

## **Major Regulations of Concern**

A nation's regulatory system is one of the most telling indicators of its business environment. On the one hand, smart regulations that clarify the "rules of the road" and are in line with broad societal values over multiple election cycles can provide an environment of stability, inspire business confidence and accelerate investment. On the other hand, regulations that create uncertainty and reflect shortsighted political interests can impose unproductive cost burdens on businesses and consumers, undermine confidence and delay investment. The key distinction, therefore, is not the quantity of regulations, but the effectiveness and efficiency of regulations as well as the balance between their costs and intended benefits.

In recent years, the overall regulatory burden to U.S. businesses has grown substantially. Some experts estimate that regulations impose hundreds of billions of dollars of costs on the U.S. economy each year. As a result, there are good reasons to believe that excessive regulation is hampering economic growth and recovery in the job market. An October 2011 Gallup poll of U.S. small business owners found that complying with government regulation is the most "important problem" facing small businesses today – more than low consumer confidence or lack of consumer demand. <sup>i</sup>

Business Roundtable CEOs have identified over 60 different pending or proposed regulations that may impose significant costs on the economy and unnecessary burdens on business. They are organized into the following categories and outlined below:

- Environmental
- Energy
- Financial regulatory reform
- Food
- Labor
- Transportation
- Health care
- Other

Issue	Description of Issue
	Environmental
Industrial Boiler	EPA has re-proposed rules that would reduce hazardous air pollutant
Maximum Achievable	emissions from existing and new industrial, commercial and
Control Technology	institutional boilers and process heaters. Final rules are expected in
(MACT)	April 2012.
Greenhouse Gas	EPA repeatedly has delayed issuances of proposed new source
Emissions	performance standards (NSPS) for electric utilities and refineries.
Regulations	Proposed rules for both types of facilities are expected in 2012.
Cooling Water Intake	Proposed rules have been issued and are expected to be finalized in
Structures Rule	2012. These rules will apply to electric power plants, and to
	manufacturing facilities with open-loop or once-through cooling
	systems.
Particulate Matter	The Clean Air Act requires EPA to promulgate primary and secondary
(PM) National	NAAQS for six air pollutants, including particulate matter. Primary
Ambient Air Quality	standards have been established for PM10 and PM2.5. A required
Standards (NAAQS)	five-year review of the PM NAAQS is in progress and a proposal to
	retain or revise those standards is expected this year.
New Source Review	"Major modifications" to major stationary sources trigger a
	requirement for New Source Review. Under EPA regulations, a major
	modification includes any physical change to or change in the method
	of operation of a major stationary source that would result in a
	significant net emissions increase of a regulated pollutant. While
	"major modification" excludes routine maintenance, repair and
	replacement, these terms are not clearly defined and have been
	interpreted differently by EPA over time. Substantial litigation has
	surrounded this program, with companies now deterred from
	upgrading existing equipment, even when the upgraded plant would
	be more efficient or reliable.
Preliminary	EPA's interim Preliminary Remediation Goals (PRG) for dioxin remain
Remediation Goals	under review by OMB while EPA prepares to finalize its Integrated Risk
for Dioxin	Information System (IRIS) human health risk reassessment on dioxin,
	responding to concerns raised by the National Academy of Science in
	2006. The EPA IRIS program will issue the reassessment in piecemeal
	fashion, with the non-cancer portion of the reassessment having been
	released in February 2012 and the cancer portion to be released at an
	unspecified time thereafter. This reassessment may be used to
	develop a final PRG. It is unclear whether EPA will issue its interim
	PRG given the possibility of issuing a final PRG this year.

Issue	Description of Issue
Coal Combustion	In response to a spill at a TVA coal ash impoundment pond, EPA issued
Residuals Regulation	proposed rules in June 2010 to regulate the disposal of coal residuals
	under <i>Resource Conservation and Recovery Act</i> (RCRA). EPA proposed two options, one of which would categorize coal residuals as a
	hazardous waste, thus significantly increasing disposal costs and
	eliminating many current beneficial recycling options. This is a
	discretionary rulemaking that EPA is not obligated to issue. It is
	unclear when or if EPA intends to finalize the rulemaking. Bipartisan
	legislation has passed the House and has been introduced in the
	Senate that would prevent EPA from regulating coal residuals as a
	hazardous waste under RCRA.
Hydraulic Fracturing	Multiple federal agencies are considering regulating hydraulic
	fracturing. EPA has proposed a suite of four new regulations for the
	oil and natural gas industry, including the first federal air standard for
	wells that are hydraulically fractured. In addition, EPA has announced
	that it intends to propose a rulemaking on disposal of fracturing water
	and fluids from shale gas extraction operations in 2014. In a related
	development, EPA has announced that it intends to propose a rulemaking on the disposal of wastewater from coal bed methane
	operations in 2013. EPA also has begun a long-term study on the
	impact of hydraulic fracturing on ground water and drinking water.
	Initial results from the study are anticipated in 2012 and a final report
	is expected in 2014. The Department of the Interior has announced it
	intends to propose regulations for hydraulic fracturing on federal
	lands it administers in 2012. The Administration has proposed
	banning horizontal drilling and hydraulic fracturing on certain lands
	while it considers hydraulic fracturing implications.
EPA Chemical Action	Thus far, EPA has issued chemical action plans for ten groups of
Plans	chemicals. EPA also recently launched an initiative to identify priority
	chemicals for review, assessment and possible risk management
	action. Although there is support for EPA to develop a sound
	prioritization process to identify chemicals of concern, the proposed
	process is not as risk-based as it should be, nor is it as transparent as it
	should be to provide regulatory certainty. There is also concern with the criteria EPA is using to evaluate chemicals for listing under the
	Toxic Substances Control Act (TSCA) Section 5(b)(4).
Lead National	A review of the current lead NAAQS is ongoing. It is anticipated that a
Ambient Air Quality	draft policy assessment will be released in 2012.
Standards (NAAQS)	
Standards (NAAQS)	

Issue	Description of Issue
Lead, Renovation,	EPA intends to regulate the renovation, repair and painting of the
Repair, and Painting	public and commercial buildings under section 402(c)(3) of <i>Toxic</i>
Program for Public	Substances Control Act (TSCA). Requirements will include lead-safe
and Commercial	work practices and other requirements for renovation of the exteriors
Buildings	of public and commercial buildings.
Non-Point Sources of	The Ninth Circuit Court of Appeals overturned 35 years of precedent
Discharge under	and ruled that forest road systems are subject to point source
Clean Water Act	regulation under the Clean Water Act and inappropriately applied the
	silvicultural exemption to those roads. The industry must now
	reallocate funds to comply with a new permitting system. The
	industry will suffer when permitting delays interrupt raw material
	supplies. While a petition for certiorari has been filed with the
	Supreme Court, new legislation or regulations may be required.
EPA Assessment of	The National Academy of Sciences (NAS) has criticized the science
Chemical Risk	underpinning EPA's risk assessment process. The criticism is aimed at
	EPA's Integrated Risk Information System (IRIS) program, which
	develops estimates of chemical risk used both by EPA and state
	environmental agencies to set regulatory standards. NAS has also
	recommended changes to reform the IRIS process, and Congress has
	recently emphasized the need for EPA to follow these
	recommendations. Because risk assessment is central to many EPA
	regulatory programs, and because objective analysis is a core
	component of the BRT "smarter regulation" agenda, EPA should
	follow the advice of NAS, and of Congress, and reform its IRIS process.
EPA Definition of	EPA is proposing new requirements and documentation for recycling
Solid Waste	certain materials in an attempt to minimize future "damage cases"
	and "sham" recycling. The new regulations will only save
	approximately \$86 million/year, but will cost more than \$100
	million/year in documentation/analysis costs. EPA does not have
	authority to impose requirements that are not solid waste; the
	proposed rule will not prevent damage cases; and the rule will
Davisia a	adversely impact legitimate recycling.
Revising	EPA, on November 18, 2011, proposed to strengthen the underground
Underground Storage	storage tank program by adding secondary containment requirements
Tank Regulations –	for new and replaced tanks and piping; operator training
Revisions to Existing Requirements and	requirements; periodic operations and maintenance requirements; new release prevention and technology standards; and updating
New Requirements	operator training codes.
for Secondary	operator training codes.
Containment and	
Operator Training	

Issue	Description of Issue
Nutrient Loading Criteria for FL	A consent decree required EPA to issue a Numeric Nutrient Criteria (NNC) rule for streams, springs and lakes in Florida. The rule includes severe limits on National Pollutant Discharge Elimination System (NPDES) permits for discharges of nitrogen and phosphorus. On December 22, 2011, EPA proposed to extend the effective date of this rule to June 4, 2012, to allow the state of Florida to develop its own rulemaking for NNC that are consistent with the requirements of the <i>Clean Water Act</i> . The consent decree also requires EPA to propose marine, estuary and canal criteria by March 15, 2012, and to finalize this rule on November 15, 2012. EPA's proposed NNC criteria for both phases of the rule could be used as a template for other states' management of water quality under the <i>Clean Water Act</i> .
Certification, Compliance & Enforcement Energy Star Rule	DOE final rule on certification, compliance and enforcement for ENERGY STAR® program was published in 2011. This rule imposes new requirements for testing of commercial HVAC and water heating products to establish and continuously verify the efficiency rating of DOE covered products. Not only has the number of tests been greatly increased, but the role of previously recognized Voluntary Independent Certification Programs, or VICP's, such as the AHRI Certification Directory Program, have been diminished, if not totally duplicated. There is also a duplication of testing added on top of this rulemaking, in the form of similar requirements by EPA for compliance with ENERGY STAR® listings.
CBI Protection for Chemical Identities of New Chemicals	EPA has proposed to eliminate most confidential business information (CBI) protection for the chemical identities of new chemicals. The lack of protection for trade secrets can be counterproductive by inhibiting innovations.
SO2 Regulations	EPA's recent revision of the National Ambient Air Quality Standards (NAAQS) for sulfur dioxide (SO2) threatens U.S. smelters. EPA reduced the NAAQS to 75ppb averaged over one hour from a standard of 140 ppb averaged over 24 hours and 30ppb averaged annually. In addition, EPA imposed stringent new monitoring and modeling requirements. The low standards and modeling requirements will unnecessarily force many areas into non-attainment. This will prevent or significantly delay expansion projects and may require a reduction in U.S. smelter production. These new standards will make U.S. smelters the most tightly regulated in the world.
011.0.11.1.1.0	Energy
Oil & Natural Gas Offshore Leasing	The Administration has announced resumption of leasing activities in the Gulf of Mexico and has approved exploration plans for offshore Alaska after further environmental review. Many promising offshore areas remain off limits to leasing.

Issue	Description of Issue
Deepwater Offshore	The Administration has lifted the moratorium on issuance of drilling
Drilling Permits	permits in the Gulf of Mexico and Alaska. The Department of the
(Alaska and Gulf of	Interior has finalized new drilling safety and emergency response
Mexico)	measures. Steady progress in eliminating the backlog of applications
,	is occurring, but the pace of approvals is slow.
Keystone XL Pipeline	The Keystone XL pipeline would carry an estimated 700,000 barrels
Project	per day of crude oil from Canada and North Dakota to U.S. refineries
	in the Gulf region. Because the pipeline would cross the U.SCanada
	border, a Presidential Permit, coordinated by the Department of
	State, is required. The Department of State issued a favorable final
	environmental impact study (EIS) earlier this year. Environmental
	groups have waged an aggressive campaign against approval of the
	project, primarily on the basis of increased greenhouse gas (GHG)
	emissions that would occur from development of Canadian oil sands
	that would supply the pipeline. The Administration repeatedly has
	delayed making a favorable decision on the Presidential Permit, thus
	denying the U.S. access to this important source of secure energy.
	Financial Regulatory Reform
Volker Rule	Section 619 of <i>Dodd-Frank</i> (Volcker Rule) aims to limit proprietary
	trading by banks. It will introduce new complexities and impose
	higher costs for businesses while slowing down the creation of new
	markets.
Over-the-counter	While the new regulatory structure for OTC derivatives is not yet
(OTC) Derivatives	completed, concerns are arising about the market structure and
	extraterritorial applications of these rules. The proposed application
	could create uncertainty in overseas markets, which will result in
	higher hedging costs. With more cash used to cover the increased
	costs, there will be less money for new job creation and growth.
	There also should be an unambiguous end-user exclusion from
	clearing, trade execution, margin and capital requirements in order to
	allow end-users to be able to prudently manage risk. Managing and
	hedging risk is essential for many businesses, particularly with respect
	to increasingly volatile commodity prices, currencies and interest
	rates.
Capital Requirements	Dodd-Frank requires the Federal Reserve to draw up rules to address
& Surcharges	capital requirements and surcharges for banks. These rules will likely
	be influenced by the global systemically important bank (G-SIB)
	surcharges (which are poorly constructed and will impose costs on
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Issue	Description of Issue
Conflict Mineral	SEC proposed rules in December 2010 to implement Section 1502 of
Disclosure Rule	the <i>Dodd-Frank Act</i> , which requires that public companies disclose
	annually whether their products contain "conflict minerals." The SEC's
	proposed rules provide for a three-step disclosure process that
	requires companies to undertake and disclose their "reasonable
	country of origin inquiry" and to provide an audited Conflict Minerals
	Report if the conflict minerals it uses originate in the Congo or
	adjoining countries. Companies commented that the costs of
	conducting the necessary due diligence is too high and that the
	achieving compliance is extremely difficult, if not impossible.
SEC Public Disclosure	The <i>Dodd-Frank Act</i> requires resource extraction industries to disclose
Regulations for	payments made to the United States or foreign governments. The SEC
Resource Extraction	issued proposed rules in December 2010, but has yet to issue final
Industries	rules. If the final rules are not carefully tailored, foreign competitors
	may be able to gain access to sensitive U.S. company information that
	could place U.S. companies at a competitive disadvantage in contract
	negotiations and in bidding for resource licenses.
	Food
Nutrition Labeling of	The Patient Protection and Affordable Care Act of 2010 requires
Standard Menu Items	restaurants and similar retail food establishments with 20 or more
in Restaurants and	locations to list calorie content information for standard menu items.
Similar Retail Food	FDA has issued proposed rules to implement this provision.
Establishments	
Food Labeling:	See above for the labeling requirements that also are applicable to
Nutrition Labeling for	vending machines.
Food Sold in Vending	
Machines	
Regulations of	In 2011, the FTC, in coordination with FDA, USDA, and CDC, proposed
Marketing of Foods	"voluntary guidelines" to have marketing of foods to children under
to Children	age 17 encourage nutritional objectives and avoid foods that
	encourage weight gain or obesity. The federal agencies aimed to have
	industry (a) refrain from promoting certain foods to children, (b)
	change the content of certain foods marketed to children, and (c)
	refrain from advertising other foods in numerous realms defined as
	targeting children. In December 2011, Congress included in the
	Consolidated Appropriations bill a requirement that required the FTC
	and other agencies to complete a cost-benefit study before
	proceeding further with these guidelines.

Issue	Description of Issue
Implementation of	Two years ago, Congress enacted the Food Safety Modernization Act,
Food Safety	Pub.L. 111-353, which among other things directs the FDA to: (1)
Modernization Act	develop preventative food safety standards for covered facilities, (2)
	conduct regular inspections of covered facilities with expanded
	record-keeping and records-inspection authorities, and (3) require
	importers to perform supplier verification activities. It also provides
	FDA with mandatory recall authority and requires enhanced
	collaboration activities with other state and federal agencies involved
	in food safety. The Act requires several new rulemakings, with
	deadlines that are now in effect.
	Labor
Occupational	OSHA has indicated its intention to propose tighter exposure,
Exposure to	monitoring, medical surveillance and worker training standards for
Crystalline Silica	workers exposed to crystalline silica.
Amendment to the	A notice of proposed rulemaking is pending to update regulations
Family and Medical	under the <i>Family and Medical Leave Act</i> (FMLA). The FMLA
Leave Act of 1993	protections will be extended to family members caring for servicemen
	and women and veterans within the last five years, and will clarify
	when airline flight crews qualify for family or medical leave.
Proposed Office of	On December 9, 2011, the Office of Federal Contract Compliance
Federal Compliance	Programs (OFCCP) proposed regulations under Section 503 of the
Programs Regulations	Rehabilitation Act of 1973 that would expand the affirmative action
Regarding Disability	obligations of federal contractors toward individuals with disabilities.
	Specifically, the rules would expand contractor obligations in
	numerous areas, including establishing a single, national utilization
	goal of 7 percent in each job group for individuals with disabilities (the
	OFCCP is seeking comment on not only the 7 percent goal but a range
	of values between 4 percent and 10 percent, as well as a 2 percent
	sub-goal for individuals with certain severe disabilities such as total
	deafness or blindness, paralysis, severe intellectual disability,
	psychiatric disability, etc.).
Motor Carrier Safety	Transportation  The Federal Motor Carrier Safety Administration (FMCSA) is expected
Fitness	to propose new safety fitness determinations based on safety from
Determination	crashes, inspections and violation history rather than standard
Determination	compliance review. The goal is to enable FMCSA to assess the safety
	performance of a greater segment of the motor carrier industry. A
	proposed rule is expected in 2012.
	proposed rate is expected in 2012.

Issue	Description of Issue
Minimum Training	Rulemaking would require behind-the-wheel and classroom training
Requirements for	for persons who must hold a commercial driver's license to operate
Entry Level	commercial motor vehicles. A final rule is expected in 2012.
Commercial Motor	
Vehicle Operations	
·	Health Care
Definition of Full	Starting in 2014, large employers will be assessed a penalty if they fail
Time & Part Time	to provide affordable health insurance, at a minimum value, to any
Employees	full-time employee who is then found eligible for a tax credit through
	the Exchange. In May 2011, the IRS proposed that a full-time
	employee be defined as one who has 130 hours of service in a
	calendar month, and that this is treated as the monthly equivalent of
	at least 30 hours of service per week. Treasury and the IRS are also
	considering a look-back/stability period safe harbor under which an
	employer would determine each employee's full-time status by
	looking back at their hours over a defined period of not less than
	three, but not more than twelve consecutive calendar months, as
	chosen by the employer. The employee's status determined under
	this look-back would then persist for a stability period of at least six,
	but not more than twelve months. Additional rulemaking is expected.
Definition of	In the August 17, 2011, IRS notice of proposed rulemaking on the
"Affordability"	"Health Insurance Premium Tax Credit," the IRS indicated that an
	employer-sponsored plan would be considered affordable if the
	employee portion of the self-only premium for the employer's lowest
	cost plan that provides minimum value does not exceed 9.5 percent of
	the employee's current W-2 wages from the employer.
Requirement to Offer	IRS Notice 2011-36 raised some concern that the Agencies would
Coverage to	require employers to offer coverage to employees' dependents. BRT
Dependents	submitted comments on this issue, which noted that the voluntary
	offering of dependent coverage is critically important to avoid
	disruptions in employer-sponsored coverage. In the August 17, 2011
	IRS notice of proposed rulemaking on the "Health Insurance Premium
	Tax Credit," the IRS indicated that the affordability of an employer-
	sponsored plan will be measured in terms of the employee portion of
	the self-only premium, indicating that the offering of dependent
	coverage will not be required.

Issue	Description of Issue
Definition of Essential	On December 16, 2011, the Center for Consumer Information and
Benefits	Insurance Oversight (CCIIO) issued guidance on Essential Health
	Benefits (EHB). The guidance proposes to give states the flexibility to
	define EHB based on a benchmark plan selected by each state. The
	benchmark would be either: (1) the largest plan by enrollment in any
	of the three largest small group insurance products in the state's small
	group market; (2) any of the largest three state employee health
	benefit plans by enrollment; (3) any of the largest three national
	federal employees health benefits plan options by enrollment; or (4)
	the largest insured commercial non-Medicaid Health Maintenance
	Organization (HMO) operating in the state. HHS intends to assess the
	benchmark process for the year 2016 and beyond based on evaluation
	and feedback.
Data Sharing	On August 17, 2011, HHS issued a proposed rule on "Patient
Requirements with	Protection and Affordable Care Act; Exchange Functions in the
the Exchanges	Individual Market: Eligibility Determinations; Exchange Standards for
and Exemended	Employers," which noted that employers possess almost all of the
	information on an employee that is required for an Exchange to make
	an eligibility determination with respect to the premium tax credit and
	cost-sharing reductions. HHS, Treasury and Labor are working to
	develop a method by which information can be reported by
	employers to Exchanges, and are considering the creation of a
	template for plan- and employee-level information, or a centralized
	database that employers could voluntarily populate as a resource for
	the verification process. The proposed rule also said that when an
	Exchange determines that an individual is eligible to receive advance
	payments of the premium tax credit or cost-sharing reductions in the
	Exchange, the Exchange must notify the employer and identify the
	employee. Additional rules are expected to provide further guidance.
Health Insurance Tax,	The health reform law imposed an excise tax on health insurance
Pharmaceutical Tax,	issuers and sponsors of self-funded group health plans, with aggregate
and Medical Device	expenses that exceed \$10,200 for individual coverage and \$27,500 for
Tax	family coverage, beginning in 2018 imposes an excise tax on insurers
Tux	of employer-sponsored health plans. The amount of the excise tax is
	40 percent of an amount considered to be an excess benefit. The
	health reform law also created an annual fee on certain
	manufacturers and importers of brand name pharmaceuticals,
	effective January 1, 2011. The IRS issued Notice 2011-9 in January
	2011, which defined the covered entities and fee calculation
	methodology. The new law also imposed an excise tax of 2.3 percent
	on sale of any taxable medical device. The IRS delayed imposition of
	the tax until 2013. The IRS issued a request for comment regarding
	this tax in December 2010.
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Issue	Description of Issue
W-2 Guidance	Starting in tax year 2011, the health reform law requires employers to report the cost of coverage under an employer-sponsored group health plan on W-2 forms. The IRS made this requirement optional for all employers in 2011 and for smaller employers in 2012. The amount reported must include both the portion paid by the employer and the portion paid by the employee. Employers will not be required to issue a Form W-2 to retirees or other former employees to whom the employer does not normally issue a Form W-2.
HIPAA Workplace Wellness	Under the health reform law, employers may continue rewarding employees for participation in a wellness program. Starting January 1, 2014, the value of these rewards may be increased up to 30 percent of the cost of coverage. The law also requires the Director of the CDC to provide employers with technical assistance, consultation and other resources to evaluate employer-based wellness programs.
Release of CMS Claims Data	CMS must have measures in place to release CMS claims data to qualified entities for the purpose of measuring provider and supplier performance, as required by the health reform law. On December 7, 2011, CMS issued a final rule (76 Fed. Reg. 76542) detailing how entities can become qualified by CMS to receive claims data under Medicare Parts A, B and D for the purpose of evaluating the performance of providers and suppliers and issuing annual reports. The rule defines the performance measures that may be used and how, and describes the kinds of data that will be released. The rule also provides the criteria qualified entities (QEs) must follow to protect the privacy of Medicare beneficiaries. Reports generated by the QEs may only include information on individual providers and suppliers in aggregate form, and may not be publicly released until providers and suppliers included have had an opportunity to review and, if necessary, ask for corrections. The rule is effective January 6, 2013.

Issue	Description of Issue
Definition of 60	Under the health reform law, an employer-sponsored plan must
Percent Actuarial Value	provide minimum value, or the employer may be subject to a penalty if any full-time employee qualifies for a tax-credit in the Exchange. A plan provides minimum value if the employer plan's share of the total allowed costs of benefits provided under the plan is at least 60 percent of those costs. The new law also requires plans not have out-of-pocket limits that exceed the limits for Health Savings Account qualified health plans, and reduces the maximum out-of-pocket limits for enrollees in families with incomes below 400 percent of the federal poverty line. Additional regulations are anticipated later this year to provide further guidance on minimum value, and the proposed rule states that the IRS is considering whether to provide transitional relief with respect to minimum value for employers already offering health care coverage.
Uniform Summary Plan Documents	On August 22, 2011, HHS released a proposed regulation requiring all insurers and plan administrators to provide enrollees with a four-page paper summary of each plan benefit that is offered, beginning March 2012. BRT commented and criticized this proposal as unworkable in the large group marketplace where innovative ways of educating employees on benefits, such as electronic information, are more useful, and urged a delay in implementing this requirement. HHS has now delayed the effective date until the final rule is promulgated.
Physician Payment Sunshine Regulations	The health reform law requires medical device and pharmaceutical manufacturers to track and report payments and other transfers of value to U.S. physicians and teaching hospitals. The first disclosure by manufacturers is due in 2013, for payments and other transfers of value occurring in 2012. On December 14, 2011, CMS published proposed rules and requested public comment on what will be required for data capture and reporting. Manufacturers incurred significant costs to develop systems to capture data in anticipation of the final rules, but these systems will most likely need to be redesigned when the final rules are issued. The significant additional costs associated with any redesign could impact manufacturers' ability to invest in R&D and interact with health care providers on the development of innovative products and therapies.

Issue	Description of Issue
Power to Subpoena Insurers	The Federal Insurance Office Act of 2010, part of the Dodd-Frank legislation created the U.S. Federal Insurance Office (FIO). Primarily responsible for studying whether additional federal regulation of the U.S. insurance industry is necessary, a little know part of the FIO Act provides FIO with the "power to subpoena" U.S. insurers and any "information or data" that they might hold with the ability to enforce such subpoena in a U.S. district court. With no enforcement authority over the U.S. insurance industry at this time, it is difficult to see how
	such subpoena power can be of possible benefit to the U.S. consumer or to an insurer's ability to comply with the regulations of 51 different state insurance authorities while dealing with a potential fishing expedition being conducted by the federal government.
HIPPA Proposed Changes to Accounting for Disclosures	HHS has previously required that covered entities and business associates account for their external disclosures of patients' protected health information upon request. Only a small number of patients have made requests for such accountings. However, in May 2011, HHS proposed a rule that, while scaling back the scope of the accounting requirement, expanded the requirement so that health plans and business associates must be capable of providing "access reports" that show who has accessed a patient's protected health information, both internally and externally, contained in their electronic health records. Implementing this requirement would be logistically and financially burdensome, especially because access reports, as currently defined, are voluminous and created in computer language that would require translation in order for patients to understand them.
Medicare Secondary Payer Regulations	Under the Medicare Secondary Payer (MSP) program, certain insurers (including liability and workers compensation) are required to be the primary payer for health care items or services related to specific claims. Implementing regulations require these insurers to take into account amounts conditionally paid or to be paid by Medicare when settling claims. This requirement is extremely difficult to implement and can result in insurers making double payments – to the claimant and as reimbursement to Medicare for improperly made primary payments.
ACA Implementation of Regulations Affecting Employer Health Plans	The Agencies will be finalizing numerous regulations that encompass thousands of pages over the next 18 months with significant shortand long-term impacts on employer health plan benefits, choice and administrative costs. These regulations will reshape the \$2.5 trillion health care sector and related employee benefit and compensation costs impacting businesses and domestic investment in innovation.
	Other

Issue	Description of Issue
Export Control	The State Department is reforming the U.S. Munitions List to reclassify
Reform	and move commercial products with a dual military use to the less
Initiative/Reform of	restrictive Commodity Control List. These reforms will facilitate
U.S. Munitions List	legitimate U.S. exports, improve U.S. competitiveness and strengthen
	the U.S. manufacturing and technology bases.
FCC Regulatory	Regulatory reform is needed to ensure the growth of the IT industry
Policies	and to prevent current regulatory frameworks from being
	implemented on new technologies. Current regulations require
	network operators to support almost obsolete circuit switched public
	telephone networks instead of investing in new technology, thus
	impeding innovation.
Air Cargo Screening	Enhanced pre-inspection and pre-clearance cargo screening
	requirements are being phased-in. Further standards are anticipated.
Consumer Product	The Consumer Product Safety Commission (CPSC) has adopted a final
Safety Improvement	rule implementing the complaint database requirement of the
Act Complaint	Consumer Product Safety Improvement Act (CPSIA). While the online
Database	database is required by the CPSIA, the CPSC final rule has substantially
	broadened beyond the Congressional mandate the individuals
	authorized to submit data (beyond injured consumers, state and local
	officials, caregivers, etc.) to plaintiff's attorneys and others with less
	direct information. Thus, the database has the potential to become
	less useful to consumers and more harmful to the reputations of
	legitimate businesses.
L-1B "Specialized	L-1B visas are important to companies who want to transfer
Knowledge" Visas	employees with specialized knowledge important to the company to
	assignments in the U.S. Because the standard for what constitutes
	"specialized knowledge" is not always clear, businesses sometimes
	face uncertainty and burdens in demonstrating their eligibility for such
	transfers.
Cont'd Ethanol RFS	EPA is responsible for developing and implementing regulations to
Mandate	ensure that transportation fuel sold in the U.S. contains a minimum
	volume of renewable fuel. Under <i>EPAct 2005</i> , 7.5 billion gallons of
	renewable fuel was required to be blended into gasoline by 2012. The
	Energy Independence and Security Act (EISA) expanded the renewable
	fuels mandate by increasing the volume of renewable fuel required to
	be blended into transportation fuel from 9 billion gallons in 2008 to 36
	billion gallons by 2022. As mandatory renewable fuel volumes
	increase, upward pressure is being put on increasingly volatile corn
	prices, thus increasing food price inflation.

Issue	Description of Issue
Pension Funding re:	The Pension Protection Act of 2006, Publ.L. 109-280, made significant
Pension Protection	changes to the funding requirements for defined benefit pension
Act	plans, as well as changes that affected most other types of pensions.
	The law also placed certain restrictions on changes to pension plans
	that would increase their benefits without funding changes. The
	Department of Labor and the PBGC have been issuing regulations and
	guidance with regard to these requirements, including some that remain underway.
Mandatory Audit	The PCAOB, under the SEC, has announced plans to consider a
Firm Rotation	requirement that companies be required to rotate among firms
	conducting audits of the company. This may raise concerns about
	whether mandatory audit firm rotation would increase the costs of
	audits and the costs for management and audit committees to change
	audit firms and bring successor auditors up to speed.
Proposed Def. of	The Department of Labor has proposed to amend the definition of
Fiduciary by Dept. of	"fiduciary" under ERISA by more broadly defining the circumstances
Labor	under which a person is considered to be a "fiduciary" by reason of
	giving investment advice to an employee benefit plan or a plan's
	participants. This substantial expansion of the definition of "fiduciary"
	would create new hurdles and potential liability for the provision of
	investment advice to individuals and employee benefit plans, without
	a clear showing that this expansion is needed. The rule, if finalized in
	its current form, is likely to lead to higher costs without corresponding benefits.
Bank Services to	Credit card issuers charge fees to merchants for credit card
Merchants	transactions. These fees were capped in the Dodd-Frank financial
	services act. Some regulators have raised the concept of further
	restricting banks from charging consumers or others transaction fees
	related to merchant transactions. In addition, several states have
	proposed legislation that would limit fees for merchant transactions.

Issue	Description of Issue
Regulation of	In December 2011, the FCC initiated a proceeding to regulate the
Internet	rates, terms and conditions for the interconnection and exchange of
	traffic between Internet Protocol (IP) networks. Interconnection of
	today's circuit-switched voice networks is highly regulated by the FCC
	and state commissions based on an outdated monopoly era regulatory
	framework, but the interconnection to IP networks has always been
	left to commercial negotiations in a dynamic and vigorously
	competitive market. The interconnection of independent IP networks
	forms the foundation of the Internet and the flexibility and
	adaptability of the commercial arrangements between these networks
	has been critical to its unparalleled growth and success. The FCC has
	not identified a market failure or a need justifying regulation of IP
	network interconnection.
OSHA Proposed	OSHA has proposed adding to its record-keeping requirements
Musculo-skeletal Rule	concerning occupational injuries for employers an additional category
	of "musculo-skeletal disorders." Because the definition and diagnosis
	of such injuries or illnesses is so vague and indeterminate, this
	requirement could impose considerable cost and burden on
	employers, particularly small businesses, and create unwarranted
	exposure for non-compliance based on subjective assessments.
Stream Buffer Rule	The Office of Surface Mining (OSM) has proposed to modify the 2008
	stream buffer rule that regulates mining activities adjacent to,
	beneath or the filling of streams. Although the OSM justifies the
	revision of the 2008 rule as the result of lawsuit negotiation, science
	and enforcement data do not support the proposed changes. Severe
	restrictions on long wall and surface mining will threaten jobs and tax
	revenues.

<sup>&</sup>lt;sup>1</sup> Jacobe, D. (2011). Government regulations at top of small-business owners' problem list. Washington, DC: Gallup. Retrieved from: <a href="http://www.gallup.com/poll/150287/gov-regulations-top-small-business-owners-problem-">http://www.gallup.com/poll/150287/gov-regulations-top-small-business-owners-problem-</a> list.aspx