

The Times, They Are *Changing*



Federal Legislative
and Regulatory
Action on
Reproductive Health
in 2006



NATIONAL
FAMILY
PLANNING &
REPRODUCTIVE
HEALTH
ASSOCIATION

The Times, They Are *Changing*

Federal Legislative and Regulatory Action on Reproductive Health in 2006



January 24, 2007

Marilyn Keefe, *Interim President and CEO*

Jennifer Lockwood-Shabat, *Director of Public Policy*

Robin R. Summers, *Senior Policy Analyst*

Stephanie Arnold, *Public Policy Associate*

In Memoriam

This report is dedicated to the memory of our very good friend and colleague, Cynthia Dailard, who passed away on December 24, 2006. Cynthia, a senior public policy associate at the Guttmacher Institute and a NFPRHA Board member, was a gifted thinker, writer, and speaker, whose highly regarded work focused on family planning-related issues in the policy and legislative arenas. Her contributions have been essential to advocacy and education efforts both in D.C. and across the country. NFPRHA truly mourns her loss less for her invaluable professional contributions to the field and to our organization than for her years of unflagging good will and friendship.

National Family Planning and Reproductive Health Association

For more than 35 years, NFPRHA has worked to assure access to voluntary family planning and reproductive health care services and to support reproductive freedom for all. A national non-profit membership organization, NFPRHA represents clinicians, administrators, researchers, educators, advocates and providers in the family planning field. Many NFPRHA members receive federal funds through Title X of the Public Health Service Act to provide family planning services to low-income women. NFPRHA members include private non-profit clinics; state, county and local health departments; Planned Parenthood Federation of America affiliates; family planning councils; hospital-based clinics; and international family planning agencies.

*This publication is made possible with the generous support of the
Robert Sterling Clark Foundation.*

Table of Contents

Lackluster Year in Reproductive Health Capped by Watershed Election	I
Congress Flat Funds Domestic Family Planning Program... for the Moment	3
Republicans Punt Appropriations to 110 th Congress	3
Skyrocketing Contraceptive Costs Galvanize Clinics, Leading Pharmaceutical Giant to Roll Back Increases	3
DASPA Appointment Sets Off Firestorm	4
Title X Receives High Marks from Federal Office of Management and Budget	5
NFPRHA Loses Appeal of Challenge to Weldon Refusal Law, Throwing Issue Back to Congress to Fix	5
FY 2007 Funding for Selected Public Health Programs	7
Prevention First in the Spotlight	8
States Press Ahead with Contraceptive Coverage Mandates	8
Alternative Bills to Reduce the Need for Abortion Fall Far Short of Prevention First	9
CMS: Agency Giveth with One Hand and Taketh Away With the Other	11
Burdensome Documentation Requirements in Place	11
Nominal Pricing Provision Devastates Clinics	12
States Allowed to Create “Benchmark” Plans That Theoretically Could Eliminate Family Planning Coverage	12
Half of States Have Expanded Medicaid-Funded Family Planning Services	12
Landmark Legislation to Expand Coverage of Medicaid Family Planning Services Introduced	13
Abstinence-Only Education Programs Flat-Funded, Harshly Reviewed by GAO	14
HHS Further Tightens Restrictions on Abstinence-Only-Until-Marriage Funds	14
New Study Undermines Role of Abstinence in Teen Pregnancy Decline	15
Conservatives Try to Undermine Comprehensive Sex Ed	15
GAO Finds Flaws With HHS’ Handling of Medical Accuracy in Abstinence-Only Programs	16
REAL Act Gets First Floor Vote	17
Congress Thwarted in Efforts to Pass Additional Abortion Restrictions	18
Fetal Pain Bill Narrowly Defeated in the House	18
Conservatives Press for Last-Minute Passage of Child Interstate Abortion Notification but Overreach	18
Bill Differences	19
South Dakota Voters Overwhelmingly Reject Challenge to <i>Roe</i> in November	20
FDA Issues Medical Abortion Health Advisory after Two Deaths; CDC and Congress Examine Drug	20
Legislation, Report Details Misleading Tactics of Crisis Pregnancy Centers	21
Senate Confirms Samuel Alito to Supreme Court	24
Senate Confirms Alito Despite Concerns Over Views on Privacy	24
Conservatives Focus on Judiciary in 2006	25

Supreme Court Avoids Major Abortion Decision in 2006	26
Supreme Court Hands Down Decision in <i>Ayotte</i>	26
Supreme Court Rules Against NOW in Clinic Violence Case	27
Supreme Court Hears Arguments on Federal Abortion Ban	27
Federal Agencies take Action on Reproductive Health Issues	29
Cervical Cancer Vaccine Gets Green Light from FDA and CDC, But Access Issues Remain	29
ACIP Endorses Routine Administration for 9-26 year-olds; Makes Vaccine Part of Vaccines for Children Program	29
Political Opposition to Approval Fails to Materialize – but Debate Shifts to Mandate for School Enrollment	29
Cost Remains Key Concern Despite Merck Patient Assistance Program	30
Issues about Confidentiality and Mandatory Administration Unanswered	30
Pap Tests Must Continue	31
New Study Finds Condoms Block HPV	31
Senator Coburn Still Angry that Condom Warning Labels Not Updated	31
FDA Approves Plan B for OTC Sales	32
Plan B Lawsuit Still in Play	32
Plan B Mechanism of Action Subject of Recent Journal Articles	32
Wal-Mart Does About-Face on EC	34
FDA Approved Three New Contraceptives; Price Issues Remain Top Concern	34
CDC Issues New HIV Screening Guidelines	35
CDC Revises HIV Recommendations to Include Universal Screening	35
CDC's Revised STD Treatment Guidelines Address Ethics, EC, and Confidentiality	35
Ryan White CARE Act Reauthorized After Lengthy Struggle	36
Status Quo for International Family Planning Programs	37
Administration Proposes Cuts for International Family Planning Funds; Global Gag Rule Remains in Effect	37
UNFPA Funding Blocked Yet Again	37
Anti-Prostitution Pledges Challenged in Court	38
International Abstinence Earmark Undermines Prevention Efforts	38
A Look Ahead	40

Lackluster Year in Reproductive Health Capped by Watershed Election *NFPRHA Celebrates 35th Anniversary in Style*

The year 2006 was an important one in the history of NFPRHA: we turned 35! This special anniversary was celebrated in conjunction with our 33rd National Conference, *Weathering the Storm*, on June 12-14. Past and present leaders of NFPRHA were feted at a French Embassy gathering, where past victories and current challenges were recounted. Long-time President and CEO Judith DeSarno was honored for her 15 years of outstanding leadership during which time the organization's funding grew, along with its stature in the Washington political and policy arenas. Judy's tenure at NFPRHA came to a close in September when she joined the Buffett Foundation in Omaha, Nebraska, where she has taken on a new—and equally critical—challenge as a key player in the reproductive rights funding community.

Another highlight of NFPRHA's conference was the Capitol Hill luncheon featuring Senator Hillary Rodham Clinton (D-NY), who received NFPRHA's Outstanding Public Service Award for her work in support of women's reproductive health. In her inspiring acceptance speech, Senator Clinton expressed her support for the prevention agenda, recognized family planning providers for the important work they do every day on the front lines, and outlined ways in which Members of Congress could go on record in support of family planning for all women. "Educating and supporting women so that they can prevent unintended pregnancies in the first place is one of the most important investments we can make. I am calling on my colleagues in Congress, Republicans and Democrats, to join me in ensuring all women have the family planning services they need, so that together we can help to decrease the number of unintended pregnancies." Senator Clinton's speech generated quite a press buzz, with articles appearing in the *New York Times* and *The Washington Times*.

While we at NFPRHA are proud of our very successful history, the 109th Congress would be hard pressed to claim an equally successful year. Very little substantive legislation was enacted this year, leading the public and press to again decry the "do nothing" Congress. This year, the moniker was well-deserved. The year began with the battle over President Bush's second anti-choice nominee to the Supreme Court, Samuel Alito, who was confirmed by the Senate on January 31 as the replacement for retiring Justice Sandra Day O'Connor. The session effectively ended on November 7, when the American electorate provided the president with a unified message from a disaffected population angry about corruption, Katrina, the war in Iraq, Terri Schiavo, and too much appeasing of the far right. The dominance of swing voters helped give Democrats the majority for the first time in twelve years.

Democrats captured 233 seats in the House—a 30-seat gain. In the Senate, Democrats were able to gain a razor thin, but all-important majority of 51, a six-seat gain. Just how tenuous this hold on the majority was became clear even before the January takeover, when Senator Tim Johnson (D-SD) became critically ill in December.

Congress adjourned in mid-December, enacting a continuing resolution that punted final action on nine of 11 "must-pass" appropriations bills to the 110th Congress. These include the Labor, Health and Human Services, and Education (Labor-HHS) spending bill, that funds the Title X family planning program; and the foreign assistance bill, that provides funding for international family planning.

Given the overall hostility of the 109th Congress toward reproductive rights, however, this failure to consider new legislation had its upside. With action on virtually all major issues postponed until the new Congress, the anti-choice majority registered no real gains. As in previous years, all anti-choice riders that limit access to and payment for abortion services remained unchallenged, including those for poor women, women in prison, and Medicaid patients. Administration-backed limitations on funding for UNFPA and international family planning funds also remained in place.

Reproductive health opponents were only able to secure a handful of votes—none successful. These efforts included a bill to make it a federal crime to transport a minor across states lines to obtain an abortion without complying with the parental consent law of the minor's home state—a measure that had been passed by the House more than a year earlier. The bill was ultimately squelched in the Senate. A post-election bid in the House to force providers to give pregnant women who are at least 20 weeks "post fertilization" a congressionally mandated brochure containing dubious scientific information regarding fetal pain, failed to garner the two-thirds majority needed to pass.

The good news is that the prevention message continued to gather steam in the 109th Congress. However, the omnibus legislation to advance this agenda, Prevention First, sponsored by Senators Clinton and Harry Reid (D-NV) and Representative Louise Slaughter (D-NY), still was not the subject of a hearing or mark-up on either side of the Capitol. Nevertheless, the appeal of the core message and rhetoric associated with the bill—that better access to and funding for contraception are keys to women's health and necessary to reduce abortion—seemed to grow, potentially paving the way for legislative action on key components of the measure in the 110th Congress, including increased funding for Title X and an expansion of Medicaid-funded family planning services. The lone pro-reproductive health activity came in an amendment, offered by New Jersey Democratic Senators Frank Lautenberg and Bob Menendez, to allow funding for comprehensive sex education that includes both abstinence and contraception, various after-school programs, and teen pregnancy prevention programs. Although the amendment narrowly failed, 48-51, supporters were buoyed by the strong showing.

Much of the most noteworthy action during 2006 took place in states, federal agencies, and the courts. In a triple setback for conservatives, South Dakotans rejected a law to ban virtually all abortions, Arizona became the first state to defeat an amendment to ban gay marriage and Missouri approved a measure backing stem cell research—an issue that contributed to the defeat of Republican Senator Jim Talent by Claire McCaskill. Another step forward in the federal arena for women's health came with the FDA's June approval of the human papillomavirus vaccine (Gardasil) for girls and women ages 9-26, followed by the agency's long-awaited decision to allow Plan B emergency contraception to be sold over-the-counter -- albeit with a politically motivated prohibition on sales to individuals under 18. In November, a White House insufficiently chastened by the election results, appointed Dr. Eric Keroack as Deputy Assistant Secretary for Population Affairs. As an anti-birth control ob-gyn now in charge of the nation's family planning program, Dr. Keroack's appointment quickly captured the attention of Congress, the mainstream media, the blogosphere, and a broad range of public health and women's organizations, mobilizing strong opposition to the misguided appointment.

The Supreme Court took action in two critical cases dealing with a woman's constitutional right to an abortion. The first came in January, when the Supreme Court ruled in *Ayotte v. Planned Parenthood of Northern New England*, a case involving a New Hampshire law that prevents doctors from performing an abortion for a young woman under the age of 18 until 48 hours after a parent has been notified. The Court sent the case back to the lower court to consider whether the New Hampshire legislature would have wanted this law to include a medical emergency exception. If not, the Court said the law should be struck down in its entirety. The second case, argued the day after the elections, was a challenge to the 2003 federal abortion procedures ban opponents call "partial-birth" abortion—the first abortion case heard with Justice Alito on the bench. The law has been struck down as unconstitutional by every lower federal court that has considered it. A decision is not expected until mid-2007.

Although 2006 was a lackluster year in reproductive health, the results of the November election give us hope for 2007.

Congress Flat Funds Domestic Family Planning Program... for the Moment

FY 2007 Spending Bills Not Yet Finished

When the 109th Congress adjourned in December, lawmakers on Capitol Hill were no closer to completing the FY 2007 appropriations bills than they were when they adjourned at the end of September to hit the campaign trail. Instead, Congress passed a series of stopgap spending measures, the last of which will keep government programs funded through February 15, 2007. As a result, Title X, along with most other public health programs, has been funded at the FY 2006 spending level of \$283 million since October 1 and will almost certainly continue at that level for the remainder of the fiscal year.

Republicans Punt Appropriations to 110th Congress

The defeated Republican majority returned to Capitol Hill on November 13 and faced a massive task—enacting the nine remaining appropriations bills—including the Labor-HHS spending bill. Legislators bought some time by enacting a continuing resolution (CR) to fund programs through December 8. Under that CR, programs were funded at the lowest of three levels: the House-passed FY 2007 level, the Senate-passed FY 2007 level, or the FY 2006 level. Since the Labor-HHS bill was not considered by either chamber, all of the programs under its jurisdiction were funded at FY 2006 levels, meaning that Title X continued at its FY 2006 level of \$283 million.

But with no time to enact stand-alone measures and no agreement within the Republican ranks about whether an omnibus bill should be enacted in order to bring the 109th Congress to a close, Congress decided to extend the CR through February 15, punting decisions over the remaining bills to the Democratically controlled 110th Congress. The move was strongly opposed by both the outgoing and incoming House and Senate appropriations committee chairs and Democrats in general, who preferred to begin the new Congress with a clean slate. The initial scuttlebutt was that incoming chairs, Senator Robert Byrd (D-WV) and Representative David Obey (D-WI), who blamed the Republicans for abdicating their responsibilities, would shepherd through an omnibus spending bill at the beginning of the 110th Congress. Instead, they announced their intention to wrap up work on the FY 2007 spending bills with a year-long.

Skyrocketing Contraceptive Costs Galvanize Clinics, Leading Pharmaceutical Giant to Roll Back Increases

Continued level funding of Title X hit many family planning clinics particularly hard this summer when Ortho-McNeil Pharmaceuticals, which has long been a critical supplier of birth control products to the public sector at reduced prices, announced sudden and dramatic increases in the cost of contraceptives on July 1. Clinics across the country who participate in the Public Health Service's 340B Drug Pricing Program were left scrambling to find new suppliers of birth control pills.

After a full court press by NFPRHA and family planning providers across the nation, Ortho-McNeil agreed to lower the price on several of its more popular oral contraceptives. The new price (\$3.20 per cycle) of five birth control pills, which went into effect on August 30, reflects a 92-94 percent reduction off list price. The affected products are: Ortho-Novum 7/7/7, Ortho-Cyclen, Ortho Tri-Cyclen, Ortho Micronor, and Ortho Tri-Cyclen Lo. In another goodwill gesture from the company, Ortho guaranteed the \$3.20 price through December 2007. The price of Ortho Evra (the patch), which the company had boosted to more than \$22, had been reduced earlier in July to \$15 per month—still an increase over the \$11-\$13 many providers had been paying.

NFPRHA's efforts also were bolstered by the involvement of key congressional offices. The offices of Senator Jay Rockefeller (D-WV) and Representative Henry Waxman (D-CA), armed with information from NFPRHA and

our members, met with company officials to express their concern about the price hikes as well. The company, which has historically been an excellent public health partner, heard the outcry loud and clear, saying that the decision to reduce the price was made after additional information was provided to the company demonstrating that Ortho products have “been relied upon as the primary source for subsidizing contraceptives to underprivileged women.”

While the \$3.20 per cycle price is considerably better than the July 1 prices, the fact remains that many contraceptive products, regardless of whether they are brand name or generic, remain unaffordable for the public health system.

DASPA Appointment Sets Off Firestorm

Although Title X received scant attention during this year’s appropriations process, some members of Congress did turn their attention to the program in late November when, despite the electorate’s clear message to the administration on November 7, the White House flexed some of its remaining political muscle and appointed Dr. Eric Keroack, a doctor with impeccable anti-choice credentials, to head the nation’s family planning program. Just before Thanksgiving, Dr. Keroack took over as the Deputy Assistant Secretary for Population Affairs (DASPA), succeeding Acting DASPA Evelyn Kappeler, a long-time civil servant who had been in charge since the departure last summer of Dr. Alma Golden, a political appointee who held the position since 2002.

Although Dr. Keroack’s appointment did not require Senate confirmation, his résumé quickly captured the attention of Congress, the mainstream media, the blogosphere, and a broad range of public health and women’s organizations. Prior to joining HHS, Dr. Keroack served as the medical director of the Christian nonprofit agency, A Woman’s Concern, a network of six crisis pregnancy centers in the Boston area, and was a popular speaker at abstinence-only-until-marriage and right to life conferences. During his tenure at A Woman’s Concern, Dr. Keroack pioneered the use of sonograms to dissuade women from seeking abortions.

There is little, if any, evidence in the public record to suggest that Dr. Keroack strongly supports the mission of Title X: providing confidential contraceptive services to low-income individuals regardless of age, income, or marital status. In fact, Dr. Keroack has equated premarital sex with “modern germ warfare.” Also troubling was the explicit policy of his organization, A Woman’s Concern, in opposition to birth control for both married and unmarried women. The organization’s website went so far as to condemn the “crass commercialization and distribution of birth control,” calling it “demeaning to women, degrading of human sexuality, and adverse to human health and happiness.”

The mainstream media had a field day with the appointment. From the *Los Angeles Times* to the *Tuscaloosa News* to the *Providence Journal*, articles and editorials opposed to the nomination appeared in newspapers across the country. The media coverage began with *The Washington Post*, which ran a front-page, above-the-fold story on November 17, followed by an editorial urging the Administration to withdraw the nomination. The *Boston Globe* came out in opposition as well, followed by *The New York Times*, which published an editorial on November 24 entitled “Family Planning Farce.” The appointment also lit up the blogosphere, where the issue was addressed by dozens of left-leaning blogs from Huffington Post, to Feministing, to RH Reality Check to MotherTalkers.

NFPRHA rallied the troops in protest against the outrageous appointment, with Interim President and CEO Marilyn Keefe and NFPRHA Public Policy Director Jennifer Lockwood-Shabat speaking with the press and appearing as guests on numerous radio talk shows. NFPRHA also worked with Members of Congress, who spearheaded several congressional letters: one by 14 Democratic Senators, another by Representative Henry

Waxman (D-CA) and 6 of his colleagues, and a third by Representative Joe Crowley (D-NY) that was signed by 107 members of the House. All three letters to Secretary Leavitt called for the ouster of Dr. Keroack and urged the administration to consider an appointee who truly demonstrated a commitment to reproductive health. NFPRHA also submitted a separate letter to Secretary Leavitt signed by 68 organizations protesting the appointment.

Although the appointment was troubling, it did serve to shine a much-needed spotlight on the program and its benefits – publicity which we hope will lay the foundation for greater congressional support in the coming year – not to mention oversight, if necessary.

Title X Receives High Marks from Federal Office of Management and Budget

Efforts to build on the renewed support for Title X that Dr. Keroack's appointment highlighted will also have help from an unlikely source – the administration's Office of Management and Budget (OMB). As part of an ongoing assessment of the performance of every federal program, OMB rated the Title X program as "moderately effective," meaning that the program set ambitious goals and is well-managed but likely needs to improve its efficiency. According to the review of Title X, "the program's overall purpose, design and management are strong. The program collects annual data that supports the provision of preventive health services and provides reliable and regularly updated information. For example, the data show the program has helped prevent over 1.3 million unintended pregnancies and maintained the cost per client 6 percent below the medical inflation rate." The program review also found that "women who utilize Title X services as their primary source of health care have significantly greater odds of receiving contraceptive services and/or care for sexually transmitted diseases (STDs) than women who utilize private physicians or HMOs." However, the review noted that the family planning program had not yet developed performance goals for some key program activities such as "measuring the reduction of infertility cases among women who receive regular screenings for Chlamydia," which is "crucial to determining the program's long-term impact on the health and well being of women served by this program." According to the OMB review, the following actions are being undertaken to improve the performance of the program: Developing performance goals for key program activities and planning for an independent evaluation, conducted at the federal level, to demonstrate the overall impact of the program.

NFPRHA Loses Appeal of Challenge to Weldon Refusal Law, Throwing Issue Back to Congress to Fix

NFPRHA's appeal of a lower court ruling in its challenge to the Weldon federal refusal law came to end when the U.S. Court of Appeals for the District of Columbia ruled on November 14 that the organization lacked standing to challenge the provision, as no actual injury had occurred, and ordered the case to be remanded to the lower Court and dismissed. The ruling was issued by Judges Ginsburg, Sentelle, and Williams, all of whom were appointed by former President Ronald Reagan. The three-judge panel had heard oral arguments in the case on September 8.

The original provision, authored by Florida Representative Dave Weldon (R), was patterned after the Abortion Nondiscrimination Act, legislation championed by the National Conference of Catholic Bishops that was first introduced in Congress in 2002. The Weldon language prohibits a federal agency, program, or a state or local government from discriminating against any health care entity that will not pay for, provide coverage of, or refer for abortions. A health care entity is broadly defined to include individual health care professionals, hospitals, preferred provider organizations, health maintenance organizations, and insurance plans, and "any other kind of health care facility, organization or plan." The Weldon law was initially signed into law as part of the FY 2005 omnibus spending bill approved in December 2004.

NFPRHA filed the lawsuit on behalf of more than 4,400 family planning clinics across the United States that receive Title X funds to provide family planning services. NFPRHA argued that the provision left its members caught between their pre-existing statutory obligations under Title X to refer for abortion services upon patient request and their newly minted obligations under the Weldon amendment to avoid “discrimination” against health care providers that refuse to provide referrals for abortion services under any circumstances. NFPRHA first filed the suit in December 2004, and the D.C. Circuit Court ruled against NFPRHA on the merits in September 2005. NFPRHA appealed the lower court’s ruling, leading to the Appellate Court ruling.

House appropriators also carried forward the Weldon refusal clause when the appropriations committee approved the bill on June 13. On the Senate side, the fate of the language is less clear. Despite assurances on the Senate side that the previous year’s genuine conscience clause—which would bar any entity that tries to force a health care professional to provide, assist, or train for abortions from receiving funding—would be included in the Senate bill, a printing error led to the inclusion of the House version of Weldon language. Appropriators are investigating how to fix this error in the context of a year-long CR.

National Family Planning and Reproductive Health Association

FY 2007 Funding for Selected Public Health Programs
LHHS Committee Mark-up (Senate and House)
(\$ in millions)

Program	FY 2007 Continuing Resolution	Senate LHHS Committee Mark	House LHHS Committee Mark	FY 2007 President's Budget Request	FY 2006 Final
Title X Family Planning	\$283	\$283	\$283	\$283	\$283
Adoption Awareness Training	\$13	\$13	\$13	\$13	\$13
Social Services Block Grant	\$1,700	\$1,700	\$1,700	\$1,200	\$1,700
MCH Block Grant	\$693	\$693	\$700	\$693	\$693
<u>Abstinence-Unless-Married Education Programs</u>					
I. Community-Based Abstinence Programs (ACF)	\$113	\$113	\$113	\$137	\$113
2. State Abstinence Grants (ACF)	\$50	\$50	\$50	\$50	\$50
3. Adolescent Family Life Abstinence Earmark (OPA)	\$13	\$13	\$13	\$13	\$13
CDC HIV/AIDS, STD and TB Prevention (total)	\$947	\$968	\$1,001	\$1,032	\$947
HIV/AIDS	\$651	\$676	\$706	\$739	\$651
STD	\$158	\$156	\$157	\$157	\$158
TB	\$137	\$136	\$137	\$136	\$137
Ryan White	\$2,063	\$2,139	\$2,133	\$2,158	\$2,063
Community Health Centers	\$1,782	\$1,926	\$1,988	\$1,963	\$1,782
Embryo Adoption Awareness Campaign	\$2	\$2	\$2	\$2	\$2

Prevention First in the Spotlight *Legislative Action Continues to Elude*

Prevention First (S. 20/H.R. 1709), the omnibus legislation designed to reduce the number of unintended/unwanted pregnancies and the need for abortion remained the centerpiece of pro-family planning advocacy efforts. The legislation continued to garner some press but little legislative activity, almost seeing the light of day as an amendment to FY 2007 budget resolution. The amendment, drafted by Senator Hillary Rodham Clinton (D-NY) and Minority Leader Harry Reid (D-NV), would have increased funding by \$347 million for programs and policies that reduce the number of unintended pregnancies and supported women's health, including Title X, contraceptive coverage, an emergency contraception public education campaign, and teen pregnancy prevention programs. The amendment was paired with other funding increases for the Child Care Development Block Grant, the Maternal and Child Health Block Grant, Healthy Start, and the Special Supplemental Nutrition Program for Women, Infants, and Children. The amendment was withdrawn by Senators Clinton and Reid minutes before a hoped-for vote when anti-choice Senator John Ensign (R-NV) threatened to link the vote on Prevention First to an amendment to provide federal grants to states for the enforcement of state parental consent laws.

Despite the foiled attempt, a new report by the Guttmacher Institute documenting the vast economic disparities in women's access to family planning buoyed Senator Clinton's efforts to highlight the importance of preventing unintended pregnancies, and in May, she and Representative Nita Lowey (D-NY) introduced a "contraception" resolution (S. Res. 485/H. Con. Res. 404). Specifically, the resolution asks Congress to go on record in support of program and policies that make it easier for all women at all income levels to obtain contraceptives.

States Press Ahead with Contraceptive Coverage Mandates

Even as Senator Clinton raised the visibility of family planning as a common ground issue, Senate Republicans were inching toward dismantling state contraceptive coverage laws by moving controversial legislation—the Health Insurance Marketplace Modernization and Affordability Act (HIMMA)—to make health insurance more affordable to small businesses by allowing insurers to offer plans across state lines that bypass state coverage mandates, such as contraception, cancer screening and treatment, and maternity care. The measure was ultimately defeated when proponents could not garner the 60 votes necessary to end debate and allow a vote on the bill.

Meanwhile several states pressed ahead on the contraceptive coverage front. New Jersey enacted a law this year, bringing the total number of states with some form of contraceptive coverage requirement to twenty-six: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Under the New Jersey law, health plans must cover outpatient prescription drugs, including prescription contraceptives. There is a religious exemption for a religious employer, such as a church, an association of churches, or a religiously sponsored school.

Eight states introduced legislation to require contraceptive coverage: Michigan, New Mexico, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, and Utah. In Michigan, the state's Civil Rights Commission ruled in August that health plans covering prescription drugs must also cover prescription contraceptives. And earlier in the year, the Utah State Senate defeated legislation to mandate contraceptive coverage. Other state action included Montana's Attorney General Mike McGrath (D) issuing an opinion requiring health plans that provide

coverage of prescription drugs to also cover contraceptives, and the New York Court of Appeals upholding the state's contraceptive coverage law.

Alternative Bills to Reduce the Need for Abortion Fall Far Short of Prevention First

Believing that the omnibus prevention legislation that has been the cornerstone of efforts to reduce unintended/unwanted pregnancy in recent years had failed to attract broad enough support from anti-choice Democrats and Republicans, Representative Tim Ryan—himself a pro-family planning but anti-choice Democrat from Ohio—sought to redefine “common ground” by crafting his own approach, embodied in the Reducing the Need for Abortion and Supporting Parents Act (H.R. 6067). The stated purpose of Ryan's bill is to “reduce abortions by preventing unintended pregnancies, supporting pregnant women, and assisting new parents.” By paring down the contraceptive provisions included in Prevention First and adding provisions focused on social supports, Ryan's hope had been to attract significant support from anti-choice members, in particular anti-choice Democrats. Although by the end of the session, his bill had twenty-four cosponsors, only three of whom were solidly anti-choice.

The failure to attract a larger contingent of anti-choice members in part reflected the bill's evolution over the course of the year from one which reflected the Democrats for Life goal of reducing abortion by 95 percent over 10 years without including major improvements to contraceptive access, to one that while flawed, contained some of the key provisions universally supported by family planning advocates. Ryan's bill also reflected input from Third Way, a relatively new think tank founded to press for policies to help more conservative “red state” Democrats who the organization felt were being harmed by the party's perceived stance on abortion.

Ryan's bill changed dramatically as a result of months of negotiations and behind-the-scenes machinations involving Ryan and his staff, pro-choice Democrats, pro-life Democrats, and family planning advocates. What emerged was a much-improved bill that included key components of the Prevention First legislation, such as Title X funding and Medicaid family planning expansions. Unfortunately, Ryan and some of his potential co-sponsors still viewed provisions related to private insurance coverage of contraception and emergency contraception as too controversial to include. Although some of the anti-choice language in the initial drafts was removed as the bill evolved, the final version of the bill still contained problematic provisions that appear to be designed to dissuade women from seeking abortion. These included a federal policy for informed consent for abortion, optional counseling services at group homes for pregnant and parenting women, funding for ultrasound equipment in community health centers, and providing additional information and support services about prenatally diagnosed genetic conditions.

Another key distinction from Prevention First, which family planning advocates were pleased that Ryan himself ultimately co-sponsored, was the inclusion of provisions under the general rubric of “parental supports,” such as an expansion of WIC, Medicaid coverage of pregnant women and SCHIP coverage of children; adoption tax credits; after-school programs; and day care programs for university students. While assisting pregnant women and low-income mothers is a widely supported goal, family planning advocates rejected the notion that these very limited supports come close to what would truly be needed to level the economic playing field for women facing unintended/unwanted pregnancies. In the end, the bill did not come far enough to be endorsed by the major family planning advocacy groups. However, to his credit, Ryan proved very willing to listen to concerns from both members and advocates and, in the process, established himself as a moderate force to be reckoned with on family planning issues.

Just one week after the introduction of the Ryan bill, anti-choice Democrat Lincoln Davis (TN) introduced a bill much closer to Ryan's original formulation—the so-called “Pregnant Women Support Act” (H.R. 6145), a bill

designed to reduce the number of abortions by establishing health care and child care-related programs to support pregnant women. The Davis bill includes no expansions in contraceptive coverage, and falls even further from the Prevention First gold standard. Not surprisingly, the Davis bill was supported by Democrats for Life, an organization which is not entirely sure whether it supports contraception and had tried to ensure that the Ryan version of the bill reflected that ambivalence.

CMS: Agency Giveth with One Hand and Taketh Away With the Other ***DRA Spells Trouble for Providers even as Waivers Continue to Expand***

Family planning providers struggled to implement a number of onerous provisions contained in the Deficit Reduction Act (DRA), the sweeping law passed by Congress in early February (Public Law No. 109-171) that cuts federal spending by \$40 billion over five years, including nearly \$5 billion in Medicaid spending. In addition to the drastic funding cuts to Medicaid, a number of problematic policy changes adversely impacting family planning providers and the low-income women they seek to serve were tucked into the bill. These included new proof of citizenship and identity requirements, along with a small but devastating provision that makes it financially unpalatable for pharmaceutical companies to continue to offer very low-priced drugs to family planning clinics that do not participate in the 340B drug pricing program. The DRA allows states to expand their flexibility in defining benefits packages and impose co-payments. Taken together or separately, these provisions could, at least in theory, reduce coverage for family planning services.

Burdensome Documentation Requirements in Place

As the Centers for Medicaid and Medicare Services (CMS) moved to implement the new proof of citizenship and identity requirement of the DRA, the agency did little to alleviate the pressures being felt by family planning providers. Prior to the enactment of the DRA, most states determined citizenship simply by allowing recipients to self-declare their status under penalty or perjury. However, the DRA now requires citizens who are applying for Medicaid, and current enrollees who are being recertified, to provide documentation demonstrating both citizenship and identity.

CMS published an interim final rule on July 12 that maintained the rigorous four-tiered “documentation hierarchy” outlined in the law. Acceptable primary documents are a U.S. passport, a Certificate of Naturalization, and a Certificate of U.S. Citizenship. If an applicant or recipient presents evidence from the listing of primary documentation, no other information is required. When this evidence cannot be obtained, the state can look to the next tier of acceptable forms of identification. However, if an applicant uses a document from the second, third, or fourth tiers, then the applicant is also required to present proof of identity, such as a driver’s license. In very rare cases, written affidavits are permissible, but the affidavits must be supplied by two individuals, one of whom may not be related to the applicant, and the individuals must attest to having personal knowledge of the applicant’s citizenship. Furthermore, individuals providing affidavits must prove their citizenship and identity.

Family planning providers joined the chorus of opponents of the documentation requirement amidst growing concern that instituting cumbersome procedures for documenting citizenship would prevent large numbers of low-income women in need of publicly funded family planning services from being able to enroll in Medicaid, even if they are American citizens who are otherwise eligible. These changes could be especially problematic in states with family planning waivers where, for many women, family planning is the sole covered service. Some family planning providers also are concerned that Title X will be unable to absorb the cost of serving patients who are unable to meet the new documentation requirements. To address this issue, NFPRHA, in conjunction with the Guttmacher Institute, the National Women’s Law Center, and Planned Parenthood Federation of America (PPFA), submitted comments on the interim final rule asking that individuals receiving benefits under Section 1115 family planning demonstrations attest to citizenship in order to comply with the statute. However, it is unlikely that CMS will make such an exemption when it issues its final rule.

Nominal Pricing Provision Devastates Clinics

In yet another blow to clinics already struggling with contraceptive cost increases from earlier in the year, in December, pharmaceutical companies began acting on another DRA provision—this one pertaining to drug pricing. Under the law, only certain sales of covered outpatient drugs at “nominal” price will be excluded from the Medicaid’s “best price” calculation. As a result, nominal prices obtained by non-340B entities, including family planning clinics neither eligible for 340B drug pricing nor designated as “safety net” providers by HHS, are negatively impacted. The change in the law does not affect 340B covered entities or 340B prices.

Responding to an implementation date of January 1, 2007, several pharmaceutical companies sent letters to those clinics impacted by this provision in December, notifying them that as of January 1, 2007, there were no longer able to receive nominally priced drugs. For some family planning clinics across the country, this change was devastating. In many cases, the price of contraceptives rose from \$3.20 per cycle to \$36 or \$38 per cycle, severely impacting the ability of these clinics to maintain operations.

NFPRHA, with key coalition partners including PPFA, attempted to fix the nominal pricing provision through both the regulatory and legislative processes. Caught up in the chaos of last-minute negotiations on a myriad of issues that always occur in the closing moments of a Congress, lawmakers ultimately declined to fix the provision legislatively. Adding insult to injury, on December 22, CMS also declined to expand the definition of safety net providers in order to include the impacted family planning clinics when it issued interim regulations on the DRA provisions impacting prescription drugs. NFPRHA and affected colleague organizations will be attempting to fix this language in the coming year – and could well encounter a more receptive audience in the new Democratic Congress.

States Allowed to Create “Benchmark” Plans That Theoretically Could Eliminate Family Planning Coverage

The DRA allows states to vary the benefit packages they offer to some groups of Medicaid beneficiaries, including most parents of reproductive age. These new “benchmark” benefit packages are not required to provide all the benefits covered by regular Medicaid, although they must receive federal approval. The new law specifically exempts elderly persons, pregnant women, people with disabilities, and some other beneficiaries from these new rules, which means those individuals cannot be required to enroll in one of the benchmark plans.

CMS has given states great flexibility by allowing them to offer exempt beneficiaries the choice of enrolling in a benchmark package or remaining in regular Medicaid. States can use Blue/Cross Blue Shield plans, large commercial HMOs, state employee plans, or any plan approved by the Secretary of HHS as benchmarks under the new law. Despite our initial fears, no state has yet shown any interest in eliminating or reducing family planning benefits.

Another DRA policy change allows states to impose “nominal” cost-sharing for some drugs prescribed as part of a family planning visit. Family planning services are exempt from a provision allowing increased co-pays under the DRA.

Half of States Have Expanded Medicaid-Funded Family Planning Services

Even as Congress slashed Medicaid funding and gave states the flexibility to reduce benefits and impose cost-sharing requirements, there was some positive news to report from CMS: the continued approval of family planning waivers designed to expand access to services. Texas became the 25th state to expand family planning services under Medicaid when its waiver was approved on December 22. First implemented in the early 1990s, waivers have been touted as an innovative way for states to use federal Medicaid funding to test new approaches to expanding coverage to additional individuals. All waivers, whether broad or narrow, must demonstrate that

they are budget neutral, and beginning in 2001, family planning waivers have been required to facilitate access to primary care services. A 2003 CMS-funded evaluation of six states that expanded Medicaid-funded family planning services found that each state realized substantial net savings. For example, Arkansas saved nearly \$30 million in a single year, while the program in Oregon saved \$20 million. Further, an August 2006 Guttmacher Institute study demonstrated that expanding Medicaid coverage for contraception to equal that of pregnancy-related care would save \$1.5 billion in annual federal and state expenditures.

Although half of states have implemented some type of family planning expansions, a number of different approaches have been undertaken. Seventeen of the 25 states have expanded Medicaid family planning services based on income, with seven states—Arkansas, California, Iowa, Louisiana, Minnesota, New York, and Washington—expanding up to 200 percent of the federal poverty level; nine states—Michigan, Mississippi, New Mexico, North Carolina, Oklahoma, Oregon, South Carolina, Texas, and Wisconsin—expanding up to 185 percent; and one state—Alabama—going to 133 percent. Six states—Arizona, Florida, Maryland, Missouri, Rhode Island, and Virginia—have expanded eligibility for two years to women who would otherwise lose their 60-day postpartum coverage; and two states—Delaware and Illinois—expand eligibility to women who would otherwise lose their Medicaid coverage for any reason.

Landmark Legislation to Expand Coverage of Medicaid Family Planning Services Introduced

Following up on the documented success that states have had with expanding eligibility for family planning services under Medicaid, Senator Hillary Rodham Clinton (D-NY) and Representative Nita Lowey (D-NY) introduced legislation, the Unintended Pregnancy Reduction Act (S. 2916/H.R. 5795), that would require states to provide coverage of Medicaid family planning services to women up to the same income level used to determine eligibility for pregnancy-related care. (States are required to provide coverage of pregnancy-related care to women with incomes up to 133 percent of the federal poverty level). The legislation also would clarify that family planning is a mandatory service under Medicaid, which up until enactment of the Deficit Reduction Act earlier this year, had been a clear requirement under federal law since 1972.

While 25 states have recognized the cost-effectiveness of helping women avoid unintended pregnancies by obtaining waivers, they have had to jump through bureaucratic hoops seeking federal permission to expand their family planning programs. This legislation would build upon the existing state effort and establish as a nationwide principle that those low-income women who would qualify for Medicaid if they became pregnant should have the opportunity and means to avoid pregnancy if they so chose.

The legislation received little attention during the 109th Congress, however, proponents are hopeful that the 110th Congress will sit up and take notice of the tremendous cost savings associated with the measure and see that this important measure be enacted into law.

Abstinence-Only Education Programs Flat-Funded, Harshly Reviewed by GAO

Skepticism regarding the benefits of greater investments in abstinence-only-until-marriage education programs appeared to grow in an unlikely place this year: Congress. At the same time, however, the President remained an unconditional supporter of abstinence-only programs, seeking a major boost in funding in his FY 2007 budget as the Department of Health and Human Services (HHS) tightened restrictions on how these funds could be spent.

The year began with the President's call for a \$24 million increase to Community-Based Abstinence Education programs (CBAE) in his FY 2007 budget request – a request that sought to bring the total for the three streams of abstinence-only-until-marriage funding to a new high of \$200 million. Under this proposal, abstinence-only-until-marriage education programs would have received \$137 million for FY 2007 through CBAE, with an additional \$50 million for state programs funded through the Maternal and Child Health (MCH) Block Grant (also known as Title V), and \$13 million for abstinence education out of the Adolescent Family Life Program administered by the Office of Population Affairs.

This increase failed to materialize when, for the first time in more than five years, both the Senate and House Appropriations Committees flat-funded abstinence-only-until-marriage programs. In the end, these programs shared the fate of most public health programs, ending at the FY 2006 level of \$176 million as part of the 109th Congress's continuing resolution for the remaining FY 2007 appropriations bills.

Congress also opted for a short-term extension of the Title V abstinence-only-until-marriage program just prior to adjournment. Both the Transitional Medicaid Assistance program (TMA) and Title V abstinence programs were set to expire on December 31, until Congress added a six month extension to a last-minute tax and trade package (P.L. 109-432). These programs are now set to expire on June 30, 2007 – presenting at least a glimmer of hope that positive changes to the program may be possible when the Democratically controlled Congress reconvenes in January.

HHS Further Tightens Restrictions on Abstinence-Only-Until-Marriage Funds

Despite renewed hopes that Democrats will be able to improve abstinence-only programs, HHS further tightened the conditions under which programs can receive CBAE funds and extended the grant cycle to five years. CBAE grants, which are administered by the Administration for Children and Families (ACF) within HHS, target programs to adolescents aged 12-18 and are required to adhere to all components of the eight-point federal abstinence education program definition. The FY 2007 CBAE grant announcement articulated thirteen "themes" that severely curtailed what programs can teach in regard to contraception, sexual activity, and marriage, stressing the need to emphasize the drawbacks of contraception in a much more detailed and prescriptive manner, explicitly prohibiting programs from promoting or encouraging the use or combining of any contraceptives in order to make sex "safer." The grant announcement also expanded the definition of "sexual activity" to include any type of "sexual stimulation," a broad interpretation that could be construed to include actions as benign as kissing.

In 2006, HHS also decreased the limited flexibility states had in using Title V abstinence funds. These funds were established through Title V, Section 510 of the Social Security Act and provide \$50 million per year to states for abstinence-only programs. Last year, HHS "strongly encouraged" states accepting these funds to adhere to all eight points of the federal abstinence-only definition, although states maintained some freedom in choosing which of the points they would incorporate. This year HHS took away that flexibility, instead mandating through the FY 2007 grant announcement that states incorporate *all* eight points.

While past announcements prohibited Title V-funded programs from promoting the use of contraceptives, the FY 2007 grant announcement requires states to provide “assurances” that funded curricula and materials “do not promote contraception and/or condom use,” a restriction that applies to both the federal Title V funds as well as state funds allocated to these programs. This year’s announcement also contained another disturbing change, shifting the focus of these “adolescent” programs away from the adolescent age group. Historically, Title V programs had no specific age restrictions, allowing many states to choose to focus on the importance of delaying sexual initiation among young people ages 9 to 14. The FY 2007 grant announcement states that Title V-funded programs must now focus on individuals ages 12 to 29, a dramatic shift from the legislative intent of directing the program at “school-age children.”

In the wake of these heightened restrictions, the state of New Jersey announced on October 24 that it would reject Title V funds for FY 2007. In a letter from top New Jersey health and education officials to HHS Secretary Michael Leavitt, the state explained its decision, saying that strings attached to abstinence-only-until-marriage funds contradict the core curriculum content standard in New Jersey’s sex and AIDS education programs. New Jersey, which has received about \$800,000 in federal funds each year since 1997, joins California and Maine in rejecting the funding.

New Study Undermines Role of Abstinence in Teen Pregnancy Decline

A study to be published in the January 2007 issue of the *American Journal of Public Health* finds that the recent decline in the U.S. teen pregnancy rate stems largely from improved contraceptive use. Between 1995 and 2002, U.S. teen pregnancy rates declined by nearly 24 percent. The study, “Explaining Recent Declines in Adolescent Pregnancy in the United States: The Contribution of Abstinence and Improved Contraceptive Use,” by John Santelli et al., finds that 86 percent of the decline is the result of improved contraceptive use, while a small percentage of the decline (14 percent) comes from teens waiting longer to initiate sexual activity. Delays in sexual activity played a greater role for younger teens (aged 15–17) than for older teens (aged 18–19), for which the decline in teen pregnancy was entirely attributable to improved contraceptive use.

The study raises serious doubts about the usefulness of the federal government’s funding of abstinence-only-until-marriage programs, which prohibit educators from discussing the benefits of condoms and contraception. A report from the Guttmacher Institute, published in the December 2006 issue of *Perspectives in Sexual and Reproductive Health*, found that only 66 percent of males and 70 percent of females received formal education about birth control in 2002, compared with 81–87 percent in 1995. The study, “Changes in Formal Sex Education: 1995–2002,” by Laura Duberstein Lindberg, also found that teens are receiving the information too late, whether it is about contraception or abstinence: in 2002, just more than half of sexually experienced males and six in ten sexually active females received any education about birth control before they had sex, and one-quarter of males and females had not received information about abstinence. Additionally, the proportion of teens receiving information only about abstinence doubled to one in five teens.

Conservatives Try to Undermine Comprehensive Sex Ed

While evidence continued to mount about the ineffectiveness of abstinence-only-until-marriage programs, congressional conservatives attempted to bolster their own cause through discrediting their opponents. In March, Representative Don Manzullo (R-IL) and 20 other anti-family planning Republicans sent a letter to the Government Accountability Office (GAO), asking the agency for a review of the content of federally funded teen pregnancy prevention programs and HIV/AIDS prevention programs. The letter claimed that “comprehensive sex education programs” actually promote sexual activity while marketing themselves as “abstinence plus,” and asked the GAO to determine whether these programs are accurate and age-appropriate.

Manzullo's request appeared to be an attempt to respond to Representative Henry Waxman's (D-CA) 2004 report, which found that the many common curricula in federally funded abstinence-only-until-marriage programs are rife with medical and scientific inaccuracies. Of the 13 federal programs reviewed by the Waxman report, 11 were found to contain subjective and/or unscientific information regarding reproductive health, gender traits, and when life begins. In another attempt to discredit the Waxman report, Representative Mark Souder (R-IN), Chair of the Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources, released a report in November reviewing the findings of the Waxman report. Souder's report, "Abstinence and Its Critics," claimed that the Waxman report was "misleadingly critical" of federally funded abstinence-only-until-marriage programs, but did little more than attack comprehensive sex-ed programs in its attempt to undermine the Waxman report's findings.

Souder has long been an opponent of family planning, as well as any program that does not teach abstinence-only-until-marriage. In May, staunch abstinence-only critic Bill Smith, of the Sexuality Information and Education Council of the United States (SIECUS), was removed from a panel at the Center for Disease Control and Prevention's (CDC) 2006 National STD Prevention Conference after one of Souder's aides complained. The panel, originally titled "Are abstinence-only programs a threat to public health?" was changed following the complaint, and two pro-abstinence speakers were added in place of Smith. One of the new speakers was Patricia Sulak, a prominent abstinence-only-until-marriage advocate who founded and directs "Worth the Wait," was later appointed by President Bush to join CDC's Advisory Committee on HIV and STD Prevention.

GAO Finds Flaws With HHS' Handling of Medical Accuracy in Abstinence-Only Programs

By the end of 2006, there was no definitive indication that GAO would initiate the investigation requested by Manzullo. In fact, in October, the GAO sent a letter to HHS Secretary Michael Leavitt urging HHS to review abstinence-only-until-marriage programs that may be in violation of a federal law requiring federally funded grantees dealing with the prevention of sexually transmitted diseases (STDs) to provide medically accurate information about condom effectiveness or the lack thereof. Ironically, this medical accuracy requirement was added by then-Representative Tom Coburn (R-OK) to the FY 2001 Labor-HHS appropriations bill in an attempt to disparage condom effectiveness, particularly with regard to HPV. ACF has maintained that federally funded abstinence-only-until-marriage programs are exempt from the requirement, thereby allowing HHS to prohibit programs from discussing condom effectiveness and allowing them to contain medically inaccurate information. GAO, however, concluded that the medical accuracy requirement does in fact apply to the abstinence-only programs.

GAO has been investigating the federal abstinence-only-until-marriage programs as part of a 2005 request by Representative Waxman and other members of Congress to review the processes within HHS for determining the accuracy and evaluating the effects of "abstinence-only" sex education. In November, GAO issued a report which found that efforts by HHS to assess the scientific accuracy of materials used in abstinence-until-marriage education programs have been "limited." The report, "Abstinence Education: Efforts to Assess the Accuracy and Effectiveness of Federally Funded Programs," attributed its findings largely to the fact that ACF does not review its grantees' education materials for scientific accuracy and does not require grantees of either program to review their own materials for scientific accuracy. In response to GAO's findings, Senator Frank Lautenberg (D-NJ) introduced the Guarantee of Medical Accuracy in Sex Education Act (S. 4059, H.R. 5598). This would prohibit the federal government from providing assistance to any entity – including all federally funded health education programs – whose materials on human sexuality contain medically inaccurate information. The bill was introduced in the House by Representatives Luis Gutierrez (D-IL) and Jim Moran (D-VA) in June.

REAL Act Gets First Floor Vote

In July, as part of the Senate debate on the Child Custody Protection Act (CCPA, S. 403), Senators Lautenberg and Bob Menendez (D-NJ) offered an amendment to CCPA to allow HHS to make grants to state and local governments and non-profit groups to provide sex education that includes both abstinence and contraception. The amendment also sought to authorize additional funds for various after-school programs and for a project to encourage new pregnancy prevention programs. The sex education portion of the amendment was in essence the Responsible Education About Life (REAL) Act, first introduced in 2005 as a means to provide funding to states for comprehensive sexuality education programs that include medically accurate information about abstinence, contraception, and disease prevention. The amendment brought about the REAL Act's first floor vote, and the narrow defeat (48-51) gave comprehensive sex education advocates hope that the bill could garner the votes needed to pass the next time around.

Congress Thwarted in Efforts to Pass Additional Abortion Restrictions *South Dakota Voters Overturn State Ban*

The GOP leadership ultimately failed in several last ditch efforts to enact restrictive abortion legislation that has been the hallmark of the anti-choice movement. These defeats, coupled with the resounding rejection of South Dakota's abortion ban, as well as the outcome of the November elections, have renewed hope that the anti-choice votes cast in the 109th Congress will be the last for the foreseeable future.

Fetal Pain Bill Narrowly Defeated in the House

House Republicans failed in their bid to enact one final anti-choice measure before the 109th Congress adjourned. The Unborn Child Pain Awareness Act (H.R. 6099), sponsored by Representative Chris Smith (R-NJ), was placed on the suspension calendar on December 13—a process generally reserved for noncontroversial bills and requires a two-thirds majority for passage. In a relatively narrow victory for pro-choice advocates, the bill garnered 162 votes in opposition, 15 more than needed to defeat the legislation.

The fetal pain bill was intended to force women obtaining abortions to read and sign a form drafted by Congress prior to any abortion performed at “20 weeks after fertilization” or later. The form, which could not be modified in order to tailor the information to a particular patient's needs, stated that “there is substantial evidence” that the abortion will cause pain to the fetus as early as 20 weeks. This is a subjective characterization of a complicated scientific debate that is anything but clear. The form also stated that the patient may request medications intended to reduce pain administered directly to the fetus. Women signing the form would have “to explicitly either request or refuse the administration of pain-reducing drugs.” The only exception to the bill's requirements was for narrowly defined medical emergencies.

NFPRHA, along with a broad range of medical, health, and advocacy organizations including Planned Parenthood, the American College of Obstetricians and Gynecologists, the American Civil Liberties Union, the National Women's Law Center, and the National Abortion Federation, strongly objected to the underlying premise of the fetal pain bill—that discussions between physicians and women seeking abortions should be subject to government-mandated information—and worked together in concert to defeat the last anti-choice measure of the 109th Congress. In contrast, NARAL Pro-Choice America sent a letter to the Hill the week before indicating that the organization would not take a position and would not score the vote.

Conservatives Press for Last-Minute Passage of Child Interstate Abortion Notification but Overreach

Legislation to require parental consent for abortion has long been a centerpiece of the anti-choice agenda. However, despite numerous votes on both sides of Capitol Hill in favor of this legislation, the House GOP leadership elected to press for the most conservative version of legislation, the Child Interstate Abortion Notification Act (CIANA), setting up a showdown with the Senate that ultimately led to the measure's defeat.

On July 25, the Senate bypassed the Judiciary Committee and took up the Child Custody Protection Act (CCPA) (S. 403), sponsored by Nevada Republican John Ensign. The bill would make it a federal crime for a non-parent to help an underage girl cross state lines to avoid parental notification and consent laws for an abortion. The bill, which does not criminalize doctors or the young women who obtain abortions, was approved by a lopsided 65-34 vote. Fourteen Democratic senators voted in favor of the bill: Bayh (IN), Byrd (WV), Carper (DE), Conrad (ND), Dorgan (ND), Inouye (HI), Johnson (SD), Kohl (WI), Landrieu (LA), Nelson (FL), Nelson (NE), Pryor (AR), Reid (NV), and Salazar (CO). Four Republicans voted against the measure: Collins (ME), Snowe (ME), Chafee (RI), and Specter (PA), along with Independent James Jeffords (VT).

Democrat Dianne Feinstein (CA) was absent for the vote.

The only amendment to pass during debate on CIANA/CCPA was one offered by Senators Ensign and Barbara Boxer (D-CA). As Senator Boxer explained, the amendment, which was intended to solve the “incest predator problem,” states that someone who has committed an act of incest with a minor and transports the minor across a state line to obtain an abortion is subject to a fine or imprisonment of not more than one year, or both. It also would bar a father who has committed incest from filing a lawsuit under the bill against an individual who transported his daughter across state lines for an abortion. The amendment was adopted by 98-0.

Immediately following the final vote, Senate Majority Leader Bill Frist (R-TN) attempted to appoint Senators to a conference committee to work out differences with a more draconian version of the bill, H.R. 748, the Child Interstate Abortion Notification Act passed by the House last year. Assistant Democratic Leader Dick Durbin (IL) objected on behalf of Senate Democrats, saying that the bill had only been debated a short time and had never gone through the Judiciary Committee. Democrats were anticipating that the Senate had too little time before adjournment for the year to press the issue further.

Then, on September 26, rather than giving blanket approval to the Senate-passed bill, which would have allowed the measure to be signed into law, the House chose to substitute its version of the legislation (H.R. 748). By a vote of 264-153, the House approved CIANA, sending the measure back to the Senate.

While it was widely believed that the Senate would not consider CIANA, in a surprise move on September 27, Senator Bob Bennett (R-UT) filed a procedural motion (cloture) on the motion to concur with the House-passed bill. Under Senate rules, 60 votes are needed to “invoke cloture,” which would have cut off debate and allowed the Senate to proceed to a final vote on the underlying bill. In the last vote cast before Senators left Washington to hit the campaign trail, the Senate defeated the cloture motion by a vote of 57-42, essentially killing the bill for the year.

Bill Differences

Both CCPA and CIANA would prohibit anyone other than a parent from accompanying a young woman across state lines to seek an abortion without first complying with her home state’s parental involvement law. Violators would be subject to both fines and imprisonment. Under both measures, a father who rapes and impregnates his daughter would be prohibited from suing any adult who helps his daughter obtain an abortion. A family member who commits incest would be prohibited from transporting a pregnant teen across state lines.

CIANA, the bill passed by the House, goes several steps further by imposing a federal parental notification requirement. Doctors would be required to provide at least 24 hours notice to the parent of a minor seeking an abortion if that minor resides in another state. To further complicate matters, the notice must be given in person either by the physician or “an agent” of the physician. A physician—defined in the bill as “a doctor of medicine legally authorized to practice medicine or a person legally empowered by the state to perform abortions”—who knowingly performs an abortion without meeting the parental notification requirements would be subject to fines and imprisonment.

NFPRHA strongly opposed both CIANA and CCPA, arguing that teens should be encouraged to seek parental advice and counsel when faced with an unintended pregnancy. When a young woman cannot involve a parent, the law should encourage her to seek out a trusted adult, and should not punish any adult trying to help. Fortunately, it is unlikely that a Democratically controlled Congress will endeavor to take up this anti-choice legislation, making this one of the last votes on this issue for the foreseeable future.

South Dakota Voters Overwhelmingly Reject Challenge to *Roe* in November

South Dakota became the test case for state abortion bans this year. Under new, far-reaching legislation enacted in South Dakota, doctors could have faced up to five years in prison for performing an abortion unless it was necessary to save the woman's life. The South Dakota ban included no exceptions for rape, incest or the preservation of a woman's health. The legislation declared that "the life of a human being begins when the ovum is fertilized by male sperm," but stated that "nothing in this Act may be construed to prohibit the sale, use, prescription, or administration of a contraceptive measure, drug or chemical, if it is administered prior to the time when a pregnancy could be determined through conventional medical testing and if the contraceptive measure is sold, used, prescribed, or administered in accordance with manufacturer instructions."

The law was signed on March 6 by Governor Mike Rounds (R) after passing the House by 50-18 and the Senate 23-12. The new law would have banned virtually all of the 800 abortions performed each year at Planned Parenthood, the state's only abortion clinic. The law was clearly unconstitutional under existing Supreme Court rulings, but its backers were hoping that the addition of Justices John Roberts and Samuel Alito to the Supreme Court may leave the Court shy of the five-vote majority needed to uphold *Roe*.

Supporters and opponents of abortion rights had been gearing up for a showdown even before Governor Rounds added his signature to the bill and both sides expected a lengthy battle. Then, on June 19, South Dakota Secretary of State Chris Nelson (R) certified that enough signatures had been collected to place the law on a statewide ballot in the November elections. Abortion rights advocates filed more than 38,000 signatures—more than double the 16,728 required to assure a vote. That move allowed the voters of South Dakota to decide whether the ban should go into effect.

After months of grassroots education and mobilization, the voters of South Dakota overturned the ban by a stunning 56 percent to 44 percent. Although South Dakota successfully defeated their arguably unconstitutional ban, other states are certain to follow suit in an effort to bring a direct constitutional challenge to *Roe*.

FDA Issues Medical Abortion Health Advisory after Two Deaths; CDC and Congress Examine Drug

The FDA issued a public health advisory on March 17, regarding sepsis and medical abortion after the agency was informed of two additional deaths following medical abortion with mifepristone (RU 486 or Mifeprex). The FDA advisory said it was aware of four confirmed deaths from sepsis in the United States, from September 2003 to June 2005, in women following medical abortion with mifepristone and misoprostol. All four cases of fatal infection tested positive for *Clostridium sordellii* and involved the off-label dosing regimen consisting of 200 mg of oral Mifeprex followed by 800 mcg of intra-vaginally placed misoprostol. One additional death involved a woman with an undiagnosed, untreated ectopic pregnancy, a dangerous condition, that mifepristone does not treat.

In addition, the FDA tested the drug from manufacturing lots of mifepristone and misoprostol and found no contamination with *Clostridium sordellii*. Reports of fatal sepsis in women undergoing medical abortion are very rare (approximately 1 in 100,000). More than 500,000 women have taken mifepristone since its approval in September 2000, according to Danco, the company that markets the drug in the United States.

The March 17th FDA alert stated that the agency was investigating all circumstances associated with the cases and was not able to confirm the causes of death. It also reminded physicians and patients to be aware of the possibility of infection following medical abortion and to watch for symptoms such as abdominal pain, nausea, vomiting, diarrhea and weakness with or without fever. The public health advisory said that the "FDA does not

have sufficient information to recommend the use of prophylactic antibiotics” because they carry their own risks of serious adverse events such as severe or fatal allergic reactions and “can stimulate the growth of ‘superbugs,’ bacteria resistant to everyday antibiotics.” In addition, no one knows which antibiotic and regimen will be effective in these types of cases.

Representative Chris Smith (R-NJ), Co-Chair of the Pro-Life Caucus in the House, stepped up his calls for passage of a bill (H.R. 1079) authored by Representative Roscoe Bartlett (R-MD) that would withdraw FDA approval of mifepristone pending a review by the Comptroller General of the FDA’s approval process for the drug. Other anti-abortion Members stepped up their efforts as well, and on May 17 the House Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resource held a hearing, entitled, “RU-486 – Demonstrating a Low Standard for Women’s Health?” The hearing title leaves no doubt as to the biases of Subcommittee Chair Mark Souder (R-IN), a longtime opponent of family planning and abortion. Congressman Souder claimed that the hearing was needed to examine whether the FDA was properly responding to reports of adverse health effects as a result of taking mifepristone, including the deaths of a handful of women who took the drug.

Asserting that “it’s very clear that there is a serious problem with RU-486,” Congressman Souder added that “to continue to defend this dangerous drug in light of mounting scientific evidence, injury and death is to allow one’s zeal for abortion to truly distort their view about what’s right for women’s health.” Expressing his disdain for the FDA’s action, he said, “Any other drug associated with a 100% fatal septic infection that kills otherwise healthy adults within days, with no apparent window for treatment, and associated with an exponential amount of severe infections, would normally prompt an immediate withdrawal.” He failed to note, however, that *C. sordellii* infections also have occurred in women who have not taken the drug—specifically after vaginal deliveries, C-sections, and miscarriages—a point emphasized by Dr. Susan Wood, former director of the FDA’s Office of Women’s Health, who testified before the subcommittee: “This is not limited to women who have been exposed to mifepristone, and to focus solely on women who have had a medical abortion is to miss the real threat to the health of women. . . Experts at CDC, FDA, and NIH reviewed the current information and appeared to recognize that the infections and deaths due to *C. sordellii* are not due to a simple drug effect. Rather this is a complex situation that involves multiple factors that are linked to pregnancy.”

Taking a strikingly different approach to problem-solving, the CDC held a May 11 public workshop on “Emerging Clostridial Disease” in order to “develop a draft research agenda to better understand the virulence, pathogenesis, host factors, and non-antimicrobial risk factors contributing to reports of morbidity and mortality” associated with *C. sordellii* and *C. difficile*.

The outcome of the CDC workshop was generally viewed as positive for pro-choice advocates. Although three presenters focused their comments exclusively on mifepristone and *C. sordellii* infection, the consensus among the panelists was that pregnancy-related morbidity and mortality in connection with *C. sordellii* should be examined through the lens of pregnancy as a whole and not be confined solely to abortion. Additionally, panelists expressed their concern that *C. difficile* currently poses a greater public health threat and warrants increased attention due to rising rates of infection in hospitals, nursing homes, and long-term care facilities. Panelists called for surveillance systems for *C. difficile*, particularly with respect to nursing homes and long-term care facilities, in addition to improved pregnancy-related morbidity and mortality surveillance systems.

Legislation, Report Details Misleading Tactics of Crisis Pregnancy Centers

Anti-choice crisis pregnancy centers (CPCs), or pregnancy resource centers as they have begun to call themselves, have found great support from within the Bush Administration. Since 2001, they have received over \$30 million

in federal funding, mostly through funding streams for abstinence-only education programs. Other federal funds have come from appropriations earmarks and the Compassion Capital Fund.

It is no secret that these centers' main objective is to dissuade women from choosing abortion. Many use intimidation and misleading information to influence the women. Some even go so far as to advertise under "abortion services" in the yellow pages or purchase advertising on internet search engines under keywords including "abortion" or "abortion clinics."

In order to protect women seeking reproductive health services and information from the deceptive practices of these centers, Representative Carolyn Maloney (D-NY) introduced the Stop Deceptive Advertising for Women's Services Act (H.R. 5052) on March 31. Original cosponsors included Democrats Maurice Hinchey (NY), Joseph Crowley (NY), James McGovern (MA), Gary Ackerman (NY), Jan Schakowsky (IL), Dennis Kucinich (OH), Henry Waxman (CA), Robert Wexler (FL), Raúl Grijalva (AZ), Lois Capps (CA) and Independent Bernie Sanders (VT).

The legislation sought to crack down on health facilities engaging in deceptive advertising practices that lead women facing unintended pregnancies to believe that they will be offered unbiased counseling and a full range of reproductive health services. These clinics often lure women with the offer of free pregnancy testing or HIV tests with the goal of talking women out of obtaining an abortion. According to *The New York Times*, there are currently more CPCs in the U.S. than there are actual abortion providers.

The bill would require the Federal Trade Commission to create rules that prohibit any organization from advertising services with the intent to deceive the public into believing that the organization is a provider of abortion services if it does not in fact provide those services. Representative Maloney's bill makes it clear that the FTC has the authority to penalize or take corrective action against organizations that purport to provide abortion services even if they are non-profits and provide their services for free.

The need for the Maloney bill was highlighted by recent press reports recounting an incident in Indiana involving a mother accompanying her 17-year-old daughter and her daughter's boyfriend to one of Indiana's Planned Parenthood clinics. They unwittingly walked into a crisis pregnancy center, where the staff took down the young woman's confidential personal information and told her to come back for her appointment, which they said would be in their "other office" (the Planned Parenthood office nearby). When she arrived at Planned Parenthood, the staff was unaware of any appointment. However, police were on hand, having been told by crisis pregnancy center staff that a minor was being forced to have an abortion against her will. The crisis pregnancy center staff then proceeded to wage a campaign of intimidation and harassment, showing up at the girl's home, calling her father's workplace and her school, and urging her classmates to pressure her not to have an abortion.

In July, Representative Henry Waxman (D-CA), then Ranking Member of the House Government Reform Committee, released a report entitled "False and Misleading Health Information Provided by Federally Funded Pregnancy Resource Centers," outlining the deceptive practices of these centers. The report detailed what happened when female investigators, posing as pregnant 17-year-olds facing an unintended pregnancy, attempted to call the 25 crisis pregnancy centers that received federal funding through President Bush's faith-based Compassion Capital Fund.

According to the report, 20 of the 23 centers that responded (87 percent) provided false or misleading information about the health effects of abortion, telling callers that having an abortion could increase the risk of breast cancer, result in sterility, and lead to suicide and post-abortion stress disorder.

Specifically, the centers provided false and misleading information about a link between abortion and breast cancer, notwithstanding a medical consensus that induced abortion does not cause an increased risk of breast cancer. Despite this consensus, eight centers told the caller that having an abortion would in fact increase her risk. One center said that “all abortion causes an increased risk of breast cancer in later years,” while another told the caller that an abortion would affect the milk developing in her breasts and that the risk of breast cancer increased by as much as 80 percent following an abortion.

Even though first trimester abortions do not affect fertility, seven centers told the caller that having an abortion could hurt her chances of having children later in life, with one center claiming that damage from abortion commonly leads to “many miscarriages” and “permanent damage.” Another center stated that if the cervix is damaged during abortion, “it won’t stay closed in future pregnancies, and it can open prematurely and you can have miscarriages.”

Additionally, 13 centers told the caller that the psychological effects of abortion are severe, long-lasting, and common. Despite the fact that the rate of severe psychological stress after an abortion is no more common than after birth, one center said that the suicide rate in the year after an abortion goes up by seven times. Another center compared the effects of abortion to the trauma soldiers suffer after returning from war.

The report concluded that the exaggerations “may be effective in frightening pregnant teenagers and women by discouraging abortion. But it denies teenagers and women vital health information, prevents them from making an informed decision, and is not an accepted public health practice.”

As the incoming Chair of the House Government Reform and Oversight Committee, Representative Waxman is expected to continue his efforts to highlight what he has deemed “waste, fraud, and abuse” within federally funded programs.

Senate Confirms Samuel Alito to Supreme Court

One, if not *the* major reproductive health event of the year came early in the session with the confirmation of Samuel Alito to fill Sandra Day O'Connor's seat on the Supreme Court. Although some Democrats questioned whether Alito, a federal appeals court judge, had the proper judicial temperament and ideology to replace the moderate O'Connor and hinted that a filibuster could be mounted, Alito was confirmed as the nation's 110th Supreme Court Justice on January 31 by a vote of 58-42. With Alito's confirmation, the threat of the so-called "nuclear option"—a rule change that would have prohibited the use of the filibuster on judicial nominations—melted away.

Senate Confirms Alito Despite Concerns Over Views on Privacy

Initial red flags on Alito's nomination went up upon review of key decisions on the right to privacy authored during his 15 years on the Third Circuit Court of Appeals. Alito was the lone dissenter in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, arguing that the spousal notification for abortion requirement should be upheld and that it would not create an undue burden on women, a view which the Supreme Court later rejected. In addition, a 1985 job application Alito completed for a promotion in the Reagan Justice Department stated that Alito was "particularly proud" of his contributions to recent cases that argued "the Constitution does not protect a right to an abortion," a legal position "in which I personally believe very strongly." Alito wrote these words just a few short months after co-authoring the government's brief in *Thornburgh v. American College of Obstetricians and Gynecologists*, in which the government urged the Supreme Court to overturn *Roe v. Wade*. A separate 1985 memo written by Alito regarding the *Thornburgh* case advocates support for a wide array of abortion restrictions and conflates birth control with abortifacients.

Further concerns were raised during the hearing, when Alito made clear that he was unwilling, unlike Chief Justice John Roberts during his confirmation hearing, to characterize *Roe v. Wade* as "settled law," although he did state his belief that there is a constitutional right to privacy based on the *Griswold* decision. He steadfastly refused, however, to articulate that the right to privacy extends to abortion. In fact, Alito acknowledged that his 1985 memo in which he stated that the Constitution does not protect the right to an abortion was "a correct statement of what I thought." Alito did not respond when Committee Chair Arlen Specter (R-PA) asked him directly, "Do you agree with that statement today?" Instead, Alito made a point of saying to Senator Specter, and again to Senator Dianne Feinstein (D-CA), that the principle of *stare decisis*—respecting a past precedent—is not "an inexorable command." Additionally, when asked by Senator Feinstein whether he agrees that an abortion law must protect a woman's health, he avoided answering and simply said past cases have held that.

Despite these concerns, the Senate voted to confirm Alito by a vote of 58-42. The confirmation vote followed a last-minute attempt led by Senators Edward Kennedy (D-MA) and John Kerry (D-MA) to block the conservative judge's nomination with a filibuster. National civil rights and reproductive rights groups, including NFPRHA, supported the filibuster, viewing it as the only mechanism available to prevent Alito's confirmation. Democrats were divided over the wisdom of pursuing a filibuster, and in the end, 19 Democrats joined 53 Republicans in voting to end Senate debate (72-25). Although Alito's confirmation was disappointing, the 42 votes in opposition to Alito's nomination were greater than any other in the last century except Clarence Thomas.

At the time, legal analysts speculated that Justice Alito would join the conservative triumvirate of Chief Justice John Roberts and Justices Antonin Scalia and Clarence Thomas, creating a four-vote conservative bloc in opposition to the current four-vote liberal bloc of Justices John Paul Stevens, David Souter, Ruth Bader Ginsburg, and Stephen Breyer. That would leave the unpredictable Justice Anthony M. Kennedy—a conservative

who has occasionally voted with liberals on gay rights, the death penalty and abortion—as the Court's new fulcrum.

By the end of the 2005-06 term, the question of precisely what impact Justice Alito would have on reproductive rights had not been clearly answered. As expected, Justice Alito did side with the Court's conservative block on a number of important, closely divided cases, involving issues such as the First Amendment, the environment, and voting rights. An analysis of voting patterns in the 2005-2006 by the Georgetown University Law Center Supreme Court Institute found that Justices Alito and Roberts agreed with each other 91 percent of the time, and that for the half-term Alito served, he agreed with ultra-conservative Justices Scalia and Thomas 77 and 74 percent of the time, respectively. Because the two key cases involving reproductive rights (*Ayotte v. Planned Parenthood of Northern New England* and *Scheidler v. The National Organization for Women (NOW)*) were unanimous decisions, they provided no window into Alito's views on abortion and the right to privacy. Instead, reproductive rights advocates will have to wait until 2007, when the Court will issue rulings on two cases challenging the constitutionality of the federal abortion ban heard in the fall of 2006.

Conservatives Focus on Judiciary in 2006

Not content with their victories in the Roberts and Alito confirmations, conservative groups demanded that Senate Republicans renew their push to approve some of the more controversial court nominations as a way to energize the party's base going into the 2006 midterm elections. In May, presidential advisor Karl Rove reportedly met with conservative activists and promised that the White House would introduce almost two dozen new judicial nominations. As a first step, Senate Majority Leader Bill Frist (R-TN) pushed forward and won confirmation for controversial nominee Brett Kavanaugh, President Bush's staff secretary and former colleague of Kenneth Starr, for the D.C. Circuit Court of Appeals by a vote of 57-36. The nomination had been blocked by Democrats since 2004, but Kavanaugh was ultimately confirmed despite concerns over the nominee's lack of courtroom experience, temperament, involvement with administration policies concerning treatment of detainees, and the American Bar Association's (ABA) nearly unprecedented step of downgrading Kavanaugh's rating from well-qualified to qualified.

By the end of the 109th Congress, the Senate had confirmed 2 Supreme Court justices, 16 Appellate Court judges, and 35 District Court judges. Ironically, and despite conservative complaints about Democratic stonewalling of judges, it was a Republican—Sam Brownback of Kansas—who held up more than a dozen district court judges over issues he had with one particular district court nominee, Janet T. Neff, who had attended her lesbian neighbor's commitment ceremony years ago.

The approval of conservative lower court nominees appointed to the federal bench dwindled dramatically following the 2006 midterm elections in November. Indeed, following the Democratic landslide at the polls, President Bush pledged to work with the incoming Democratic majority in a bipartisan manner. Less than two weeks after the election, however, Bush re-nominated five of his most extreme nominees: William Haynes, Terrence Boyle, Peter Keisler, William Myers, and Michael Wallace. Possibly recognizing that the confirmation landscape has dramatically shifted, however, Wallace asked in December for his nomination to be withdrawn. It is likely that other controversial nominees will do the same in the new year. Whether President Bush will continue to push extremist nominees or whether new nominees will reflect the new Democratic strength in the Senate is anyone's guess.

Supreme Court Avoids Major Abortion Decision in 2006 *Pro-Choice Advocates Await Ruling on Federal Abortion Ban*

It was a busy year for reproductive rights in the Supreme Court, with Court rulings in two cases and oral arguments in two more. Yet the year ended with more speculation than answers as to how the new Roberts Court would impact reproductive rights in the immediate future. The Court surprised many with two unanimous abortion decisions, one that sidestepped directly upholding or undermining its own precedent that abortion laws must protect women's health and safety, while the other narrowed the legal means abortion clinics can use to protect their patients from protesters. The Court seemed to be waiting for a different case—and issue—to make a statement on abortion, which many thought might come in the form of the federal abortion ban.

Supreme Court Hands Down Decision in *Ayotte*

In the first of the Supreme Court's two abortion-related decisions for the year, *Ayotte v. Planned Parenthood of Northern New England*, the Court avoided the major legal questions involved in the case while recognizing that abortion laws must protect women's health and safety, and remanded the case back to the lower courts for further consideration.

The *Ayotte* case concerns a 2003 New Hampshire law that subjects doctors to criminal and civil penalties if they do not notify the parent of a teen 48 hours before performing an abortion. Two critical issues were at stake in the *Ayotte* case: whether health exceptions for abortion statutes are constitutionally required; and how many women must be harmed by an abortion restriction law before a court can declare it unconstitutional. The parental notification provision itself was not at issue.

For more than 30 years, the Supreme Court's abortion decisions have required protections for women's health, and this doctrine has repeatedly been reaffirmed. The most recent of these cases, *Stenberg v. Carhart*, invalidated a Nebraska law banning abortion procedures on the ground that it failed to protect women's health. The New Hampshire law at issue in *Ayotte* includes an exception allowing an emergency abortion when necessary to *prevent the woman's death*, but contains no exception where it is necessary to *protect the woman's health*. The law was struck down by two lower courts and a federal appeals court for lacking a health exception.

While the *Ayotte* case had the potential to be a landmark ruling, the Court's January 18 ruling was anything but. In the unanimous decision, written by retiring Justice Sandra Day O'Connor, the Court reaffirmed its precedent that abortion laws must protect women's health and safety, writing, "New Hampshire does not dispute, and our precedents hold, that a State may not restrict access to abortions that are 'necessary, in appropriate medical judgment, for preservation of the life or health of the mother.'" However, the Court chose to not explicitly rule on either of the two significant legal questions at issue in the case.

Instead, the Court ruled on essentially technical grounds and remanded the case to the lower courts. The Court held that invalidating a statute in its entirety is not always necessary or justified; lower courts could issue narrower declaratory and injunctive relief. The Court explained that "the lower courts need not have invalidated the law wholesale," and could have instead crafted a health exception by issuing an injunction that would prohibit the state from enforcing the law in cases involving medical emergencies.

Although the Court's decision reaffirmed the health exception requirement, it represents a new and potentially ominous remedy in reproductive rights jurisprudence. Before *Ayotte*, a law lacking a health exception would have been struck down in its entirety, not "fixed" by the courts. Now, however, courts are seemingly invited to issue a

type of partial injunction, upholding challenged laws for the majority of affected individuals and striking them down as they apply to a limited group of individuals.

Following the ruling, the case was sent back to the federal judge who first heard the case, U.S. District Judge Joseph DiClerico, to determine whether the New Hampshire legislature intended for the law to exist without a medical emergency exception. If not, the Supreme Court said the law should be struck down in its entirety. As of year's end, Judge DiClerico had not made a final decision. In the meantime, the injunction prohibiting enforcement of the law remains.

Supreme Court Rules Against NOW in Clinic Violence Case

On March 1, the Supreme Court issued its second, and also unanimous, abortion decision, in *Scheidler v. The National Organization for Women (NOW)*. The Court ruled 8-0 that abortion clinics cannot use the federal Racketeer Influenced and Corrupt Organizations Act (RICO) to block antiabortion protests, lifting a nationwide injunction protecting virtually all women's health clinics in the nation. Justice Alito, who was confirmed in January, had not been a member of the Court during oral arguments in November and therefore did not take part in the *Scheidler* decision.

The case stemmed from a lawsuit filed in 1986 by NOW and other women's rights groups against several individuals and groups that oppose abortion rights, including Operation Rescue and the Pro-Life Action League, alleging that abortion-rights opponents used aggressive and illegal means to protest against and attempt to close abortion clinics. NOW argued that by blocking access to the clinics, the protesters deprived the clinics of the use of their property and thereby violated the Hobbs Act of 1946, which prohibits the obstruction of commerce "by robbery or extortion." Violating this act on at least two occasions can constitute a "pattern of racketeering activity," which would entitle the plaintiffs to triple damages under the RICO Act.

In 1994, the Supreme Court ruled in favor of NOW, saying that women's rights groups and abortion clinics could sue antiabortion protesters under RICO even if the advocates did not have an economic motive for their protests. The Supreme Court in February 2003 reversed its previous decision, ruling that the RICO Act could not be applied because the protesters' actions did not qualify as extortion or racketeering. The Seventh U.S. Circuit Court of Appeals in Chicago renewed the case in 2004 when it did not dismiss the lawsuit on different grounds, saying threats of violence and violent acts might have qualified NOW to sue antiabortion protesters under the RICO Act. Joseph Scheidler, national director of the Pro-Life Action League, appealed the case to the Supreme Court, arguing that the appeals court misread the Supreme Court's 2003 opinion and that the case should have been dismissed.

Justice Stephen Breyer wrote the Court's opinion, saying that "Physical violence unrelated to robbery or extortion falls outside the Hobbs Act's scope." He also noted that the ruling does not leave abortion clinics without a means of blocking violent protests. The Freedom of Access to Clinic Entrances Act, which Congress passed in 1994, is "aimed directly at ... abortion clinic violence."

Supreme Court Hears Arguments on Federal Abortion Ban

Neither the *Ayotte* nor *Scheidler* cases represented the dramatic narrowing of abortion rights that advocates feared there could be, but did fuel speculation that the new Roberts Court would be willing to re-examine—and possibly overrule—Supreme Court precedents that have protected reproductive rights. This speculation was confirmed early in the year when the Court agreed to review *Gonzalez v. Carhart*, the case in which the U.S. Court of Appeals for the Eighth Circuit upheld a lower court ruling declaring the federal abortion ban signed into law in 2003 unconstitutional. In June, the Court announced it would also hear arguments in *Gonzales v. Planned*

Parenthood, as the Ninth Circuit ruling that the federal abortion ban is unconstitutional was broader and provided the most complete available record on the likely impact of the statute.

The Supreme Court heard oral arguments in both *Carhart* and *Planned Parenthood* on November 8. In both cases, lower courts found the 2003 federal law is incompatible with the Supreme Court's 2000 ruling in *Stenberg v. Carhart*, in which the Court ruled 5-4 that Nebraska's "partial birth" ban was unconstitutional because it could be read to prohibit pre-viability abortion procedures and lacked an exception to protect a woman's health, creating an "undue burden" on the right to abortion under *Roe*. Before the Supreme Court, the government argued that *Stenberg* does not apply to the federal ban because of new congressional findings that distinguish it from the Nebraska law at issue in *Stenberg*. Lawyers for Planned Parenthood and Carhart argued that *Stenberg* applies to the federal abortion ban, and as such, the law must be struck down.

How the Court will rule is anyone's guess, although all eyes have been on Justice Anthony Kennedy, who authored the dissent in the *Stenberg* case, and could well be the deciding vote in the current cases. The Court's decision will not necessarily be "all or nothing." At one end of the spectrum, the Court could decide that it is bound by its own precedent in *Stenberg*, and thus strike down the federal ban. At the other extreme, the Court could decide to overrule *Stenberg* altogether, eliminating the requirement of a health exception and undermining 30 years of abortion jurisprudence. More likely is something in between, in the vast middle ground between strict adherence to and overruling of precedent, which could leave *Stenberg* seemingly intact while still allowing the federal abortion ban to stand. The final decision could fall on the shoulders of Justices Kennedy, Roberts, and Breyer, who may be the most amenable to splitting the difference in a way that would diminish but not eviscerate the protections of *Stenberg*. The final outcome of the two cases in 2007 should represent a clear indication of the effect Justices Roberts and Alito will have on reproductive rights in the years to come.

Federal Agencies take Action on Reproductive Health Issues *HPV Vaccine is Approved*

Much of the federal progress in reproductive health came from long-awaited federal agency actions, including the approval of a cervical cancer vaccine, Plan B over-the-counter, and several new contraceptives.

Cervical Cancer Vaccine Gets Green Light from FDA and CDC, But Access Issues Remain

One major step forward took place in June with the approval of Merck's long-awaited HPV vaccine (Gardasil), which got two thumbs up from the federal government. The first endorsement came on June 8 from the Food and Drug Administration (FDA), which approved the breakthrough vaccine for 9-26-year-old girls and women. The vaccine is 100 percent effective against two strains of HPV (16, 18) that cause 70 percent of cervical cancers, as well as two strains (6, 11) that cause 90 percent of genital warts. The vaccine is most effective if used before the onset of sexual activity, and over time should help to reduce the 9,710 new cases and 3,700 deaths from cervical cancer in the United States each year.

ACIP Endorses Routine Administration for 9-26 year-olds; Makes Vaccine Part of Vaccines for Children Program

A second victory for the newly licensed vaccine came on June 29 with the unanimous endorsement of the CDC's Advisory Committee on Immunization Practices (ACIP), a committee charged with providing guidance on the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

ACIP voted to recommend that three doses of the new vaccine routinely be given to girls 11-12 years old. ACIP also recommended "catch-up" vaccination of girls and women 13-26 years old. The advisory committee noted that the vaccination series can be started as early as age nine at the discretion of the physician or health care provider. Although the vaccine should be administered before onset of sexual activity, females who are sexually active, or who have an abnormal pap, should still be vaccinated. ACIP recommendations become CDC policy when they are accepted by the director of CDC and are published in CDC's *Morbidity and Mortality Weekly Report* (MMWR).

The committee also recommended inclusion of the vaccine as one of 16 mandatory vaccines covered by the Vaccines for Children (VFC) program. VFC is an entitlement program that provides immunizations for children under age 19 who are uninsured, Medicaid recipients, Native Americans, and/or Alaska Natives. VFC also helps children whose insurance does not cover vaccinations when they are vaccinated at participating federally qualified health centers and rural health clinics. Experts estimate that the ACIP vote all but commits the federal government to spend as much as \$2 billion on the VFC program—almost doubling expenditures for the program.

Political Opposition to Approval Fails to Materialize – but Debate Shifts to Mandate for School Enrollment

Controversy over the product began before it was licensed, when some religious conservatives expressed concern that the availability of a vaccine against a sexually transmitted disease would undermine abstinence-based prevention messages. However, by the time of the ACIP meeting, the few religious groups and family-values advocates who argued early on that the HPV vaccine would encourage sexual promiscuity were nowhere in evidence. In fact, many had gone on record in support of the vaccine, while making clear that any move to make the vaccine compulsory will ignite a new round of polarizing debates.

This issue of mandatory vaccination is sure to resurface in the coming year, although there was little debate when on September 12, three months after the FDA licensed Gardasil, Michigan lawmakers became the first in the United States to propose that vaccination be compulsory for girls entering sixth grade. Under the Michigan bill, parents who objected would be able to opt out of the requirement under the same provisions that apply to other vaccinations. The bill passed the Michigan State Senate by an overwhelming margin but died at the end of the session. It is expected to be considered in the 2007 session, and other states are sure to follow Michigan's lead.

The most concrete step by a state government came from the New Hampshire Department of Health and Human Services, who recommended to all health care providers that Gardasil be routinely administered to 9-26 year-old females and that the state's Immunization Program (NHIP) supply the vaccine to medical providers for young women ages 11-18, as funding and supply allow. The state indicated that it would have access to funding and supplies over a 12-month period to cover 25 percent of 11-18-year-old females. NHIP began taking orders for the vaccine in December and expected to begin shipment to providers in early January of 2007. New Hampshire health insurers were expected to cover a substantial portion of the cost of HPV vaccine purchased through NHIP, with remaining vaccine costs covered by VFC funds.

Cost Remains Key Concern Despite Merck Patient Assistance Program

Shortly after the FDA approval, Merck announced a \$120 fee per dose for a total of \$360 for the three-dose regimen—making the vaccine one of the most expensive—if not the most expensive vaccine ever. In early November, CDC announced that it had entered into a contract with Merck to purchase Gardasil for the VFC program for a 20 percent discounted price of \$96 per dose—a n astronomical \$288 for the three-dose series. The price alone makes it extremely problematic to include it as part of Title X covered services, and although VFC coverage is a good first step, it fails to come close to guaranteeing universal access, particularly in light of the high price.

Earlier in the year, Merck had announced that its patient assistance program will “provide free vaccines to adults who are uninsured and who are unable to afford vaccines.” As described in a Merck press release, the program is targeted to physicians in private practice who provide Merck vaccines to adults who have no insurance coverage and limited income (less than \$19,600 for individuals, \$26,400 for couples, or \$40,000 for a family of four). To participate in the program, patients must complete forms in their physicians' offices, and these forms will be faxed for processing during the patients' visits. The company expects to process the forms quickly enough for qualifying patients to receive the vaccine during that visit. All of Merck's vaccines for adults are included in the program.

Although the Merck vaccine assistance program is geared toward making the product available at private physicians' offices, the company is also making the program available to private, non-profit clinics that serve low-income women and do not purchase the vaccine with government funds.

Issues about Confidentiality and Mandatory Administration Unanswered

Public health experts are clear that the broadest possible acceptance is essential to achieve the goal of significantly reducing cervical cancer. However, there are no federal laws requiring the immunization of children. In addition, all school and daycare entry laws are regulated by the states. Whether a young woman should have the right to decide for herself if she wants the vaccine or whether her parents decide is certain to be a hotly debated question. In Title X agencies, providers are required to prescribe contraceptives confidentially to adolescents, but precisely how the HPV vaccine fits into the existing structure is altogether unclear. State laws generally require parental permission for vaccines to be administered, however, in states with clear laws protecting confidentiality for STD prevention services (as opposed to treatment), confidential HPV vaccination would appear to be permissible.

Pap Tests Must Continue

Even as we cheered this important advance, NFPRHA continued to caution women and health care providers that Gardasil is not a replacement for Pap tests. This test is still a critical screening tool. The CDC's advisory panel reinforced this message, approving language that urges women to continue to get pap tests as a safeguard against cervical cancer. Experts estimate that half the women diagnosed with cervical cancer today have never had a Pap test, and another 10 percent were not screened in the 5 years before their cancer was diagnosed. Furthermore, since the vaccine will not prevent 30 percent of cervical cancers, regular Pap tests remain crucial to protecting women's health and lives.

New Study Finds Condoms Block HPV

Another bright spot in the battle against HPV came in the June 21 issue of the *New England Journal of Medicine* (NEJM) with the publication of a new study which found that the consistent use of condoms protects against human papillomavirus (HPV). The study, authored by Rachel Winer, et al., found that among newly sexually active women, those whose male partners used condoms every time they had sexual intercourse had less than half the rate of HPV infection as did women whose partners used condoms less than five percent of the time—37.8 as compared with 89.3 per 100 patient-years at risk. The study followed 82 female students at the University of Washington in Seattle and is relevant to ongoing discussions at the FDA about how to change condom labels to address HPV risk.

Senator Coburn Still Angry that Condom Warning Labels Not Updated

HPV remains a burning legislative issue for conservative Senator Tom Coburn (R-OK), who held up passage of Johanna's law, a measure (P.L. 109-475) that authorizes \$16.5 million over two years to create prevention education materials for gynecologic cancers, until sponsors agreed to add HPV-related language directing the FDA and CDC to implement a 2000 law that he authored.

Senator Coburn took to the Senate floor in early December to rail against federal agencies, claiming they have "abdicated their responsibility and missions and intentionally ignored the law and, in so doing, placed the health and lives of millions in jeopardy." One component of the 2000 law was to update condom labels to add a warning related to HPV. The FDA had published a proposed label in late 2005 but is reviewing comments and new scientific data to revise the proposed label. Senator Coburn said, "Six years after this law was signed, the FDA is still in the beginning stages of crafting a new medically accurate informational label for condom packages. By way of comparison, it took 410 days to build the Empire State Building and 2 years, 2 months and 5 days to construct the Eiffel Tower."

In order to accommodate Senator Coburn, Johanna's law was amended to require compliance by March 1, 2008, with earlier provisions that require medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing STDs. According to CDC, these provisions have been complied with. Under the new Coburn language, if the CDC and the FDA do not enact the provisions of Johanna's law and the existing law—317P of the Public Health Service Act—by March 1, 2008, HHS is required to submit to Congress a "a detailed description of all actions taken" to bring the department into compliance every three months until the law has been fully implemented.

FDA Approves Plan B for OTC Sales

Decision Places Age Restriction on Sale, Impeding Access for Many

After a protracted and hard-fought battle, on August 24, the FDA finally approved Plan B emergency contraception for over-the-counter (OTC) sales three years after the application was first submitted. Excitement over the announcement was tempered by the inclusion of a politically motivated restriction that allows for OTC access for women ages 18 and older, while women 17 and under must still obtain a prescription for the drug.

Barr, the manufacturer of Plan B, has reiterated its commitment to pursuing OTC access for all women, as have the many women's health advocates who have long supported OTC access.

Coincidentally, renewed interest in acting on Barr's long-stalled application came on July 31, just one day before the Senate Health, Education, Labor and Pensions (HELP) Committee was scheduled to hold a hearing on the nomination of acting FDA Commissioner Dr. Andrew von Eschenbach to permanently head the agency. At that time, the FDA issued a press release announcing that it was ready to re-engage in talks with Barr and once again changed the approval age from 17 to 18.

Although the product is available both OTC and by prescription, the packaging and labeling do not differ. Family planning clinics can distribute the product OTC but must have procedures in place for verifying age. In accordance with the FDA's approval, the product is available behind the counter in retail pharmacies across the nation, with Barr responsible for conducting age monitoring in these pharmacies. NFPRHA fully expects that individuals or groups opposed to emergency contraception will attempt their own monitoring in both retail pharmacies as well as in publicly funded clinics. Barr began shipping the product on November 1 and announced that the average manufacturer's price for the product is \$27.95; however, pharmacies can mark up the cost, and to date, retail prices have ranged from \$35 to \$85, depending on geographic location. As of October 1, the 340B price for Plan B increased from roughly \$7 to \$8.58.

The dual-status approval poses a host of novel questions for the public health system. Some states have indicated that they are uncertain as to how to handle coverage of the dual status products under Medicaid; other states will cover Plan B OTC, but only if a prescription is written. A few states are exploring whether Plan B can be made available to adult women through Medicaid without requiring a prescription.

A bit of good news in terms of the nine states—Washington, California, New Mexico, Alaska, Hawaii, Maine, New Hampshire, Massachusetts, and Vermont—with pharmacy access laws: the FDA's dual status approval does not impact minor's access in those states. However, pharmacists' refusal to fill prescriptions for Plan B may continue to threaten women's timely access to the product.

Plan B Lawsuit Still in Play

The FDA's OTC approval of Plan B did nothing to slow down the Center for Reproductive Rights' (CRR) lawsuit against the agency over its handling of the application to make Plan B available OTC. In fact, a federal magistrate ruled in November that CRR could subpoena more than three years worth of White House emails and other documents relating to Plan B. The request for documents came after earlier depositions in the case revealed that FDA staff updated White House officials on the status of the application.

Plan B Mechanism of Action Subject of Recent Journal Articles

The debate over whether Plan B prevents pregnancy after unprotected sex by preventing ovulation, preventing fertilization, or by some other mechanism of action flared up again in the wake of the OTC approval. While

there is no scientific basis to the contention by EC opponents that Plan B is an abortifacient, what remains unclear is whether the drug ever works post-fertilization, but pre-implantation.

Two nuanced editorials revisited this issue. Both ultimately concluded that while evidence suggests that emergency contraception does not work post-fertilization, scientists cannot unequivocally rule out that possibility. The first editorial, published in the August 2006 edition of *Contraception* and authored by James Trussell of Princeton University and Beth Jordan of the Association of Reproductive Health Professionals, examined the leading published emergency contraception pill (ECP) studies. Trussell and Jordan caution that we cannot yet say that ECPs *never* prevent pregnancy after fertilization, writing that the “statistical evidence regarding effectiveness of combined ECPs suggests that there must be a mechanism of action in addition to delaying or preventing ovulation.” As a result, they recommend that women be told that emergency contraception “may prevent pregnancy by delaying or inhibiting ovulation, inhibiting fertilization, or inhibiting implantation of a fertilized egg in the endometrium.”

A subsequent editorial published in the October 11 edition of the *Journal of the American Medical Association* (JAMA), and authored by Dr. Frank Davidoff and Trussell, draws the same conclusion and again recommends that women be given accurate information in order to make an informed decision about whether to use Plan B: “In the absence of absolute proof about Plan B’s mechanism of action, the right to make personal decisions about whether its use is morally acceptable must be respected and for that reason women should continue to be informed, as they are now in the Plan B labeling, that its use may affect post-fertilization events.” At the same time, they recommend that “all women should be informed that the ability of Plan B to interfere with implantation remains speculative, since virtually no evidence supports that mechanism and some evidence contradicts it. Women should also be informed that the best available evidence indicates that Plan B’s ability to prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with post-fertilization events.”

A September 16, 2006, editorial in the *British Medical Journal*, points to the European experience with emergency contraception and questions whether increased access to Plan B will truly reduce abortion rates. Despite increases in emergency contraception use in the United Kingdom, abortion rates have risen from 11 per 1,000 in 1984 to 17.8 per 1,000 in 2004. Anna Glasier, author of the editorial, states that in three studies measuring “subsequent pregnancy rates, advance provision of emergency contraception increased its use but had no measurable effect on rates of pregnancy or abortion. When reasons for not using emergency contraception, despite having a supply at home, were documented three out of four women said they did not realize they had put themselves at risk.” In asking whether emergency contraception is “worth the fuss,” Glasier concludes, “If you are looking for an intervention that will reduce abortions rates, emergency contraception may not be the solution, and perhaps you should concentrate most on encouraging people to use contraception before or during sex, not after it.”

A review of the existing published studies examining the effect of increased access to emergency contraception on pregnancy rates, found that increased access has enhanced use but has not resulted in an overall reduction in pregnancy rates. Published in the December 29 edition of *Obstetrics and Gynecology* and authored by Beth Raymond, James Trussell, and Chelsea Polis, the article also found that contrary to opponents’ arguments, increased access to emergency contraception does not result in increased risk-taking. Rather, the article determined that emergency contraception does reduce the risk of pregnancy for individual women, and as such, improved awareness of and access to the contraceptive are needed.

Wal-Mart Does About-Face on EC

Three Massachusetts women backed by pro-choice groups filed suit against Wal-Mart in Boston on February 1 after being turned away from Boston area stores when they tried to buy emergency contraception. The suit argued that the retail giant violated a state regulation that requires pharmacies to provide all "commonly prescribed medicines" by failing to stock emergency contraception pills in its pharmacies. The lawsuit sought \$25 in damages for each woman and attorneys' fees. Shortly thereafter, Wal-Mart did an about-face and agreed to sell Plan B in its 3,700 pharmacies beginning March 20. In a statement on March 3, Wal-Mart's pharmacy division vice president stated, "We expect more states to require us to sell emergency contraceptives in the months ahead. Because of this, and the fact that this is an FDA-approved product, we feel it is difficult to justify being the country's only major pharmacy chain not selling it." However, the chain kept its "conscience objector policy," which allows an individual pharmacist to refuse to fill the prescription as long as he or she refers the customer to another pharmacist in the store or another pharmacy.

FDA Approved Three New Contraceptives; Price Issues Remain Top Concern

In terms of expanding the range of contraceptive products available to women, 2006 saw the approval of three new contraceptives—Yaz, Seasonique, and Implanon—however, their high costs prevented them from being widely available at publicly funded family planning clinics across the country. The FDA also delayed the approval of another contraceptive, Lybrel, over manufacturing concerns.

Yaz: A low-dose version of Yasmin, produced by Berlex, was approved on March 16. The oral contraceptive is taken once a day for 24 days followed by four days of placebo to induce a menstrual period. Most oral contraceptives are taken for 21 consecutive days followed by seven days of placebos. Berlex launched the pill in April.

Seasonique: In May, the FDA approved Duramed's Seasonique, an extended-cycle oral contraceptive designed to reduce the number of menstrual periods to four per year. Women take Seasonique once a day for 84 days, followed by seven days of a low-dose estrogen pill. Although the number of menstrual periods is reduced to four per year, side effects include spotting or bleeding between periods.

Implanon: A single-rod implantable contraceptive that is effective for up to three years and manufactured by Organon, Implanon was approved in July. About the size of a matchstick, Implanon is inserted just beneath the skin on the inner side of a woman's upper arm by a healthcare provider during an in-office procedure. The product continually releases a low, steady dose of progestin for a period of up to three years. Removal can occur at any time at the request of the user, after which the woman's fertility returns to her pre-existing fertility level. Organon is conducting a national clinical training program to train healthcare providers on the insertion and removal procedures. Only healthcare providers trained through the Organon-sponsored programs are able to order the product.

Lybrel: The FDA delayed the approval of a new 365-day birth control pill that prevents users from getting their period. The new birth control pill, known as Lybrel, is manufactured by Wyeth. Unlike traditional birth control pills, Lybrel is taken 365 days a year with no placebo pills. Lybrel contains a lower daily dose of synthetic hormones than traditional pills, so the cumulative monthly dose is equal to, or lower than, some traditional regimens. According to Wyeth, the FDA delayed approval because it needed more time to review how the company's proposed manufacturing method for the pill affects its shelf life. There were also concerns about the dropout rate of subjects in studies and the rate of pregnancy and bleeding patterns in users of Lybrel.

CDC Issues New HIV Screening Guidelines *Ryan White Reauthorized*

While other reproductive health issues received scant attention, sexually transmitted diseases (STDs) and HIV/AIDS programs were in the “limelight” this year, with Congress finally reauthorizing Ryan White, the Centers for Disease Control and Prevention (CDC) issuing two sets of new guidelines, and the President seeking additional funding for HIV/AIDS prevention.

Despite the President’s proposed \$88 million increase for HIV/AIDS prevention, which sought to bring overall funding to \$739 million and was intended to fund a broader HIV screening policy proposed as part of the President’s Domestic HIV/AIDS Initiative, the CDC’s STD, HIV/AIDS, and tuberculosis programs will be consigned to the funding fate of so many other public health programs—flat funding of \$947 million for FY 2007.

CDC Revises HIV Recommendations to Include Universal Screening

Although the new funding for HIV testing did not materialize, CDC issued new HIV screening guidelines on September 22 in its Morbidity and Mortality Weekly Report (MMWR), intended to set the stage for increased HIV testing in medical settings. The new guidelines moved sharply away from the concept of risk-based testing and instead recommended that all patients ages 13-64 be tested routinely unless they opt-out. While the recommendation that testing be voluntary remained unchanged, the new recommendations dropped earlier requirements for written informed consent and pre-test counseling, something to which some advocacy groups objected.

The “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings” are intended for all public and private sector health care providers, including hospital emergency departments, urgent care clinics, inpatient services, public health clinics, community clinics, and primary care settings. While the new guidelines generally recommend routine testing, they specifically state that “health care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be less than one in a thousand.” In addition, the guidelines state that “all patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patients are known or suspected to have specific behavior risks for HIV infection.”

It is too early to predict the impact of the new guidelines on patients in family planning clinics. Providers first must grapple with existing state laws that may reflect the earlier standards, as well as financial constraints. CDC recommendations in no way override state law or other grant requirements; they are merely recommendations. In recent years, HIV testing in family planning settings has varied considerably from clinic to clinic, with few clinics routinely testing clients. According to a Guttmacher Institute study, “Provision of Contraceptive and Related Services by Publicly Funded Family Planning Clinics, 2003,” nine in ten clinics offer on-site HIV testing, with most of those clinics (91 percent) providing the test to any client who requests it. Among those clinics offering HIV tests, the majority (95 percent) used the traditional blood stick, while 22 percent used cheek swabs, and 3 percent used rapid tests. For those clinics providing HIV tests, 48 percent had a dedicated HIV funding source.

CDC’s Revised STD Treatment Guidelines Address Ethics, EC, and Confidentiality

In the August 4 MMWR, CDC revised its guidelines for the treatment of patients who have STDs. The new guidelines call for health care providers who treat patients at risk for STDs to counsel women on emergency

contraception (EC), and to provide it if desired by the woman. CDC suggests that patients should be treated regardless of their ability to pay, citizenship or immigration status. The guidelines also note the Advisory Committee on Immunization Practices' recommendation that children and adolescents receive the HPV vaccine. In a potential attempt to address confidentiality and consent issues surrounding implementation of the vaccine, CDC states that while consent laws for vaccinations of adolescents vary from state to state, all adolescents in the United States can legally consent to the confidential diagnosis and treatment of STDs without parental consent or knowledge, with few exceptions. CDC ultimately concludes, "Because of the crucial importance of confidentiality, health-care providers should follow policies that provide confidentiality and comply with state laws for STD services."

Ryan White CARE Act Reauthorized After Lengthy Struggle

AIDS activists began the year with renewed hope that the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act (H.R. 6143), which expired in September 2005, would be reauthorized by Congress in a bipartisan. But it took until the final moments of the session for this optimism to be justified.

Enacted in 1990, the CARE Act provides primary health care, pharmaceutical treatments, and support services for low-income people living with HIV/AIDS. These programs, which are administered by the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration (HRSA), provide services to more than 500,000 people affected by HIV across the United States. The CARE Act has been previously reauthorized and amended twice, in 1996 and in 2000. Although the CARE Act has expired, Congress continued to fund the program in FY 2006 with funding at just over \$2 billion.

As the year wore on, however, hopes for reauthorization dimmed significantly. The House passed its version of the bill in September by a vote of 325-98, but the measure stalled in the Senate, despite a previous version being overwhelmingly approved by the Senate Health, Education, Labor and Pensions Committee in May. Several Democratic Senators, concerned with new funding formulas that would shift money away from states and cities with large numbers of people living with HIV/AIDS to regions facing a smaller, but growing, epidemic, blocked the measure in the Senate as they tried to negotiate. A compromise was reached at the eleventh hour, leading to passage in the Senate by voice vote on December 6. The House passed the Senate's amended bill in the final hours of the 109th Congress on the morning of December 9. The Ryan White CARE Act was signed into law on December 19 (P.L. 109-415).

The revised Ryan White extends the law for three years but explicitly repeals it at the end of that period, and also ensures that no state's Ryan White funding will be reduced to less than 95 percent of what it was for FY 2006. It also establishes a \$30 million Early Diagnosis Grant Program, of which \$20 million is available for states that have voluntary opt-out HIV testing of pregnant women and mandatory testing for newborns. The other \$10 million is available for states that have voluntary opt-out HIV testing of clients at STD clinics and voluntary opt-out testing of clients at drug treatment centers.. This initiative, a compromise between Senators Ted Kennedy (D-MA) and Tom Coburn (R-OK), will be funded through a carve out of CDC's HIV prevention funding, and could result in cuts to CDC's existing cooperative agreements. No state currently appears to qualify for grants through the Early Diagnosis Grant Program.

Status Quo for International Family Planning Programs

The year began with the controversial recess appointment in January of Ellen Sauerbrey to a key post within the State Department as Assistant Secretary of State for Population, Refugees, and Migration. Sauerbrey's nomination drew widespread criticism from international family planning advocates, who recalled her past as an actively anti-choice legislator in Maryland who had shown outright hostility toward women's human rights and abortion rights during her stint on the United Nations Commission on the Status of Women. She approved of President Bush's withholding of funds to the United Nations Population Fund (UNFPA) and called abstinence-only sex education "the healthiest and most responsible method" of HIV prevention suitable for adolescents.

Administration Proposes Cuts for International Family Planning Funds; Global Gag Rule Remains in Effect

The Bush Administration confirmed its lackluster support for international family planning programs in the President's FY 2007 budget, which contained clues to a funding decline for international family planning programs but failed to specify actual numbers. It quickly became apparent that what the administration had in mind was an 18 percent cut in funding for the U.S. Agency for International Development-funded programs for FY 2007, a reduction from \$436 million in FY 2006 to \$357 million. For the second year in a row, the budget proposal also made clear that any congressionally appropriated monies for UNFPA, up to a limit of \$25 million, would have to come from the USAID funding pot, rather than from the separate program account that had historically been the source of funding for contributions to UNFPA and other UN agencies.

Both the House and Senate Appropriations Committees rejected the administration's proposed cuts, with the Senate Appropriations Committee approving \$465 million and the House approving \$432 million. A continuing resolution (CR) that will keep the government operating through February 15, 2007, funds international family planning programs at the House-passed level of \$432 million—an amount well above the President's recommendation but still well below the 1995 high water mark of \$541 million.

Programs funded by USAID remain subject to the "global gag rule"—a policy reinstated by President Bush in 2001 that prohibits U.S. international family planning aid to organizations that provide counseling or referral for abortion, lobby to make abortion legal or safer in their respective countries, or provide abortions, unless in cases of rape, incest or if a woman's life is at risk—even if they use non-U.S. funds to do so. Advocates hope that the Democratic takeover will focus renewed attention on the global gag rule.

UNFPA Funding Blocked Yet Again

Even congressional supporters of UNFPA paid scant attention to the program in 2006 – in part because the upcoming election shifted many potentially controversial amendments to the back burner and in part because members on both sides of the aisle understood that Republican leaders could quickly squelch any positive changes. The continuing resolution level funds the program for FY 2007 at \$34 million. The lone attempt to ensure that UNFPA receives funds in FY 2007 was put forward by Representative Carolyn Cheeks Kilpatrick (D-MI). During the House Appropriations Committee mark-up of the foreign aid bill, she offered an amendment that would have directed that the full U.S. contribution to UNFPA be used specifically for obstetric fistula prevention and treatment efforts; however, the amendment failed.

The administration's continuing antipathy toward UNFPA was again evident with the mid-September decision to block, for the fifth year, the entire \$34 million FY 2006 appropriation for UNFPA. As in prior years, the administration based its decision on a misinterpretation of the Kemp-Kasten law, which precludes funding to organizations participating in coercive activities, despite the fact that U.S. fact-finding missions have found such

allegations to be false. Under the terms of the FY 2006 foreign operations appropriations bill, \$22.5 million of the contribution appropriated by Congress for UNPFA can be reprogrammed to USAID for bilateral family planning and reproductive health programs.

Adding to the list of unknowns this year was the Administration's effort to restructure foreign assistance programs and the respective roles of the State Department and USAID. Without greater clarity, U.S. agencies that disperse funding to overseas programs are in a virtual holding pattern, a situation that has led to a de facto moratorium on new approval of reproductive health projects. In addition, little of the previously approved funding is being disbursed to organizations and field programs.

Anti-Prostitution Pledges Challenged in Court

The Administration did suffer one setback this year, losing two separate challenges by non-governmental organizations (NGOs) to its prohibition blocking overseas HIV/AIDS assistance from being provided to any group or organization that does not have an official policy explicitly opposing prostitution and sex trafficking. Adopted by Congress in 2003, the Administration began to require U.S. organizations providing HIV/AIDS-related services in other countries to sign the pledge in order to be considered for federal funding in 2005. (Prior to 2005, the anti-prostitution pledge requirement was applied to foreign NGOs.) As a result, the pledge requirement applies to organizations based in the United States that do AIDS work abroad, as well as foreign NGOs.

One suit was brought by the Alliance for Open Society International (AOSI) and Pathfinder International, and the other by DKT International, a social marketing firm. Both argued that signing the pledge as a condition for receiving government funding was unconstitutional and, furthermore, would stigmatize and alienate the sex workers who were among the intended beneficiaries of their programs. Federal courts ruled in both cases that the government policy violates the First Amendment right to free speech and enjoined the enforcement of the pledge requirement. While the rulings only apply to the plaintiffs rather than the entire class of entities affected by the policy, Interaction and the Global Health Council have sought to be added as original plaintiffs in the AOSI-Pathfinder case in order to provide injunctive relief to their numerous organizational members. The government is appealing the original rulings in both cases, as well as challenging the effort to expand the reach of the court decisions to other affected U.S. organizations.

International Abstinence Earmark Undermines Prevention Efforts

An April report by the Government Accountability Office (GAO) examining the effect of a set-aside for abstinence-only-until-marriage programs on global HIV prevention found that prevention efforts are being hampered by the administration's focus on ideology instead of public health. The report looked specifically at funding for the President's Emergency Plan for AIDS Relief (PEPFAR) program, which was authorized by the U.S. Global Leadership on HIV, Tuberculosis, and Malaria Act of 2003. The cornerstone of PEPFAR's prevention strategy is the ABC approach—Abstain, Be faithful, use Condoms—with a strong emphasis on A and B, over C, in most settings.

The GAO report confirmed what public health advocates have suspected—that workers on the ground are struggling to implement PEPFAR's ideologically driven prevention strategy in part because the abstinence-only-until-marriage earmark required under the law is squeezing out available funding for other key prevention interventions, such as primary maternal-to-child transmission, blood safety activities, and condom social marketing. The report concluded that the earmark and the restrictive interpretations of the law by the Office of the Global AIDS Coordinator (OGAC) have prevented programs from responding to local epidemiological needs and cultural realities and thwarted efforts to integrate prevention efforts.

In July, Senators Dianne Feinstein (D-CA) and Olympia Snowe (R-ME) introduced the HIV Prevention for Youth Act (S. 3656). The bill sought to provide local communities with greater flexibility to stop the spread of HIV, especially among young people. It did not strike the original 33 percent earmark for “abstinence-until-marriage” programs. However, under the new legislation, country teams could take into account country needs, including cultural differences, epidemiology, population age groups, and the stage of the epidemic in designing the most effective prevention programs. At least one-third of prevention funds would be spent to prevent the sexual transmission of HIV under the legislation.

In the House, Representative Chris Shays (R-CT) held a hearing in the Government Reform Subcommittee on National Security, Emerging Threats and International Relations entitled “HIV Prevention: How Effective Is the President’s Emergency Plan for AIDS Relief?” At the hearing, U.S. Global AIDS Coordinator Mark R. Dybul attempted to defend the 33 percent earmark. He argued that it was necessary, at least originally, in order to compensate for USAID’s historic emphasis on promoting condoms. He also added that other donors seem to be emphasizing condoms now, so the U.S. emphasis on abstinence and being faithful was resulting in a comprehensive approach from a global perspective. He did acknowledge, however, that the earmark would not be necessary in order to assure that the U.S. would allocate funds to A and B programs. Representative Henry Waxman (D-CA) noted that the amount reserved for these programs was arbitrarily determined and that a host of other prevention interventions were being squeezed because of the high priority U.S. law has placed on them, according to the April GAO report.

A Look Ahead

Democrats will be in charge of both chambers when the 110th Congress convenes on January 4 for the first time since 1994. The differences between then and now are certain to be profound—with the ascendancy of the first woman Speaker of the House Nancy Pelosi (CA) topping that list of notable differences. Women will be in both chambers in record-breaking numbers: 74 Democratic women in the U.S. House, 16 in the U.S. Senate — the largest increase in a single election of Democratic women. While the margin in the House allows Speaker-Elect Pelosi to rightly claim a mandate, the 51-49 majority in the Senate is far more precarious, and the urge to work in a bipartisan fashion is generally stronger in the Senate regardless of which party is in control.

Despite the unequivocal nature of the House victory, Speaker-Elect Pelosi immediately tried to set the tone and reign in any temptation to seek revenge, using pragmatic, measured tones to talk about the upcoming agenda—knowing that even the most partisan Democrats must be realistic about the gains that can be made. There are financial constraints stemming from the Republican spending spree, not to mention the tempering effect of the impending 2008 presidential elections, and the unforgettable fact that President Bush still controls the White House and federal agencies.

As a result, even though the atmosphere is certain to be very different, few promises are being made by the Democratic leadership in either body about the agenda for reproductive rights. What is clear is that abortion rights gains will not be front and center on the leadership agenda. At the same time, however, highly charged anti-choice bills such as “fetal pain” and the Child Custody Protection Act—legislation that may not strike at the heart of access to abortion but which has been used effectively to paint Democrats as extreme—is almost certain to fall by the wayside given the ability of the party in control to set the agenda.

Whether Democrats can avoid the bitter partisan divide within their own caucus is anyone’s guess, particularly given the more conservative bent of some of the thirty newly elected Democrats, but the incentives for doing so are high. That having been said, the talk over the conservative leanings of new members seems to have been greatly exaggerated, given that the majority of the newly elected Democrats are pro-choice and more than three-quarters are considered pro-family planning by NFPRHA. However, this belief that the party owes its majority to the election of a large class of centrists determined to search for practical solutions to problems they believe have been neglected during years of partisan wars in Congress may well inure to the benefit of family planning supporters eager to gain more traction on the prevention agenda embodied in the omnibus Prevention First legislation. The good news is that both House Speaker Pelosi and Majority Leader Harry Reid are cosponsors of the measure.

We will enter the session hoping that Democratic control of the leadership and committees in both the House and Senate will translate into a focus on the prevention agenda we have been touting for so long—shining a spotlight on issues like increased Title X funding, an expansion of Medicaid-funded family planning services, reduced funding for abstinence-only programs, and a new emphasis on comprehensive sex education programs. In addition, the slim Democratic majority in the Senate should temper the President’s desire to appoint extremist judges. At the same time, the close ideological divisions on the Supreme Court should embolden Democrats to go to the wall to defeat controversial nominees. Democrats can also be expected to push legislation to expand federal funding for embryonic stem cell research.

Some other good news is that we can also count on the new Congress to rev up the congressional oversight machine. On the House side, Representative Waxman will head up the Government Reform Committee and Senator Joe Lieberman (D-CT) will head up Homeland Security and Government Affairs. Representative



NATIONAL
FAMILY
PLANNING &
REPRODUCTIVE
HEALTH
ASSOCIATION

1627 K Street, NW - 12th Floor, Washington, DC 20006-1702
Tel: 202-293-3114 / Fax: 202-293-1990 / Website: www.nfprha.org



Waxman is expected to aggressively investigate a wide range of issues, which could include decision making at the FDA, abstinence-only-until-marriage education programs, or even activities related to Title X, depending upon policies and practices implemented by Dr. Eric Keroack, the controversial DASPA at HHS.

So, although it is altogether unclear how much headway reproductive rights supporters will be able to make in the coming session, the good news is that hope for progress just became a lot more realistic, and we can now redefine success to be tangible improvements rather than the critical—if not nearly as satisfying—ability to hold the line on our hard-fought gains.