

LEGISLATIVE

Update

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Public Policy Opportunities and Risks in the 109th Congress

The reelection of President Bush and strengthened Republican control of Congress present favorable conditions for members of the business community to seek legislative redress in the 109th Congress. However, the legislative process involves risks—including the risk of adverse legislation if one does not become engaged in the process—and is difficult to predict. At this early stage, it is yet unclear whether, or on what issues, Republicans and Democrats will develop the bipartisan working relationships that will be necessary to pass most significant reform proposals.

This bulletin provides a look back at the achievements of the 108th Congress and a look ahead at the political and institutional dynamics, and agenda of the 109th Congress. We focus herein on the major substantive areas of most interest to our clients in which legislation is expected to be considered this Congress.

The President's Second-Term Agenda. The President campaigned on a number of issues for which he is now seeking legislative action. Chief among them is Social Security reform and the establishment of private accounts, which the President views as necessary for the program's long-term health. He also has promised to pursue fundamental tax reform and a move toward simplification, but he will await the recommendations of a special advisory committee this summer before detailing his proposals. During the campaign and in recent weeks, the President has talked about the economic costs of our civil litigation system and has promised to fight for tort reform in a number of areas, which were considered but not resolved by the last Congress, including interstate class actions, asbestos exposure litigation and medical malpractice lawsuits.

The Politics and Agenda of the New Congress. Congress convened this month with a full agenda, which includes a number of legislative proposals carried over from the 108th Congress. Republicans have strengthened their majority in the House by four seats, for a roster of 232 Republicans to 201 Democrats (with one independent and one vacancy). In the Senate, the Republicans gained four seats, one by defeating former Senate Democratic Leader Daschle, and they now have a majority of 55 to 44 (with Senator Jeffords of Vermont, an Independent, caucusing with the Democrats). Republicans are still short of the 60 votes needed in the Senate to end a filibuster and bring more controversial bills to a vote. Therefore, this Congress may continue to see bills that

Major Issues for the New Congress

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easily pass the House but stall in the Senate, as tort reform measures have in the past, unless a bipartisan Senate strategy is employed. In addition, a core group of moderates of either party could wield significant power this Congress in moving, or thwarting, legislation. Finally, the continuing presence and cost of U.S. forces in Iraq, and expected partisan battles over the President's judicial nominees, may complicate efforts to advance a domestic policy agenda.

Be Early, Be Ready. In this environment, it is important to engage key Members and their staffs early by offering reform ideas and draft legislative proposals. As bills begin moving through subcommittee and committee markup and to the floors of the House and Senate, there will continue to be opportunities to shape the legislation through the amendment process. Making the most of these opportunities, as well as heading off potential risks, requires early preparation, vigilance, and the ability to move quickly.

Be Strategic. A federal legislative strategy can be an important element of a company's strategic plan. A comprehensive look at business goals, litigation risk, regulatory costs and corporate priorities is the best way to assess whether a legislative opportunity is worth pursuing. We would be glad to assist you in making this determination and in developing and implementing a legislative strategy.

TAXES, SOCIAL SECURITY AND PENSIONS

During his first term, President Bush signed into law three major tax bills. The first, enacted in 2001, repealed the estate tax, reduced individual tax rates and provided a range of additional individual tax relief. The second, enacted in 2003, accelerated the individual tax relief contained in the 2001 law, provided investment incentives for small businesses and reduced the maximum tax rates on capital gains and dividends received by noncorporate shareholders of domestic corporations. The final bill, enacted right before the 2004 elections, significantly amended the tax laws affecting U.S. businesses. Initiated to repeal extraterritorial income tax provisions judged by the World Trade Organization to violate international trade agreements, the bill attracted a variety of provisions on issues ranging from international trade to tax shelters. Many provisions in the tax legislation enacted during the Bush Administration's first term are temporary and, without further legislative action, will expire in the next several years.

The 109th Congress will be faced with a number of challenging issues, including making permanent the tax cuts enacted during the Bush Administration's first term—at a projected cost of more than \$1 trillion. Social Security reform, pension reform, and fundamental reform of the tax code are other major issues identified by the President and congressional leaders. Regarding fundamental tax reform, the President has appointed a bipartisan commission to review and make reform recommendations by July 31, 2005. A number of broad reform proposals may be considered by the panel, including a flat tax, national sales tax and a value added tax.

Leadership of the tax committees is unchanged. Senator Charles Grassley (R-IA) remains Chairman of the Senate Finance Committee, and Senator Max Baucus (D-MT) remains the Ranking Democrat. Chairman Grassley has said the Committee's agenda for the 109th Congress will include tax relief, closing abusive tax opportunities, Social Security reform and fundamental tax reform. Senator Judd Gregg (R-NH), the new Chairman of the Senate Budget Committee, also has made Social Security reform a top priority, along with deficit reduction. On the House side, Rep. Bill Thomas (R-CA) remains Chairman of the House Ways and Means Committee, and Rep. Charles Rangel (D-NY) remains the Ranking Democrat.

Social Security Reform. President Bush has made Social Security reform a top domestic priority for the 109th Congress. The Congressional Budget Office has projected that by 2019 the expense of the Social Security system will overtake revenues, which are derived primarily from employment taxes on wages, and that by 2042 the Social Security trust fund will be entirely depleted. Although the Administration has yet to reveal the substantive details of its plan, the President has made clear that he intends to provide workers the opportunity to divert a portion of their payroll taxes into private investment accounts. Among other controversial aspects of this proposal is the projected cost of \$1–\$2 trillion to cover the loss of contributions during the transition period. In addition, cost savings from changing benefits will be discussed, if not made part of the proposal.

Pension Reform. In the 108th Congress, legislation was enacted to replace temporarily the rate that

employers use to determine the value of their defined-benefit pension plans—the interest rate on 30-year Treasury Bonds—with an index based on higher paying corporate bonds for plan years beginning after 2003 and before 2006. The bill also permits certain companies with chronically underfunded pensions to reduce their “catch up” contributions by 80 percent for those plan years.

In November 2004, the Pension Benefit Guaranty Corporation (the “PBGC”), the government agency that insures the nation’s defined benefit pension system, reported a net loss of \$12.1 billion for FY2004 for its program that insures single-employer, defined benefit pension plans, increasing its deficit to \$23.3 billion. The PBGC’s deficit is likely to worsen, as it is poised to assume liability for underfunded plans sponsored by U.S. Airways and potentially United Airlines, which is currently in bankruptcy. PBGC’s troubles, as well as the expiration of the key provisions of the 2004 legislation, have placed pension reform high on the agenda of the Congress and the Bush Administration.

The Administration has announced that its pension reform proposal will focus on three key areas: (a) funding rules; (b) disclosure to workers, investors, and regulators; and (c) the pension insurance premium structure. Notably, the Administration’s proposal would permanently replace the rate that employers use to determine the value of their defined benefit plans with a current duration-matched yield curve of corporate bond rates, and would allow plan sponsors to make additional deductible contributions above its targets. In addition, the Administration proposes an increase in flat rate pension insurance premiums to reflect the growth of worker wages since 1991, when the

current \$19 rate was set, to an indexed rate of \$30. The calculation of risk-based pension insurance premiums also would be adjusted based on plan underfunding relative to the appropriate funding target.

Rep. Boehner (R-OH), Chairman of the committee with jurisdiction over private pension plans, the Education and Workforce Committee, has made clear his interest in pension reform, and in September of last year articulated “Six Principles to Reform & Strengthen the Defined Benefit System”: (a) enacting a permanent interest rate to calculate pension liabilities accurately; (b) requiring companies to fully fund their plans; (c) reducing funding volatility in pension plans; (d) preventing employers and unions from making promises to workers that cannot be kept; (e) providing more accurate and complete disclosure to workers about the status of their pension plans; and (f) ensuring that cash balance pension plans remain a viable part of the defined benefit system. Chairman Boehner and Senate Finance Committee Chairman Grassley have promised to examine the Administration’s proposals. Pension plan reform is ripening politically, and action by the 109th Congress is likely.

Tax Exempt Organizations. On June 21, 2004, the Senate Finance Committee released a staff discussion draft outlining various proposed reforms to the governance and operation of tax-exempt organizations. The Committee held hearings on June 22, 2004, as its Chair stated in a press release, “to expose unscrupulous behavior by some tax-exempt organizations.” A roundtable discussion on the need for legislative reforms in this area was held on July 22, 2004. Following these discussions, the Committee encouraged the Independent Sector, a group

representing tens of thousands of charitable groups, to organize members of the nonprofit community to develop recommendations for legislation to improve the governance, ethical conduct and oversight of nonprofit organizations. In particular, the Senate Finance Committee is focusing on revising or tightening the rules governing (a) insider transactions between tax-exempt organizations and their officers and directors, (b) nonprofit compensation, (c) the operation of donor-

advised funds, (d) the composition and compensation of nonprofit boards, (e) the involvement of nonprofits in tax shelter transactions, and (f) financial disclosure by tax-exempt organizations. The Committee is expected to begin considering draft legislation on these and other tax-exempt issues during the first half of 2005.

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TRADE

The 108th Congress passed legislation implementing free trade agreements with Chile, Singapore, Australia, and Morocco, extending the African Growth and Opportunity Act, imposing economic sanctions against Burma, and extending normal trade relations to Laos as part of a miscellaneous trade bill. Although the Bush Administration had signed the U.S.-Central American Free Trade Agreement (“CAFTA”), it delayed sending implementing legislation to Congress due to concerns over controversial provisions on labor, textiles, and agriculture.

The 109th Congress will face a similarly active trade agenda. The Senate and House committees with responsibility for trade issues, Senate Finance and House Ways and Means, will continue to be led by Senators Grassley and Baucus, and Reps. Thomas and Rangel (see discussion above under “Taxes”), but the Trade Subcommittee in the House will have a new Chair, Rep. Clay Shaw (R-FL). Committee Chairman Thomas is expected to continue his significant involvement in trade legislation, notwithstanding the many other non-trade issues his committee will face this year.

The new Congress will have to tackle some contentious trade issues. The first big fight—particularly in the House—is likely to occur over approval of the U.S.-Central American Free Trade Agreement (“CAFTA”). CAFTA is opposed by unions and environmentalists, as well as various agricultural interests (particularly sugar). Congress may also be asked to approve other free trade agreements, including an agreement already completed with Bahrain, and possibly agreements with Panama and the Andean countries after those negotiations are concluded.

Before March 1, 2005, the President is expected to request a two-year extension, until June 1, 2007, of Trade Promotion Authority (“TPA”). TPA allows trade agreements to be considered by Congress under “fast-track” procedures that minimize Congressional amendments and voting delays. Although there was a big battle over TPA in 2002, it is not clear how vigorously TPA will be attacked this year because significant procedural hurdles will make it difficult for opponents to succeed.

Following the restart of talks last July in Geneva, the Bush Administration will continue to press for progress

in the Doha Round of World Trade Organization (“WTO”) negotiations. Congress will have an opportunity, for ninety days after March 1, 2005, to pass a joint resolution withdrawing congressional approval of the Uruguay Round Agreement creating the WTO. In light of unhappiness with a number of WTO dispute-settlement decisions and increasing polarization on trade matters, some members of Congress are likely to attempt to pass such a resolution, but they are unlikely to succeed.

Agricultural issues will continue to be a major focus of WTO negotiations. Congress is likely to start working on renewal of the 2002 Farm Bill (which includes various U.S. farm support programs) well in advance of the 2007 deadline—in part to provide instructions for U.S. negotiators before the WTO agriculture negotiations are completed. Congress may also need

to deal with a WTO dispute settlement panel’s ruling against the U.S. cotton program and its implications for the overall U.S. farm credit guarantee program.

Another battle could focus on the Byrd Amendment, which requires the distribution to injured U.S. companies of antidumping and countervailing duties collected by the U.S. government, and which has been found to violate WTO trade rules. Particularly if, as permitted under the WTO ruling, other countries begin to impose retaliatory tariffs on U.S. exports, the Administration and Congress may be forced to make a decision whether to repeal the Byrd Amendment. This could lead to a fight resembling the just-completed, prolonged fight over repeal of the extraterritorial income tax provisions (see discussion above under “Taxes”).

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TORT REFORM

In the 108th Congress, the House passed a number of tort reform measures that ultimately stalled in the Senate. These included bills to address interstate class actions, asbestos litigation, and medical malpractice liability, and other bills to provide liability protection for gun manufacturers and dealers, to address obesity litigation (the so-called “cheeseburger bill”) and to tighten “Rule 11” to mandate sanctions for lawyers who file meritless claims in federal court.

Since his reelection in November, President Bush has vowed to make tort reform a central focus of his legislative agenda in 2005. His efforts will be aided by increased Republican majorities in the House and Senate. In the House, the Judiciary Committee will

continue to be chaired by Rep. Sensenbrenner (R-WI), and House rules will permit the Republican leadership to move tort reform measures without delay. Because the Republicans now hold 55 instead of 51 seats in the Senate—although not the 60 they need to end a filibuster—the leadership’s ability to move tort reform is stronger than in the last Congress. Incoming Judiciary Committee Chairman Specter (R-PA) historically has not been a strong supporter of tort reform but has taken an active role in advancing asbestos litigation reform.

Class action reform. For over a decade, the business community has sought federal legislation to constrain state class action lawsuits by making it easier to

remove such cases from state to federal court. In the 108th Congress, legislation was introduced in both the House and the Senate. The House passed its bill in July 2003. The Senate took up its bill in July 2004, but Senate Majority Leader Frist removed it from the calendar in response to Senate Democrats' efforts to attach unrelated measures to the bill.

The House bill went further than the Senate bill, but both bills would have given federal courts jurisdiction over class action lawsuits involving more than 100 plaintiffs and over \$5 million, if less than two-thirds of the plaintiffs were citizens of the same state as the primary defendants. (The federal courts could decline to exercise jurisdiction if more than one-third but less than two-thirds of plaintiffs were citizens of the same state as the primary defendants and certain other factors were present.) Certain claims were excepted from the bill including shareholder actions arising under state law and certain securities-related claims. The bills also address class action settlements, particularly the calculation of attorney's fees in so-called "coupon settlements," prohibit judges from approving settlements in which class members are given higher payouts based solely on their closer proximity to the courthouse, and constrain the ability of judges to approve settlements if attorney's fees would result in a net loss to class members.

Although it became embroiled in election year politics last year, the Senate bill has bipartisan support in excess of the 60 votes needed to defeat a filibuster. Senate Finance Committee Chairman Grassley is expected to reintroduce the Senate bill shortly, and Senate Majority Leader Frist has said he will take up the bill on the Senate floor in early February. If the House agrees to the

Senate bill, the legislation could be enacted by Easter, according to bill supporter Senator Dodd (D-CT). The only remaining issue is whether House Republicans will attempt to take the opportunity of increased Republican majorities in the Congress to strengthen the bill's provisions. Should this occur, Senate Democratic support for the bill will decrease.

Asbestos litigation reform. Resolving the avalanche of lawsuits across the country by workers exposed to asbestos was a major priority of the business community in the 108th Congress. Early on, two competing approaches vied for support: (1) replacing asbestos litigation with a no-fault administrative compensation system underwritten by a business and insurance industry-supported trust; and (2) a medical criteria proposal to screen out of the litigation system plaintiffs who were not injured by asbestos exposure. The business community ultimately supported the trust fund concept.

The House passed its bill in 2003. Senate consideration was more difficult. The bill that the Senate Judiciary Committee reported out could not bridge the gap between business and labor. Senate Majority Leader Frist and Senator Hatch introduced a new bill in April 2004, which died when supporters were unable to get the 60 votes needed to limit debate on the bill.

Last Fall, Senator Frist and Minority Leader Daschle negotiated and ultimately agreed on some key issues, such as the size of the trust fund—approximately \$140 billion—but some critical issues were left unresolved. In the meantime, Senator Specter asked retired Third Circuit Judge Becker to mediate between the stakeholders. Now-Chairman Specter recently circulated a draft bill

based on Judge Becker's consultations. The Senate Judiciary Committee held a hearing on January 11 to consider the draft. Witnesses raised a variety of concerns including, initial funding levels, procedures to address inadequate funding (so-called "sunset" provisions), payments to be provided to smokers and ex-smokers who contract lung cancer but have no visible signs of asbestos injury, workers' compensation payments to those who obtain payments from the fund, lawsuits by plaintiffs claiming to have been exposed to asbestos and other dust (like silica), treatment of rail workers, and an offshore reinsurer issue.

Senator Specter has said he would like to introduce a new bill by the end of January and move to Committee mark up by early February, which may be optimistic. In addition, there are indications that some Senators may introduce a rival medical criteria bill, which Senator Specter has said he will oppose. The White House has avoided taking a position on the rival approaches. House passage of an asbestos bill is expected, although it is not yet clear when this will occur.

Medical malpractice legislation. Concern in the medical community over the threat of lawsuits and high medical malpractice premiums, and the decision by some doctors to stop practicing in high-litigation risk specialty areas like obstetrics and neurosurgery, have led state legislatures

across the country to pass medical malpractice liability reform measures in recent years. The issue became part of the federal legislative agenda during the 108th Congress. The House passed a medical malpractice bill containing a \$250,000 cap on noneconomic ("pain and suffering") awards in 2003. The Senate took up a bill in 2003, but it was stalled when Democrats prevented the Senate leadership from limiting debate on the bill. As part of various election year maneuverings, the Senate took up two other medical malpractice bills, one to limit damage awards against obstetricians, gynecologists and nurse midwives to \$250,000, and one to extend these protections to emergency and trauma center personnel. The Senate failed to invoke cloture on both bills.

Congressional consideration of the issue in the 109th Congress is a certainty, although timing is not clear. Although the issue has a lot of support in the Congress, the remedy of caps on damages and the fact that the bill extends to managed care providers and pharmaceutical companies has attracted strong opposition from Democrats. While it is clear that last year's bill cannot attract the 60 votes needed in the Senate, it is not clear whether a compromise that can achieve 60 votes is possible.

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HEALTHCARE FINANCING

The 108th Congress enacted the most sweeping changes to Medicare since the program's establishment nearly 40 years ago. The legislation established a

new Medicare Part D prescription drug benefit, the implementation of which is ongoing. The legislation also made numerous important changes to existing

aspects of the Medicare program—including reform of drug payments under the Part B outpatient benefit—with broad implications for all healthcare industry stakeholders, including pharmaceutical, biologics, and medical device manufacturers; healthcare providers and insurers; and Medicare beneficiaries and patient advocacy and assistance organizations. Key Committees, such as the House Energy and Commerce and Senate Finance Committees, also launched investigations to gather information on the Medicaid program, the uninsured, and other healthcare-related issues. These efforts set the stage for further changes to the Medicare program and reform of the Medicaid program during the 109th Congress. In addition, the healthcare agenda of the 109th Congress is likely to feature proposals to cap medical malpractice awards (see discussion under “Tort Reform”) and improve access to health insurance through market-based incentives.

Consideration of healthcare proposals will be heavily influenced by a renewed emphasis on reining in the costs of government programs and the Administration’s goal of cutting in half the size of the federal deficit in five years. Two new leaders also will influence the healthcare agenda: Michael Leavitt, the newly nominated Secretary of the Department of Health and Human Services (HHS), and Senator Enzi (R-WY), the new Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee.

Medicaid. Many view the President’s appointment of Michael Leavitt as a sign of the Administration’s commitment to aggressive reform of the Medicaid program. As Governor of Utah, Leavitt spearheaded a state reform effort that expanded the population eligible for Medicaid coverage while cutting benefits

to existing beneficiaries. Upon confirmation by the Senate, which is expected, Leavitt likely will play an active role in advancing proposals to realize cost savings in the program.

Several Medicaid reform proposals will be on the table. One likely will aim to generate substantial program savings by reforming the current average wholesale price (AWP)-based Medicaid payment formula for prescription drugs, in the wake of a similar reform enacted last year for Medicare Part B. House Energy and Commerce Committee Chairman Barton (R-TX) has announced that his Committee will take the lead in this effort, following an investigation the Committee concluded on the issue late last year and a Congressional Budget Office report raising concerns with the level of drug payments under the current system. It currently is not clear whether Medicaid drug payment reform will be modeled after the Medicare Part B changes or take a different approach. Other proposals to reform Medicaid—including by capping entitlement allotments or switching to block-grant funding to the states—likely will trigger bitter partisan fights in Congress. Capping entitlements may have limited support in the Administration, as former Governor Leavitt, who recently chaired the National Governors Association, may be unwilling to support a proposal likely to draw strong opposition from state governors.

Medicare. Notwithstanding last year’s Medicare reforms, key Members involved in crafting the healthcare agenda seem to agree that Medicare will be the subject of further action this Congress. At a minimum, a technical measure will be needed to address issues arising from last year’s bill. In addition,

many Democratic Members—led by Senator Ted Kennedy (D-MA), Ranking Member of the Senate HELP Committee—have expressed concerns with certain of the reforms (including those under Part D that restrict the federal government’s involvement in direct negotiations with drug companies), and may pressure the Republican leadership to open up the Medicare statute for further revision. It also appears likely that Congress once again will grapple with the issue of Medicare payments to physicians; some Members may target this area for additional cost savings, while others will work to ward off cuts expected to begin in 2006 as a result of application of the Medicare physician fee schedule payment formula.

Access to Healthcare. The 109th Congress also likely will continue considering proposals to improve access to health care for the uninsured, an issue that attracted

the interest of key Members and Committees last Congress. Some Republicans, including Senate Majority Leader Frist and House Ways and Means Chairman Thomas, have expressed strong support for proposals to cap or otherwise limit the tax exclusion for employer-provided health insurance, and to allow individuals who buy their own health insurance to fully deduct the cost of their coverage. Other proposals include expanding tax breaks for individual health savings accounts, and renewing efforts to give small businesses the right to band together to buy health insurance through association health plans. Many of these measures likely will be considered in the context of broader tax reform sought by the President.

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PHARMACEUTICALS AND MEDICAL DEVICES

Importation of drugs, approval mechanisms for “generic” biologics, adverse event reporting for dietary supplements, ensuring adequate supplies of flu vaccine, and improvements in BioShield legislation (see discussion under “Biosecurity”) were issues considered in the 108th Congress, and likely will be addressed again in the 109th. In addition, publicity over risks associated with widely used pharmaceuticals led to Congressional oversight hearings on FDA’s activities. This oversight is expected to continue and may lead to legislation to address any problems that Congress ultimately concludes exist.

Increased Republican majorities in Congress and a recent report by an Administration task force raising

questions about the safety and savings associated with importation of pharmaceuticals, may put those opposed to radical changes in a stronger position this Congress. The bill that then-HELP Committee Chairman Gregg (R-NH) introduced in the 108th Congress to permit importation in some circumstances was generally more conservative in its approach than that sponsored by a bipartisan group of Senators, including Senator Dorgan (D-ND). Senator Enzi (R-WY), who has replaced Senator Gregg as HELP Committee Chairman, was a co-sponsor of the Gregg bill. The House Republican leadership may decide either to delay action or to shape a bill more in line with the Administration’s concerns about safety than the

bill the House passed last year. While President Bush has expressed a willingness to permit importation if it could be done safely, the FDA generally has taken the position that importation would reduce the safety of the country's drug supply.

Both the FDA and Congress are considering how generic or "follow-on" versions of biologic drugs might be approved under an abbreviated process. Concerns about safety of some dietary supplements have led supporters of that industry to seek legislation requiring mandatory reporting of adverse events by supplement makers. Senator Hatch (R-UT), who has yielded the chairmanship of the Judiciary Committee to Senator Specter (R-PA), has been a supporter of moving toward a mechanism for approval of generic biologics and of adverse event reporting for supplements.

The flu vaccine shortage, and the perceived failure of the BioShield statute to encourage the development of measures to defend against bioterrorism raise questions about how the government can best incentivize industry

to meet public health needs. Various ideas, such as a guaranteed government purchase of vaccines, liability protection and patent incentives are being considered. It is too early to predict what legislative solutions, if any, will be enacted.

Aggressive oversight of FDA's activities will inevitably continue in the 109th Congress. In the Senate, Finance Committee Chairman Senator Grassley (R-IA) has asserted authority over FDA through the Committee's jurisdiction over the Medicare program. It is not clear whether the HELP Committee under Senator Enzi will yield its historic prerogative in this area, or whether there will be competing investigations in the Senate. In the House, Energy and Commerce Committee Chairman Barton (R-TX) also is expected to continue that committee's oversight of FDA and its regulated industries.

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BIOSECURITY

In July 2004, the President signed a "BioShield" bill, which created a \$5.6 billion 10-year fund for federal government purchases of countermeasures to bioterror agents and toxins. Concern over the private sector's reluctance to engage in the research and development necessary to produce the BioShield-funded countermeasures has led to consideration of BioShield II legislation. The legislation, introduced by Senators Hatch (R-UT) and Lieberman (D-CT) last Congress would provide to biotech companies tax incentives for capital formation, patent protection

incentives, liability protection and a government purchase guarantee for the development of countermeasures (diagnostics, vaccines, treatments and research tools to enable quick development of vaccines and treatments for new agents/toxins) against priority bioterror agents/toxins.

Broad support exists in the Congress for promoting the rapid development of bioterror countermeasures. However, at an October 6 hearing by the Senate Finance and HELP Committees, one of BioShield II's provisions evoked strong opposition, the so-called "wild

card” patent provision, which would provide a two-year patent extension to a company that developed a bioterror countermeasure. Senator Schumer (D-NY) has vowed to work to defeat the legislation if the provision, which is directed at companies with paid-in capital of less than \$750 million but could be extended to larger companies

by DHS, remains in the bill. BioShield II legislation is expected to be reintroduced early in the 109th Congress and to be a priority for enactment in 2005.

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INTELLIGENCE, HOMELAND SECURITY AND CYBERSECURITY

In December 2004, the President signed legislation to create a Director of National Intelligence and reorganize and revitalize the United States intelligence community. The new law also requires information sharing among intelligence, law enforcement, and homeland security agencies, addresses a broad range of aviation, visa, and driver’s license security issues, requires the Department of Homeland Security to develop a biometric entry and exit data system for U.S. ports of entry, and creates a Privacy and Civil Liberties Board to review Executive Branch policies.

Senate Governmental Affairs Committee Chairman Susan Collins (R-ME) and Ranking Democrat Carl Levin (D-MI) led the Senate’s consideration of intelligence legislation last Congress. Senator Pat Roberts (R-KS) will remain Chairman of the Senate Select Committee on Intelligence (SSCI), and Senator John Rockefeller (D-WV) will remain Ranking Democrat. The Senate continues to distribute oversight responsibilities for homeland security matters among several committees, including Government Affairs, Commerce, Science and Transportation, and Judiciary.

In the House, Rep. Peter Hoekstra (R-MI) has become Chairman of the House Permanent Select Committee on

Intelligence, and Rep. Jane Harman (D-CA) continues as Ranking Democrat. The House Select Committee on Homeland Security is still chaired by Rep. Chris Cox (R-CA), while Rep. Bennie Thompson (D-MS) has become the Ranking Democrat with the retirement of Rep. Jim Turner (D-TX). Other House committees with homeland security oversight responsibilities include Energy and Commerce, Government Reform, Judiciary, Science, and Transportation.

In addition to oversight of intelligence reform implementation, the new Congress faces other difficult homeland security and intelligence issues. Several controversial provisions of the USA PATRIOT Act expire on December 31, 2005, and the Administration has begun to advocate their renewal or permanence. These provisions include the requirement that foreign intelligence constitute a “significant” rather than the “primary” purpose of electronic surveillance and physical search authorized under the Foreign Intelligence Surveillance Act, and a provision in the Electronic Communications Privacy Act permitting foreign intelligence information derived from law enforcement wiretaps to be shared with intelligence, protective, immigration, and national security officials

who are not part of the law enforcement community.

Rep. Adam Putnam (R-FL), outgoing chair of the House Government Reform Committee's Technology, Information Policy, Intergovernmental Relations and the Census Subcommittee has been active in efforts to identify market-driven ways to improve cybersecurity in the private sector, without imposing mandatory measures on companies. An industry working group convened by Rep. Putnam has been developing such proposals and also

considering a variety of supporting legislative proposals to encourage companies to adopt best cybersecurity practices and to enhance the security of U.S. critical infrastructures. With Rep. Putnam's departure from the Committee, it is unclear whether he or another champion will take up the issue this Congress.

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EXPORT CONTROLS AND TRADE SANCTIONS

Export controls. At the beginning of almost every Congress over the past decade, business groups and the members of the then-current Administration sought a renewal and update of the Export Administration Act ("EAA"). The EAA provides the statutory basis for control of dual-use commodities (those items designed for civil purposes but which can have military applications such as computers, lasers, machine tools, semiconductors, as well as certain biological and chemical agents). The EAA has lapsed. The controls remain in place through Executive Order. Once again, representatives of the business community seek to streamline export controls, a goal the Administration supports. The prospects for approval, however, are not high.

Prior to 9/11, advocates of stronger export controls clashed with business representatives over the need for new legislation. After 9/11, the call for stronger national security controls has all but eliminated the possibility of streamlining controls. In the last session, some

Members of the House sought to impose new licensing requirements on computers, which would have required export licenses for exports of ordinary desktop computers to many destinations now available for license-free trade. The computer industry had to undertake a major lobbying effort to defeat the initiative.

In the 109th Congress, the EAA most likely will be reintroduced. It is equally likely that a few Republican House members will once again break ranks with the Administration and introduce proposals for enhanced licensing requirements, while other Members will introduce bills to ease export controls.

Trade Sanctions. In the 108th Congress, Senator Lautenberg (D-NJ) proposed an amendment to eliminate the ability of foreign subsidiaries of U.S. companies to trade with countries subject to U.S. sanctions. Republican leaders defeated it by one vote. Similar provisions may be introduced this session.

For further information, please contact John Barker (202.942.5328) or Jeffrey Smith (202.942.5115).

INTELLECTUAL PROPERTY

Numerous intellectual property bills were introduced in the 108th Congress. Of those that were enacted, many were approved during the post-election lame duck session. On the patent front, Congress enacted legislation to promote cooperative scientific research by allowing the sharing of confidential information without triggering a statutory bar to the patentability of a joint invention. Other legislation enacted increases patent fees, including maintenance fees, and provides for separate patent filing fees, search fees, and examination fees, and additional fees for larger applications. In the copyright area, the concluding days of the Congress saw approval of legislation to: restructure the process for determining royalty rates and terms under compulsory licenses by substituting permanent Copyright Royalty Judges for the ad hoc Copyright Arbitration Royalty Panels; extend the compulsory license for satellite retransmissions of broadcast television stations; prohibit trafficking in holograms and other labels used to authenticate legitimate products; and expand the antitrust exemption for negotiation of licenses for the use of songs in recorded music products. Also enacted was legislation to provide enhanced trademark remedies when false contact information is provided in connection with a domain name registration.

The 109th Congress is likely to have a similarly active agenda. Senator Hatch (R-UT), who was required to relinquish his position as Chairman of the Senate Judiciary Committee due to term limit rules, will be replaced by Senator Specter (R-PA). However, Senator Hatch, who has been active in advancing intellectual property legislation, is expected to lead a newly-reconstituted Intellectual

Property Subcommittee. Senator Patrick Leahy (D-VT) remains Ranking Democrat on the Judiciary Committee. In the House, Reps. Sensenbrenner (R-WI) and Conyers (D-MI) continue to lead the Judiciary Committee, and Reps. Smith (R-TX) and Berman (D-CA) will continue to lead the Subcommittee on Courts, the Internet, and Intellectual Property.

The busy conclusion to the 108th Congress nonetheless left numerous proposals for possible consideration in the 109th Congress. Patent owners have long sought to prevent the use of patent fees to subsidize general federal revenues. Legislation to eliminate fee diversion made some progress in the 108th Congress and is likely to be pursued again in the 109th. Other patent legislation may include a proposal to improve the quality of issued patents through a post-grant opposition procedure. An assortment of copyright bills came very close to enactment in the 108th Congress, only to fail on the last day of the lame duck session, including bills to prohibit recording of motion pictures in theaters, permit use of technology to skip objectionable content on DVDs, address piracy of pre-release works, and allow civil infringement suits by the Justice Department. Any of these proposals could resurface in the 109th Congress. Other issue areas that received attention in the 108th Congress and may be revived include peer-to-peer file sharing services that intentionally induce users to commit copyright infringement (an issue that is now before the U.S. Supreme Court), database protection, and music licensing. Proposals for trademark dilution legislation are under discussion, but consensus has thus far proven elusive.

For further information, please contact Steve Englund (703.720.7009) or Michele Long (202.942.5719).

OUTSOURCING/GOVERNMENT CONTRACTS

U.S. companies have long entrusted their data centers, voice networks and the like to contractors who promise better performance at a lower cost. Often these contractors are located offshore, in places such as India. More recently, offshore outsourcing has been expanded to the areas of human resources, customer care, logistics, procurement, accounting and other business processes.

Some Democrats have argued that outsourcing offshore is tantamount to “exporting American jobs.” In the 108th Congress, a variety of bills on this subject were introduced. (Over 180 bills were introduced in over thirty states as well). These proposals generally fell into one of the following categories: (1) restricting or banning the performance of federal contracts overseas; (2) providing job adjustment assistance to displaced workers; (3) requiring certain disclosures to be made by call centers located abroad; (4) directing companies to provide notification to the government of any job losses as a result of off-shoring operations; and (5) protecting the privacy of consumer data that is sent abroad for processing.

The area that has obtained the greatest attention is government contracting restrictions. For example, the so-called “Dodd Amendment” to restrict offshore performance of federal contracts and federally funded state contracts was passed by the Senate as part of the “Jumpstart Our Business Strength (JOBS) Act of 2004,” but was quietly dropped in conference. Additional restrictions on government contractors who transfer certain operations overseas (such as requiring a certain percentage of workers be employed domestically) gained no momentum. None of the

proposals in the other areas, such as privacy, saw any action other than bill introduction.

In the 109th Congress, Senate Democrats may seek to pursue the Dodd Amendment approach again. Another potential area for Democratic efforts is privacy. Senator Hillary Clinton (D-NY) has spearheaded an effort to restrict the transmission of personal data to a country where privacy protections are deemed inadequate. Senator Clinton likely will resurrect one of the draft alternative proposals she floated last year: (1) to require individual consent for privacy information to be transferred overseas (unless the FTC deemed offshore protection adequate); or (2) to give the individual a right to object to the transfer. Senators Nelson (D-FL) and Feinstein (D-CA), who introduced a competing privacy bill focusing on offshore transfers of financial and health-related data, also are likely to rejoin the debate.

Although to date this issue has been driven primarily by Democrats, it bears close scrutiny. The politics of the issue are complex. “Saving American Jobs” is a popular goal that crosses party lines. Privacy is another theme that resonates on both sides of the aisle. However, both parties dislike the “protectionist” label, and there are some real concerns with these proposals in the areas of foreign policy and international trade rules. Finally, these proposals are largely opposed by services industries (banking and insurance) as well as major U.S.-based outsourcing service providers, most of which have very substantial operations offshore.

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FINANCIAL INSTITUTIONS AND SECURITIES

The principal accomplishments of the 108th Congress with respect to financial institutions were enactment of the Fair and Accurate Credit Transactions Act, which, among other things, made permanent the preemption provisions of the Fair Credit Reporting Act, and the Check Clearing for the 21st Century Act, which enables banks to clear checks based on electronic copies. Other legislation that received significant attention but remained pending at the end of 2004 included proposals to reform government-sponsored enterprises, provide regulatory relief to the banking industry, address so-called “predatory” lending, and preempt state law with respect to national banks.

The leadership of the Senate and House committees with principal jurisdiction over financial institutions remains the same in the 109th Congress. Senator Richard Shelby (R-AL) chairs the Senate Banking Committee, and Senator Paul Sarbanes (D-MD) is the Ranking Democrat. In the House, Rep. Michael Oxley (R-OH) is Chairman of the Financial Services Committee, and Rep. Barney Frank (D-MA) is the Ranking Democrat.

Housing and lending. A key priority for the new Congress will be possible changes in regulation of the two government-sponsored enterprises for housing, Fannie Mae and Freddie Mac. Chairman Shelby is expected to reintroduce legislation to replace the current regulatory body, the Office of Federal Housing Enterprise Oversight, with a regulator housed within the Treasury Department. House Financial Services Committee member Rep. Richard Baker (R-LA), who offered his own restructuring bill in 2003, may well lead the charge for action on the House

side—promoting either a renewed version of his prior proposal or a companion to Senator Shelby’s bill.

The predatory lending issue also will likely receive renewed attention from the new Congress. Concern among consumer protection advocates and others about predatory lending—issuing sub-prime loans in a manner alleged to be abusive to lower-income consumers—has prompted calls for the adoption of federal legislation that would provide for nationwide consumer protection from this practice. Housing and Community Opportunity Subcommittee Chairman Bob Ney (R-OH) and Financial Services Committee member Rep. Paul Kanjorski (D-PA) plan to revive legislation setting standards for such protection early this session.

Insurance. A number of insurance matters also are anticipated to be on the agenda. One is renewal of the insurance program established under the Terrorism Risk Insurance Act of 2002 (“TRIA”), which provides federal backup financing to cover a large portion of commercial property and casualty losses from terrorist attacks. The TRIA program currently is set to expire at the end of 2005, and thus near-term action on extending legislation is a key priority for the program’s advocates.

The new Congress also may address federal oversight of the insurance industry. Representatives of the life insurance industry, as well as some members of the property-casualty insurance industry, have for several years been pressing for a federal insurance charter as a means of relief from the disparate regulatory requirements of the individual states’ laws. While the chartering proposal has been highly controversial,

the recent disclosures of insurance broker misconduct revealed through New York Attorney General Eliot Spitzer's investigations have fueled new calls for some form of federal intervention. One possible approach proposed by Committee Chairman Oxley is establishing a federal-state partnership, comprised of both federal and state regulators, to coordinate on uniform regulatory standards and market conduct oversight of insurers nationwide. Chairman Oxley will likely proffer that approach in the form of his so-called "SMART" Act (State Modernization and Regulatory Transparency Act) proposal, a draft of which underwent review and comment in the latter half of 2004.

Also likely to fuel continued debate are the regulations promulgated by the Office of the Comptroller of the Currency in 2004 that preempt the application of a range of state laws to national banks, and proposals for bankruptcy reform that would limit individuals' use of bankruptcy to avoid repaying unsecured loans.

Securities. In the securities area, although both House and Senate committees held numerous hearings on the need for new laws regulating the mutual fund industry, and the House passed a comprehensive bill, the Securities and Exchange Commission ("SEC") has addressed most of the relevant issues in a series of rulemakings over the past year and a half. However, the committees may continue oversight of this area, including the SEC's new regulations to require hedge fund managers to register as investment advisers. Members of Congress also again may attempt to block the Financial Accounting Standards Board's new rule requiring expensing of employee stock options. The House passed legislation in this area last year, and a Senate companion bill garnered 30 co-sponsors, but Senate Banking Committee Chair Shelby declined to move the bill.

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TELECOMMUNICATIONS

Telecommunications legislation passed by the 108th Congress fine-tuned the existing regulatory framework by creating a spectrum relocation fund to aid in the deployment of advanced wireless services, changing accounting rules for the E-rate program for schools and libraries, providing grants for E911 deployment, imposing restrictions on unsolicited commercial emails, renewing satellite-TV providers' right to carry local TV stations, and extending the Internet access tax moratorium. Bills to increase penalties for indecent broadcasts, clarify restrictions on junk faxes, and preempt state jurisdiction over

VoIP (Voice over Internet Protocol) service were not successful.

The 109th Congress is poised to undertake a major overhaul of the country's telecommunications laws to accommodate numerous technological advances and marketplace developments that were not foreseen or addressed in the Telecommunications Act of 1996. These include the widespread deployment of high-speed Internet service, the development of new technologies such as Internet protocol (IP)-based services, the rapid growth of wireless services, the provision of telephone

service by cable companies, and the imbedded subsidies in the current telephone system.

In the House, the leadership of the committee with responsibility for communications issues is unchanged. Rep. Joe Barton (R-TX) is Chairman of the Energy and Commerce Committee; Rep. John Dingell (D-MI) is the Ranking Democrat. Rep. Fred Upton (R-MI) will remain the Chairman of the Telecommunications and Internet Subcommittee, with Edward Markey (D-MA) as the Ranking Democrat. Reps. Chip Pickering (R-MS) and Rick Boucher (D-VA) are expected to continue to be among the most vocal members on communications issues. In the Senate, Senator Ted Stevens (R-AK) will take over as Chairman of the Commerce Committee from Senator John McCain (R-AZ). Senator Daniel Inouye (D-HI) will take over as Ranking Democrat.

A rewrite of the Telecommunications Act of 1996 likely will focus on three topics: (1) the regulatory treatment of IP-based services, which were not foreseen by the 1996 Act and do not fit comfortably within the Act's strictures; (2) funding of universal service costs (the present mechanisms are inadequate to assure continued service to rural areas at reasonable rates without overly burdening technological developments like IP-based services and broadband wireless); and (3) the manner in which carriers that interconnect to complete calls compensate each other, which is being rendered obsolete by technological developments like IP-based services, and may no longer be able to serve as a vehicle for funding universal service costs. Network unbundling requirements, spectrum allocation, the role of state regulators, and Bell company antitrust liability also may be taken up during consideration of telecommunications legislation.

Opinions are mixed on whether the 109th Congress will succeed in addressing these issues. House Chairman Barton has said that telecommunications legislation is a priority for this Congress. Senate Commerce Committee Chairman Stevens has identified overhauling the 1996 Telecommunications Act as a major goal, and is planning regional hearings during the first half of this year. Commerce Committee member Senator Sununu (R-NH) has said that an overhaul can be accomplished by 2006. Others, however, are skeptical that Congress can act so quickly, noting that debate over what became the 1996 Act began in the early 1980s.

Passing such legislation will require resolution of complex issues affecting a variety of interests. Any revision to the 1996 Act will likely retain the basic deregulatory approach of the Act, in keeping with the ideological bent of the current Congress, but also will need to protect well-represented rural interests. It also will have to balance the interests of and differing regulatory treatment of cable companies, incumbent telephone companies, competitive carriers and new entrants such as VoIP providers, all of which may, over time, provide similar bundles of services, and all of which are well represented in both political parties. The rapid pace of technological change may force the issue, as many believe that it is rendering the existing regulatory structure unsustainable.

In addition to a rewrite of the 1996 Act, other issues likely to be raised in the 109th Congress include hastening the digital television transition and return of analog broadcast spectrum, tightening restrictions on multiple ownership of the broadcast media, encouraging broadband deployment in rural areas, prohibiting spyware, strengthening penalties

for broadcast indecency, addressing the disparity in treatment of indecency questions between broadcast and cable, clarifying the junk fax rules, and restricting Internet file sharing services. In addition, several of the Federal Communications Commission's

commissioners may leave, and Senate confirmation will be required for their successors.

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ENERGY AND THE ENVIRONMENT

Energy and environmental issues were highly contentious during the 108th Congress, with Senate Democrats and northeastern Republicans joining forces to oppose Administration and Congressional leadership efforts to enact energy supply and environmental regulatory reform initiatives. Regarding energy legislation, two initiatives were unsuccessful—an attempt to permit oil and gas drilling in the Arctic National Wildlife Refuge (“ANWR”) through the budget reconciliation process, and efforts to pass a comprehensive energy bill, which failed largely due to Senate opposition to a provision prohibiting product liability lawsuits against companies who made or put in their gasoline the additive MtBE pursuant to a congressional mandate. However, some of the bill's provisions were enacted through other legislation, e.g., various tax incentives through a corporate tax bill, and authorization for federal loan guarantees for a natural gas pipeline from the Northern Slope to the lower 48 states through the military construction appropriations bill. The Administration and Congressional leaders will be pursuing an ambitious agenda in the energy and environment areas in the 109th Congress.

Energy. House Energy and Commerce Committee Chairman Barton (R-TX) has expressed strong

continuing support for comprehensive energy legislation but has indicated that the Senate will have to reach agreement on a filibuster-proof bill if legislation is to be enacted this Congress. The Chairman of the Senate Energy and Natural Resources Committee, Senator Domenici (R-NM), has committed to working closely with the Committee's Ranking Democrat, Senator Bingaman (D-NM) to take up a scaled-back version of the energy bill early this year. The bill will focus on increasing U.S. energy production, e.g., through tax and royalty incentives for domestic oil and gas producers, expanding production of renewable fuels, and conservation measures (including the President's hydrogen initiative).

Increasing natural gas prices will obtain particular attention this year. The chemical industry and other natural gas consumers have expressed strong concern over prices. Chairman Domenici has scheduled a public forum on January 24th to discuss the issue. Energy Subcommittee Chairman Alexander (R-TN) is working on legislation to increase natural gas production. Senators Domenici, Alexander and Landrieu (D-LA) have asked Interior Secretary Norton to seek public comment on lifting the current moratoria

on oil and gas drilling on the Outer Continental Shelf, a move that would meet strong opposition, including from Florida Governor Jeb Bush and the Florida and California congressional delegations. Finally, prospects are better in the new Congress for efforts to permit oil and gas drilling in ANWR through the budget process, because the budget reconciliation bill is not subject to a filibuster and, therefore, only 51 votes are needed to approve the bill in the Senate.

Environment. The most prominent environmental matter on the agenda for the 109th Congress is the Administration's "Clear Skies Initiative": legislation to control emissions of nitrogen oxides, sulfur dioxide and mercury from coal-fired power plants via an expansive cap-and-trade program. Although EPA has been proceeding with regulations to achieve much of this via emissions trading, both EPA's air chief, Jeff Holmstead, and Sen. James Inhofe (R-OK), Chairman of the Senate Committee on Environment and Public Works, have indicated that Clear Skies legislation is a top priority for the coming Congress. Oversight of the New Source Review regulatory and enforcement litigation concerning emissions from coal-fired utilities will continue, with a National Academy of Science study anticipated in December 2005. Other

air quality-related issues on the legislative agenda include changes to requirements that transportation projects "conform" to clean air plans and provisions to address details on new fine particulate and ozone nonattainment area designations.

The Superfund program also will receive attention in Congress in 2005. Democrats will push to reinstate the "polluter pays" tax and will promote increased appropriations for EPA's brownfields program, while Republicans may push to expand liability exemptions, for example for service station dealers from liability for waste oil. Another issue expected to draw attention is the fallout from the U.S. Supreme Court's ruling in December in *Cooper Industries v. Aviall Services, Inc.* (U.S. No. 02-1192, 12/13/04), in which the Court held that parties who initiate private cleanups may not bring contribution suits against third parties, prior to the filing of an enforcement action against them. Legislation to encourage voluntary cleanup of contaminated sites also may be introduced during this congressional session. Another issue likely to remain on the agenda from the last Congress is revision of the Endangered Species Act.

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