



**“FALL 2009 UPDATE ON CURRENT FEDERAL PUBLIC POLICY  
ISSUES AFFECTING THE LIFE SCIENCES”**

**By Life Sciences Group, Polsinelli Shughart PC**

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## **FEDERAL LEGISLATIVE UPDATE – RECENT DEVELOPMENTS**

### **Removing Barriers to Responsible Scientific Research Involving Human Stem Cells (Executive Order 13505)**

On March 9, 2009, President Barack Obama issued Executive Order 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The Order permits the Secretary of Health and Human Services, through the Director of the National Institutes of Health (NIH), to “support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.” In so doing, the Order expressly revokes the prior Presidential statement (August 9, 2001) and Executive Order 13435 (June 20, 2007), which limited Federal funding for research involving human embryonic stem cells.

The NIH adopted Guidelines for Human Stem Cell Research that implemented the Order and established policy and procedures under which the NIH will fund research. These Guidelines became effective on July 7, 2009. The Guidelines defines human embryonic stem cells as “cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.” The eligibility of human embryonic stem cells for research with NIH funding is largely dependent upon whether the embryos from which such stem cells are derived were created for reproductive purposes, and whether donors freely consented to their use in research.

NIH funding of the derivation of stem cells from human embryos is still prohibited by the annual appropriations ban on funding of human embryo research, as is NIH funding of research using human embryonic stem cells derived from other sources.

### **American Recovery and Reinvestment Act of 2009 (Public Law 111-5)**

Enacted on February 17, 2009, the Act, which provides about \$300 billion in tax cuts for individuals and businesses, was touted as an economic stimulus package to create jobs, spur investment, and life the economy out of recession. The Act would effect the following changes relevant to the life sciences industry and businesses in general.

- **Extension of Renewable Energy Production Tax Credit.** Extends the “eligibility dates” of a tax credit for facilities producing electricity from wind, closed-loop biomass, open-loop biomass, geothermal energy, municipal solid waste, qualified hydropower and marine and hydrokinetic renewable energy. The new law extends the “placed in service date” for wind facilities to Dec. 31, 2012. For the other facilities, the placed-in-service date was extended from December 31, 2010 (December 31, 2011 in the case of marine and hydrokinetic renewable energy facilities) to Dec. 31, 2013.
- **Election of Investment Credit in Lieu of Production Credit.** Businesses who place in service facilities that produce electricity from wind and some other

- renewable resources after Dec 31, 2008 can choose either the energy investment tax credit, which generally provides a 30% tax credit for investments in energy projects or the production tax credit, which can provide a credit of up to 2.1 cents per kilowatt-hour for electricity produced from renewable sources. A business may not claim both credits for the same facility.
- **New Clean Renewable Energy Bonds.** Increases the amount of funds available to issue new clean renewable energy bonds from the one-time national limit of \$800 million to \$2.4 billion. These qualified tax credit bonds can be issued to finance certain types of facilities that generate electricity from renewable sources (for example, wind and solar).
  - **Qualified Energy Conservation Bonds.** Increases the amount of funds available to issue qualified energy conservation bonds from the one-time national limit of \$800 million to \$3.2 billion. These qualified tax credit bonds can be issued to finance governmental programs to reduce greenhouse gas emissions and other conservation purposes.
  - **Repeal of Certain Limits on Business Credits for Renewable Energy Property.** Repeals the \$4,000 limit on the 30% tax credit for small wind energy property and the limitation on property financed by subsidized energy financing. The repeal applies to property placed in service after Dec. 31, 2008.
  - **Coordination With Renewable Energy Grants.** Business taxpayers also can apply for a grant instead of claiming either the energy investment tax credit or the renewable energy production tax credit for property placed in service in 2009 or 2010. In some cases, if construction begins in 2009 or 2010, the grant can be claimed for energy investment credit property placed in service through 2016, and for qualified renewable energy facilities, the grant is 30 percent of the investment in the facility and the property must be placed in service before 2014 (2013 for wind facilities).

### **BioSecurity, Food Chain Safety, Infectious Diseases, and NBAF**

Since the terrorist attacks of September 11, 2001, our nation's focus on protecting its citizens and its food and water resources from bioterrorist attack has radically increased. These threats might manifest themselves in many ways, from anthrax and smallpox contamination of public areas to rapidly spreading attacks on our food chain and water supplies. The damage that could be caused by one simple terrorist act, or for that matter one act of nature, could be far more devastating than the attacks of 9/11. The threat of the rapid spread of infectious diseases in humans, animals, and plants could lead to similarly dire consequences.

The Federal government has reacted to these threats in a number of ways. Beginning with the USA Patriot Act of 2001, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, through to the Pandemic and All-Hazards Preparedness Act of 2006, Congress has taken legislative steps to combat bioterrorism and to protect our food chain.

Numerous Federal agencies are involved in this effort. The Department of Homeland Security, the Department of Defense, DARPA, and the FDA, among others, all have instituted initiatives to address these threats. For example, the Project BioShield Act of 2004 establishes a Special Reserve Fund of \$5.6 billion over ten years to purchase medical countermeasures against a broad array of chemical, biological, radiological, and nuclear pathogens, which are to be administered by the DHS and the DOD, among others, and authorizes the FDA to permit rapid distribution of promising but not-yet-approved drugs and antidotes in emergencies.

In January of 2009, the Federal government selected Manhattan, Kansas as the new site for the \$450 million National Bio and Agro-Defense Facility (NBAF). This new national laboratory will replace the Plum Island national laboratory. Expected to be completed by 2015, the half million square-foot facility will employ as many as 500 people, with an annual operating budget of around \$125 million. Attempts have been made to delay construction or block funding, but Kansas officials remain confident the construction of NBAF will go on as planned.

### **2008 Farm Bill (Public Law 110-234)**

On June 19, 2008, Congress enacted the 2008 Farm Bill as part of the Food, Conservation, and Energy Act of 2008. The complete Act concerns a wide array of issues, from administrative and funding authorities for programs that cover income and commodity price support, farm credit, and risk management, to initiatives for attracting and retaining beginning and socially disadvantaged farmers and ranchers. Of special note to the life sciences community are the Act's renewable energy provisions, which include the following:

- **Biorefinery Assistance Program.** This program provides loan guarantees for the development, construction, and retrofitting of commercial-scale biorefineries. It also provides grants to help pay for the development and construction costs of demonstration-scale biorefineries.
- **Bioenergy Program for Advanced Biofuels.** This program provides for payments to be made to eligible agricultural producers to support and ensure an expanding production of advanced biofuels.
- **Rural Energy for America Program (REAP).** The bill expands and renames the program formerly called the Renewable Energy Systems and Energy Efficiency Improvements Program. The increased funding will support farmers and small rural businesses in developing clean energy technologies including wind, solar, biofuels, electricity, biogas, and hydroelectric source technologies.
- **Biomass Research and Development Initiative.** This initiative provides competitive grants, contracts, and financial assistance to eligible entities to conduct research of, and carry out development and demonstration of, biofuels and biobased products, as well as the methods, practices, and technologies for their production.

## **Federal Preemption: Warning Labels**

Two cases recently decided by the Supreme Court of the United States protect the ability of plaintiffs to pursue state law claims that product labeling approved by federal regulatory agencies, such as the FDA, are false and misleading or fraudulent, based on federal preemption arguments. Preemption is based on the Supremacy Clause of Article VI of the U.S. Constitution, which states that when federal and state laws are at odds, federal law takes precedence.

### ***Wyeth v. Levine***

*Wyeth* concerned a patient, Diana Levine, who lost her arm after receiving two injections of Wyeth's anti-nausea drug Phenargan (promethazine HCl) for migraine symptoms. Wyeth, a drug manufacturer appealed a Vermont Supreme Court decision that upheld a \$6.8 million jury award to Diana Levine after her use of the drug resulted in serious complications and, ultimately, amputation. Wyeth argued that the claim is preempted by the U.S. Food, Drug, and Cosmetic Act.

The Supreme Court of the United States granted certiorari and heard the case on November 3, 2008. On March 4, 2009, the Supreme Court held, in a 6-3 decision, that Federal regulatory approval of a medication does not shield the manufacturer from liability under state law. Ruling against Wyeth, the Court upheld the lower court decision that decided against effectively immunizing drug companies from state-level tort litigation if their products that have been approved by the FDA are later found to be defective.

### ***Altria Group v. Stephanie Good***

In a related case, on October 6, 2008, the Supreme Court of the United States began hearing oral arguments on another federal preemption case regarding the labeling of cigarettes. Although a federal district court threw out the lawsuit, the First Circuit Court of Appeals said the case could go forward.

Altria Group asked the Court to stop a class action lawsuit claiming the cigarette company engaged in deceptive advertising related to the labeling of cigarettes as "light" or "low tar." The plaintiffs alleged the advertising of cigarettes with such labeling misled them into believing "light" or "low tar" cigarettes were a safer alternative to cigarettes void of such labels. Specifically, Altria argued that tobacco products are regulated generally by the Federal Trade Commission and not by the individual states. Altria pointed to specific federal legislation, namely the Federal Cigarette Labeling and Advertising Act of 1965, which bars states from regulating any aspect of cigarette advertising that involves smoking and health. Thus, Altria argued the federal act preempts the class action claims.

On December 15, 2008, the Supreme Court, in a 5-4 decision, held that a state law prohibiting deceptive tobacco advertising was not preempted by a Federal law regulating cigarette advertising, dealing another blow to food and drug-makers seeking to limit their exposure to state law claims.

## **FEDERAL LEGISLATIVE UPDATE – PENDING LEGISLATION**

### **Patent Reform Act of 2009**

Comprehensive patent reform legislation has been a serious focus of Congress in recent years, the goal being the harmonization of U.S. patent law with that of the rest of the world. With a flurry of bills recently introduced in Congress, such legislation is anticipated within the next year or two as legislators attempt to reach a compromise on some key issues, including damages and venue.

Three bills have been introduced during the 111<sup>th</sup> Congress. Senate Bill 610 was introduced March 17, 2009 to the Senate and referred to the Judiciary Committee; Senate Bill 515 was introduced and referred to the Judiciary Committee on March 3, 2009, and was reported by the Judiciary Committee on April 2, 2009; and a House version (H.R. 1260), was introduced and referred to the House Judiciary Committee on March 3, 2009. These latest House and Senate dual bills omit provisions included in the 2008 version, such as provisions granting to the USPTO broad rulemaking authority and provisions on equitable conduct as a defense to infringement. However, the 2009 bill contains several provisions similar to its predecessors, most of which will likely be included in a finally agreed upon bill. Those provisions include:

- **First to File.** The U.S. patent system would be converted from a first-to-invent system to a first-to-file system. The U.S. is alone in the world in granting priority to the first inventor as opposed to the first inventor to file a patent.
- **Reexamination Proceedings.** Reexamination requests would be expanded to allow any person at any time to file a request for reexamination of any claim on a patent on the basis of any prior art or documentary evidence.
- **Post-Grant Review.** Third party filings to cancel a petition, which would have to be filed within twelve months of issuance and could be based on any ground of invalidity, would be conducted by administrative patent judges.
- **Inventor's Oath or Declaration.** The 2009 bills, like its predecessors, would relax current rules by allowing assignees and others with rights to patents to file patent applications on behalf of an inventor.
- **Submissions by Third Parties.** Under these new bills, any person would be allowed to submit prior art for consideration during the prosecution of the application. Such prior art would have to be submitted by the later of (1) six months after publication or (2) before the first office action on the merits.
- **Patent Trial and Appeal Board.** Such patent legislation would likely replace the Board of Patent Appeals and Interferences with a new Patent Trial and Appeal Board, which would hear appeals from final decisions on applications and reexaminations, to determine priority, patentability, and conduct post-grant review proceedings.

Provisions that have been hotly debated in Congress, which contain noticeable differences between the 2007, 2008, and 2009 bills, again, include apportionment of damages and venue.

The following is a brief description of the glaring differences between the older and newer versions of these provisions:

- **Apportionment of Damages.** Under current U.S. patent law, courts are permitted to award damages based on the value of the entire product containing the infringed patent, as opposed to just the value of the infringed patent. The 2009 bills, like the 2007 bills, would have required that a damages award not be less than a reasonable royalty. The reasonable royalty, however, would be applied only to the patent's specific contribution over the prior art. Also, a court would be required to identify all of the factors relevant to the determination of a reasonable royalty, and the court or jury, as the case may be, would only consider those factors in determining a reasonable royalty. The 2008 bill, on the other hand, laid out rules and guidelines favoring precise economic analysis of an invention's value over less precise methods. The 2009 bill also contemplates that treble damages would only be available where a judge determines that the infringer, after receiving detailed written notice from the patentee continued to perform the acts of infringement.
- **Venue and Jurisdiction.** The 2007 and 2009 bills address changes to venue by allowing cases to be brought in a variety of locales, including the jurisdiction in which the plaintiff resides or in a jurisdiction in which the defendant is incorporated or has its principal place of business. By contrast, the 2008 proposed legislation included an "activities-based" test for determining proper venue. This test would establish proper venue, for example, where the invention claimed in a patent in suit was conceived or actually reduced to practice, or where significant research and development of an invention claimed in a patent in suit occurred at a regular and established physical facility.

### **SBIR/STTR Reauthorization Act of 2009**

On July 8, 2009, the House of Representatives by roll call vote passed the SBIR/STTR Reauthorization Act of 2009 (H.R. 2965), and on July 13, the Senate passed a markedly different SBIR reauthorization bill (S. 1233) by unanimous consent. Representatives and Senators from the House Small Business and Science Committee and Senate Small Business Committee, respectively, are now negotiating a single, reconciled version of the two bills to give to the President. Congress faced a looming deadline as the SBIR program was set to expire on July 31; however, the Senate passed a continuing resolution on July 24 that would extend the expiration date to September 30, 2009. A similar continuing resolution from the House is expected shortly.

The Senate bill limits SBIR and STTR awards available to small businesses substantially backed by venture capital companies. The legislation would allow the NIH to award up to 18% of its SBIR dollars to VC-owned firms, whereas the other 10 agencies that participate in the SBIR program could award up to 8% of their SBIR dollars to such companies. The House bill contains no such restrictions on funding available to venture capital-backed businesses. The Senate version also seeks to increase SBIR program funding from the current 2.5% to 3.5% of R&D budgets by increasing it 0.1% for each year from fiscal year 2011 to 2020. The award amounts also would be increased under the Senate bill. Awards for participation at the Phase I level would increase from \$100,000 to \$150,000 and awards for participation at the Phase II level would increase from \$750,000 to \$1 million.

Under the bill, a small business concern would not be excluded from qualifying for the SBIR program on the basis that the small business concern is owned in majority part by, or controlled by, more than one United States venture capital company, so long as no single venture capital company owns more than 50% of the small business concern. However, the Administrator would be charged with establishing other requirements relating to the affiliation by small business concerns with venture capital companies.

### **Stem Cell Research Enhancement Act of 2009**

Two bills titled the Stem Cell Research Enhancement Act of 2009 (H.R. 873 and S. 487) were introduced during the current Congress. H.R. 873 was introduced and referred to the House Energy and Commerce Committee on February 4, 2009 and S. 487 was introduced and referred to the Senate Health, Education, Labor, and Pensions Committee on February 26, 2009. The purpose of the proposed legislation is to amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct and support research that utilizes human embryonic stem cells, regardless of the date on which the stem cells were derived from a human embryo. However, under the 2009 Act, human embryonic stem cells would only be eligible for research if the following three conditions are met:

- The stem cells were derived from human embryos donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the needs of the individuals seeking such treatment;
- Prior to donation, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded; and
- The individuals seeking fertility treatment donated the embryos with written informed consent and received no financial or other inducements.

In light of the significant potential for beneficial therapeutic applications for embryonic stem cells on one hand and the significant ethical and religious issues on the other, the debate over the use of embryonic stem cells and other related therapies is likely to continue as a topic of significant debate and disagreement in the future

### **Pathway for Follow-On Biologics (FOBs) Legislation**

Two bills were introduced in each of the House of Representatives and the Senate during the current Congress. The Promoting Innovation and Access to Life-Saving Medicine Act (H.R. 1427) was introduced March 11, 2009 and referred to the House Energy and Commerce Committee and the House Judiciary Committee. A companion Senate bill to H.R. 1427 (S. 726) was introduced March 26, 2009 and referred to the Committee on Health, Education, Labor, and Pensions. The Pathway for Biosimilars Act (H.R. 1548) was introduced March 12, 2009 and referred to the House Energy and Commerce Committee and the House Judiciary Committee. Lastly, the Bill to Prohibit the Use of Federal Funds to Approve Certain Biologics License Applications by the Food and Drug Administration (S. 613) was introduced March 17, 2009 and referred to the Senate Health, Education, Labor, and Pensions Committee.

Unlike general chemical drugs that are currently approved by the FDA, FOBs have not pathway for FDA approval, as they are not identical to their originator products. Although

Congress and the biologics industry agrees as to the necessity of a pathway for regulatory approval, the debate surrounding the regulation of FOBs is focused on two main issues. First, whether an extra period of data exclusivity is necessary to encourage the development of new drugs, and, second, if data exclusivity is necessary, how long the exclusivity period should last. This is one big difference between the two House bills – H.R. 1427 sets the length of an additional exclusivity period at five years and H.R. 1548 does the same for up to fourteen years.

At the end of July of 2009, the House Energy and Commerce Committee approved an amendment to the broader health-care legislation making its way through Congress that would give brand-name makers of FOBs twelve years of exclusivity. President Obama, some key Democrats, and consumer groups have pushed for an exclusivity period lasting no longer than five to seven years. The amendment would further allow pharmaceutical companies to make minimal adjustments to drugs, such as creating extended-release versions, to lengthen the exclusivity period, a practice known as “evergreening.”

### **American Clean Energy and Security Act of 2009**

The American Clean Energy and Security Act of 2009 (H.R. 2454) was introduced May 15, 2009 in the House, and on June 26, 2009 the bill narrowly passed in the House by a roll call vote, but has yet to be approved by the Senate. In addition to establishing a cap-and-trade plan for greenhouse gases to address climate change, the bill would also address the following issues, among many others:

- Amends the Public Utility Regulatory Policies Act of 1978 (PURPA) to establish a combined efficiency and renewable electricity standard that requires utilities to supply an increasing percentage of their demand from a combination of energy efficiency savings and renewable energy (6% in 2012, 9.5% in 2014, 13% in 2016, 16.5% in 2018, and 20% in 2021-2039);
- Amends the Clean Air Act (CAA) to require the Administrator of the Environmental Protection Agency (EPA) to: (1) set forth a national strategy to address barriers to the commercial-scale deployment of carbon capture and sequestration; (2) establish an approach to certify and permit geologic sequestration; and (3) promulgate regulations to minimize the risk of escape to the atmosphere of carbon dioxide injected for purposes of geological sequestration;
- Amends the Energy Policy and Conservation Act to revise: (1) rules regarding improving energy efficiency in industrial equipment; (2) efficiency standards for electric motors; (3) conservation standards for lighting and appliances; and (4) the Energy Conservation Program for Consumer Products Other Than Automobiles;
- Requires the Secretary of Energy to establish a program to make monetary awards to encourage owners and operators of electric energy generation facilities or thermal energy production facilities using fossil or nuclear fuel to use innovative means of recovering any thermal energy that is a potentially useful byproduct of their processes to: (1) generate additional electric energy; or (2) make sales of thermal energy not used for electric generation, in the form of steam, hot water, chilled water, or desiccant regeneration, or for other commercially valid purposes; and

- Authorizes the Secretary of Energy to make grants to community development organizations to provide financing to businesses and projects that improve energy efficiency, develop alternative, renewable, and distributed energy supplies, provide technical assistance and promote job and business opportunities for low-income residents, and increase energy conservation in low income rural and urban communities.

## **“IN THE PIPELINE” ISSUES**

### **NIH Funding**

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the primary Federal agency for funding medical research. Headquartered in Bethesda, Maryland, the NIH has more than 18,000 employees on the main campus and at satellite sites across the country. NIH scientists investigate ways to prevent disease as well as the causes, treatments, and even cures for common and rare diseases. Composed of 27 Institutes and Centers, the NIH provides guidance and financial support to researchers in every state and throughout the world. .

The NIH annually invests over \$28 billion in medical research. More than 83% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world. About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus.

In recent years, the rate of increase in federal funding for NIH programs has significantly flattened, thus reducing the rate of advance of scientific endeavors. For fiscal year 2008, the funding to the NIH increased by 0.8% from 2007 to \$29.46 billion, whereas the cost of conducting research is estimated to increase by as much as 6% every year. This marks the continuation of a stagnant five-year period following a period between 1999 and 2003 when funding for NIH nearly doubled – from \$15 billion to \$26.4 billion. In light of the other significant demands on the Federal budget posed by the war in Iraq, the governmental initiatives to support the financial economy, and the ongoing budget deficits, the challenges in obtaining increased Federal funding for these NIH sponsored research programs is likely to continue.

### **Clinical Trial Transformation Initiative**

The FDA has been criticized as of late for lack of sufficient oversight and inefficiency in the process of approving new drugs. With drug companies increasingly conducting global clinical trials in order to enroll more patients at more sites to obtain more data sooner to meet FDA requirements for new-drug review, the FDA's role in monitoring the quality of these trials has become increasingly difficult. For example, the FDA approved only 19 new drugs in 2007, the lowest total since 1983.

In response to the demands placed on the FDA by a global economy, on November 26, 2007, the FDA's Office of Critical Path Programs announced a new public-private partnership,

the Clinical Trials Transformation Initiative (CTTI), aimed at modernizing the way clinical trials are conducted. Under this agreement between the FDA and Duke University, Duke will serve as host for the collaboration. According to CTTI, the scope of the initiative is as follows:

- **Quality and Efficiency.** CTTI will conduct projects in support of its mission to identify practices that will increase the quality and efficiency of clinical trials. In this context “quality” is characterized by the ability to effectively and efficiently answer the intended question about the benefits and risks of a medical product (therapeutic or diagnostic) or procedure, while assuring protection of human subjects.
- **Design and Execution.** CTTI will generate evidence about how to improve the design and execution of clinical trials. Projects about design will address principles generally applicable to clinical trials to assure that they are fit to accomplish their intended purpose.
- **Scope of Initiative.** While CTTI focuses on clinical trials, it may study other types of clinical research (e.g., registries) that can provide data to regulatory agencies. Although CTTI will concentrate initially on the design and conduct of clinical trials in the United States, it seeks to identify practice improvements that can be applied internationally.

## **The Ethanol Debate**

Ethanol producers have faced difficult times as of late as rising prices of feedstock corn, the source of most ethanol, have combined with lower ethanol prices due to oversupply. On February 4, 2009, the Renewable Fuel Pipeline Act (H.R. 864) was introduced in the House. The driving purpose of this bill is to qualify a renewable fuel pipeline as an eligible project under the federal loan guarantee program with the Department of Energy. The Energy Independence and Security Act of 2007 requires an annual increase in the amount of ethanol produced domestically, from 4.7 billion gallons in 2007 to 15 billion gallons in 2015. Such pipelines, which produce 30% less emissions than railcars and 87% less than trucks, would likely assist in the transportation of such increased ethanol production.

Significant policy issues arise in connection with the use of commodity foodstocks (such as corn) as the energy source for biofuels, the international conversion of rain forests and other ecologically sensitive areas into crop production, and the development of alternative non-food stock energy sources that can be converted more efficiently into biofuels, such as switch grass, biomass, and algae.

The economic pressure on the ethanol market has had a local impact on grain and livestock producers, food processors that use corn, and communities that host biofuel facilities. On October 5, 2008, Gateway Ethanol, LLC, a company out of Pratt, Kansas, sought Chapter 11 protection. Gateway is the latest addition to a list of regional ethanol producers to shut down or declare bankruptcy, including Alternative Energy Sources, Inc., a publicly owned Kansas City-based ethanol company, which recently said it would cease operations, Ethanex Energy, Inc., based in Basehor, Kansas, which recently declared bankruptcy, and E3 BioFuels, LLC, based in Shawnee, Kansas, which filed for bankruptcy late in 2007.

## **The Arctic National Wildlife Refuge (ANWR) Debate**

The debate regarding whether to drill for oil in ANWR has been raging since the late 1970s. ANWR comprises over 19 million acres of the northern Alaskan coast, which, according to the federal Energy Information Administration, is estimated to house up to 16.0 billion barrels of recoverable oil. Ecological factors and the difficulty, cost, and time that it would take to realize oil from development in the ANWR have been major factors in a governmental policy against developing these sources.

Although oil prices and consumer gasoline prices have decreased by nearly half from highs in 2008, President Obama has continued to push for the development of renewable and alternative energy sources. With his vision to decrease our dependence on oil, President Obama will likely leave undisturbed the executive order issued by President George H. W. Bush in 1990, which banned coastal oil exploration on most of the outer continental shelf. Key elements to this debate are the ecological issues implicated by disturbing the ANWR, the risk in continuing our nation's dependence on fossil-based fuels, and the potential negative impact that developing more oil resources could have on efforts to develop alternative energy sources, which have significant domestic security and economic ramifications.

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