Bush Okays Some Stem Cell Research Funding; Debate Continues

After months of consultation and "agonizing," President Bush announced on August 9 that he will allow the use of federal funds for embryonic stem cell research but only in the most limited way. In so doing, despite his insistence to the contrary, he arrived at a truly political compromise. While largely successful, at least in the short-term, in appealing to the majority of Americans who say they are in favor of stem cell research going forward, the decision did not fully satisfy the most fervent partisans on the either sides of the stem cell debate. Researchers and patient advocacy groups, while generally praising the president for his thoughtfulness, contend that his decision will still impede significant scientific progress, while social conservatives as well as the National Conference of Catholic Bishops have labeled the president's compromise "morally unacceptable."

The president declared that federal funds may be used to support research only on *existing* embryonic stem cell "lines." Cell lines (sometimes referred to as colonies) emanate from cells extracted from single, days-old embryos, which in turn reproduce themselves infinitely to create a line of cells with identical genetic material. The embryos themselves are created in private fertility clinics but are "excess" and would otherwise be discarded. The embryos are destroyed in the process of extracting the cells.

The president's claim that there are as many as 60 of these cell lines worldwide (as opposed to somewhere between a handful and 30) came as news to the leading U.S. scientists engaged in this research, however, and it remains a matter of dispute. The actual number—and the quality—of these lines is significant, since the promise stem cell research holds for possible treatment or cures for Alzheimer's or Parkinson's diseases or spinal cord injuries, for example, depends on their stability and genetic diversity.

Accordingly, while patient advocacy groups such as the Juvenile Diabetes Research Foundation were relieved that Bush is permitting the government to engage in the research at all, its president said he is "concerned whether this is sufficient to do the work that needs to be done." Harold Varmus, former head of the National Institutes of Health, went further in saying that it would be "a very poor investment federally, and a very cruel investment, if we ended up with knowledge of how to make differentiated cells to treat people and then we were stuck" without the necessary lines.

For their part, social conservatives are relieved that the president refused to permit the use of federal funds for the actual derivation of stem cells or even for research using those cells that may be extracted from "excess" embryos in the future. The president rationalized that subsidizing research only on existing cell lines is morally defensible since "the life and death decision [for those embryos] has already been made." The immediate reaction of the National Right to Life Committee—in sharp contrast to its usual allies such as the Family Research Council, for example—was to take a similarly pragmatic approach to this parsing of the debate by applauding the president for "prevent[ing] the federal government from becoming a party to any *further* killing of human embryos" (emphasis added).

When Congress reconvenes, this issue is almost certain to be reexamined as more information becomes available about the real implications of the president's position. While th president's Solomon-like decision seems to have softened the initial responses of most of the key stakeholders in this debate, it would see that his announcement has marked only the beginning, not the end, of this larger debate about the true meaning of being "prolife."

Administration's New Medicaid Rules Could Limit Family Planning

Recent policy changes unveiled by Department of Health and Human Services (DHHS) Secretary Tommy G. Thompson have the potential to seriously diminish low-income women's coverage for family planning services under Medicaid.

The first hint of a change came in mid-July, when DHHS officials quietly informed states with pending applications to expand Medicaid eligibility for family planning that thei proposals would not be approved. A the same time, states with existing waiver programs—so-called because they technically waive certain requirements set out in the Medicai statute—were told their programs, which had been authorized for five years, would not be renewed. When the media picked up the story that Bush administration retreat on family planning support was underway, DHHS officials argued that the move were not targeted at family planning but were part of a broader strategy t promote waivers offering at least a limited package of primary care ben efits rather than "single-service" waivers—a policy shift many states quickly said would make expansion prohibitively expensive.

Since the first of these waivers was approved in 1993, 14 states have obtained approval to extend eligibil ity for family planning services to populations that would otherwise not be eligible ("California Program Shows Benefits of Expanding Famil

Planning Eligibility," *TGR*, October 2000, page 1). Generally, the programs cover women for two years postpartum or women (and in some cases men) based solely on having a low income that is nonetheless too high for regular Medicaid eligibility. Data collected by The Alan Guttmacher Institute indicate that these programs serve at least 1.3 million enrollees a year.

Reaction was swift. Within days, a bipartisan group of members of Congress sent a letter to Thompson asking DHHS to reconsider. In addition, Sen. Lincoln Chafee (R-RI) and Rep. Nita M. Lowey (D-NY), along with 23 of their colleagues, introduced legislation to allow states to implement family planning expansion programs without first having to obtain DHHS permission.

Meanwhile, Thompson was moving along a seemingly separate track to carry out a long-standing promise to expand governors' latitude over their overall Medicaid efforts. When he unveiled the administration's major new Medicaid initiative on August 4, however, the two issues were joined.

Along with increasing state flexibility, the initiative, according to the administration, is targeted at reducing the number of people in the United States with no source of insurance coverage. To accomplish that goal, states will be able to expand their Medicaid programs, but only in a way that will not increase costs to the federal government. To meet this requirement, states will have to trim the benefits covered or increase the amount enrollees have to pay out of pocket for their care. Significantly, however, the initiative does not *require* that states use any savings accrued from trimming benefits to expand eligibility, leading many advocates to question the extent to which the plan will result in increased coverage for the uninsured.

Current Medicaid law requires states to cover three categories of individuals, each at different income levels: indigent parents (up to regular, state-set ceilings that are as low as 15% of the federal poverty level), pregnant women (up to 133%) and children (up to 133% for children through age 5 and up to 100% for children 6–18). States are *permitted* to cover individuals in these same categories who have slightly higher incomes. It is individuals in this so-called optional group—which also includes children eligible for the State Children's Health Insurance Program—who are most likely to be affected by the administration's policy. Breaking with the bedrock Medicaid principle of "comparability," states will be allowed to offer optional enrollees a more meager benefit package than they provide to their mandatory enrollees. States, for example, may choose to increase cost-sharing requirements for optional enrollees and/or trim services, including family planning, from their benefit packages.

States are encouraged to use the savings accrued from the optional-enrollee group to extend Medicaid enrollment to a new, third group of people. The policy calls on states to submit requests for waivers that would provide an undefined but presumably quite limited package of "primary care services" to low-income individuals who would otherwise not be eligible for Medicaid under either of the other two categories. The creation of this new group of potential Medicaid enrollees effectively is the formal articulation of the administration's earlier policy shift on "single-service" family planning waivers.

Meanwhile, seemingly feeling the heat for that shift, DHHS has very publicly informed several states that it fully intends to approve their family planning waiver requests. Significantly, however, reports conflict about whether those waivers will be approved just for the set of preventive services, such as blood pressure screenings, STD services and Pap tests, that along with contraception are provided under the rubric of "family planning" or whether the administration will still require the inclusion of additional primary care services. About all that is clear at this point is that this controversy will continue to play itself out over the coming weeks and months.

Condom Effectiveness Examined in New Government Report

In June 2000, a panel of experts convened for a two-day workshop to assess the effectiveness of condoms in preventing the transmission of eight sexually transmitted diseases (STDs): HIV, gonorrhea, chlamydia, syphilis, chancroid, trichomoniasis, genital herpes and human papillomavirus (HPV). More than a year later, on July 20, the Department of Health and Human Services finally issued the eagerly anticipated summary report from that workshop. The report concludes that there are sufficient, condition-specific data to demonstrate that when used correctly and consistently, condoms prevent HIV infection and gonorrhea transition from women to men (in addition, of course, to pregnancy), but that the published epidemiologic literature is insufficient to warrant definitive statements about condom effectiveness specific to the other six STDs considered by the panel.

The report explicitly notes that the panel—which the National Institutes of Health had convened at the behest of congressional condom opponents—"stressed that… inadequacies of the evidence available…should not be interpreted as proof of the adequacy or inadequacy of the condom." Yet condom opponents, who advocate abstinence for all unmarried people as the only acceptable means of preventing STDs and pregnancy, were quick to do just that. Tom Coburn, the former Republican representative from Oklahoma who initially requested the report while still in office, issued

a press release that was headlined, "Condoms Do Not Prevent Most STDs." In the release, Coburn said, "This report finally exposes the 'safe' sex myth for the lie that it is.…[W]hen condom use is discussed, it is no longer medically accurate—or legal for the CDC—to refer to sex as 'safe' or 'protected.'" Coburn has called for the resignation of Centers for Disease Control and Prevention (CDC) Director Jeffrey Koplan for not providing "medically accurate" information about condom effectiveness, as required by federal law. The CDC's overarching "prevention message" for HIV and other STDs, set forth in a fact sheet also issued in July, reads, "Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV…. In addition, correct and consistent use of latex condoms can reduce the risk of other sexually transmitted diseases."

Indeed, supporters of public health messages that promote condom use for sexually active individuals point to a critical conclusion in the workshop summary report that largely has been ignored by the popular press: "Studies…have demonstrated that condoms provide a highly effective barrier to transmission of particles of similar size to those of the smallest STD viruses. These data also provide a strong probability of condom effectiveness when used correctly, where the etiology of STD transmission is linked to containment of pre-ejaculate and seminal fluids or barrier coverage of lesions on the penis and there is no slippage or breakage." In other words, supporters say, despite the lack of definitive, disease-specific studies, condoms should be regarded as protective against "discharge diseases" beyond HIV (gonorrhea, chlamydia and trichomoniasis) and would also be expected to protect against infections that are transmitted through "skin-to-skin" contact (genital herpes, syphilis, chancroid and HPV) *provided* that the source of the infection is in an area that is covered or protected by the condom. Although the three "genital ulcer diseases" and HPV can occur in genital areas that are covered or protected, they also can occur in areas that are not. Accordingly, again in the words of the CDC prevention-messages fact sheet, condom use "would be expected to protect against transmission of genital ulcer diseases and HPV in some, but not all, instances."

Supporters of HIV and STD prevention efforts say the fact that condoms are not 100% effective does not mean that they have no value in prevention, noting, for example, that most vaccines are not 100% effective. To the contrary, condoms must be the mainstay of prevention efforts both in the United States and globally, they argue, for the simple reason that as the workshop summary report itself says, "Beyond mutual lifelong monogamy among uninfected couples, condom-use is the only method for reducing the risk of HIV infection and STDs available to sexually active individuals."

120 Wall Street, 21st floor
New York, NY 10005