

Federalism & Bioethics

States and Moral Pluralism

by JAMES W. FOSSETT, ALICIA R. OUELLETTE, SEAN PHILPOTT, DAVID MAGNUS, AND GLENN MCGEE

Bioethicists are often interested mostly in national standards and institutions, but state governments have historically overseen a wide range of bioethical issues and share responsibility with the federal government for still others. States ought to have an important role. By allowing for multiple outcomes, the American federal system allows a better fit between public opinion and public policies.

The latent causes of faction are thus sown in the nature of man. . . . A zeal for different opinions concerning religion, concerning government, and many other points, as well of speculation as of practice; an attachment to different leaders ambitiously contending for pre-eminence and power . . . have, in turn, divided mankind into parties, inflamed them with mutual animosity, and rendered them much more disposed to vex and oppress each other than to co-operate for their common good. . . . [T]he CAUSES of faction cannot be removed, and . . . relief is only to be sought in the means of controlling its EFFECTS.

—*Federalist*, No. 10

Bioethicists can be fairly accused of wanting to solve complex problems with single standards and national institutions. Both liberal and conservative bioethicists have pressed for national standards administered by federal agencies across a wide variety of issues, ranging from research ethics and assisted reproduction to the governance and financing of stem cell research. Despite this national focus, states have been and will continue to be principal players in bioethical decision-making. By contrast with other disciplines, bioethics has paid little systematic attention to the division of labor between state and federal governments. As a consequence, it has not adequately understood how federalism affects the development of policy and the rights of individuals.

The premise of this paper is that bioethicists' neglect of federalism is a mistake on two levels: it gets the facts

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wrong, and it downplays the important benefits of the division of power between the states and the federal government. Rather than being peripheral actors, state legislatures and courts have been and continue to be major participants in the establishment and implementation of bioethics policy. Moreover, state activism in bioethics is not a bad thing. A federalist system—a system that distinguishes between the limited but supreme powers of a central government on the one hand and the broad sovereign powers of each of the states on the other—offers considerable advantages in managing the political conflicts that inevitably arise from moral pluralism, particularly around questions where there is no clear national consensus. Attention to federalism is especially critical now, given the many current and emerging issues that either touch areas where states are already major actors or seem likely to produce the divided views among both policy-makers and the public that have driven recent state activism.

This paper develops these arguments in five parts. First it examines the current state of federalism in bioethical discussions. The second part then documents the states' current role as major actors across a wide range of bioethical issues and notes several factors that enhance state influence. The third presents the normative case for a larger state role in bioethical decision-making. Fourth, we offer two case studies that illustrate the empirical and normative features of the federal system in making decisions about bioethical issues. And finally, we consider the questions that need to be addressed in a "federalist" approach to bioethics in which both state and federal governments are recognized as important actors.

Federalism and Bioethics: Pluralism without Representation

The notion that questions of federalism have not received ade-

quate attention in bioethical discussion should not be controversial. Bioethicists have had notably more to say about what happens in Washington than about events in state capitals. There is, for example, a large literature on presidential bioethics commissions and the role of bioethicists in national public debates,¹ while little has been written about the equally numerous state and local bioethics commissions.² Although bioethicists have examined important decisions by individual states—such as the experiments with physician-assisted suicide and health care rationing in Oregon, medical marijuana in California, health care reform in Massachusetts, and the futility law in Texas—their discussions of such bioethical issues as abortion or emergency contraception

seem to value national uniformity and consistency in regulation—the major context for noting disparities between states is to decry them as evidence of a "patchwork" or inconsistent framework. A recent article on assisted reproduction, for example, listed a dozen articles advocating an American version of the British Human Fertilization and Embryology Authority, with only one favoring a more decentralized structure.⁴ Similar disparities could likely be produced for arguments about embryonic stem cell research, emergency contraception, HPV vaccines, and a variety of other bioethical issues.⁵ In spite of the significant amounts of money states are spending on embryonic stem cell research, for example, bioethicists and advocates continue to

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have focused largely on national institutions like the Supreme Court or the Federal Drug Administration and have neglected state actions that significantly affect women's access to abortions or Plan B.³ There are large bodies of literature in political science, public economics, law, and other social sciences that document the cultural, religious, and political diversity of the American states and examine the consequences of this diversity for a variety of major policy areas—welfare, health care, environmental protection, and even "values" issues—but bioethicists have not devoted much attention to these findings or examined the consequences of federalism for the bioethical regimes under which citizens in different states live.

There also appears to be a strong *preference* for national solutions to bioethical issues. Most bioethicists

press for expanded funding from the National Institutes of Health for this research, complaining about the "patchwork and haphazard" approach that state funding allegedly entails.⁶ Again, there are ongoing debates in other disciplines about the standards that should govern the division of labor between national and subnational governments and the conditions under which these standards should be applied. Economists, for example, have debated the welfare gains of decentralized public spending decisions compared to the provision of a uniform level of public spending nationwide, and political scientists and economists have examined the effects of "competition" between local jurisdictions for jobs, companies, and upper income taxpayers.⁷ Debates over the appropriate roles of federal and state governments are common in legal scholarship and

in scholarly discussions of welfare, health care, environmental protection, and a variety of other policy areas.⁸

Such debates are largely absent from the bioethics literature. While individual bioethicists have written about federalism in the context of particular issues, little systematic attention has been given to the variety of bioethical regimens currently in place across the states, the extent to which this variation in outcomes is tolerable or even preferable to more uniform national standards, or the manner in which the federalist system decides and implements bioethical policy.⁹

The States and Bioethics: Principal Players and Perpetual Partners

State involvement in bioethics is not new. While the last half-century saw the federal government become involved in regulating everything from health care finance to Terri Schiavo's death, the states' primary role in formulating "health laws of every description" has remained steady since 1905, when the Supreme Court upheld a compulsory vaccination law in Massachusetts.¹⁰ We predict that the states will continue their important role in bioethics and will in fact become preeminent over the next decade as a result of recent Supreme Court decisions that curb the power of the federal government, a shift in funding for scientific research from the federal government to private and state sources, and the political gridlock created by a divided national electorate.

The source of the states' role in the regulation of health care is what is commonly called the police power, a term frequently employed in constitutional jurisprudence to describe governmental duties that are best exercised locally. The regulation of the health and safety of the citizenry is the classic example of a state police power. States have used the police power to regulate everything from

newborn screening to physician licensure to living wills. The state's police power is not unbridled, however. Even in its ruling upholding the Massachusetts vaccination law, for example, the Supreme Court explained, "the mode or manner in which those results are to be accomplished is within the discretion of the State, *subject, of course, so far as Federal power is concerned, only to the condition that no rule prescribed by a State . . . shall contravene the Constitution of the United States or infringe any right granted or secured by that instrument.*"¹¹ Later cases confirm that a state cannot pass laws that conflict with federal laws.

In the 1930s, the federal government's power to directly regulate matters concerning health and safety expanded dramatically. During this era, the Supreme Court decided a series of cases involving challenges to New Deal legislation. The decisions allowed the federal government to regulate anything that touched on interstate commerce, and the Court's definition of interstate commerce was so broad as to give Congress virtually limitless power. The Court also approved the federal government's use of its spending power to coerce state action in areas that had previously been entirely within the control of the states. The spending power allows the federal government to make the receipt of federal dollars by the states contingent on particular state action. Congress used its commerce and spending powers to enact previously unimaginable federal programs like Medicaid and Medicare, which placed the federal government in the health care business for the first time. The federal government's expanded interest in regulating health-related matters also gave rise to the Food and Drug Administration, the Centers for Disease Control and Prevention, and eventually the President's Council on Bioethics. In recent years the federal government has passed laws and issued orders that directly regulate the types of services health care providers can perform and the types of scientific inquiry that may be federally fund-

ed. For example, federal law prohibits so-called partial birth abortion and the creation of cloned human embryos for research.

Even in the height of federal regulation of health-related matters, however, the primary locus of regulation (and concomitant bioethical issues) remained in the states. The most famous and frequently cited bioethics cases—*Cruzan*, *Glucksberg*, and *Quill*—are ones that involve state laws. Others come from state courts. The most oft-quoted passage involving the right to refuse medical treatment, for example, comes from the New York Court of Appeals case *Schloendorff v. New York Hospital*, in which the court said, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."¹² The New Jersey Supreme Court decided *Quinlan*; the Massachusetts Supreme Judicial Court decided *Saikewitz*; and California courts decided *Bowvia*, *Moore*, and *Tarasoff*. Even the disastrous Schiavo case ultimately was decided as a matter of Florida state law, despite misguided federal intervention.

To be sure, the federal judiciary has played a critical role in ensuring that states do not trample individual liberties in their efforts to protect the public good. Most famously, of course, the Court has condemned state laws that ban or restrict access to contraception and abortion. The Court has also ruled unconstitutional state laws that allowed compulsory medical treatment of inmates, involuntary sterilization, and involuntary confinement of the mentally ill. In all of these cases, the laws at issue are state laws, passed by state legislatures. While the federal judiciary plays an essential role as supervisor of the states in the federalist system, it is the state legislatures—not the federal one—that have acted to resolve bioethical issues in the first place.

The states will probably become even more important in resolving bioethical issues over the next decade. One factor behind this trend is the

“new federalism” adopted by the current Supreme Court. The Supreme Court is no longer willing to accept tenuous connections to commerce to justify federal intervention in matters that are traditionally of local or state concern. To date, the Supreme Court has not applied broad limitations on Congress’s power in bioethics cases, and the way in which the new federalism will apply to federal statutes or regulations that raise bioethical issues is not yet clear. The two relevant cases decided by the current Supreme Court offer little guidance. *Oregon v. Gonzalez*, in which the Supreme Court held that the federal official trying to interfere with a state’s exercise of its police power had overstepped his authority, was decided based on a narrow interpretation of a federal statute that is unlikely to affect the federalism debate more broadly. In *Gonzales v. Raich*, the Court rejected a commerce clause challenge to the federal government’s interference with California’s medical marijuana laws, but did so based on the obvious connection between the distribution of drugs and interstate commerce. The reasoning in *Raich* seems unlikely to apply to federal attempts to limit state control in areas with more attenuated connections to commerce, such as interactions between physicians and patients in the abortion or end of life context.

A second reason the states will continue to take an increasingly visible role in resolving bioethical issues is political. Some issues are simply too contentious to be resolved by federally elected lawmakers, given the sharply divided electorate. It is unlikely, for example, that Congress will reach any resolution about the moral status of an embryo. Regulation of sensitive policy matters concerning artificial reproductive technology is virtually nonexistent at a federal level. The Clinton administration failed in its effort to reform the health care financing system on a national scale. Likewise, efforts to pass national standards governing end of life issues have gone nowhere. The inability of the

federal government to resolve these contentious issues leaves states to fill the voids. So, for example, Louisiana prohibits the destruction of human embryos, Massachusetts has passed innovative health reform laws, and Oregon legalized physician-assisted suicide. None of these innovations seems politically feasible at a federal level.

When the current administration has managed to take action on bioethical issues, its inclination to limit central government involvement has created even more opportunity and motivation for state action. The federal regulation of embryonic stem cell research is the most vivid example. The limitation on federal or federally funded research beyond the small number of lines existing before 2001 has led both supporters and detractors

than from design, but it has significant advantages over unitary systems that promulgate a single national standard. States are not federal branch offices, but rather separately elected governments with their own revenue sources, court systems, written constitutions, and traditions of judicial interpretation of these constitutions. Unlike classic federal systems, where the division of labor between federal and provincial governments is clear and well defined,¹³ intergovernmental responsibilities and authorities in the American system are complex, fragmented, overlapping, malleable, and ambiguous.

This complex and decentralized system of shared and overlapping responsibilities, independent revenue sources, and multiple constitutional authorities has several advantages in

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of embryonic stem cell research to seek favorable state legislation on the allowable scope of such research. It has also encouraged disease advocates and researchers to seek less restrictive funding from state and private sources.

As state involvement in bioethics continues to grow over the next decade, it makes sense to ask how responsibility for regulating particular issues is or should be divided between levels of government. The answer to whether a particular issue is better resolved at the state level or at the federal level remains a policy-based or political one.

The Case for States as Bioethical Actors

The current American system for resolving bioethical disputes may result more from historical accident

dealing with complex bioethical issues over simpler national structures that establish and implement single nationwide standards. We focus here on three: recognition of moral pluralism, increased access to decision-makers, and the ability to experiment when designing and implementing programs.

First, a federalist system is better than a national structure at managing conflicts arising from moral pluralism. Absent a national consensus on how to deal with complex and controversial bioethical issues, a single national structure may be unable to take action at all, given the intense political cross-pressures bearing on it. Both the advocates and the detractors of embryonic stem cell research, for example, have been frustrated by the lack of apparent consensus on how to proceed with such research. As a result, neither group has been able to as-

semble a stable majority coalition in Congress.¹⁴

By allowing for multiple outcomes, the federal system permits local majorities to form even when national ones are elusive, allowing for a better fit between public preferences and public policies than a single national standard. Individual states are not demographically, culturally, economically, or politically identical to the country as a whole. Rather, states were and continue to be settled by different ethnic and cultural groups with widely different religious and cultural traditions. As a result, ethnic, religious, and cultural groups are not evenly distributed geographically across the country. Instead, they are concentrated to a greater or lesser extent in particular states.¹⁵ Similarly, state economies are not replicas of the national economy. Some states are significantly wealthier than others, and industries are frequently concentrated in a small number of states. For example, the “biotech” industries, which have a direct economic stake in the outcome of many bioethical disputes, are concentrated in a small number of states on both coasts.¹⁶ These differences among states in religion, culture, ethnicity, wealth, and economies, and in the political interests to which these differences give rise, are associated with differences in political ideology and values across the states.

Not surprisingly, these differences in popular ideology and political values are associated with differences in state spending and other policies. It is important in a democracy that public policies at least partially reflect popular values and public opinion. A decentralized system of public decision-making is more responsive to a broader range of public opinion than a centralized system, which is likely to produce uniform policies that do not reflect local differences. Oates summarizes the findings of many economists on this question:

[I]ndividual local governments are presumably much closer to the

people and geography of their respective jurisdictions; they possess knowledge of both local preferences and cost conditions that a central agency is unlikely to have. And, second, there are typically political pressures (or perhaps even constitutional constraints) that limit the capacity of central governments to provide higher levels of public services in some jurisdictions than others. These constraints tend to require a certain degree of uniformity in central directives. There are thus important informational and political constraints that are likely to prevent central programs from generating an optimal pattern of local outputs.¹⁷

In fact, there is a broad consensus among students of state politics that local public opinion and institutions are significant determinants of state spending and other policies, meaning that policy differences between states are, in part, the result of differences in public opinion.¹⁸ While there is lively debate about the most appropriate way to measure state public opinion and the precise mechanisms through which public opinion influences state policy, it seems clear that differences in state governments’ spending and policy decisions reflect, to a considerable extent, differences in the wishes of their public and organizational constituents.

Given the broad range of political views across states, differences in spending and other policies are substantial. The top spending state, for example, spent 60 percent more per person than the lowest spending state in 2003. Disparities in spending in particular program areas such as education or corrections are even larger. Even in federally supported social programs such as Medicaid and Temporary Aid to Needy Families (TANF), there are significant disparities among states. Federal legislation and regulations give states considerable discretion in deciding who is covered for what services and at what

level under Medicaid and TANF, and the ability of federal agencies to waive particular program requirements provides states with further flexibility.¹⁹ Debates over the extent to which states should be permitted to shape programs to accommodate their own particular circumstances and the extent to which they should be held to a national standard have been common in almost every domestic policy area. This question of striking the proper balance between local preferences and minimal national standards has yet to be addressed by bioethicists, in spite of the significant differences in practice that already exist among states.

The point of all this is that states are able to take action on complex and controversial bioethical issues if the federal government is unable to do so. Differences in the configuration of political forces across states mean that individual states may be able to achieve a majority opinion in areas where a national majority has proven elusive. By recognizing differences in policy preferences across states and allowing for multiple outcomes, a federalist system allows local majorities to form and provides for a better “fit” between public opinion and public policy than a single national standard would allow. The resulting pattern of policies or spending is almost certain to be extremely diverse, but such diversity is in some measure a reflection of the underlying diversity of views among the American population. Federalism tolerates great diversity in domestic policy and levels of spending; the question of how much diversity can be tolerated specifically in bioethical matters remains unconflicted and undecided.

A second, related advantage is that federalism provides advocates with multiple forums within which to press their claims. The role of national and state governments in “checking” each other and moderating each other’s policies has been claimed as a major advantage of the federal system since the Federalist Papers. Hamilton’s original justification along these lines is instructive:

Power being almost always the rival of power, the general government will at all times stand ready to check the usurpations of the state governments, and these will have the same disposition towards the general government. The people, by throwing themselves into either scale, will infallibly make it preponderate. If their rights are invaded by either, they can make use of the other as the instrument of redress.²⁰

In today's political context, this means that advocates who lose at one level have alternative forums in which to press their case. "Venue shopping" among federal and state courts to find a favorable setting is a common feature of the American judicial system, and the use of institutions at one level of government to frustrate or overcome unfavorable policies at another level is a longstanding feature of American politics. Advocates of racial segregation, for example, were able to use state-based institutions—constitutions, legislatures, and electoral politics, particularly Senatorial elections—to maintain legalized segregation in the Southern states well into the 1960s, a pattern that was only slowly broken down by federal court decisions and legislation. In the current setting, conservative actors dominate national institutions, yet liberals have been pressing arguments—in many cases successfully—at the state level for changes in minimum wage, environmental protection, gay marriage, lobbying reform, energy policy, and other issues.²¹

Among bioethical issues, embryonic stem cell research provides an excellent example of political venue shopping.²² Frustrated by the inability to secure federal research funding for an expanded set of stem cell lines, researchers and disease advocates have turned to private funding and state governments as an alternative source of research support. State capitals have frequently been more hospitable to stem cell advocates than Washington because of the potential contribu-

tion of stem-cell-related industries to local economic development. A variety of research suggests the importance of economic voting in state elections.²³ Elected officials, particularly governors, see their electoral futures as tied to state economic growth and frequently feel obliged to devise strategies for stimulating investment and employment growth. In many states—even those where stem cell detractors are strong—governors have invested large amounts of political capital in advancing biotechnology as an economic development strategy.²⁴

While not all state strategies include explicit attention to embryonic stem cells, the need for states competing for biotech investment to appear proscience may make it difficult for governors and other state officials to

in others. The availability of alternative funding sources and supportive political settings in many states has mitigated the influence of adverse federal policies and provided stem cell advocates with a means of both keeping their agenda visible to the public and furthering their policy goal of increasing funding to support research.

Finally, an active role for states in developing and implementing bioethical policy provides for experimentation in the design and implementation of complex bioethical decisions. Many bioethical issues are management problems as well as intellectual ones, and we should consider what types of management structure would best serve to perform the complicated tasks suggested by many proposals. An American version of the British

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support anti-stem-cell advocates with whom they might otherwise be sympathetic.²⁵ Claims that states that do not support stem cell research will suffer “brain drain” to other states or will lose jobs and prestige have considerable political appeal in many states. In such states, governors may see considerable political value in supporting stem cell research at some level, even at the risk of offending anti-stem-cell groups. Republican parties in many states are becoming increasingly split between probusiness groups interested in economic growth and Christian conservatives who are opposed to stem cell research on moral grounds.²⁶ These political considerations have made “venue shopping” an effective strategy for stem cell advocates. A number of states have adopted programs of financial support for stem cell research, and similar programs have been proposed

HFEA, for example, would confront enormous logistical tasks ranging from developing systems for licensing providers of assisted reproduction services, establishing information systems to collect, audit, analyze, and disseminate a wide range of data from providers, and developing and managing complex guidelines for service eligibility. While exact numbers are unclear, there are approximately four times as many providers in the United States as in Great Britain, and over forty thousand children are born via in vitro fertilization²⁷ versus roughly ten thousand annually in the United Kingdom, suggesting that the management task for an American HFEA would be significantly larger, and potentially more complex, than that of its British model.²⁸

Moreover, it is far from clear that a centralized, HFEA-type organization is preferable to the more decentralized

ones that typify American domestic programs to manage such a complex and potentially controversial program. Advocates of centralized organizations have claimed that they (1) ensure uniformity in policy and procedure and thus encourage equity, (2) realize any economies of scale that would result from having a single regulatory structure, and (3) provide an efficient means of addressing problems that cross state lines. Absent minimal national standards, competition among states for jobs and investment may lead state governments to sacrifice environmental quality, necessary public spending, or other important goals in order to appear attractive locations for business. It's also easier to find sufficient scientific talent to staff one central agency than fifty smaller ones, so national structures are more likely to make effective use of scarce scientific expertise than a more decentralized structure.

A variety of evidence suggests these claims are overstated. While national standards are certainly appropriate in some cases, interstate competition only sometimes acts to depress program quality or spending and occasionally has the opposite effect. Competition among states for biotech industrial development has led to increased spending on scientific research and other services in order to appear supportive of science. A number of trade associations and publications facilitate this competition by publishing descriptions and rankings of state and university programs that can be used by local advocates to press claims that their state is insufficiently "friendly" to a particular industry and will lose jobs, tax revenue, and prestige if appropriate action—frequently in the form of funding or other support—is not taken.²⁹

Such widely reported and easily understood measures of population health as infant mortality and birth weights can also be used to compare states. Particularly among states that rank near the bottom on such measures, concern over poor state "performance" has been widely publicized,

creating pressure on politicians to respond in some fashion. It has frequently proven politically possible to cast this low standing as an obstacle to economic improvement and to present efforts to address low standing as important to improving a state's reputation as a desirable location for families and companies. For example, southern governors, whose states have among the highest rates of infant mortality and low birth weights in the country, were among the strongest initial supporters of Medicaid eligibility expansions to pregnant women and children during the late 1980s and 1990s.³⁰ Further, there is evidence that states don't need scientific expertise to be locally available. They have managed public health issues like vaccination policy by relying on advice from federal agencies, such as the Centers for Disease Control and Prevention, and on the experience of other states.

More generally, little evidence exists to prove that nationally administered programs uniformly produce better results than the decentralized, jointly managed and financed programs that characterize most American domestic policy. While states unquestionably vary widely in their managerial sophistication and capacity to operate complex domestic undertakings,³¹ programs operated by the federal government are equally diverse in their managerial capabilities. A variety of reports dating back to the early 1990s, for example, have identified significant management problems around the Medicare program.³² Brown and Sparer's comparison between Medicare, which is completely federally administered, and Medicaid, which is largely managed by the states, notes that Medicaid contains a much richer service package, has significantly expanded coverage over the last fifteen years, and has been more successful than Medicare in implementing such reforms as placing beneficiaries into managed care.³³ Nor has Medicare been particularly successful in insuring equal access to care—one of the frequently claimed

benefits of supposedly uniform national standards. An enormous body of literature has documented persistent, significant geographic disparities in access to a wide range of procedures among Medicare patients.³⁴ Equally voluminous research has documented significant and persistent racial and ethnic disparities in access to care among Medicare patients.³⁵ The notion that federal programs are inherently better managed and more effective than intergovernmental ones seems difficult to sustain.

A decentralized program structure, by contrast, provides for more experimentation in program design and management, in accordance with Justice Brandeis's oft-quoted comment that states can function as "laboratories of democracy." There is frequently no clear consensus on the most appropriate way to manage complex programs and little evidence on the likely consequences of alternative strategies. Allowing for variations in program structure and implementation both permits the tailoring of program management to local conditions and allows other states and the federal government to gain valuable information on the most effective means of improving program performance. Numerous domestic programs, ranging from TANF and Medicaid to environmental protection, education, and workforce development, permit the administering federal agencies to grant states waivers of existing program requirements or otherwise to alter program structure and management, frequently in major ways.³⁶ States and federal officials pay close attention to the results of these experiments, which are circulated via publications and conferences sponsored by associations both of elected officials, such as the National Governors' Conference and the National Conference of State Legislatures, and of specialized program administrators, such as the National Association of Medicaid Directors. Program features that seem to "work" are frequently adopted by other states and incorporated into subsequent

federal policies. Many of the features of the TANF program—which replaced the Aid to Families with Dependent Children program (AFDC) as the country’s primary welfare program for low income families in 1996—grew out of earlier waivers of particular AFDC program requirements. These waivers allowed states to experiment with a variety of ways of discouraging welfare dependence and encouraging self-support among low income families.

Federalism Illustrated— Comparative Case Studies

The empirical and normative features of the federalist system of bioethical decision-making currently in place in this country are best illuminated by example. While any number of issues might be selected for such analysis, we have chosen to focus on two: embryonic stem cell research (a case in which states have become increasingly active in an area where the federal government has traditionally been dominant) and emergency contraception (a case in which the roles of federal and state governments have been more traditional). Taken together, these two issues present a tolerably complete picture of the strengths and weaknesses of the American bioethical decision-making system.

Embryonic stem cell research—federalism by accident. Embryonic stem cell research presents a case of “federalism by accident” in which states have become active in an area which has traditionally been a federal function. In the past, public funding of biomedical research has been dominated by the National Institutes of Health, which spends approximately \$25 billion each year to support a wide range of research activities. Patenting and licensing of biomedical discoveries and products is governed by federal law, and NIH funding has become the dominant metric by which medical schools and biological science researchers compare their performance to other institutions. This

dominant funding position has meant that the NIH awards process has been the primary arena for debating and applying rules governing biomedical research ethics.

There is also widespread agreement that research funding is most efficiently performed centrally, at least in the economic sense. Economists have argued that states are likely to underspend on biomedical research because most of the benefit of such research will flow to individuals residing outside their borders. Collaboration between researchers in different states is extremely common, which makes a universal set of rules to govern patenting and licensing, research ethics, and research administration more useful than potentially conflicting rules for each state. Federal funding also offers

the NIH and other federal agencies. One effect has clearly been to increase significantly the total amount of money spent on stem cell research compared to what would likely have been spent if federal restrictions were absent and support for this research had been allocated through the normal federal budget process. Federal support for all forms of stem cell research has averaged \$640 million annually over the last three years, but less than \$40 million annually has supported human embryonic stem cell research.³⁷ Potential state funding for this research, by contrast, could reach over \$500 million annually over the next eight to ten years. The largest portion of state funding has come from California, which has committed approximately \$300 million an-

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a better-coordinated process for setting research priorities and minimizes the chances of duplicate funding for the same research.

Earlier in this article, we described the process by which states became actively involved in large-scale funding of embryonic stem cell research, but the reader should note that state reaction to federal funding limitations has been far from uniform. While some states have developed large programs for funding this research with their own resources, others have imposed restrictions on the use of their own funds or on the type of research that can be performed within their borders—some states even impose criminal penalties.

The effects of this state-centered funding system are complex and somewhat counterintuitive when compared to the usual system of funding scientific research through

annually for the next ten years. Stem cell research has also attracted significant private funding—a total of over \$1.7 billion in recent years. While difficult to count precisely, this combination of state and private support is almost certainly larger than what would have been available through the federal budget process in a less restrictive funding environment.

This pattern of outcomes also illustrates the benefits claimed here for a federalist system of bioethical decision-making. Political venue shopping by stem cell advocates has already been noted. Further, a national majority about the proper direction for embryonic stem cell research policy has, at least to date, proven elusive. Stem cell supporters and detractors alike have been frustrated by the lack of congressional support sufficient to override presidential vetoes of proposals to expand federal funding on the

one hand or to further restrict or prohibit research on the other. Nationally, public opinion on this issue is frequently described as “fluid”; most surveys indicate a majority of the public supports this research, but the size and strength of the majority varies widely among surveys and is influenced by the manner in which the question is framed and the terms of political debate.³⁸

However, majorities on this issue have been constructed in a number of individual states. The resulting state policies have been extremely diverse, ranging from large-scale state financial support to outright criminalization, and seem to result from corresponding diversity in public opinion across the states. Arguably, this variegated set of policy choices better reflects differences in public opinion than any single national standard would.

This decentralized pattern of policy development also provides a desirable means to develop national answers to the ethical and political questions surrounding stem cell research, which is more controversial than many other areas of scientific research. Addressing such issues as what sources of eggs may be used for research, whether women or fertility clinics should be paid to provide eggs or supply embryos, and how we should regulate intellectual property and royalties has proven contentious. There is no clear bioethical or political consensus on any of these issues, and there is no evidence on the consequences of adopting one position on these issues as opposed to another. Several organizations have issued guidelines for stem cell research, but these guidelines must be translated into detailed rules. California has the most extensive experience in developing a regulatory framework for embryonic stem cell research, and other states contemplating funding programs are likely to draw on it when developing their own rules. What “works” politically, judicially, or administratively in California may not work in other states, however, and a

variety of approaches will result. This experimentation will provide useful evidence on the consequences of different policy choices and will allow both state and federal governments to make subsequent decisions based on better knowledge.

These advantages have come at the cost of considerable time and efficiency compared to spending the same amount of money through established biomedical research funding channels.³⁹ Start-up problems have been significant—the California initiative, for example, has been subject to considerable legal challenge and has yet to sell the bonds that will be the major source of state funding. States seeking to fund embryonic stem cell research have also had to “reinvent the wheel” around a host of administrative and policy issues that are more or less settled under current federal funding arrangements. The California Institute for Regenerative Medicine (CIRM) is trying to insist on preferential access for California citizens to treatments developed using state resources and to secure a “cut” of licensing revenues from state-supported treatments for the state government. Both of these ideas deviate from established practices with federally funded treatments.⁴⁰ The biotech firms that will produce treatments have resisted these ideas, and the dispute may require further litigation to resolve. Universities and research institutes receiving both state and federal funds have had to resort to extraordinary administrative measures, including the construction of separate labs, to segregate the activities supported by these two funding streams in order to avoid charges that they are illegally using federal funds to support research on stem cell lines not currently eligible for federal funding. And finally, state funding of stem cell research has incurred considerable start-up costs and delays in getting support to researchers than would have been the case had the same funds been allocated through established federal channels.

All of these difficulties aside, comparable amounts of money have not been available at the federal level, and current restrictions on the stem cell lines eligible for federal research support are likely to remain in place at least through the current administration. Even if the 2008 elections produce a national environment more supportive of stem cell research, expanding the number of stem cell lines eligible for federal support does not increase federal funding. In order to spend as much money annually on embryonic stem cell research as California, the federal government would have to increase its spending almost eight-fold, and that much money would likely not be forthcoming in the short run. In contrast with other types of biomedical research, the federal government will probably remain only one among many public funders of embryonic stem cell research, and not even the largest one.

Plan B—federalism by design. The states have played a different but equally important role in regulating access to the emergency contraception drug levonorgestrel, commonly called “Plan B.” The intergovernmental division of labor around drug access is more typical than that illustrated by embryonic stem cell research because the FDA has the authority to set minimum national standards for drug efficacy, safety, and prescription status, while states have considerable influence over access to particular drugs via their traditional regulation of the practices of pharmacy and medicine. What is especially telling about a federalism-centered study of the regulations affecting Plan B is that while the clear locus of control over the drug itself rests with a federal agency, state legislatures are the ones resolving the most heated disputes. They have done so by tapping their available powers to pass laws that promote local preferences.

The federal government has had direct authority to regulate Plan B since it was first brought on the market in 1999. Until recently, the FDA limited its approval of Plan B to pre-

scription use, and states were bound by that limitation. On August 24, 2006, after nearly three years of heated debate, the FDA approved Plan B as an over-the-counter medication for those eighteen and older; it remains a prescription-only drug for minors. Under the FDA rule, the manufacturer can sell the drug only to stores and clinics where a pharmacist works; the medicine must be kept behind the counter; and store employees must verify the age of the purchaser.

The federal regulation of Plan B has not stopped states from taking an active role in controlling access to the drug. Prior to FDA approval of Plan B as an over-the-counter medication, state legislatures used creative legislation to expand access to emergency contraception despite the federal prescription-only rule. Using their police power to regulate doctors who prescribe the drugs and pharmacists who dispense them, nine states—Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington—allowed specially-trained pharmacists to give emergency contraception to patients who hadn't visited a doctor. State laws gave pharmacists who partnered with doctors the authority to write prescriptions on their own.⁴¹

While the recent federal rule allowing over-the-counter sales expanded access to Plan B nationally, it left states to resolve some of the more complex ethical issues surrounding use of the drug. Should stores be required to stock Plan B? Will pharmacists and pharmacy employees be covered by existing conscience clauses? Should other states follow the lead of the nine states listed above that currently allow girls who are under eighteen to get the drug without seeing a doctor?

States are stepping in to answer some of these questions. For example, Illinois Governor Rod Blagojevich issued a rule that requires pharmacies to provide emergency contraception.⁴² A Massachusetts regulatory board ordered Wal-Mart to stock emergency contraception in its Bay

State stores, leading to the corporation's decision to stock Plan B in its stores nationwide.⁴³ Washington's Board of Pharmacies will not give legal protection to pharmacists who refuse to dispense Plan B.⁴⁴ California law requires pharmacists to dispense prescriptions, including contraception, unless their employer approves their refusals and people can fill their prescriptions elsewhere.

To be sure, not all state legislation expands access to Plan B. Arkansas, Georgia, Mississippi, and South Dakota have laws that allow pharmacists to refuse to dispense Plan B. Colorado, Florida, Maine, and Tennessee have broad conscience clauses that do not specifically mention pharmacists but may apply to them.⁴⁵ Other state

resulting variation in policies is a direct result of our federalist system.

While we favor expanding access to appropriate health care from a systematic perspective, the variation among state laws governing access to Plan B can be seen as a good thing. First, the emergence of divergent state policies is fostering nuanced debate based on evidence generated through studies of the states' experiments with different approaches. Second, the experimental approaches taken by Illinois or Mississippi would not be politically feasible at a national level; the approval of the FDA's simple August 2006 rule was a major political achievement despite the reasonably straightforward science behind it. At least some of those experiments ex-

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legislatures are introducing bills that would explicitly grant pharmacists the right to refuse to dispense drugs related to contraception on moral grounds.

The various state actions around Plan B show that even where the federal government has taken charge of a particular subject, local variation persists because states use the powers allocated to them in the federalist system to control morally and ethically complex issues surrounding health policy. With respect to Plan B, the local resolutions have in some cases expanded consumers' access to the drug by limiting the individual rights of providers. In other cases, state legislators have protected the rights of providers with the effect of limiting access to the drug for consumers. The

expanding access is desirable, it can only happen on a state level. Is it even imaginable, for example, that a federal agency would order Wal-Mart to stock Plan B?

Finally, the ongoing debate and evidence generated from comparisons between state policies has brought renewed attention to conscience laws, which have been on the books since *Roe v. Wade* was decided in 1974. Not only are those rules subject to increased scholarly and political attention, they are the subject of court and regulatory action. By driving the issue to the courts, individual states may very well create national policy by forcing courts to examine individual constitutional rights to access FDA-approved medications.

Federalism and the Future of Bioethics

That bioethics is and will remain a federalist enterprise seems certain. Many issues in bioethics are likely to arise in areas that have been the traditional province of state governments, a preeminence that Supreme Court decisions may continue to reinforce. Other issues may fall to the states because their moral and political complexity makes agreement on acceptable national standards impossible. Whatever the cause, it is a foregone conclusion that many major bioethical decisions will continue to be made in state capitals rather than in Washington.

It is also clear—at least in our view—that this is a good thing. A decentralized system of making decisions about controversial bioethical issues allows different outcomes that reflect the underlying diversity of public views. It also increases the number of people who live under a regime of which they approve, compared to a single national standard. Judicial and political venue shopping ensures that multiple perspectives remain on the national agenda, and potentially aggrieved minorities have multiple opportunities to press their claims.

The federal government will remain the preeminent authority when deciding issues that have clear national importance, including judicial enforcement of individual civil rights. Even the most ardent states-rights advocate would find it difficult to argue, for example, that the movement of food from field or feed lot to grocery is not interstate commerce, making it unlikely that individual states will be able to sustain attempts to bar produce from other states because they object to their genetic composition. In similar fashion, the continued preeminence of the NIH as a source of biomedical research funding in most areas ensures that a wide range of issues concerning research ethics will continue to be decided at the federal level.

This system—in which some issues are clearly under the federal government's jurisdiction, others are clearly the province of states, and still others may be acted on by either or both levels of government—is more complicated than many bioethics discussions have assumed. Most of these discussions have focused solely on national policy, and particularly on national bioethics commissions of various types as the major policy-making bodies for important issues.

To the extent that our argument is correct, bioethicists must broaden their focus. They have paid little attention to such basic questions as whether state governments have access to their advice or how states debate, decide, and implement bioethical policy. Without such attention, bioethical discussions will continue to neglect an important part of the nation's institutional machinery for considering and deciding complicated and controversial issues. Discussions of the appropriate division of labor between federal and state governments are major elements of policy debates in other domestic policy areas, and it seems both important and necessary for bioethics to begin the same discussions. Although it seems unlikely that any decision process can resolve the "mischiefs of faction" associated with significant moral differences around many complex bioethical questions, the American federal system provides a workable means of mitigating many of these mischiefs. Awareness of the decentralized and complicated institutional and political machinery that governs bioethical decision-making in this country would make bioethical discussions more immediately relevant to public debates about these issues.

References

1. For a useful recent review of this literature, see S. Johnson, "The Impact of Presidential Bioethics Commissions: An Assessment of Outcomes in Public Bioethics" (Ph.D. dissertation: Johns Hopkins University, 2006).

2. For a partial exception, see C.B. Cohen, "Searching for a Variety of Bioethics Forums," *Politics and the Life Sciences* 13, no. 1 (1994): 82-84.

3. For recent examples of this Washington-centered discussion, see F. Davidoff, "Sex, Politics, and Morality at the FDA: Reflections on the Plan B Decision," *Hastings Center Report* 36, no. 2 (2006): 20-25, and R. Dresser, "Plan B: Politics and Values at the FDA, Again," *Hastings Center Report* 34, no. 6 (2004): 9-10.

4. A. Ouellette et al., "Lessons across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States," *American Journal of Law and Medicine* 31 (2005): 419-46, at 420.

5. For one example of antistate rhetoric, see R. Hayes, "A Majoritarian Proposal for Governing Human Biotechnology," <http://www.bioethicsforum.org/Fukuyama-Furger-bioethics-regulation.asp>. For another, which referred to state attempts to regulate assisted reproduction as a "bioethics fire drill," see "Transcript of the Meeting of the President's Commission on Bioethics, Section 4: Stem Cell Research: Current Law and Policy with an Emphasis on States," July 23, 2004, <http://www.bioethics.gov/transcripts/july03/session4.html>. For still another, see S. Burger, "When in Rome (or Wisconsin)," November 13, 2006, http://www.americanprogress.org/issues/2006/11/when_in_rome.html.

6. For a recent example of such complaints, see J. Medina, "Connecticut Takes a Lead in Stem Cell Research Aid," *New York Times*, December 10, 2006.

7. For a useful summary of these debates, see W. Oates, "An Essay on Fiscal Federalism," *Journal of Economic Literature* 37 (1999): 1120-49, and J. Fossett and T. Gais, "A New Puzzle for Federalism: Different Responses to Medicaid and Food Stamps," presented at the Annual Meeting of the American Political Science Association, September 2002, http://www.rockinst.org/publications/federalism/fossett_and_gais_apsa_2002withtables.pdf.

8. See, for example, D. Esty, "Revitalizing Environmental Federalism," *Michigan Law Review* 95 (1996): 570-653.

9. See, for example, L. Andrews, "Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cell Research, Therapeutic Cloning, and Human Cloning," in *Monitoring Stem Cell Research* (Report of the President's Commission on Bioethics, 2004, Appendix E), http://www.bioethics.gov/reports/stemcell/appendix_e.html; as well as C.E. Schneider, "A Government of Limited Powers," *Hastings Center Report* 35, no. 4 (2005): 11-12; and C.E. Schneider, "Political Questions, Judicial Questions, and the Problem of *Washington v. Glucksberg*," in *Law at the End of Life: The Supreme Court*

and Assisted Suicide, ed. C.E. Schneider (Ann Arbor: University of Michigan Press, 2000).

10. *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

11. *Ibid.*, at 35 (emphasis added).

12. 105 N.E. 92, 93 (1914).

13. K.C. Wheare, *Federal Government* (New York: Oxford University Press, 1964); A. MacMahon, "The Problem of Federalism: Survey," in *Federalism Mature and Emergent*, ed. A. MacMahon (Garden City, N.J.: Doubleday, 1955).

14. Ouellette et al., "Lessons across the Pond."

15. *Ethnicity in Contemporary America: A Geographical Appraisal*, 2nd ed., ed. J. McKee (New York: Rowman & Littlefield, 2000); *Reinventing the Melting Pot: The New Immigrants and What It Means To Be American*, ed. T. Jacoby (New York: Basic Books, 2004).

16. J. Cortright and H. Meyer, *Signs of Life: The Growth of Biotechnology Centers in the U.S.* (Washington, D.C.: Brookings Institution, 2002), <http://www.brookings.edu/es/urban/publications/biotech.pdf>

17. Oates, "An Essay on Fiscal Federalism."

18. The relevant literature is enormous. For a decent sampling, see R. Erikson, G. Wright, and J. McIver, *Statehouse Democracy: Public Opinion and Policy in the American States* (Cambridge, U.K.: Cambridge University Press, 1993); K.Q. Hill and A. Hinton-Anderson, "Pathways of Representation: A Causal Analysis of Public Opinion-Policy Linkages," *American Journal of Political Science* 39 (1995): 924-35; B. Norrander, "The Multilevel Impact of Public Opinion on Capital Punishment Implementation in the American States," *Political Research Quarterly* 53 (2000): 771-94; and K. Arceaux, "Direct Democracy and the Link between Public Opinion and State Abortion Policy," (unpublished paper, Rice University Department of Political Science).

19. T. Gais and J. Fossett, "Federalism and the Executive Branch," in *The Executive Branch*, ed. J. Aberbach and M. Peterson (New York: Oxford University Press, 2005).

20. A. Hamilton, "The Same Subject Continued (The Idea of Restraining the Legislative Authority in Regard to the Common Defense Considered)," *Federalist*, No. 28, <http://www.foundingfathers.info/federalistpapers/fedindex.htm>.

21. R. Nathan, "There'll Always Be a New Federalism," *Journal of Public Administration Research and Theory* (advance access, published February 14, 2006), <http://jpart.oxfordjournals.org/cgi/reprint/muj011v1.pdf?ijkey=wzfsdcDmluL1buc&keytype=ref>.

22. For an excellent summary of the venue shopping literature, see S.B. Pralle,

"Venue Shopping, Political Strategy and Policy Change: The Internationalization of Canadian Forest Advocacy," *Journal of Public Policy* 23 (2003): 233-60.

23. For example, see J. Chubb, "Institutions, the Economy and the Dynamics of State Elections," *American Political Science Review* 82 (1988): 13-54; R. Stein, "Economic Voting for Governor and U.S. Senator: The Electoral Consequences of Federalism," *Journal of Politics* 52 (1990): 29-53; and A. Lowery, J. Alt, and K. Ferec, "Fiscal Policy Outcomes and Electoral Accountability in the American States," *American Political Science Review* 92 (1999): 759-74.

24. R. Jones, "After California, More States Eye Stem Cell Research," February 9, 2005, <http://www.msnbc.msn.com/id/6847933/from/ET/>.

25. J. Hopkins, "Stem Cells' Promise Pit Jobs vs. Values," *USA Today*, February 15, 2005.

26. E. Clift, "Widening Rift," *Newsweek*, October 21, 2005, <http://www.msnbc.msn.com/id/9776982/site/newsweek/>.

27. D. Spar, "Where Babies Come From: Supply and Demand in an Infant Marketplace," *Harvard Business Review* (February 2006): 133-42.

28. Human Fertilization and Embryology Authority, "Fertility Problems and Treatment: Facts and Figures," 2006, http://212.49.193.187/cps/rde/xbcr/SID-3F57D79B-463E71AF/hfea/facts_and_figures.pdf.

29. See, for example, the rankings of state and university programs in micro- and nanotechnology published by *Small Times* magazine, a trade publication, and the detailed descriptions of state biotechnology programs published by the Biotechnology Industry Organization, a major trade group.

30. For a detailed statement of these arguments, see Fossett and Gais, "A New Puzzle for Federalism."

31. K. Barrett and R. Greene with Z. Patton and J.M. Keeling, "Grading the States '05: The Year of Living Dangerously," *Governing* (February 2005), <http://www.governing.com/gpp/2005/intro.htm>.

32. National Academy for Public Administration, *An Agency at Risk* (Washington, D.C.: National Academy for Public Administration, 1991); S.M. Butler et al., "Open Letter to Congress and the Executive: Crisis Facing HCFA and Millions of Americans," *Health Affairs* 18 (1999): 8-10; L. Etheredge, "Medicare: Governance and Structure: A Proposal," *Health Affairs* 19 (2000): 61-73.

33. L. Brown and M. Sparer, "Poor Program's Progress: The Unanticipated Politics of Medicaid Policy," *Health Affairs* 22 (2003): 31-44.

34. See J. Wennberg et al., "Geography and the Debate over Medicare Reform,"

Health Affairs Web exclusive, February 13, 2002, w96-w119; and E.S. Fisher et al., "Variations in the Longitudinal Efficiency of Academic Medical Centers," *Health Affairs* Web exclusive, October 7, 2004, var19-var32, <http://content.healthaffairs.org/cgi/content/full/hlthaff.var.19/DC3>.

35. For a recent examination of this research, see N. Lurie, "Health Disparities: Less Talk, More Action," *New England Journal of Medicine* 353 (2005): 727-29.

36. See T. Gais and J. Fossett, "Federalism and the Executive Branch."

37. The spending data cited in this paragraph are reported in J. Fossett, "Federalism by Necessity: State and Private Support for Human Embryonic Stem Cell Research," *Rockefeller Institute of Government Policy Brief* (Albany, New York: Rockefeller Institute of Government, 2007).

38. For a detailed explanation of survey findings, see M. Nisbet, "Public Opinion about Stem Cell Research and Human Cloning," *Public Opinion Quarterly* 68, no. 1 (2004): 131-54; and M. Nisbet, "Political Communication in the 2007 Stem Cell Debate: Framing Messages and Defining Public Opinion" *Science and the Media*, January 5, 2007, <http://www.csicop.org/scienceand-media/stem-cell/2007.html>.

39. For a prescient discussion of many of these issues, see R. Noll, "The Politics and Economics of Implementing State Sponsored Embryonic Stem Cell Research," SIEPR Discussion Paper No. 04-28, June 2005, <http://siepr.stanford.edu/papers/pdf/04-28.pdf>.

40. For ongoing coverage of these disputes, see <http://californiastemcellreport.blogspot.com/>.

41. D.C. Vock, "FDA Ruling Puts Pharmacists in Crossfire," September 6, 2006, <http://www.stateline.org/live/details/story?contentId=139338#comments#comments>.

42. *Ibid.*

43. R.E. Gee, "Plan B, Reproductive Rights and Physician Activism," *New England Journal of Medicine* 355, no. 1 (2006): 4-5.

44. Vock, "FDA Ruling."

45. *Ibid.*