and the important social and policy contributions it makes to our democracy—will be profoundly affected if authoritarian populism displaces constitutional democracy.

A decade ago, authoritarian populist regimes were arising primarily in low- and middle-income countries in south-central Europe, Asia, Africa, and South America. Now they are also arising in high-income countries. The growth of nationalistic political parties in several major European countries, such as France, Germany, and Hungary; the rejection of European Union membership in the United Kingdom; and the recent presidential election in the United States are all part of this trend. In these countries, leaders once on the fringe

of politics have rapidly ascended, due in part to the backlash against the emigration of displaced persons, austerity policies and high unemployment, and other growing social-class divisions based on region, lifestyle, educational level, as well as wealth.

Populism feeds on discontent with the established social and political order. Discontent, in turn, feeds on fear, anger, frustrated expectations, and alienation. Large numbers of people lose their sense of investment in the mainstream institutions of politics and civil society; distrust in government grows. Potential supporters of populist parties and movements long for a return to what is perceived as a more prosperous and dignified condition of living that they have lost. Authoritarian populist leaders are quick to seize on these sentiments, cater to them, and reinforce them, but once in power often do not act to address the voters’ legitimate concerns.<sup>3</sup> Elected by majorities, populist leaders and parties often proceed to function as if they were above the law, as seen recently in Brazil and the Philippines, for example. Having ridden in on a movement, they often turn away from building an inclusive democratic consensus that could achieve that movement’s original aspirations. The populist elite goes on to mirror the earlier political elite it replaced. The economic interests of those in power then swamp the interests and needs of middle- and low-income families, precisely the constituents who placed their trust in, and voted for, the populist leaders.

One way of distinguishing authoritarian populism from constitutional democracy lies in the way the boundaries of membership in the political community are set and in the way the notion of “We, the people” is construed. Both constitutional democracy and authoritarian populism ostensibly rest on popular sovereignty: they share a stated belief that the people are the basis of governmental legitimacy. However, in the discourse of constitutional democracies, “the people” is an inclusive, egalitarian, and culturally and religiously diverse conception, while in today’s populist discourse, the people are

Mildred Z. Solomon and Bruce Jennings, “Bioethics and Populism: How Should Our Field Respond?,” *Hastings Center Report* 47, no. 2 (2017): 11-16. DOI: 10.1002/hast.684

defined as an exceedingly selective and antipluralistic entity. They are a We hyperconscious of boundaries and divisions. This We sees the world outside the true community as locked in a zero-sum competition with other nations, other races and ethnicities, and outsiders of all kinds.

Another antidemocratic turn in today's populist outlook is that even those who gain entry to this circumscribed world do not get to define themselves. The leadership defines who the "real" people are and what they want. Dissent turns into disloyalty and betrayal.<sup>4</sup>

The United States has opened the door to populism in two ways. First, for many years, few in power have adequately heard or responded to the legitimate concerns of those left behind by growing income inequality, technological change, and the transition from an economy grounded in industrial systems of mass production to one grounded in specialized production and information-based services. This is a problem of justice.

Second, opportunities for democratic deliberation and informed civic learning have declined and been replaced by highly partisan and polarized forums where little, if any, informed and mutually respectful discussion can occur. This is coupled by a gradual and general decline in active community involvement in private life and the increase in time spent in solitary activities or in virtual communities. This is a problem of civic learning and citizenship.

Thus, while the United States has relatively open and fair elections, our nation has allowed the communal and civic foundations upon which constitutional democracy rests to atrophy. This diminishes our capacity to develop a practical consensus on how best to redress the growing economic, social, and health disparities and injustices we face. Failure to do so fosters support for the simplistic and authoritarian promises of populism. Well-reasoned and informed civic discourse about common values and problems, like justice, equality, full membership and respect, have been lost in rhetorical white noise. More opportunities for ordinary citizens to engage in respectful listening, mutual exchange, and compromise should be created—for these are the conditions needed for building a practical pathway to solving problems of injustice together.

### Why and How Should Bioethics Respond?

Our thesis is that the field of bioethics has a significant contribution to make by explaining and addressing both the problems of inadequate attention to justice and inadequate civic learning and deliberation. Why should we, as bioethicists, go about doing this, and how?

First, it is important to recognize that the values and norms of discourse basic to bioethics are similar if not identical to those of constitutional democracy. Although bioethics is often known for its scholarly analyses and recommendations regarding specific policy issues in health care, life sciences research, and biotechnologies, in fact, from its inception, bioethics has been concerned with the age-old communitarian

question, how should we live together?<sup>5</sup> Bioethics has often contributed to political philosophy and political culture by exploring essential democratic values such as liberty, equality, justice, pluralistic solidarity, and parity of voice and participation. In doing so, it has in turn drawn upon the political and moral traditions and culture of constitutional democracy. If the environment of free and open normative discussion and debate became constricted, our field would be intellectually and morally hobbled. The historical record suggests that the ethos of authoritarian populism depends on exactly this sort of constriction.

For its part, constitutional democracy relies on social norms, professional practices, and governing institutions, each of which is guided by and made legitimate by appeal to those same democratic values and by service to the protection, dignity, and flourishing of individuals and groups. Over time, constitutional democracy cannot take these values for granted; they must be rearticulated and reaffirmed by many discursive fields, including bioethics.

Too often, these values remain invisible, with policy-makers presenting only a superficial gloss on the values or merely providing data about why one policy may be more effective than another. They fail to recognize that below the policy disputes are morally salient reasons people might have for diverging views. Bringing these values to the fore could help all parties see that they have legitimate moral concerns. And without this deeper understanding, it is easier for policies to be cynically attacked or criticized on purely ideological grounds. Framing policy issues in ways that mask basic fundamental ethical or philosophical considerations promotes the setting of divisive agendas and thereby misses an opportunity for both the political left and the right to engage with these values more thoughtfully.

For example, in *National Federation of Independent Business v. Sebelius* (2012), the U.S. Supreme Court's analysis of the insurance mandate within the Affordable Care Act revolved around whether health care is or is not interstate commerce. In question was the constitutional authority of the federal government, which more clearly had the authority to tax than to regulate the way states handle access to health insurance.<sup>6</sup> However, framing this as a narrow question about federalism and interstate commerce obscured the reality that there is legitimate philosophical disagreement across the political spectrum, from libertarian to progressive, about personal versus social responsibility, solidarity, and what fairness requires in the pooling and sharing of risk through insurance. In this instance, perhaps bioethics could have done more to foster a richer and deeper discussion and even offered a bridge between political viewpoints. Talking about the deeper underlying values would not have erased the differences among people in this country—it would probably have accentuated them—but simultaneously, the conversations would have demonstrated that both sides have underlying moral concerns worthy of mutual respect and consideration.<sup>7</sup> To play this role, bioethics needs to take its rigorous scholarly analyses

## *Bioethics needs to place more scholarly attention on the common good, with greater emphasis on interdependence and the justice concerns that have fueled today's populism.*

into the public square in ways that will be accessible to lay audiences—something that is done far too infrequently.

Finally, bioethics depends on the effective ongoing functioning of constitutional democracy. Bioethics will not be able to do its work if constitutional democracy erodes into authoritarian populism. There would be no protection for fair-minded, independent, and inclusive discussion of community goals and policy options. Further, an important part of the unfolding populist movement is a growing disregard for facts and an extreme form of epistemological relativism, promoting the falsehood that truth resides only in the eye of the beholder or is fabricated by those who control mass communications. If good bioethics depends on good facts, bioethics and the public's ability to weigh in on bioethical issues are deeply compromised.

These are three reasons that bioethics should respond to authoritarian populism, but *how* should those of us who make up the field do so? In our view, bioethics needs to place more scholarly attention on the common good, with greater emphasis on interdependence and the justice concerns that have fueled today's populism. In addition, bioethics should take those scholarly analyses into the public square far more vigorously, so that the field does not become its own academic echo chamber. Working with many others, bioethics should be a critically constructive voice within our constitutional democracy. We should not only bring our analyses of controversial issues to the public, but we should also work with others to create more motivation to participate in civic life, greater access to trustworthy information, and more opportunities for authentic deliberation at community, regional, national, and cyber levels.

### **Working for the Common Good**

*Through a more relational view of autonomy.* During the past half century, bioethics has worked effectively to advance respect for persons and autonomy, which it has generally construed as negative liberty—the right to be *free from* obstacles and constraints and to make one's own personal choices. Often, discussions of autonomy have been narrowed down to freedom from outside interference in personal choices. To be sure, choice is a deeply held American value, reflecting the nation's commitments to liberty and individualism. Maximizing choice is often a very good thing because it allows people the opportunity for broader self-expression and the realization of personal goals and preferences. However, respecting individual choice and protecting an individual

from interference by others should not be understood to require isolating or insulating an individual from a web of just social relationships and ties.

For instance, to be truly self-determining, people need to live within strong communities where they have opportunities for loving relationships, education, safe spaces for exercise and leisure, healthy food, and health care services. Bioethics can articulate the ways in which independence relies on interdependence. This can counteract the conflict, resentment, and fear of increasing diversity that populism exploits. A rediscovery of moral mutuality and solidarity is urgently needed right now.

To be sure, bioethics has given considerable attention to these issues. Thoughtful commentators have underscored not only the importance of negative liberty but also positive and relational liberty—the right to be *free to* have options and to realize individual freedom through mutually supportive and respectful relations with others—to be empowered and enabled through the human capabilities realized through education, health, and diverse cooperative and relational supports and activities.<sup>8</sup> The field of bioethics should undertake more scholarship and more writing for the public to build a moral vocabulary that focuses on the interdependence required for healthy human development.

*Through a greater focus on justice.* While the grievances and concerns of contemporary populist citizens are susceptible to manipulation and demagoguery, those grievances are not imaginary. Political elites of both major parties in our constitutional democracy have been either indifferent or tone deaf to those whose lives and communities have declined in the past several decades. Professional elites and policy-makers in health care have done little better. Persistent racial and class disparities are well documented, but health policy has been halting in its attempts to improve access to and the efficiency of the health care system. Bioethics needs to move beyond its traditional conversations about liberty and equality to produce scholarship and policy analysis that jump-starts new discussions about the problem of injustice.

In dealing with justice, one needs to understand it as both a distributional issue and a “structural” issue. Distribution or fairness issues involve a pattern of who gets what, when, where, how, and how much. Structural justice recognizes that distributional procedures and outcomes are shaped by an underlying system of power that is institutionalized. That system of power sets the parameters that allow certain patterns of distribution to be possible while ruling out other logically possible patterns. The move from constitutional democracy

to an authoritarian populist regime would transform the underlying structural conditions of justice. This is evident, for example, in the emphasis that populist leaders are now placing on immigration and border-control policy.

Bioethics needs to be prepared to grapple with the issue of justice at both the distributional level, as it has for decades, and at the structural level, which it has done far less. In the future, public policy inquiry will require this. Assumptions about choice and decision that have often been taken for granted in the bioethics literature and in policy debates are belied by structural injustice, violence, racism, and discrimination. Ethical analyses and criticism of these phenomena are regularly absent altogether from policy debates because both political discourse and academic bioethics tend to think individualistically rather than institutionally.<sup>9</sup>

Public health is one area where bioethics has been focusing on justice and should do more. For example, bioethics has begun to address the social determinants of health and the interconnection between social conditions that promote healthy behaviors and human flourishing and those, such as excessive levels of inequality, that undermine them.<sup>10</sup> The more bioethics engages with the social determinants of health, including the problem of climate change, the more that large justice questions related to poverty, racism, and violence will come to the fore.<sup>11</sup>

A very different example in which justice issues are important comes with the emergence of new technologies like the gene editing tool known as CRISPR/Cas9 and enormous advances in artificial intelligence. These technologies offer the power to change the very nature of the human species and the natural and social worlds people inhabit. If people do not work together to ensure that all sectors of society have fair access to the benefits these technologies bring, the disparities that have fueled populism will only grow. But fair access to benefits is but half the equation. Our nation should also consider those who will be most negatively affected by the introduction of these technologies. Bioethics can and should debate the merits of compassionate and just social responses, like income subsidies to offset the economic disruptions caused by automation.

Is expanding the scope of the ways in which bioethics addresses justice asking too much of our field? We do not think so, for bioethics is a genuinely interdisciplinary field, and its collective experience in the study of health and biomedical research and technology places it at the epicenter of such questions anyway. As bioethics has achieved academic acceptance, it has narrowed or pulled back on its interdisciplinary potentials. It can no longer afford that luxury. Our field's biggest challenge will be to get outside its silo and connect ethical and social issues in health care with parallel (or identical) issues in other domains—such as social service and environmental sustainability. For example, creating a continuum of medical and social services is key to caring for an aging population, and it has been shown to have systemic health effects as well.<sup>12</sup> Similarly, the connection between human health and broader environmental and ecological issues is rightly

gaining careful attention in public health and should do so in bioethics as well.<sup>13</sup>

*Through democratic deliberation and civic learning.* Robust democracies involve more than voter choice in elections. Constitutional democracy demands an active, engaged mode of civic learning and democratic deliberation in which citizens are exposed to trustworthy information and come together to discuss and make decisions.<sup>14</sup> Civic learning and deliberation create the opportunities for citizens to discuss the problems of injustice and other morally salient issues.

Democracy is more than a collection of political institutions. It is also expressed and fortified—or diminished—in educational institutions, books and periodicals, grassroots activities of all kinds, entertainment and the news media, and increasingly today in social media.<sup>15</sup> These modes of civic learning must themselves value truth, remain open to real debate, and frame their inquiries in good faith. In short, they need to value and cultivate civic capacities for truly informed discussion, trust among the parties, and mutual dialogue in genuine pursuit of solving common problems.

There are many challenges to establishing robust civic learning; two are especially important. The first is the problem of motivating participation in civic deliberation. The second is the challenge of creating and receiving trustworthy information.

Increasingly, the United States' cultural narrative has demeaned government as a paternalistic and overbearing “nanny state” or as wasteful and inefficient, and it has construed citizens as mere clients or consumers. This is a phenomenon sometimes described as “civic privatism.”<sup>16</sup> Behind fake news, lack of transparency, and the generation of conflict seemingly for its own sake, there is an increasing cultural denigration of public service and governmental function.<sup>17</sup>

An example of the ethos of civic privatism at work is the movement to privatize public functions and services, promising greater efficiency, better quality, taxpayer savings, and choice—promises often broken in practice after the profits have been taken.<sup>18</sup> Bioethics routinely encounters issues in which private consumer interests should not necessarily trump the public interest or the common good. The field can promote civic learning by giving careful consideration to the responsibilities of democratic citizenship and the significance of public service—at all levels of government.

Civic learning is necessary for the protection and maintenance of those rights, institutions, and activities that unite the political community and justly benefit all. However, citizens gain the motivation to participate in civic life only when they recognize their interdependence and feel that they share a common purpose—namely, the creation of an inclusive community capable of solving problems with all parties' interests in mind. This kind of commitment to collective problem solving is a crucial means of blocking the ascendancy of authoritarianism. In pluralistic societies, different ethnic groups need to be able to recognize the value of sharing a common purpose. Without such an overriding sense of common purpose and commitment to actively achieving it in partnership

with others, pluralistic societies devolve into self-interested tribes jockeying for power.<sup>19</sup>

Civic learning cannot occur in the absence of trustworthy information about social and economic conditions or without realistic policy options. The constitutional rights of freedom of speech, assembly, and the press are integral to constitutional democracy, and they are often the first targets of an authoritarian turn in a political culture. The news media are key to holding institutions, corporations, and government accountable and to fostering civic learning. But journalism is not only under siege by populist leaders. It is also weakened by its own corporatization, the lack of a business model to support its independence, and by the Internet, where people are increasingly receiving only news and information that align with their preconceived beliefs and attitudes. Given the reality of fake news sites, the lack of substantive debate, the framing of most policy questions in “win or lose” terms, the echo chambers on the Internet, the erosion of public schools, and the economic threats to institutional and individual integrity, it is an understatement to say that we now face a crisis in how the public learns.

The complexity and fluidity in how information is conveyed and processed today calls for adaptation to the new technological reality and to the political as well as the cultural influences of social media and the Internet. Democratic citizens must try to curb and offset the most disruptive and irrational effects of today’s political information environment.

For example, top-down journalism, while critical, is not sufficient for civic learning and for the sustainability of constitutional democracy. It must be complemented by the testing and corrective influence of community-based dialogue and debate among diverse perspectives and life experiences. Most political information requires interpretation. Deliberative and participatory forums at the community level are essential settings in which conflicting interpretations encounter one another and are corrected and revised.<sup>20</sup> Similarly, the social and political interpretations and judgments of political and intellectual elites interact with community-based perspectives in a civic learning process that greatly benefits from that up and down exchange and informational checks and balances. We must develop new forms of information sharing that are trustworthy and broadly available. Moreover, we must work to restore the public’s willingness to trust information that is in fact trustworthy.

### The Task Ahead

We must come to the aid of civil liberties and political rights—the rights to vote, assemble, and engage in free speech—when they are threatened. Bioethics should be part of their defense. There is also a need to ensure the integrity of our government agencies, by holding them accountable for acting for the public good, and of our nongovernmental organizations, by ensuring that their public-interest missions are not undermined by government intrusion. Further, bioethicists should be alert to the ways in which professional

elites, especially medical professionals, have in the past been co-opted for state purposes. Academic medicine and practicing health care professionals played key roles in the early twentieth-century eugenics movement,<sup>21</sup> assisted the U.S. government with human radiation experiments during the Cold War,<sup>22</sup> and most recently were involved in the support of torture.<sup>23</sup> Bioethicists are now ourselves just such a professional elite, so it behooves us to consider how we could be co-opted and to call out instances where medical professionals may be asked to approve or implement state policies counter to their professional obligations.

At the same time, bioethics’ scholarship should offer concepts and arguments that clarify how profoundly and inextricably individual well-being is bound up with justice. The usual contrasts drawn between liberty and justice, which are often seen as principles needing to be either balanced or prioritized, do not hold up. Rather, attention to justice *enhances* individual liberty by creating the conditions necessary for its responsible and successful pursuit. Bioethics can clarify this relationship.

Yet intellectual clarity is only one aspect of the work before us. The public needs to participate in the development of these ideas and have trustworthy avenues of exposure to them and engagement with them. Civic learning, where impartial facts and diverse values and ideas are available, is crucial to collective problem solving and informed democratic participation. We need to build opportunities for civic learning through innovation at city, county and regional levels and on the Internet, even if civic learning has temporarily ceased to be a priority for the federal government. Bioethics can help introduce clarity about the underlying values at stake in policy disputes and work to build respect for our fragile, shared experiment in constitutional democracy.

No one can say for certain where our society is headed, nor what the best responses should be from those of us within bioethics. In offering these suggestions, we are sure of only one thing. Bioethics needs to have this conversation.

1. See H. C. Boyte, “Civic Populism,” *Perspectives on Politics* 1, no. 4 (2003): 737-42; H. C. Boyte and F. Riessman, eds., *The New Populism: The Politics of Empowerment* (Philadelphia, PA: Temple University Press, 1986); L. Goodwyn, *Democratic Promise: The Populist Movement in America* (New York: Oxford University Press, 1976).

2. F. Zakaria, “The Rise of Illiberal Democracy,” *Foreign Affairs* 76, no. 6 (1997): 22-43.

3. D. Runciman, “Is This How Democracy Ends?,” *London Review of Books* 38, 23 (2016): 5-6.

4. J.-W. Müller, “Capitalism in One Family,” *London Review of Books* 38, no. 23 (2016): 10-14.

5. On the formative role of this question in bioethics, see D. Callahan, *In Search of the Good: A Life in Bioethics* (Cambridge, MA: MIT Press, 2012).

6. G. H. Reynolds and B. P. Denning, “National Federation of Independent Business v. Sebelius: Five Takes,” *Hastings Constitutional Law Quarterly* 40, no. 4 (2013): 807-32.

7. For an example of how bioethical analysis can illuminate the underlying values shared by libertarians and progressives, see M. Powers and R. Faden, “Racial and Ethnic Disparities in Healthcare: An Ethical Analysis of When and How They Matter,” in *Unequal Treatment:*

*Confronting Racial and Ethnic Disparities in Health Care* (Washington, D.C.: National Academies Press, 2003), 722-38.

8. See J. Nedelsky, *Law's Relations: A Relational Theory of Self, Autonomy, and Law* (New York: Oxford University Press, 2011); C. Mackenzie and N. Stoljar, eds., *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (New York: Oxford University Press, 2000); and M. C. Nussbaum, *Creating Capabilities: The Human Development Approach* (Cambridge, MA: Harvard University Press, 2011).

9. See I. M. Young, *Responsibility for Justice* (New York: Oxford University Press, 2011).

10. An early call for this came in D. Callahan and B. Jennings, "Ethics and Public Health: Forging a Strong Relationship," *American Journal of Public Health* 92, no. 2 (2002): 169-76.

11. M. Danis, Y. Wilson, and A. White, "Bioethicists Can and Should Contribute to Addressing Racism," *American Journal of Bioethics* 16, no. 4 (2016): 3-12.

12. See E. H. Bradley and L. A. Taylor, *The American Health Care Paradox: Why Spending More Is Getting Us Less* (New York: Public Affairs, 2013); J. Lynn, *Medicaring Communities: Getting What We Need in Frail Old Age at an Affordable Price* (Washington, D.C.: Altarum Institute, 2016).

13. See H. Frumkin and A. J. McMichael, "Climate Change and Public Health: Thinking, Communicating, Acting," *American Journal of Preventive Medicine* 35, no. 5 (2008) 403-410; B. Jennings, "Putting the Bios Back into Bioethics: Prospects for Health and Climate Justice," in *Climate Change and Health: Bioethical Insights into Values and Policy*, ed. C. C. Macpherson (New York: Springer Press, 2016), 11-37; A. Kessel and C. Stephens, "Environment, Ethics, and Public Health," in *Public Health Ethics: Key Concepts and Issues in Policy and Practice*, ed.

A. Dawon (Cambridge: Cambridge University Press, 2011), 154-73; T. Lang and G. Rayner, "Ecological Public Health: The 21st Century's Big Idea?" *BMJ* 345 (2012): e5466, doi: 10.1136/bmj.e5466; K. Shrader-Frechette, *Environmental Justice: Creating Equality, Reclaiming Democracy* (New York: Oxford University Press, 2005).

14. A. Gutmann and D. F. Thompson, *Democracy and Disagreement* (Cambridge, MA: Harvard University Press, 1996).

15. J. Dewey, *Democracy and Education: An Introduction to the Philosophy of Education* (New York: The Free Press, 1944 [1916]).

16. Jürgen Habermas calls this "civil" privatism, but the idea is the same; J. Habermas *Legitimation Crisis* (Boston: Beacon Press, 1975), 75-92.

17. On the loss of a culture of public and civil service, see T. Judt, *Ill Fares the Land* (New York: Penguin, 2010).

18. S. Kahn and E. Minnich, *The Fox in the Henhouse: How Privatization Threatens Democracy* (San Francisco: Berrett-Koehler, 2005).

19. C. Taylor, *Multiculturalism: Examining the Politics of Recognition* (Princeton, NJ: Princeton University Press, 1994).

20. C. Sirianni and L. Friedland, *Civic Innovation in America: Community Empowerment, Public Policy, and the Movement for Civic Renewal* (Berkeley, CA: University of California Press, 2001).

21. P. Lombardo, *Three Generations, No Imbeciles: Eugenics, the Supreme Court and Buck v. Bell* (Baltimore, MD: Johns Hopkins University Press, 2010).

22. United States Advisory Committee on Human Radiation Experiments, *Advisory Committee on Human Radiation Experiments Final Report* (Washington, D.C.: Joseph Henry Press, 1995).

23. S. H. Miles, *Oath Betrayed: Torture, Medical Complicity and the War on Terror* (New York: Random House, 2006).

# Reprioritizing Research Activity for the Post-Antibiotic Era: *Ethical, Legal, and Social Considerations*

BY SPENCER PHILLIPS HEY AND AARON S. KESSELHEIM

Many commentators have emphasized the looming threat of the "post-antibiotic era."<sup>1</sup> According to this view, the so-called golden era of antibiotic discovery has passed, leaving only a limited clinical pipeline for new antibiotics.<sup>2</sup> A logical conclusion of such arguments is that we need to reform the current system of antibiotic drug research—including clinical trials and regulatory requirements—to spur activity in discovery and development.<sup>3</sup>

The United States Congress in the past few years has debated a number of bills to address this crisis. In 2012, the

Generating Antibiotic Incentives Now (GAIN) Act mandated expedited regulatory review times for all new antibiotics and extended their guaranteed minimum exclusivity period from five to ten years. In 2016, the 21st Century Cures Act created a pathway for approval of new antibiotics based on laboratory data or preliminary, uncontrolled clinical studies in small numbers of patients.

Experts have also sought to advance antibiotic development by encouraging greater use of trials with noninferiority hypotheses. Noninferiority trials are thought to be easier to conduct because they involve comparing new antibiotics with available therapies in populations of patients with treatable disease, rather than focusing on patients with resistant

Spencer Phillips Hey and Aaron S. Kesselheim, "Reprioritizing Research Activity for the Post-Antibiotic Era: Ethical, Legal, and Social Considerations," *Hastings Center Report* 47, no. 2 (2017): 16-20. DOI: 10.1002/hast.685