904 Challenging the Government Successfully - Whether to Fight, Negotiate or Settle

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Faculty Biographies

Craig V. Richardson

Craig V. Richardson is vice president and general counsel for El Paso Corporation's Western Pipeline Group, in Colorado Springs, Colorado, consisting of El Paso Natural Gas, Colorado Interstate Gas, Wyoming Interstate Company, Mojave Pipeline, and El Paso's newest interstate pipeline, Cheyenne Plains. Mr. Richardson is responsible for all legal matters concerning the Western Pipeline Group.

Before joining El Paso, Mr. Richardson focused on commercial litigation in antitrust, oil and gas, environmental, and international areas at Greenberg Traurig and Gibson, Dunn & Crutcher. Prior to his legal career, Mr. Richardson worked on the staff of the Reagan White House's National Security Council, in the U.S. Department of State's Politico-Military Affairs and Intelligence Bureaus, in the Mutual Defense Assistance Office of the U.S. Embassy in Tokyo, and in the Office of the Secretary of Defense.

Mr. Richardson holds the rank of commander in the United States Navy Reserves. He is currently assigned as the reserve officer in charge of naval intelligence for U.S. Northern Command. After 9/11, Mr. Richardson was recalled to active duty in operation enduring freedom. While on active duty, Mr. Richardson provided space-based intelligence analysis in direct support of combat operations in Southwest Asia. For his service, he was awarded the Joint Service Achievement Medal by the secretary of defense and the Meritorious Service Medal by the president. He is a member of the California, Colorado and Denver Bar Associations, and The Federalist Society.

Mr. Richardson received his B.A. from Pomona College. He also studied at the Universidad de Costa Rica and at the Instituto Internacional in Madrid. He received an M.P.A. from Princeton University's Woodrow Wilson School. Mr. Richardson earned his J.D. from Stanford University.

Thomas L. Sansonetti

Thomas L. Sansonetti is a partner at Holland & Hart LLP in Cheyenne, Wyoming. He is a recognized expert in air quality, water rights, water quality, port security, the Endangered Species Act, surface mining, Indian law, natural resource damage assessments, takings, public lands management, Superfund, and many other areas of natural resources law. He has argued before the U.S. Supreme Court and in the Federal Circuit Courts of Appeal, and served as a federal prosecutor in environmental crimes cases.

Previously, he served as the assistant attorney general for the environment and natural resources division of the Department of Justice. As one of the top leaders in the Justice Department, he was deeply involved in responding to post-9/11 events, including working with the new Department of Homeland Security. Mr. Sansonetti supervised all federal district court civil litigation and criminal prosecutions on environmental issues for the Departments of Interior, Agriculture, Energy, Transportation, and the Environmental Protection Agency. Mr. Sansonetti also supervised Alternative Dispute Resolution (ADR) actives when deemed appropriate to resolve any of the 7100 cases under his jurisdiction. He has personally been part of five ADR negotiations. Mr. Sansonetti was also solicitor of the Department of the Interior. Mr. Sansonetti was the administrative assistant and legislative director for Wyoming Congressman Craig Thomas and was appointed associate solicitor for energy and resources by Interior Secretary Don Hodel during the Reagan administration. He also served as Wyoming's Republican national committeeman and as general counsel for the Republican National Committee.

Mr. Sansonetti received a B.A. from University of Virginia, an M.B.A from University of Virginia, Colgate Darden School and a J.D. from Washington & Lee University.

Stanley E. Soper

Stanley E. Soper is vice president, legal affairs of Nutraceutical International Corporation in Park City, Utah, where he is responsible for a legal and regulatory affairs department that includes three lawyers and a paralegal.

Mr. Soper has held this position at Nutraceutical prior to Nutraceutical's initial public offering (IPO), except for a stint in Boston where he was founder of MyCounsel.com, a legal services internet start-up. Prior to joining Nutraceutical, Mr. Soper was an associate at the Salt Lake City office of Holland & Hart LLP, with a practice focused primarily in the area of mergers and acquisitions, international business transactions, and general business and commercial matters.

Mr. Soper has served as the president of ACC's Mountain West Chapter since its founding.

Mr. Soper received his B.A. with honors from Brigham Young University and his J.D. from Yale Law School.

904 Challenging the Government Successfully – Whether to Fight, Negotiate or Settle

Lessons Learned in the Trenches

By Craig V. Richardson
Vice President & General Counsel
El Paso Western Pipelines

I. Whether to Fight, Negotiate or Settle? The Answer is Yes!: El Paso's Controversy with Navajo Nation as a Case Study in Portfolio Theory

a. Issue:

i. *A looming deadline.* El Paso's right-of-way grant from the Department of the Interior (crossing lands held in trust by the United States for the Navajo Nation and last negotiated in 1985) was due to expire on October 17, 2005. El Paso has 900 miles of pipeline traversing Navajo trust lands, buried 6-10 feet below the surface of the Earth, and supplying nearly all of the natural gas consumed in Arizona and approximately 35% of the natural gas consumed in California. It was first constructed in the early 1950s, with the Eisenhower Administration's build-out of the interstate highway system, and generally follows I-40.

ii. *Buying a state of mind – not real property.* The Department of the Interior takes the position that, in order to renew the United States' grant, El Paso must obtain the "consent" of the Navajo Nation. In 1985, El Paso agreed to pay approximately $2 million dollars per year to induce such consent – already about six or seven times the fair market value of a *perpetual* easement in the local area (the going rate paid to ranchers and farmers upstream and downstream of Navajo trust lands) – for a term of 20 years and CPI-adjusted.

iii. *Hyper-inflation in Navajo demands.* By the spring of 2005, it was evident that Navajo Nation was going to demand a stratospheric increase to $25 million per year or well over half a billion dollars over 20 years (with inflation adjustments). This amounts to a $50,000 per acre "consent" fee for a *20-year* period where nearby, off-reservation "comparables" are at $100-$500 per acre for a real property easement in *perpetuity* (e.g., the life of the infrastructure).

b. Method: A Portfolio Theory in Responding to Uncertainty: "Predicting is hard, especially about the future." - Yogi Berra.

i. *Constructive engagement of the Navajo Nation.* El Paso's vastly preferred means of resolving its controversy with the Navajo Nation is through direct negotiation. We have found Roger Fisher's *Getting to Yes* approach invaluable in making considerable progress. We continue to explore ways of narrowing our differences with the Navajo Nation by identifying in-kind activities as to which the costs to El Paso are less than the benefits to the Nation.

ii. *Initiation of litigation option.* Even as negotiations continued, El Paso filed its application for a right-of-way renewal with the DOI, making extensive legal arguments that (a) Navajo consent was given in the Treaty of 1868, (b) that consent is not required in any event, (c) that DOI's consent requirement impermissibly collides with the jurisdiction of the Federal Energy Regulatory Commission (FERC) to certificate El Paso's pipelines, and (d) that the Navajo Nation's demands run afoul of the U.S. constitutional limits on a tribe's authority to regulate non-Indians.

iii. *Government affairs effort to achieve public policy reform.* While direct negotiations with the Navajo Nation are continuing and while the litigation option is being further developed as a substantial possibility, El Paso also undertook a meaningful effort to achieve true reform in an area of unambiguous public policy failure. El Paso advocated that Congress commission a study to examine the issues, and the result was Section 1813 of the Energy Policy Act of 2005.

c. Outcomes: Ongoing

i. *Constructive engagement.* Direct negotiations with the Navajo Nation are continuing.

ii. *Litigation.* El Paso has filed additional briefing with the Department of the Interior in support of its litigation position, which remains a possibility in various Article III courts.

iii. *Government affairs.* The Departments of the Interior and Energy have submitted the Section 1813 Study to Congress and the most meaningful opportunity for public policy reform in this area in over a half-century is before us. An industry-wide coalition has now joined the fray.

d. Lessons Learned (so far):

i. *Take a portfolio approach.* Don't put all your eggs in one basket, and do your best to ensure that you have a richly diverse set of options.

ii. *The Wisdom of humility.* The most underestimated quality in contending with the government is a sense of restraint borne of humility. They have the Army, Navy, Air Force and Marines – and you don't. If

you are in a particularly unsympathetic industry – such as the energy industry in the early 21st century – triple the dose of humility.

iii. *Patience in staying the course.* This is difficult, particularly amid a withering public relations attack. But it is a key ingredient to ultimate success.

iv. *The criticality of talent.* Assemble a 'dream team' to ensure strategic planning is excellent and execution is accurate.

v. *Consistent credibility and unwavering integrity.* When engaging the government in controversy, credibility is hard to earn and easily lost. Make certain you have your facts straight and that your presentation of the law is always accurate. Admit when you are uncertain about the law or the facts. I like the analogy of the lawyer in the context of an *ex parte* application for a TRO: when in the public policy arena, conduct yourself as an officer of the court, a champion of the public interest, and not a mere advocate for a narrow, parochial or purely economic interest.

vi. *Believe in your cause.* In this matter, we truly believe that we are on the side of the public policy angels. The standard of living of the Navajo people (70% of traditional homes – or *hogans* – don't have running water and wood-burning remains the greatest source of energy consumed on the reservation) is nothing short of a national scandal. It needs to be addressed and El Paso wants to be part of that much-needed national conversation. However, funding Navajo economic needs effectively via a regressive tax on the backs of natural gas consumers is horrible, horrible policy. Ultimately, the exponential increases we are seeing across the board in tribal demands for right-of-way "consent" payments is self-defeating for the tribes because it will drive away infrastructure investment, job creation, and economic opportunity.

2. **El Paso and the Arizona Department of Environmental Quality as Reciprocal Stakeholders: A Case Study in Cooperative Conflict Resolution, Problem-Solving, and Positive Thinking.**

a. Issue.

i. After a series of difficult Notices of Violation received from the Arizona Department of Environmental Quality (ADEQ) – involving interpretations of applicable regulations as to which El Paso vociferously disagreed with the Department -- we realized our relationship with ADEQ was in tatters.

ii. We were facing millions of dollars in fines.

iii. Local outside lawyers were counseling a "take-no-prisoners" litigation approach in a jurisdiction where *Chevron*-type deference to agency statutory interpretations was the law.

b. Method: Taking a New, Reciprocal Stakeholder Approach.

i. As soon as I was confident I understood what was going on in El Paso's relationship with ADEQ (I was new in the job and didn't want to violate the "First do no harm" principle), I personally went to Phoenix for half-day series of meetings with the Department's senior leaders. I prepared for that meeting extensively – reading biographical materials, news clips on the Department's enforcement activities and initiatives, and details about El Paso's pending NOVs. I arranged to have my boss, the Company's President, pay a follow-up courtesy call on the Department's principals.

ii. We told the Department's Director, Deputy Director, and Division Directors what we *truly* believed then and believe now: El Paso is a stakeholder in ADEQ, and ADEQ is a stakeholder in El Paso. Stated differently, our success is inextricably linked to ADEQ's mission success, and vice versa.

iii. We also indicated we could "disagree without being disagreeable." While we would doubtless have different views about the relevant science, the facts and the law, we should approach our disagreements with a problem-solving attitude, *not* with an attitude of acrimony and conflict.

iv. We reaffirmed El Paso's sincere commitment to a clean environment and that we wanted to receive awards and recognition from ADEQ, *not* NOVs and fines.

v. We did a good deal of listening, and asked the Department's principals "When you think of El Paso, what comes to mind?" The answers were candid – and sobering.

vi. We also did a good deal of listening with trusted local sources. I met with several of our important local customers in Arizona to obtain some "ground truth" about our previous approach, our proposed new approach, our existing outside counsel, and options for new outside counsel. We adjusted our plan to many of their comments, discontinued our outside counsel relationship, and retained some of the very brightest lawyers we could find who were comfortable with, supported, and helped refine the new "reciprocal stakeholder" approach.

c. Outcomes: Ongoing improvement in our relationship with ADEQ, but much work remains to be done. Now comes the hard part: we're going to have to walk the talk.

d. Lessons learned:

i. *Understand the iterative nature of regulatory relationships.* Chances are, you're going to have to live with the agency long after the dispute d'jour has ended. The career staff will be there for sure, and even the political appointees (particularly in technical agencies) will be there for a substantial interval. Approach every encounter with that iterative relationship foremost in mind. You can win the technical legal battle (convinced that you're right in one instance – and maybe you are!) but lose the war.

ii. *Again, the wisdom of humility.* Have a profound sense of restraint and a realistic assessment of just how much lawyers bringing lawsuits can achieve vis-à-vis government regulators: generally, not much in my view.

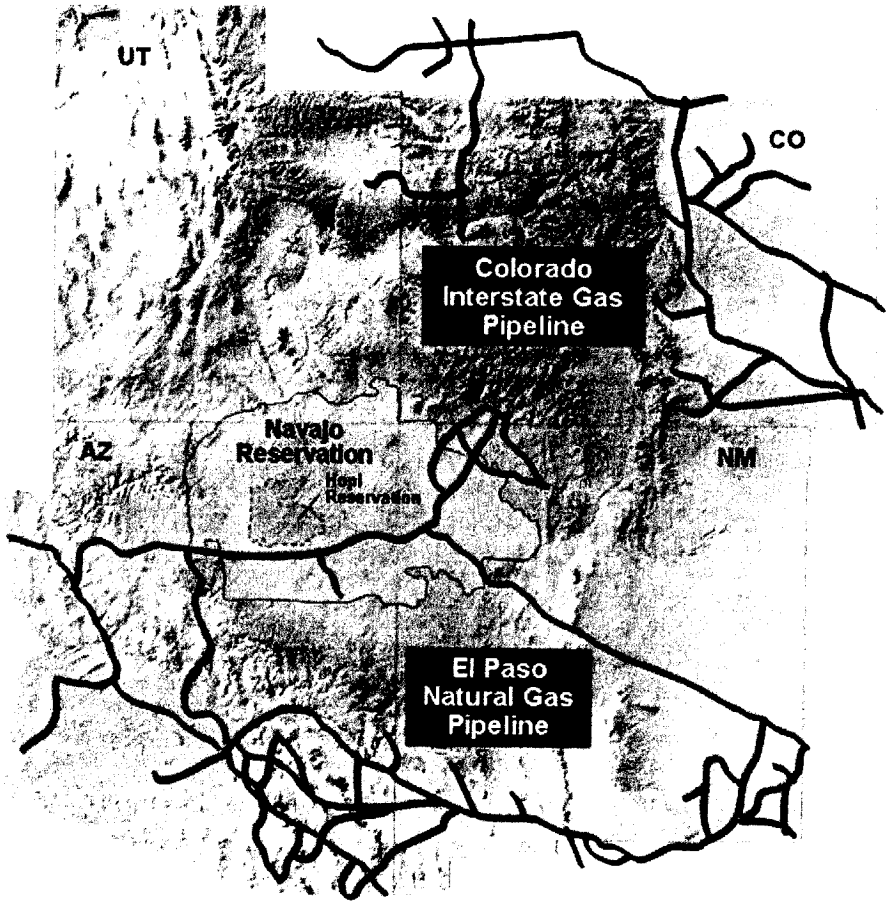
iii. *A human touch.* It is truly amazing how far a little bit of warmth and humanity can go in changing hearts and minds. Meet with regulatory stakeholders in person and do your homework in preparing for the meeting (demonstrating you actually care about the issues).

iv. *Make sure local counsel and in-house colleagues are aligned with a more cooperative approach.* Even after I made the decision to change local counsel and take a new, more problem-solving approach with ADEQ, I still faced considerable resistance at working levels in my own organization. Some folks just don't want to let go of the fight and they had become psychologically invested in the conflict. We had to exercise some tough love and tell them to get on board or get out of the way.

v. *Look for early opportunities to demonstrate you're walking the talk.* El Paso has volunteered to serve as the industry "test bed" for a number of new ADEQ initiatives. We've also taken an open, high-visibility position in favor of a budget allocation that would increase the Department's permitting FTEs. We're doing that not in a sycophantic sense, but because we truly believe having more ADEQ personnel processing environmental permits serves the public interest.

Exhibit A
Navajo Map

Exhibit B
McCain-Kyl Letter



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[illegible] 202 224 5429 INDIAN AFFAIRS 002

United States Senate
WASHINGTON, DC 20510

Exhibit C
Arizona Corporate Commission Letter

May 10, 2005

The Honorable Joe Shirley, Jr.
President
Navajo Nation
P.O. Box 9000
Window Rock, AZ 86515

The Honorable Lawrence T. Morgan
Speaker
Navajo Nation Council
P.O. Box 3390
Window Rock, AZ 86515

Jim Cleary
President
Western Pipeline Group
El Paso Corporation
Two North Nevada Avenue
Colorado Springs, Colorado 80903

Gentlemen:

We write to encourage you to negotiate and reach an agreement regarding the extension of the El Paso Natural Gas pipeline easement across the Navajo Nation.

We are told that the easement on Navajo trust land includes approximately 900 miles of pipelines and six compressor stations traversing northeastern Arizona and northwestern New Mexico. With the current 20-year easement set to expire in just six months, we urge the parties to make every effort to achieve a final agreement that reflects your own best interests, avoids protracted litigation, and does not hold hostage energy consumers in Arizona and California.

Failure to reach agreement would have serious repercussions for all. As you are aware, these negotiations affect not only the Navajo Nation and El Paso Natural Gas Corporation, but also a great many people in Arizona and throughout the southwestern United States. We hope you are able to resolve this matter.

Let us be clear that we are not favoring either party in this dispute. We are urging that the matter be resolved in a fair and equitable manner.

Sincerely,

John McCain Jon Kyl

ARIZONA CORPORATION COMMISSION

September 8, 2005

The Honorable Joe Shirley, Jr.
President
Navajo Nation
P.O. Box 9000
Window Rock, AZ 86515

The Honorable Lawrence T. Morgan
Speaker
Navajo Nation Council
P.O. Box 3390
Window Rock, AZ 86515

Jim Cleary
President
Western Pipeline Group
El Paso Corporation
Two North Nevada Avenue
Colorado Springs, CO 80903

Dear Gentlemen:

We, the undersigned members of the Arizona Corporation Commission want to take this opportunity to contact the parties involved in the ongoing right-of-way easement negotiations between the Navajo Nation and El Paso Natural Gas Corporation and encourage you to reach an agreement that is in the interest of all parties involved as well as the people of the state of Arizona.

As you are aware, the negotiations for this easement have been taking place for over one year, with the current easement agreement set to expire in October, just one month away. While we stress that we remain neutral in regard to the parties involved in this case, we feel it is important, and in the public interest, for the parties to reach a mutually beneficial agreement. The natural gas line at issue has an important impact on Arizona ratepayers. It is in ratepayers' best interest that an equitable agreement is reached.

While we have met with representatives from El Paso Natural Gas Corporation, we would welcome, and encourage representatives from the Navajo Nation to meet with the Commission to discuss this issue. Again, we urge the parties to come to agreement on this important matter.

Sincerely,

Jeff Hatch-Miller, Chairman

Marc Spitzer, Commissioner

William A. Mundell, Commissioner

Kristin K. Mayes, Commissioner

Exhibit D
EPNG Press Release

El Paso Natural Gas Company Announces Expiration of Navajo Right of Way

HOUSTON, Oct. 17 /PRNewswire-FirstCall/ -- El Paso Natural Gas Company (EPNG), a wholly owned subsidiary of El Paso Corporation (NYSE: EP), announced today that it expects its right-of-way agreement across lands held by the United States in trust for the Navajo Nation to expire at midnight tonight. The company does not expect any interruption in service to its customers.

"We are deeply disappointed that after more than a year of good-faith effort we have not been able to reach agreement with the Nation's negotiating team," said James J. Cleary, president of El Paso Natural Gas. "We greatly value our history of cooperation with and respect for the Navajo people that spans more than 50 years. However, we owe it to consumers in the states we serve to oppose the Navajo negotiators' current demand of more than $50,000 per acre for a 20-year renewal of our agreement. As a result, we have asked the U.S. Department of the Interior to renew our right of way without tribal consent at a rate that is fair for the Nation and fair for consumers."

EPNG has paid the Nation $29 million during the past 20 years for the expiring right of way. The current demand from the Navajo negotiators of more than $50,000 per acre totals roughly $440 million during a 20-year period. In contrast, the fair market value for perpetual rights of way on privately owned land in this area is $100 to $500 per acre. El Paso has offered the Nation $138 million in cash and restricted common stock, as well as non-cash consideration of approximately $60 million. This offer is generous by any measure. The non-cash consideration derives from two alternative projects that EPNG has proposed (one of which the Nation may select): fully capitalizing a helium project on the Nation to develop prolific Navajo helium reserves or converting some of EPNG's natural gas-fueled compression to electric compression and purchasing the necessary electricity from the Nation's utility.

El Paso's application with the Department of the Interior is available on El Paso's Web site at http://www.elpaso.com and can be found under Resources in the "El Paso and the Navajo Nation" section. This site also includes Section 1813 of the Energy Policy Act of 2005, in which Congress commissioned a comprehensive study of energy infrastructure rights of way on tribal lands to be conducted jointly by the Departments of Energy and the Interior. The study signals Congress' growing concern over recent tribal right-of-way trends and indicates that EPNG is not the only energy transporter confronting this phenomenon.

El Paso Corporation provides natural gas and related energy products in a safe, efficient, and dependable manner. The company owns North America's largest natural gas pipeline system and one of North America's largest independent natural gas producers. For more information, visit http://www.elpaso.com .

Cautionary Statement Regarding Forward-Looking Statements

This release includes forward-looking statements and projections, made in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The company has made every reasonable effort to ensure that the information and assumptions on which these statements and projections are based are current, reasonable, and complete. However, a variety of factors could cause actual results to differ materially from the projections, anticipated results or other expectations expressed in this release, including, without limitation, the uncertainties associated with potential legal and other action the Navajo Nation may take in the future; the uncertainties associated with the U.S. Department of Interior's actions with respect to our renewal request; the uncertainties associated with governmental regulation, including our ability to recover the costs associated with any payments for rights of way on the Navajo Nation; and other factors described in the company's (and its affiliates') Securities and Exchange Commission filings. While the company makes these statements and projections in good faith, neither the company nor its management can guarantee that anticipated future results will be achieved. Reference must be made to those filings for additional important

factors that may affect actual results. The company assumes no obligation to publicly update or revise any forward-looking statements made herein or any other forward-looking statements made by the company, whether as a result of new information, future events, or otherwise.

SOURCE El Paso Corporation
10/17/2005

CONTACT: investor and public relations, Bruce L. Connery, Vice President, 1-713-420-5855, or media relations, Richard Wheatley, Manager, 1-713-420-6828, both of El Paso Corporation

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Exhibit E
Navajo Brief

September 29, 2005

Honorable Sue Ellen Wooldridge
Solicitor
United States Department of the Interior
1849 C Street N.W., Room 6352
Washington, D.C. 20240

Re: Renewal of El Paso Natural Gas Company's Rights-of-Way for Interstate Pipelines Crossing Lands of the Navajo Nation

Dear Solicitor Wooldridge:

El Paso Natural Gas Company ("El Paso") is an interstate transporter of natural gas certificated by the Federal Energy Regulatory Commission ("FERC"). In June of 1950, the Federal Power Commission ("FPC"), FERC's predecessor, issued El Paso a certificate of public convenience and necessity for the construction of a natural gas pipeline across portions of Texas, New Mexico, and Arizona, including lands owned by the United States and held in trust for the Navajo Nation ("Nation") ("Navajo Lands"). Thereafter, the United States Department of the Interior ("Interior"), Bureau of Indian Affairs ("BIA"), granted El Paso rights-of-way for its pipeline system crossing Navajo Lands.

El Paso constructed its original pipeline system across Navajo Lands in 1951. Since that time, El Paso has invested millions of dollars in maintaining and expanding its pipeline infrastructure to provide an adequate, stable supply of natural gas to millions of end-users in New Mexico, Arizona, Nevada, and California. At present, El Paso's interstate pipeline system traverses nearly 900 linear miles of Navajo Lands and is maintained pursuant to certificates of public convenience and necessity issued by FERC.[1] El Paso's rights-of-way were last renewed by the BIA in 1985 and are set to expire on October 17, 2005. Today, El Paso is submitting an application ("Application") to renew its rights-of-way crossing Navajo Lands with the Secretary of the Interior.

El Paso has been engaged in lengthy negotiations with the Nation in an effort to renew the parties' 1985 right-of-way contract on fair and reasonable terms. To date, the Nation has demanded that El Paso remit several hundred times fair market value as remuneration for the Nation's consent to the renewal.[2] This equates to a $22 million payment annually over a twenty (20) year period. The Nation has rejected El Paso's most recent offer worth in excess of $200 million dollars over a twenty (20) year period, which is still many times larger than fair market value of comparable private lands in the area. The parties are therefore approximately one quarter of a billion dollars apart on a twenty (20) year renewal. With the October 17 expiration of its rights-of-way, this impasse threatens to disrupt El Paso's pipeline operations and service to millions of consumers in Arizona, New Mexico, Nevada, and California who depend on these very rights-of-way for their energy needs. However, the Nation's unreasonable conditions for consent do not bar Interior's immediate approval of the Application and of El Paso's rights-of-way for the following reasons:

- First, under the Nation's 1868 Treaty with the United States, the Nation expressly agreed to permit construction of works of utility or necessity upon Navajo Lands subject to the payment of damages. Congress has not abrogated the Treaty, and Secretary Norton may not act in a manner or impose a regulation that abrogates the Treaty's provisions.

- Second, the BIA's implementing regulation requiring tribal consent to rights-of-way crossing Indian land cannot be lawfully applied to tribes, including the Nation, that have chosen not to reorganize under the Indian Reorganization Act ("IRA"). Having declined to reorganize itself under the IRA, the Nation is barred from invoking the consent provisions that are available solely to IRA tribes. Even if the consent requirement imposed by the regulation were applicable to non-IRA tribes, which it is not, this consent has already been secured by virtue of the Nation's 1868 Treaty.

- Third, renewal of El Paso's rights-of-way is necessary to avoid a conflict with FERC's jurisdiction over El Paso under the Natural Gas Act ("NGA"). Neither Secretary Norton nor the Nation can effectively veto the decision of FERC to certificate El Paso's pipeline for public convenience and necessity. Indeed, the Secretary has an obligation to consider El Paso's fifty-four (54) year history of natural gas transportation over these rights-of-way and to ensure that her actions do not interfere with the continuous supply of this gas at reasonable rates over rights-of-way maintained on reasonable terms.

- Finally, the Nation's imposition of unreasonable terms for its consent to renewal of the rights-of-way at issue here is tantamount to an unlawful exercise of regulatory authority over non-Indians and is well beyond the scope of its tribal jurisdiction as defined by federal law. As such, the Nation's terms of consent are invalid and cannot prevent Secretary Norton from granting the rights-of-way sought in El Paso's renewal Application.

El Paso intends to continue good faith negotiations with the Navajo Nation. The enclosed memorandum of points and authorities ("memorandum," enclosed as

[1] Sections of pipeline also traverse parcels of land allotted by the United States to individual Indian allottees. Because El Paso expects to acquire the necessary rights-of-way across these allotted lands through negotiation, such allotted lands are not addressed in this letter and accompanying memorandum.

[2] The Nation's demand translates to about $50,000 per acre for an easement. In contrast, the fair market value of a perpetual easement on comparable off-reservation land is generally between $100 and $500 an acre.

Attachment 1) details El Paso's position as summarized above. The memorandum further requests that the Assistant Secretary for Indian Affairs decide El Paso's renewal Application and any appeal thereof directly, to avoid the need for a lengthy and costly appeal to the Interior Board of Indian Appeals and thus avert a disruption to the secure flow of natural gas while such an inevitable appeal is pending.

El Paso looks forward to working with Interior to timely process its Application and renewal of the rights-of-way. Please do not hesitate to contact me if you or your colleagues have questions.

Sincerely,

HOLLAND & HART LLP

Thomas L. Sansonetti

Enclosure

EL PASO NATURAL GAS COMPANY'S

MEMORANDUM OF POINTS AND AUTHORITIES

REGARDING

RENEWAL OF RIGHTS-OF-WAY ACROSS NAVAJO LANDS

September 29, 2005

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INTRODUCTION

Since 1950, El Paso Natural Gas Company ("El Paso") has built, operated, and maintained an extensive network of pipelines that transport natural gas to millions of Americans in the southwestern United States, including the Navajo Nation ("Nation"). Nearly 900 miles of pipeline traverse lands owned by the United States and held in trust for the Nation ("Navajo Lands"). The Federal Energy Regulatory Commission ("FERC") has determined that El Paso's interstate pipeline system crossing Navajo Lands is in the public interest, and it has issued certificates of public convenience and necessity under which El Paso operates. In the past, the Department of the Interior ("Interior"), Bureau of Indian Affairs ("BIA"), as trustee for the Nation, has granted and renewed rights-of-way to El Paso for its pipelines that cross Navajo Lands. In return, El Paso has paid to the Nation substantially more than the fair market value of those rights-of-way.

On October 17, 2005, the current rights-of-way will expire. El Paso seeks a twenty-year renewal of those rights-of-way and has been engaged in lengthy negotiations with the Nation, dating back to early 2004. The parties have been unable to agree on the value of the rights-of-way renewal.

For a number of reasons detailed in this memorandum, Interior can and should renew the rights-of-way before October 17, 2005. Renewal will secure the flow of natural gas to millions of consumers in Arizona, New Mexico, Nevada, and California who depend on these rights-of-way for their critical energy needs. Moreover, renewal is in the best interest of the Indians, many of whom (including the Nation) rely on El Paso's rights-of-way for the delivery of vital natural gas and earn royalties from the natural gas produced from tribal lands and transported through El Paso's pipelines. Before and after renewal, El Paso will continue to negotiate in good faith with the Nation to determine a fair value for the rights-of-way.

DISCUSSION

I. UNDER THE NATION'S 1868 TREATY WITH THE UNITED STATES, THE NATION EXPRESSLY AGREED NOT TO OPPOSE FEDERALLY-CERTIFICATED WORKS OF UTILITY OR NECESSITY CROSSING NAVAJO LANDS.

A. The Nation has already consented to El Paso's pipeline rights-of-way pursuant to the clear and unambiguous terms of the Treaty.

In 1868, the Nation's chiefs and headmen exercised their authority on behalf of the Nation and entered into a treaty with the United States (the "Treaty"). *See* Treaty Between the United States of America and the Navajo Tribe of Indians, June 1, 1868, Ratified July 25, 1868 and Proclaimed August 12, 1868, 15 Stat. 667. Under the Treaty, the Nation "expressly agree[d]" that:

> *They will not in future oppose the construction of* railroads, wagon roads, mail stations, or other *works of utility or necessity which may be ordered or permitted by the laws of the United States*; but should such roads or other works be constructed on the lands of their reservation, the government will pay the tribe whatever amount of damage may be assessed by three disinterested commissioners to be appointed by the President for that purpose, one of said commissioners to be a chief or head man of the tribe.[1]

[1] El Paso recognizes that Interior practice under similar provisions requires the non-Indian applicant to pay such damages. To the extent a Commission is appointed pursuant to Treaty Article IX, clause 6th to determine appropriate damages for the rights-of-way, El Paso stands ready to participate and pay such damages as may be assessed.

Treaty Preamble & Article IX, clause 6th (emphasis added).[2] Pursuant to Article II, the Treaty further created a non-exclusive reservation "for the use and occupation of the Navajo tribe," providing that:

> *no persons except those herein so authorized to do*, . . . or the orders of the President, *shall ever be permitted to pass over, settle upon, or reside in, the territory described in this article.*

(Emphasis added). The Treaty between the Nation and the United States is "the 'supreme Law of the Land. . . .'" *See Menominee Tribe of Indians v. United States*, 391 U.S. 404, 411 (1968).[3] As such, the "courts can no more go behind it for the purpose of annulling its effect and operation than they can go behind an act of Congress." *United States v. Minnesota*, 270 U.S. 181, 201 (1926).

Under the Treaty, the Nation relinquished its power to oppose, then and in the "future," works of utility or necessity upon Navajo Lands ordered or permitted by the laws of the United States. *See* Treaty Article IX, clause 6th. Moreover, the Nation acquired its lands subject to the right of the Government to order or permit construction and operation of works of utility or necessity thereon. *See* Treaty Article II. Thus, the Nation's right to occupy and use its lands has, since its inception, been subject to and burdened by the right of persons, including El Paso, "to pass over, settle upon, or reside in [Navajo Lands]" as authorized by the United States and "ordered or permitted" by FERC. *See* Treaty Articles II and IX; *cf. Del Rio Drilling Programs, Inc. v. United States*, 35 Fed. Cl. 186, 194 (1996) (the estate the tribe received was "burdened from birth by a right-of-way"); *Del-Rio Drilling Programs, Inc. v. United States*, 146 F.3d 1358, 1361 (Fed. Cir. 1998) (the Government retained an easement when it conveyed the lands to the tribe).

Significantly, canons of construction applicable to Indian matters cannot alter the plain language of a treaty.

> While it has long been the rule that a treaty with Indians is to be construed so as to carry out the Government's obligations in accordance with the fair understanding of the Indians, we cannot, under the guise of interpretation, create presidential authority where there was none, nor rewrite congressional acts so as to make them mean something they obviously were not intended to mean.

Confederated Bands of Ute Indians v. United States, 330 U.S. 169, 179 (1947) (citing *Choctaw Nation of Indians v. United States*, 318 U.S. 423, 432 (1942); *see also DeCoteau v. District County Court*, 420 U.S. 425, 447 (1975) (the rule by which legal ambiguities are resolved to the benefit of Indians "is not a license to disregard clear expressions of tribal and congressional consent").

The Nation's consent in the Treaty to "construction" of works of utility or necessity is not an ambiguous provision and clearly encompasses the continued operation of such works once constructed. Were the Treaty interpreted to provide for the construction of works of utility or necessity but to exclude their operation once completed, such an interpretation would render the "construction" provision utterly meaningless. Neither the plain language of the Treaty nor the canons of treaty

[2] This consent to federally-permitted works of utility extends to the lands added to the 1868 Reservation by the Executive Orders of January 6, 1880 and April 24, 1886.

[3] By the Act of March 3, 1871, ch. 120 § 1, 16 Stat. 566, codified at 25 U.S.C. § 71, Congress ended treaty making with Indian tribes. However, the statute expressly recognizes that the 1871 Act did not impair or alter obligations and commitments in extant treaties.

interpretation permit such a result. *See United States v. Andrews*, 179 U.S. 96, 99 (1900) (the Chisom Trail was a work of utility or necessity within the nearly identical article of the treaty with the Kiowa and Comanche Tribes of Indians, Concluded October 21, 1867, and Proclaimed August 25, 1868, 15 Stat. 581, 585, which "the Government would naturally seek to provide and obtain permission to lay out or to keep in use for the convenience of its citizens. . . .").

In short, the Nation has already consented to El Paso's pipeline rights-of-way pursuant to the clear and unambiguous language of the Treaty. The Treaty is the supreme and controlling law with regard to works of utility or necessity crossing Navajo Lands. Having forsaken and failed to preserve any right it may have had to oppose construction and operation of federally-ordered works of utility or necessity across Navajo Lands, the Nation does not now possess the power, whether by purporting to withhold its consent or otherwise, to prevent the Secretary of the Interior ("Secretary") from renewing the rights-of-way as certificated by FERC. *See Del-Rio Drilling Programs, Inc. v. United States*, 37 Fed. Cl. 157, 161 (1997) (Interior "erred as a matter of law" in giving the tribe a veto over access across its reservation).

B. Congress has not abrogated the Treaty through subsequent legislation.

Only "Congress may abrogate rights reserved to Indian tribes in treaties." *See, e.g., Rosebud Sioux Tribe v. Kneip*, 430 U.S. 584, 594 (1977); *Lone Wolf v. Hitchcock*, 187 U.S. 553, 566 (1903). Nevertheless, there is a strong presumption against subsequent legislative abrogation of Indian treaty provisions. *See United States v. Winans*, 198 U.S. 371 (1905); s*ee also Washington v. Washington State Commercial Fishing Vessel Ass'n*, 443 U.S. 658, 690 (1979) ("[a]bsent explicit statutory language, we have been extremely reluctant to find congressional abrogation of treaty rights...."). To abrogate treaty rights, Congress must "clearly and unequivocally express its intent to do so." *Williams v. Clark*, 742 F.2d 549, 553 (1984) (quoting *Idaho v. Andrus*, 720 F.2d 1461, 1464 (9th Cir. 1983)). Here, Congress has not abrogated the Treaty through any subsequent legislative enactments. No where in any statute has Congress "clearly and unequivocally express[ed] its intent" to abandon the rights and obligations of the Nation as set forth in the Treaty. *See id.*

The 1948 Rights-of-Way for All Purposes Act, 62 Stat. 17, codified at 25 U.S.C. §§ 323-328 (the "1948 Act"), and in particular, 25 U.S.C. § 324, leaves the 1868 Treaty undisturbed and in full force. *See Mille Lacs Band of Chippewa Indians v. Minnesota*, 861 F. Supp. 784, 836 (D. Minn. 1994), ultimately *aff'd*, 526 U.S. 172 (1999). Any requirement of tribal consent imposed by the 1948 Act is clearly and plainly limited to "certain tribes" that elected to reorganize under the Indian Reorganization Act ("IRA").[4] The Nation is not among those "certain tribes." Section 324 reads:

[4] The Indian Reorganization Act, June 18, 1934, 48 Stat. 984, is codified as amended at 25 U.S.C. § 461, *et seq.* As originally enacted, the IRA exempted from its coverage Indian tribes located in Oklahoma and the then Alaska Territory. In 1936, the provisions of the IRA were extended to the reorganized tribes of the Alaska Territory. Act of May 1, 1936, 49 Stat. 1250, codified at 25 U.S.C. § 473a. Extension of the IRA to Oklahoma was accomplished by the Oklahoma Indian Welfare Act, 49 Stat. 1967, codified as amended at 25 U.S.C. §§ 501-509 ("OIWA"). Because the Nation is neither an Alaska nor an OIWA tribe, all references herein are restricted to "IRA" and "non-IRA" tribes.

> **Sec. 324. Consent of certain tribes; consent of individual Indians**
>
> No grant of a right-of-way over and across any lands *belonging to a tribe organized under the Act of June 18, 1934 (48 Stat. 984) [the IRA]*, . . . , shall be made without the consent of the proper tribal officials. . . .

(Emphasis added).

It is undisputed that the Nation is not an IRA tribe. Therefore, 25 U.S.C. § 324's application only to tribes organized under the IRA is significant. The IRA vested tribes electing to reorganize with certain powers in addition to those rights which may have been granted or reserved to them in prior treaties. The tribes that chose not to reorganize under the IRA were therefore confined to the original rights and obligations articulated in the original treaties. *See* 25 U.S.C. § 478b. Having declined to become an IRA tribe, the Nation did not gain the additional power of consent granted pursuant to 25 U.S.C. § 324 and must rely solely upon the terms of its Treaty with the United States. *See Navajo Resources, Inc. v. Deputy Assistant Secretary – Indian Affairs (Operations)*, 10 IBIA 72, 89 I.D. 412, 414 (1982) (the meaning of the conditions in the 1938 Indian Mineral Leasing Act bestowing rights upon IRA tribes but not upon the Nation are "absolute"). Thus, the 1948 Act is neither an abrogation of, nor an authorization for the Secretary to abrogate, Treaty Articles II and IX.

C. The Secretary cannot act in a manner or impose a regulation that effectively abrogates the Treaty's provisions.

Unlike Congress, the executive branch does not have authority to abrogate a treaty provision. *See Mille Lacs Band of Chippewa Indians*, 861 F. Supp. at 823-24 ("The Constitution does not provide the President with the power to remove Indian tribes or to abrogate rights guaranteed under treaties") (citations omitted). Therefore, neither the Secretary nor the BIA has the authority to act in a manner or impose a regulation that effectively abrogates the terms of the Nation's Treaty with the United States.

Notwithstanding this limitation, Interior first promulgated 25 C.F.R. § 169.3 in 1971, requiring the "prior written consent of the tribe" before granting a right-of-way over and across *any* tribal Indian land. As written, this regulation applies equally to both IRA and non-IRA tribes, including the Nation. The regulation's requirement that the consent of the Nation, a non-IRA tribe, be obtained prior to renewal of El Paso's pipeline rights-of-way is an impermissible attempt by an executive department to abrogate the Treaty provisions by revesting the Nation with the right to oppose works of public utility or necessity – a power it expressly surrendered under the Treaty and that was never restored by Congress. *See Mille Lacs Band of Chippewa Indians*, 861 F. Supp. at 823-24. The Secretary, as an appointee of the President, does not possess the authority to abrogate the Treaty, by BIA regulation or otherwise. *Id.*

II. THE BIA'S IMPLEMENTING REGULATION REQUIRING TRIBAL CONSENT TO RIGHTS-OF-WAY CROSSING INDIAN LAND CANNOT BE LAWFULLY APPLIED TO NON-IRA TRIBES, INCLUDING THE NATION.

A. 25 C.F.R. § 169.3 cannot be lawfully applied to require the consent of the Nation before El Paso's rights-of-way are granted.

As articulated above, the 1948 Act expressly limited its requirement of tribal consent to tribes that had elected to reorganize under the IRA. *See* 25 U.S.C. § 478

(providing that IRA "shall not apply to any reservation wherein a majority of the adult Indians, voting at a special election duly called by the Secretary of the Interior, shall vote against its application").[5] For those Indian tribes declining to reorganize under the IRA, 25 U.S.C. § 478b provides that:

> *All laws, general and special, and all treaty provisions affecting any Indian reservation which has voted or may vote to exclude itself from the application of sections . . . 476 to 478 . . . of this title shall be deemed to have been continuously effective as to such reservation, notwithstanding passage of said sections.* Nothing in said sections shall be construed to abrogate or impair any rights guaranteed under any existing treaty with any Indian tribe, where such tribe voted not to exclude itself from the application of said sections.

(Emphasis added). The Nation's June 1935 election failed to garner the vote for IRA status. The Nation is therefore precluded by the IRA itself from claiming any of the benefits of being an IRA tribe. The Secretary and the BIA are equally forbidden by that statute from extending such status to the Nation via regulatory or administrative fiat.

The present form of 25 C.F.R. § 169.3, requiring the "prior written consent of the tribe" before granting a right-of-way over and across *any* tribal Indian land,[6] has appeared in the regulations of the BIA since 1971.[7] Nevertheless, the regulation's requirement for obtaining the consent to rights-of-way from non-IRA tribes substantially exceeds and is not "in line"[8] with the tribal consent provision of the 1948 Act. As the Secretary explained in 1968, the 1948 Act "make[s] clear that *tribal consent is required only in the case of tribes organized under the [IRA]. . . . It has always been understood . . . that the Secretary has the authority, regardless of regulations, to grant . . . [rights-of-way] on his own initiative in the case of tribes not organized under the above acts.*" H.R. Rep. No. 91-78 at 40-41 (emphasis added).[9]

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[5] Indeed, while the House Committee on Government Operations recommended that 25 U.S.C. § 324 be amended to pertain to any and all Indian tribes and thereby eliminate the plain and absolute distinction between IRA and non-IRA tribes, this recommendation was never adopted by Congress. *See* H.R. Rep. No. 91-78 at 19. "Since it should be generally assumed that Congress expresses its purposes through the ordinary meaning of the words it uses, . . . absent a clearly expressed legislative intention to the contrary, [statutory] language must ordinarily be regarded as conclusive." *Escondido Mut. Water Co. v. La Jolla Band of Mission Indians*, 466 U.S. 765, 772 (1984) (citation and internal quotation omitted). More specifically, where a statute "names the parties who come within its provisions, other unnamed parties are excluded." *See Foxgord v. Hischemoeller*, 820 F.2d 1030, 1035 (9th Cir. 1987).

[6] 25 C.F.R. § 169.19 provides for renewals of rights-of-way, "with the consent required by § 169.3 . . . ." Neither the Treaty, the 1948 Act, nor the Act's implementing regulations contain limitations on the length of term for which a right-of-way may be granted. *See* 25 C.F.R. § 169.18 (specifying that "rights-of-way granted under the [1948 Act], for. . . oil, gas, and public utility water pipelines (including pumping stations and appurtenant facilities), . . . and for service roads and trails essential to any of the aforestated use purposes, may be without limitation as to term of years . . . ."). Similarly, neither the 1948 Act, the BIA's regulations, nor the Treaty limit the number of renewals which the Secretary may issue. *See* 25 U.S.C. § 169.19 (permitting the Secretary to "extend the grant for a like term of years . . . .").

[7] *See* 36 Fed. Reg. 8520, Proposed Rule Making (May 7, 1971) and 36 Fed. Reg. 14183, Final Rule (July 31, 1971), revising 25 C.F.R. § 161.3 to require the "prior written consent of the tribe." Prior to that revision and since 1951, 25 C.F.R. § 256.3, required the "prior written consent of the tribal council . . . ." In either case, and although not pertinent to the Nation as a non-IRA tribe, the Treaty contains the Nation's prior written consent and was entered by its "duly authorized" chiefs and headmen.

[8] January 27, 1968 Letter from Secretary Stewart L. Udall to Robert E. Jones, Chairman, Natural Resources and Power Subcommittee of the Committee on Government Operations, House of Representatives, attached to H.R. Rep. No. 91-78 at 40-41 (1969) (emphasis added).

[9] The current BIA Manual casts further doubt on the Secretary's authority to require that the Application comply with 25 C.F.R. § 169.3. The current BIA Manual at 54 BIAM 2.3, Supp. 7, Rel. 1 (August 23, 1971), instructs in pertinent part that:

> (a) The regulations require that the consent of the tribe be obtained prior to . . . granting a right-of-way over tribal land of tribes that are organized under the Indian Reorganization Act . . . ; and tribal land belonging to all other tribes which have a governing body recognized by the Secretary.
>
> As to tribes which do not have a recognized governing body, the Secretary can, as a matter of law, grant a right-of-way; however, such cases would have to be handled as an exception to the regulations. . . .

(Emphasis added). The regulations in fact make no such distinction.

Accordingly, under the authority of 25 C.F.R. § 1.2, the Secretary may, and should, waive the consent requirement of 25 C.F.R. § 169.3 in this instance. 25 C.F.R. § 1.2 allows the Secretary to "waive or make exception to" her regulations "in all cases permitted by law and . . . in the best interest of the Indians." *See, e.g.*, Solicitor's Opinion M-32071, 58 I.D. 351, 354 (February 19, 1943) (finding that the construction of a helium plant on the Nation's reservation was a direct pecuniary benefit to the Nation because it was paid a royalty from the helium processed in the plant). Similarly, El Paso's pipelines transport natural gas produced from lands of the Nation, Jicarilla Apache, Southern Ute, and Ute Mountain Ute Tribes. El Paso's pipelines deliver such natural gas into interstate commerce allowing the tribes and individual Indians to earn royalties therefrom. In addition, El Paso's pipelines deliver natural gas to the Navajo Tribal Utility Authority, Navajo Agricultural Products Industry, Jicarilla Tribal Utility Authority, and other Indians. These deliveries of critical energy supplies are manifestly and immediately beneficial to the Nation and to other Indian tribes and individual Indians. Indeed, the Nation's unbridled demands for exponential increases in "consent" payments by El Paso disserves the Nation's interest and is massively self-defeating. Such demands send a powerful signal to the marketplace, to investors, to entrepreneurs, and to infrastructure stakeholders: "Don't build or invest here." Failure to waive the consent regulation will, thus, adversely affect short- and long-term Indian interests.

Unlike the provisions of 25 C.F.R. § 169.3, the distinction between IRA and non-IRA tribes codified in the 1948 Act is plain and absolute.[10] The Secretary can only give meaning to Congress' express reference to IRA tribes in the 1948 Act and is without jurisdiction or authority to remove that distinction by regulation. Imposing the consent requirement of 25 C.F.R. § 169.3 on the Application, in light of the strict limitations of the 1948 Act's consent provision to IRA tribes, would be arbitrary and capricious and exceed the Secretary's statutory authority. *See* 5 U.S.C. § 706. Simply put, 25 C.F.R. § 169.3 cannot be lawfully applied to require the consent of the Nation before El Paso's rights-of-way are renewed.

In 1952, the Secretary faced an identical situation where the Bureau of Reclamation sought Interior's approval of a grant of right-of-way for an electric transmission line crossing tribal lands of the Crow Tribe of Indians, a non-IRA tribe. The Crow Tribe refused to consent.[11] The Acting Solicitor of the Interior opined that:

> there is ample authority under the [1948 Act] . . . , to grant the right-of-way, notwithstanding the lack of Indian consent.

[10] Congress never intended for the "consent" provisions of the 1948 Act to apply to non-IRA tribes, such provision being inserted in the 1948 Act for the sole purpose of recognizing the "consent" powers granted to IRA tribes. Specifically:

> The proposed legislation would vest in the Secretary of Interior authority to grant rights-of-way of any nature over the Indian lands described in the bill. The bill preserves the powers of those Indian tribes organized under the Indian Reorganization Act of June 18, 1934 (48 Stat. 984); the act of May 1, 1936 (49 Stat. 1250), extending certain provisions of that act to Alaska; and the Oklahoma Welfare Act of June 26, 1936 (49 Stat. 1967), with reference to the disposition of tribal land.

July 22, 1947 Letter from Under Secretary Oscar L. Chapman to Arthur H. Vandenberg, President pro tempore of the Senate, attached to H.R. Rep. No. 79 and S. Rep. No. 823 at 1036 (1948).

[11] *See* Memorandum of Acting Solicitor W.H. Flanery to the Secretary of the Interior, *Right-of-way for transmission line across Crow tribal lands to Yellowtail dam site* (September 10, 1952) (the "*Flanery Memorandum*"), attached as Exhibit "A" to this memorandum.

> Such consent is not necessary unless required by the act of Congress authorizing the grant of a right-of-way, and traditionally tribal consent had not been required by Congress in authorizing the grant by the Secretary . . . of various rights of way (see 25 U.S.C., 1946 ed., secs. 311-22). *The 1948 act requires the consent of the tribe only if it has organized under the Indian Reorganization Act . . . in view of the wide powers of Congress over the management of Indian tribal property, the necessity of securing tribal consent cannot be read into the statute by implication.*

Flanery Memorandum at 1-2 (emphasis added).[12] The consent of the non-IRA Navajo Nation to the Secretary's granting of the Application here is likewise unnecessary because, as the *Flanery Memorandum* recognized, the 1948 Act does not require the Nation's consent. The Secretary, therefore, should grant the Application pursuant to 25 U.S.C. § 323.[13]

While Interior has continued to apply 25 C.F.R. § 169.3 to non-IRA tribes in violation of the 1948 Act, "an agency's interpretation, even if well established [by passage of time], cannot be sustained if, as in this case, it conflicts with the clear language and legislative history of the statute." *Escondido*, 466 U.S. at 779 n.22. The consent requirement of 25 C.F.R. § 169.3 impermissibly expands upon and directly conflicts with the plain language of the 1948 Act. The Secretary need not obtain the Nation's consent as a condition precedent to renewal of El Paso's rights-of-way, when such condition is contrary to the IRA and not required by the 1948 Act.

B. Even if the consent requirement imposed by 25 C.F.R. § 169.3 were applicable to non-IRA tribes, which it is not, this consent has already been secured by virtue of the Nation's 1868 Treaty.

Even if the consent requirement imposed by 25 C.F.R. § 169.3 were applicable to non-IRA tribes, which it is not, such consent has already been secured by virtue of the Nation's 1868 Treaty. The people of the Nation affirmatively voted in 1935 not to reorganize under the IRA. As such, the Treaty – not the IRA – determines the Nation's rights and obligations with respect to rights-of-way. The Treaty, being "continuously effective" as to the Nation's reservation, *see Means v. Navajo Nation*, 420 F.3d 1037, 2005 U.S. App. LEXIS 18031 at *28-*30 (9th Cir. Jan. 28, 2005); *Tsosie v. United States*, 825 F.2d 393, 394 (Fed. Cir. 1987), expressly authorizes federally-ordered works of utility and necessity on Navajo Lands. The Nation clearly consented to the construction and operation of such works of utility or necessity by agreeing not to oppose the same. Accordingly, 25 C.F.R. § 169.3's consent requirement does not stand as a barrier to the immediate approval of El Paso's Application, inasmuch as such consent has already been given under the terms of the Treaty.

[12] *See also* Memorandum of Solicitor Nathan R. Margold to the Commissioner of Indian Affairs, *Isleta and Santo Domingo Pueblos – Rights-of-Way* (September 2, 1936), *reprinted in* 1 OPINIONS OF THE SOLICITOR OF THE DEPARTMENT OF INTERIOR RELATING TO INDIAN AFFAIRS, 1917-1974, at 668-69 (explaining that non-IRA tribes such as the Nation may not veto BIA's issuance of a right-of-way because Section 16 of the IRA is "without application" to such non-IRA tribes), attached as Exhibit "B" to this memorandum.

[13] As the *Flanery Memorandum* makes clear, the consent of the non-IRA Nation is also not required for the granting of pipeline rights-of-way under 25 U.S.C. § 321. Notably, the contemporaneous Treaty with the Crow Tribe of Indians, 15 Stat. 649, does not contain those express consent provisions to works of utility or necessity found in the Navajo Treaty's Article IX, clause 6th, and the Kiowa and Comanche Treaty's Article XI, clause 6th, 15 Stat. at 585, at issue in *Andrews*, wherein the tribes agreed not to oppose works of utility or necessity ordered or permitted by the laws of the United States. In this case, the plain language of the Treaty conveying the Nation's consent warrants further adherence to the Solicitor's opinion in the *Flanery Memorandum*, given the Solicitor's recognition of the distinction between IRA and non-IRA tribes even absent a similar express consent to works of utility or necessity in the contemporaneous treaty with the Crow Tribe.

C. The Interior Board of Indian Appeals' decision in *Transwestern* does not prevent approval of El Paso's renewal Application.

The Interior Board of Indian Appeals' ("IBIA") decision in *Transwestern Pipeline Company v. Acting Assistant Secretary*, 12 IBIA 49, 90 I.D. 474 (1983), applied the 1948 Act consent requirement to federally-ordered works of utility or necessity on Navajo Lands. However, this holding does not prevent approval of El Paso's renewal Application.

In rendering its decision, the IBIA failed properly to distinguish *United States v. 2,005.32 Acres of Land*, 160 F. Supp. 193 (D.S.D. 1958). In *2,005.32 Acres*, the United States, acting through the Corps of Engineers, sought to *condemn* a significant portion of the Standing Rock Sioux Indian Tribe's reservation for construction of a dam and reservoir. *See 2,005.32 Acres*, 160 F. Supp. at 195, 201. The issue of treaty-based consent to rights-of-way was not before the district court.[14] As explained in the opinion, "it is unreasonable and contrary to the rule of *ejusdem generis* to include the huge takings of reservation land . . . within the context of the provisions of Article 11 of the 1868 [Sioux] treaty concerning 'other works of utility or necessity.'" *Id.* at 201. El Paso does not herein request a "taking" of Navajo Lands. Rather, unlike the Government in *2,005.32 Acres*, it simply seeks renewal of its existing rights-of-way in accordance with the Treaty, including the obligation to pay the Nation such damages as the Commission may assess. *Id.* at 201.

[14] The Sioux Treaty at issue in *2,005.32 Acres* contains nearly identical provisions to the Navajo Treaty's Articles II, IX and X. As stated above, the same is true of the Kiowa and Comanche Treaty examined in *Andrews*. Significantly, the Standing Rock Sioux Tribe *is* reorganized under the IRA and therefore *could* avail itself of 1948 Act "consent" requirements that are wholly unavailable to the Nation.

In reaching to find further support for its "consent" finding in *Transwestern*, the IBIA improvidently relied upon the Ninth Circuit's opinion in *Southern Pacific Transportation Co. v. Watt*, 700 F.2d 550 (9th Cir. 1983), *cert. denied*, 464 U.S. 960 (1983), *reh'g denied*, 464 U.S. 1064 (1984). That decision is inapposite to the question of the Nation's consent to the construction and operation of works of utility or necessity under the Treaty. This is partly so because, as the Ninth Circuit acknowledged, the Walker River Piaute Tribe of Nevada is an IRA tribe. *See Southern Pacific*, 700 F.2d at 554 n.1. Therefore, as applied to the Walker River Piaute Tribe, an IRA tribe, application of the consent provisions of 25 C.F.R. § 169.3 was consistent with the statutory authorization.

Moreover, the question before the court in *Southern Pacific* was whether a specific railroad right-of-way granted pursuant to 25 U.S.C. §§ 312-318 (*not* the 1948 Act), was an *in praesenti* grant under which the Secretary was prohibited from imposing tribal consent-for-grant requirements. *See Southern Pacific*, 700 F.2d at 553-54. The railroad act expressly authorized the Secretary to establish by "regulation, grant preconditions, including one of tribal consent [if she so chooses]." *Id.* at 552. However, unlike the railroad act at issue in *Southern Pacific*, the 1948 Act expressly applies only to IRA tribes, such as the Walker River Piaute Tribe. Therefore, unlike *Southern Pacific's* railroad act, the 1948 Act does not authorize the Secretary to impose consent-for-grant requirements for the Nation, a non-IRA tribe.

Finally, the IBIA in *Transwestern* could not reach the issue of whether departmental regulations imposing consent requirements for non-IRA tribes are illegal.

See Oklahoma Petroleum Marketers Assoc. & Muskogee County Oklahoma, Commissioners v. Acting Muskogee Area Director, 35 IBIA 285 (2000). That being the rule, the IBIA in *Transwestern* could not, and did not, examine 25 C.F.R. § 169.3 to determine its validity. The Solicitor's Office is the only office of Interior to have ruled upon the Secretary's authority to extend IRA rights to non-IRA tribes when issuing rights-of-way. The Acting Solicitor found no such authority. *See Flanery Memorandum* at 1-2. *See also* OPINIONS OF THE SOLICITOR at 668-69.

The Secretary's regulation at 25 C.F.R. § 169.3, which purports to apply the 1948 Act's consent requirement to the Nation, a non-IRA tribe, exceeds the express congressional intent embodied in the IRA and the 1948 Act. Denial of El Paso's renewal Application on the basis of this consent requirement would be arbitrary and capricious and beyond the Secretary's statutory authority. *See* 5 U.S.C. § 706. Nor does *Transwestern* dictate a denial of El Paso's renewal Application. *Transwestern*'s holding cannot withstand authoritative review, and the Secretary, unlike the IBIA, may disregard or waive her regulation and properly refuse to apply 25 C.F.R. § 169.3's consent requirement to El Paso's Application.

III. EL PASO'S APPLICATION MUST BE GRANTED TO AVOID A CONFLICT WITH FERC'S JURISDICTION OVER EL PASO UNDER THE NATURAL GAS ACT.

As a result of orders issued by FERC and its predecessor agency, the Federal Power Commission ("FPC"), millions of end-users of natural gas in New Mexico, Arizona, Nevada, and California, including Indian customers, have come to rely on El Paso's interstate pipeline system to provide the vital natural gas needed to heat their homes and businesses, run their factories, and generate electric power for cooling, lighting, and other uses.

FERC has exclusive authority to authorize the construction, operation, and abandonment of El Paso's interstate natural gas pipeline facilities. While the Secretary clearly lacks authority to permit any tribe to override FERC's jurisdiction, it is not necessary to reach that broader issue here because the Nation is not organized under the IRA, and thus has no claim to exercise the consent provision set forth in 25 U.S.C. § 324 or 25 C.F.R. § 169.3. Accordingly, the narrow question presented is whether the Secretary can acquiesce in a non-IRA tribe's attempt to override FERC's authority by, in effect, requiring El Paso to abandon service through its pipelines crossing Navajo Lands. As explained below, the clear answer is that the Secretary cannot.

A. Failure to grant the Application would be tantamount to requiring an unauthorized abandonment of El Paso's pipeline facilities.

The Natural Gas Act ("NGA") provides FERC with broad regulatory authority over El Paso's interstate pipeline facilities, including El Paso's pipeline facilities crossing Navajo Lands and the services provided by those facilities. Pursuant to its exclusive

authority to certificate the construction of interstate pipeline facilities under Section 7(c) of the NGA, the FPC first authorized El Paso to construct and operate its interstate pipeline, known as the San Juan Mainline, in 1950. *See El Paso Natural Gas Co.*, Docket No. G-1177, 9 FPC 170 (1950) (construction of facilities with capacity to transport 167,000 Mcf of natural gas per day). A series of subsequent orders issued by FPC and FERC in the intervening decades authorized El Paso to expand the San Juan Mainline several times to serve the increasing demand for natural gas by residential, commercial, governmental, and tribal customers located in New Mexico, Arizona, Nevada, and California.[15]

Three fundamental principles define FERC's authorization of El Paso's interstate pipeline. First, as the U.S. Supreme Court has held, the federal interest in interstate commerce with respect to natural gas sales and natural gas pipeline facilities extends continuously from the wellhead all the way to the burner tip, without interruption. *People of the State of California v. Lo-Vaca Gathering Co.*, 379 U.S. 366, 369 (1965) ("The result of our decisions is to make the sale [or transportation via pipeline] of gas which crosses a state line at any stage of its movement from wellhead to ultimate consumption 'in interstate commerce' within the meaning of the [Natural Gas] Act."); *Associated Gas Distrib. v. FERC*, 899 F.2d 1250, 1255 (D.C. Cir. 1990) ("[I]f gas crosses a state line at any time from its production at the wellhead to its consumption at the burner tip, then that gas is deemed to be 'in interstate commerce' throughout the entire journey."). FERC's broad regulatory power over interstate transportation of natural gas unquestionably includes interstate transportation across Navajo Lands.

Second, FERC's authority over the interstate flow of gas is exclusive. Where FERC has jurisdiction, *no* governmental entity may attempt to assert concurrent authority or otherwise interfere with FERC's authority to regulate interstate pipeline facilities. *See, e.g., Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 301 (1988); *Nat'l Fuel Gas Supply Corp. v. Public Serv. Comm'n of State of N.Y.*, 894 F.2d 571, 576 (2d Cir. 1990); *Public Utilities Comm'n of the State of Cal. v. FERC*, 900 F.2d 269 (D.C. Cir. 1990) ("First we must correct California's assumption that FERC's and its jurisdiction are concurrent . . . . Here, if there be Commission jurisdiction over some component of the transaction, it is exclusive over that component."); *see also* the discussion *infra* of *Chapman v. El Paso Natural Gas Co.*, 204 F.2d 46, 52 (D.C. Cir. 1953) (holding that the

[15] *El Paso Natural Gas Co.*, Docket No. G-2106, 12 FPC 1037 (1953) (construction of facilities for the transport of an additional volume of 404,610 Mcf of natural gas per day), *modified*, 13 FPC 787 (1954), *further modified*, 14 FPC 536 (1955); *El Paso Natural Gas Co.*, Docket No. G-8940, 14 FPC 157 (1955) (enlargement of pipeline system to provide for an increase in system sales of 455,175 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. G-10499, 16 FPC 1354 (1956) (construction of facilities for the transport of an additional 151,725 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. G-11797, 19 FPC 393 (1958) (construction of facilities to provide additional capacity of 185,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. G-12580, 22 FPC 900 (1959) (construction of facilities to enable the supply of an additional 100,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. CP61-202, 25 FPC 1115 (1961) (construction of facilities necessary to provide approximately 20,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. CP61-296, 27 FPC 85 (1962) (construction of facilities to increase transport capacity by approximately 100,000 to 109,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. CP64-76, 36 FPC 176 (1966), *rev'g* Presiding Examiner's Initial Decision Upon Application for Certificate of Public Convenience and Necessity Under the Natural Gas Act, issued Dec. 16, 1965, *modified*, 36 FPC 491, *reh'g denied*, 36 FPC 1010 (1966) (expansion of present pipeline system to deliver an additional 250,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. CP79-337, 12 FERC ¶ 61,215 (1980) (construction of facilities to increase transport capacity by 195,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket CP89-896, 53 FERC ¶ 61,020 (1990) (construction of facilities to increase transport capacity by approximately 165,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. CP90-2214, 56 FERC ¶ 61,198 (1991) (construction of facilities to provide an additional capacity of 400,000 Mcf of natural gas per day); *El Paso Natural Gas Co.*, Docket No. CP94-575, 72 FERC ¶ 61,174 (1995) (construction of facilities to provide an additional 300,000 Mcf of natural gas per day of incremental pipeline capacity).

Secretary of the Interior's refusal to grant rights-of-way to El Paso without certain conditions encroached on the FPC's jurisdiction under the NGA).

Third, once FERC has authorized the construction and operation of an interstate pipeline facility by issuing a certificate of public convenience and necessity, that pipeline cannot abandon such facility or terminate service until it obtains an order from FERC authorizing the abandonment under Section 7(b) of the NGA. *Nat'l Fuel,* 894 F.2d at 573. Section 7(b) states: "No natural gas company shall abandon all or any portion of its facilities subject to the jurisdiction of [FERC], or any service rendered by means of such facilities, without the permission and approval of the [FERC] first had and obtained, after due hearing . . . ." 15 U.S.C. § 717f(b). A certificate of public convenience imposes a "continuing duty" on an interstate pipeline to deliver natural gas to its customers until further order from FERC. *Farmland Indus., Inc., v. Kansas-Nebraska Natural Gas Co., Inc.*, 486 F.2d 315, 317 (8th Cir. 1973). Based on the clear language of Section 7, the Supreme Court has found that "once gas [or an interstate pipeline facility] has been dedicated to interstate commerce, 'there can be *no* withdrawal of that supply from continued interstate movement *without Commission approval.*'" *United Gas Pipe Line Co. v. McCombs*, 442 U.S. 529, 536 (1979) (quoting *Atlantic Refining Co. v. Public Service Comm'n of State of N.Y.*, 360 U.S. 378, 388 (1959)) (emphasis in original).

These principles require the Secretary to grant El Paso's renewal Application to avoid a conflict with FERC's powers, and El Paso's duties, under the NGA. By certificating El Paso's interstate pipelines, FERC has determined that the "public convenience and necessity" require El Paso to transport natural gas through those facilities and across Navajo Lands for the benefit of millions of residential, commercial, governmental, and tribal end-users in the southwestern United States who depend on natural gas. To the extent a denial of the Application would require El Paso to terminate service, El Paso would be required to abandon its pipeline facilities and service in violation of Section 7(b) of the NGA. Only FERC can authorize El Paso to abandon its facilities or the service El Paso provides through those facilities, and only then upon a determination that "the available supply of natural gas is depleted to the extent that continuance of service is unwarranted, or that the present or future public convenience or necessity permit such abandonment." 15 U.S.C. § 717f(b). FERC has made no such determination. The supply of gas in the San Juan Basin has not been depleted. Nor has the "present or future public convenience or necessity" for access to that gas abated, and it is not likely to abate in the foreseeable future.

In *Escondido*, 466 U.S. 765, the Supreme Court interpreted language of the NGA's sister act, the Federal Power Act ("FPA"). The FPA, unlike the NGA, gives the Secretary authority to impose certain conditions on FERC-licensed hydroelectric projects for the protection of Indian tribes on whose reservation the projects would be located. In rejecting a tribe's argument that it could veto a FERC facility under the FPA, the Court, after observing that the Secretary lacks authority to veto FERC-licensed facilities under the FPA, stated: "[w]e cannot believe that Congress nevertheless intended to leave a veto power with the concerned tribe or tribes. The Commission need not, therefore, seek the Bands' permission before it exercises its licensing authority with respect to their lands." *Escondido*, 466 U.S. at 787.

The Court's holding in *Escondido* is equally applicable to FERC-certificated pipelines under the NGA. Under the rationale of *Escondido*, because the Secretary lacks authority to veto a FERC certificate, the Secretary also lacks authority to vest the Nation with veto authority. This conclusion is particularly germane to non-IRA tribes such as the Nation, where the consent provision set forth in 25 U.S.C. § 324 applies only to tribes organized under the IRA and does not apply in this case. In this situation, the public interest in the uninterrupted flow of natural gas to consumers in states across the southwestern United States, as clearly expressed in the NGA, trumps any parochial interest the Nation may have and deprives the Nation of any argument that it can veto a FERC certificate by effectively requiring an abandonment of El Paso's pipelines crossing Navajo Lands.

Consistent with the numerous precedents affirming FERC's exclusive authority under the NGA, the D.C. Circuit has previously enjoined the Secretary from imposing unlawful conditions on El Paso's construction and operation of the very same pipeline facilities at issue here. *See Chapman v. El Paso Natural Gas Co.*, 204 F.2d 46 (D.C. Cir. 1953). The injunction issued in *Chapman* foreshadowed the *Escondido* holding that the Secretary may not veto a FERC-approved facility. In *Chapman*, the D.C. Circuit affirmed a district court order requiring the Secretary to issue rights-of-way to the extent the El Paso pipelines crossed public lands. The court found the Secretary lacked authority to refuse to issue the rights-of-way unless El Paso agreed to certain conditions, and held that the conditions the Secretary sought to impose on El Paso conflicted with the "careful and detailed standards" set forth in the NGA (including provisions of NGA Section 7).[16] According to the court, "Congress expressed itself fully concerning the extent to which pipe line companies are to be regulated within the scope of federal authority, and jurisdiction for such regulation was placed in the Federal Power Commission," FERC's predecessor. *Chapman*, 204 F.2d at 52. "[I]n the absence of unequivocal language placing jurisdiction for regulation in both the Commission and the Secretary of the Interior, we are not persuaded that the Secretary of the Interior is authorized to impose the conditions which he has sought to attach to the issuance of rights-of-way concerned in this litigation." *Id.*

The *Escondido* and *Chapman* decisions stand for the proposition that, in cases in which a federal agency seeks to rely upon its statutory authority to take an action that creates a conflict or apparent conflict with another federal agency or statute, then the relevant statutory provisions must be harmonized to ensure a result in furtherance of congressional policies. *See* 2B NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION 53:01 (6th ed., rev. vol. 2000) (Courts have "a duty to construe statutes harmoniously where that can reasonably be done.") (footnote omitted). The Supreme Court in *Escondido* held that conditions the Secretary imposed must stop short of vetoing FERC's authorization of a facility FERC deemed to be in the public interest. Similarly, the D.C. Circuit's decision in *Chapman* furthered the broad congressional objectives reflected in the NGA to ensure the transportation and delivery of natural gas in interstate

[16] The Secretary sought to impose, as a condition of granting the right-of-way, a requirement to expand the pipeline and other common carrier obligations. The court found that this conflicted with Section 7(a) of the NGA, which specifically states that FERC shall have no authority to compel a pipeline to expand its facilities except in limited circumstances. *Chapman*, 204 F.2d at 51.

commerce for the benefit of residential and business consumers, and held that the Secretary cannot establish conditions that interfere with the congressional mandate expressed in the NGA.

Here, these precedents dictate that the Secretary's statutory authority should be construed in a manner that is consistent with the fundamental public interest objectives Congress enacted in the NGA and the authority of FERC to take actions implementing those objectives. Where, as here, there would be a conflict between, on the one hand, any refusal by the Secretary to grant the Application and, on the other hand, the certification and abandonment requirements of Section 7 of the NGA, the public interest objectives FERC serves must be preserved. *See Escondido*, 466 U.S. at 776-77 ("Congress could not have intended to paralyze with one hand what it sought to promote with the other . . . .") (citations and internal quotation omitted). In short, the Secretary cannot encroach on FERC's exclusive jurisdiction to regulate interstate pipelines. A refusal to renew El Paso's rights-of-way crossing Navajo Lands would do just that, amounting to a *de facto* order to abandon the El Paso pipelines, in derogation of FERC's exclusive jurisdiction to certificate the San Juan Mainline facilities and to determine whether an abandonment of pipeline service to El Paso's numerous customers through these facilities is in the public interest.

Indeed, the interest in avoiding a conflict is even greater here than it was in *Chapman*. The *Chapman* court prohibited the Secretary from effectively preventing the construction of the San Juan Mainline. In part as a result of the *Chapman* court's order, the San Juan Mainline has been in operation for more than fifty-four (54) years, and millions of end-users have come to rely on the pipeline to meet their need for natural gas. Given this reliance, the interest in renewing El Paso's rights-of-way crossing Navajo Lands is even more compelling than the interest that the *Chapman* court found to bar the Secretary's actions.[17]

It also bears mention that, even if the Secretary refused to renew the rights-of-way, El Paso would still be required to continue operating its pipelines crossing Navajo Lands in the absence of any abandonment authorization from FERC. An abandonment without FERC authorization constitutes a serious violation of the NGA, for which FERC can impose significant civil penalties and for which the United States Attorney General can seek substantial criminal penalties (in the case of a knowing and willful violation).[18] *See, e.g., Tenn. Gas Pipeline Co.*, 8 FERC ¶ 61,137 (1979). A denial of El Paso's Application, or any effort by the Nation to initiate a civil trespass action or otherwise prevent El Paso from operating its interstate pipelines, could put El Paso in an impossible

[17] As one commentator has observed:

> At the [pipeline right-of-way] renewal stage, . . . frustration of federal interests in efficient natural gas production is significant enough to conflict with the tribe's dependent status. A tribe's interest in imposing a consent restriction [on any pipeline right-of-way] is attenuated at renewal. The tribe has presumably already granted consent for the initial right-of-way issuance. It faces little threat of detriment to the reservation beyond the continuing encumbrance of the pipeline company's operations. In effect, this "encumbrance" amounts to the continuing underground flow of gas.

Andrew S. Montgomery, *Tribal Sovereignty and Congressional Dominion: Rights-of-Way for Gas Pipelines on Indian Reservations*, 38 STAN. L. REV. 195, 220-21 (1985).

[18] The Energy Policy Act of 2005, Section 314, Pub. L. No. 109-58, 119 Stat. 594 (Aug. 8, 2005) (the "Act"), increases FERC's criminal penalty authority from $5,000 to $1,000,000, with the possible maximum jail term increasing from 2 years to 5 years. The Act also increases the criminal penalty for willfully and knowingly violating a FERC rule, regulation or order issued under the NGA from $500 to $50,000 for each day of continued violation. The Act further amends the NGA to grant FERC authority for the first time to assess civil penalties for violations of the NGA or any FERC action made under the authority of the NGA. This new authority allows FERC to impose civil penalties of not more than $1,000,000 for each day of continued violation.

"Catch 22," and expose the Nation to the sanctions provided under the NGA. To avoid any conflict with the civil and criminal penalty provisions imposed by the NGA, the Secretary must grant El Paso's Application to renew its rights-of-way.

B. El Paso's use of the rights-of-way, combined with the terms of the 1948 Act, impliedly provide El Paso a right to renewal upon reasonable terms.

El Paso's fifty-four year history of use of the rights-of-way crossing Navajo Lands, combined with the 1948 Act, impliedly provide El Paso with a right to renew its existing rights-of-way upon reasonable terms. In 1950, the FPC issued El Paso a certificate of public convenience and necessity pursuant to the NGA for the construction and operation of its interstate natural gas pipeline across portions of Texas, New Mexico and Arizona, including Navajo Lands. *See* 9 FPC 170 (1950). Since that time, El Paso, with FPC (and later FERC) approval,[19] has invested millions of dollars in constructing, maintaining and expanding its pipeline system to provide an adequate and stable supply of natural gas to millions of residential, commercial, governmental, and tribal end-users in New Mexico, Arizona, Nevada, and California.

As discussed above, the NGA mandates that El Paso continue its interstate gas transportation service until FERC authorizes the cessation of such service. *See* 15 U.S.C. § 717f(b). FERC also regulates the rates and charges for El Paso's services to protect the interest of consumers in an adequate supply of gas at reasonable rates. *See Clark v. Gulf Oil Corp.*, 570 F.2d 1138 (3d Cir. 1977); *Florida Power & Light Co. v. FERC*, 598 F.2d 370 (5th Cir. 1979).

Nothing in the 1948 Act or its implementing regulations authorizes the "Secretary to disregard or sweep aside legitimate existing contractual" or business expectations of El Paso or the customers it serves. *See Woods Petroleum Corp. v. United States Dep't of the Interior*, 18 F.3d 854, 858 (10th Cir. 1994), *op. adhered to on reh'g*, 47 F.3d 1032 (10th Cir. 1995). In *Woods*, the Tenth Circuit set aside the Secretary's administrative order that rejected an agreement to communitize Indian and non-Indian mineral interests for oil and gas drilling and production. In doing so, the court reminded the Secretary of the need to weigh "the contractual rights of oil-producing companies such as plaintiffs, which commit millions of dollars in drilling costs in reliance on provisions in leases executed" with Interior's knowledge, against the duty to protect and maximize the return to Indians from their lands. 18 F.3d at 855; *see also Yavapai-Prescott Indian Tribe v. Watt*, 707 F.2d 1072, 1075 (9th Cir. 1983) (holding that tribe lacked authority to terminate commercial lease without obtaining Secretarial approval thereby avoiding an "impasse between the Secretary and a unilaterally terminating tribe" which might "insist upon new terms in any new lease which the Secretary might not be inclined to approve"). The Ninth Circuit also observed that a unilateral tribal cancellation of power ultimately could adversely affect the value of tribal leases. *Id.*

The 1948 Act empowers the Secretary to "grant rights-of-way for all purposes," 25 U.S.C. § 323, and directs that the compensation for such rights-of-way to be "as the Secretary . . . shall determine to be just." 25 U.S.C. § 325. In exercising that authority,

[19] See note 15, *supra,* for a list of FPC and FERC orders pertinent to El Paso's pipelines crossing Navajo Lands.

the Secretary must take into account the fifty-four year history of investment, reliance and expectations that El Paso and its customers bring to the table. El Paso has obtained renewals of these rights-of-way on acceptable terms that have not adversely affected the rates of El Paso's customers. The Nation's current and exponentially increasing demands for compensation at a rate that is many multiples of the fair market value for the rights-of-way exceed any "just" compensation. Such demands should not be sanctioned or facilitated by the Secretary. Not only are such demands contrary to past dealings between El Paso, the Secretary, and the Nation concerning these very rights-of-way, but they could increase the costs borne by El Paso's customers by hundreds of millions of dollars, as FERC is required by law to give El Paso a reasonable opportunity to recover its prudently incurred expenses. *See, e.g., FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944).

Acceding to the Nation's unreasonable demands would also set a dangerous precedent for all customers of utilities and pipelines that cross tribal lands, creating the specter of significantly increased costs at a time when energy prices are already approaching record high levels. At a time when one of the Administration's central goals is to encourage policies that yield reasonably priced and geographically diverse supplies of domestically produced energy for all Americans, *see generally* discussion of Energy Policy Act of 2005, note 18, *supra*, the Secretary should reject any effort by the Nation that would frustrate that goal.

IV. IMPOSITION OF UNREASONABLE RIGHT-OF-WAY TERMS BY THE NATION WOULD BE AN UNLAWFUL EXERCISE OF REGULATORY AUTHORITY OVER NON-INDIANS, BEYOND THE SCOPE OF ITS TRIBAL JURISDICTION, AND IN NO WAY IMPEDES THE SECRETARY'S ABILITY TO APPROVE EL PASO'S RENEWAL APPLICATION.

It is undisputed that Indian tribes are "unique aggregations possessing attributes of sovereignty over both their members and their territory." *United States v. Wheeler*, 435 U.S. 313, 323 (1978). However, these attributes of sovereignty are not unlimited and, in many respects, have been divested by virtue of an Indian tribe's dependent status. *Id.* at 326. Specifically, any "exercise of tribal power beyond what is necessary to protect tribal self-government or to control internal relations is inconsistent with the dependent status of the tribes, and so cannot survive without express congressional delegation." *Montana v. United States*, 450 U.S. 544, 564 (1981). Thus, "the inherent sovereign powers of an Indian tribe do not extend to the activities of nonmembers of the tribe." *Id.* at 565.

The prevailing case law, starting with the Supreme Court's decisions in *Montana* and *Strate v. A-1 Contractors*, 520 U.S. 438 (1997), makes clear that the Nation lacks regulatory and adjudicatory authority over El Paso as it relates to the pipeline rights-of-way at issue here. The Nation's attempt to impose unreasonable renewal terms is tantamount to an unlawful exercise of regulatory authority over non-Indians. Stated differently, and irrespective of the terms of the 1868 Treaty or the application of the 1948 Act and its implementing regulations, the Nation's unreasonable terms of "consent" are invalid and do not, under any circumstance, act as a barrier to the Secretary's renewal of El Paso's rights-of-way. *See Strate*, 520 U.S. at 442 (holding that state highway built on federally-granted right-of-way crossing Indian trust land is the functional equivalent of

non-Indian fee land over which tribal court lacked jurisdiction); *Burlington Northern R.R. Co. v. Red Wolf*, 196 F.3d 1059, 1063 (9th Cir. 1999), *cert. denied*, 529 U.S. 1110 (2000) (Tribe lacks adjudicatory jurisdiction over federally granted railroad right-of-way because the tribe lost "dominion and control over the right-of-way"); *Big Horn County Elec. Co-op., Inc. v. Adams*, 219 F.3d 944, 950 (9th Cir. 2000) (concluding that right-of-way easements owned by electric cooperative over Indian reservation were equivalent of non-Indian fee land and that tribe's 3% *ad valorem* tax on all utility property located on tribal or trust lands was unlawful exercise of tribal regulatory authority); *see also Nevada v. Hicks*, 533 U.S. 353, 374 (2001); *Atkinson Trading Co., Inc. v. Shirley*, 532 U.S. 645, 653 (2001).

A. Neither of *Montana's* two exceptions to the limitation on tribal sovereignty applies.

Noting the tribes' "diminished status as sovereigns," the *Montana* Court pointed to two narrow exceptions to the general rule that a tribe has no civil regulatory authority over tribal non-members. *Id.*, 450 U.S. at 565. First, "[a] tribe may regulate, through taxation, licensing, or other means, the activities of nonmembers who enter consensual relationships with the tribe or its members, through commercial dealing, contracts, leases, or other arrangements." *Id.* Second, "[a] tribe may also retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe." *Id.* Neither of *Montana*'s two exceptions to the limitation on tribal sovereignty applies so as to confer upon the Nation regulatory jurisdiction over El Paso and its rights-of-way.

1. A federally-created right-of-way does not amount to a continuing consensual relationship between the Nation and El Paso.

As previously stated, "[a] tribe may regulate, through taxation, licensing, or other means, the activities of nonmembers who enter consensual relationships with the tribe or its members, through commercial dealing, contracts, leases, or other arrangements." *Montana*, 450 U.S. at 565. However, a federally-created right-of-way does not amount to a continuing consensual relationship between the tribe and the grantee. *See Red Wolf*, 196 F.3d at 1064 (citations omitted). *See also Chiwewe v. Burlington Northern & Santa Fe Ry.*, 239 F. Supp. 2d 1213, 1217 (D.N.M. 2002) ("An unconditional transfer of Indian

property interests, whether by a direct congressional grant or through the procedure[s] established [by Congress] in [the federal statutes], does not create a 'continuing' consensual relationship between the tribe and the owner of the right-of-way."); *Reservation Tel. Co-op. v. Henry*, 278 F. Supp.2d 1015, 1023 (D.N.D. 2003) (statutes and regulations authorizing the Secretary to grant rights-of-way over Indian lands for construction of telephone lines and for all other purposes with tribal consent does not equate to a "consensual relationship" with an Indian tribe because "federal law requires the rights-of-way and provides a statutory mechanism to acquire the rights-of-way"); *Adams*, 219 F.3d at 951 (agreements creating an electric cooperative's rights-of-way for transmission and distribution systems over tribal lands, which were granted by the Secretary with the consent of the tribe, "were insufficient to create a consensual relationship with the Tribe[.]"). Consistent with this prevailing precedent, El Paso's federally-created rights-of-way across Navajo Lands, certificated by FERC and granted by Interior, are insufficient to establish a consensual relationship with the Tribe.

Even assuming the existence of a consensual relationship, the first exception to *Montana* does not grant a tribe unlimited regulatory or adjudicative jurisdiction over a non-member. *See Adams*, 219 F.3d at 951. Rather, *Montana* limits tribal jurisdiction under the first exception to the regulation of "the *activities* of nonmembers who enter [into] consensual relationships." *Id.* (quoting *Montana*, 450 U.S. at 565) (emphasis added). The Nation's efforts to regulate El Paso's pipeline through the imposition of unreasonable renewal terms does not amount to a regulation of the *activities* of a non-member, but instead represents a regulation of *property* owned by a non-member, a form of regulation that is not included within *Montana*'s first exception. *See id.* (concluding that tribe's *ad valorem* tax on value of utility property "is not a tax on the activities of a nonmember, but is instead a tax on the value of property owned by a nonmember, a tax that is not included within *Montana*'s first exception"). In short, the *Montana* "consensual relationship" exception has no application to the facts of this case.

2. <u>There is no threat to the Nation's political integrity, economic security, or welfare.</u>

Montana's second exception holds that the Nation may exercise civil authority over the conduct of non-Indians on non-Indian fee lands when that conduct "threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe." *Montana*, 450 U.S. at 566. This exception is equally unavailing.

Courts have given *Montana*'s second exception a narrow construction and only allow an Indian tribe to do "what is necessary to protect tribal self-government or to control internal relations." *Strate*, 520 U.S. at 459; *County of Lewis v. Allen*, 163 F.3d 509, 515 (9th Cir. 1998). As the Supreme Court's decision in *Atkinson Trading Co.*, 532 U.S. at 656, n.12, explains:

> *Montana's* second exception "can be misperceived." The exception is only triggered by non-member conduct that threatens the Indian tribe; it does not broadly permit the exercise of civil authority wherever it might be considered "necessary" to self-government. Thus, unless the drain of the non-member's conduct upon tribal services and resources is so severe that it actually "imperils" the political integrity of the Indian tribe, there can be no assertion of civil authority beyond tribal lands.

See also Yellowstone County v. Pease, 96 F.3d 1169, 1176-77 (9th Cir. 1996), *cert. denied*, 520 U.S. 1209 (1997) (noting that the "impact must be demonstrably serious and must imperil the political integrity, the economic security, or the health and welfare of the tribe").

The Nation cannot colorably claim that El Paso's pipeline "imperils" the health or welfare of the Nation or that it otherwise threatens the Nation's political integrity and interest in self-government. *See Reservation Tel. Co-op.*, 278 F. Supp.2d at 1024 (finding that provision of telephone services from rights-of-way and related sales and service of equipment did not endanger tribe's political integrity, economic security, health or welfare); *Adams*, 219 F.3d at 951 (rejecting tribe's argument that tribal treasury would be irreparably harmed and essential tribal services would have to be scaled back absent *ad valorem* tax on electric utility easements); *Bugenig v. Hoopa Valley Tribe*, 229 F.3d 1210, 1221 (9th Cir. 2000), *cert. denied*, 535 U.S. 927 (2002) (while recognizing cultural, social, and religious importance of White Deerskin Dance, non-member's proposed logging was not type of activity that triggers second *Montana* exception). El Paso's pipeline facilities have been located on Navajo Lands since 1950, and those facilities have operated without the slightest consequence to the Nation's self-government, political integrity, or security. That half-century record constitutes overwhelming evidence that renewal of El Paso's rights-of-way will not remotely imperil the Nation's ability to self-govern, nor its ability to control its internal relations so as to invoke the second *Montana* exception.

By requiring the Nation's consent to Treaty-established rights-of-way, the Secretary would be facilitating and endorsing the Nation's conduct beyond the scope of its regulatory powers and jurisdiction as defined by federal law. The Nation's unreasonable and unlawful consent terms are invalid and do not, under any circumstance, impede the Secretary's ability to approve El Paso's Application.

V. THE ASSISTANT SECRETARY FOR INDIAN AFFAIRS SHOULD DECIDE EL PASO'S RENEWAL APPLICATION AND ANY APPEAL THEREOF.

Renewal of El Paso's rights-of-way is critical to the United States' profound public interest in the stable supply of natural gas in interstate commerce. Interior's decision to approve or deny the renewal Application will dramatically affect El Paso's pipelines, the United States' interstate natural gas market, those who transport gas on the interstate system, and those utilities, industrial and governmental facilities, families and businesses in the southwestern United States who consume the gas. Because of the expansive regulation of El Paso's pipeline facilities and the duties imposed upon it by FERC, the matter also implicates far-reaching inter-agency decisions and governmental policy best-suited for review and decision by the Assistant Secretary. Regardless of the route the issues take, it seems certain that the Assistant Secretary will be called upon to review and decide the Application.

Assistant Secretarial review should be conducted in concert with the BIA's analysis of the Application. Together, the Assistant Secretary and the BIA should make a

decision on the Application for the reasons set forth in this memorandum.[20] The Assistant Secretary's decision on the Application itself, or to approve the BIA's decision prior to promulgation, will be a final Interior determination and will preclude lengthy and costly appeals at the IBIA by any party interested in the BIA's decision on renewal of the rights-of-way. *See* 25 C.F.R. § 2.6(c); and 43 C.F.R. § 4.331(b). Such potential administrative appeals would inject unacceptable risks of disruption to the secure flow of natural gas through the pipelines.

The Assistant Secretary cannot avoid the issues raised in the Application by declining to exercise his authority and deferring a decision on the Application to the BIA. If the BIA were to deny the Application, El Paso would surely appeal to the IBIA. Likewise, if the BIA were to approve the Application, the Nation would likely appeal to the IBIA. Upon appeal, the appellant is required to send a notice of the appeal to the Assistant Secretary – Indian Affairs. 25 C.F.R. § 2.20(a). The purpose of the regulation is to give the Assistant Secretary twenty days to decide whether to issue a decision in the appeal. *Id.* at (c)(1); 43 C.F.R. § 4.332(b). During that twenty-day period, the Assistant Secretary would need to review the Application and the arguments in light of the Treaty and the law, including FERC's preemptive authority, before deciding whether or not to take the appeal from the IBIA.[21] Thus, rather than waiting to conduct this analysis until after El Paso or some other party appeals a BIA decision, the Assistant Secretary should exercise his lawful authority to consider the Application in the first instance and issue a decision on the Application which is final for Interior. *See* 5 U.S.C. § 704; 25 C.F.R. § 2.6(a) & (c); and 43 U.S.C. §§ 4.314 and 4.331(b).

Finally, if left without the direction of the Assistant Secretary, the BIA would be called upon to exercise its discretionary authority in deciding the fate of the Application. For example, BIA would have to decide the lawfulness of 25 C.F.R. § 169.3 in this setting and the inapplicability of the IBIA's *Transwestern* decision, both of which the BIA may argue are matters within its discretion. The IBIA may not adjudicate "[m]atters decided by the Bureau of Indian Affairs through exercise of its discretionary authority." 43 C.F.R. § 4.330(b)(2). If the IBIA were to take an appeal of a discretionary decision of the BIA, the IBIA would be compelled to dismiss the appeal or refer the issues to the Assistant Secretary for his further consideration. *See* 25 C.F.R. § 2.20(f); and 43 C.F.R. § 4.337(b).

The inescapable conclusion is that all roads lead to the Assistant Secretary when it comes to making a final departmental decision on the Application. The best course, therefore, would be for the Assistant Secretary to consider the Application immediately upon its submission and approve or disapprove the Application at the outset rather than

[20] *See* 25 U.S.C. § 323 (authorizing the Secretary to grant rights-of-way for all purposes); 25 U.S.C. § 1a (delegating powers of the Secretary concerning Indian Affairs); 109 DM 8.2 (delegating to the Assistant Secretary leadership over the Bureau of Indian Affairs); 209 DM 8.1 (authorizing the Assistant Secretary to exercise all Secretarial authority except where otherwise limited); and SO#3259A1 (August 11, 2005) (temporarily redelegating all functions, duties, and responsibilities of the Assistant Secretary delegated by 209 DM 8, except as otherwise required by statute or regulation, to the Associate Deputy Secretary).

[21] *See also* 43 C.F.R. § 4.5(a)(1) (the authority reserved to the Secretary and her delegatees includes the authority to take jurisdiction at any stage of any case before any employee of the Department including the IBIA and render a final decision in the matter); and 209 DM 13.7.B (same).

delaying a final appealable decision by Interior and risking damage to and interruption of the interstate gas market during the interim. *See* 43 C.F.R. § 4.331(b).

CONCLUSION

For the reasons set forth above, El Paso respectfully requests the United States Department of the Interior approve its Application for renewal of El Paso's rights-of-way crossing Navajo Lands without regard to the Nation's consent.

Respectfully submitted,

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Exhibit F
Energy Policy Act of 2005

109TH CONGRESS }	HOUSE OF REPRESENTATIVES	{ REPORT
1st Session	SENATE	109–___

ENERGY POLICY ACT OF 2005

_____

_____, 2005.—Ordered to be printed

_____

_____, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany H.R. 6]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 6), to ensure jobs for our future with secure, affordable, and reliable energy, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment, insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Energy Policy Act of 2005".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 1813. INDIAN LAND RIGHTS-OF-WAY.

(a) STUDY.—

(1) IN GENERAL.—The Secretary and the Secretary of the Interior (referred to in this section as the "Secretaries") shall jointly conduct a study of issues regarding energy rights-of-way on tribal land (as defined in section 2601 of the Energy Policy Act of 1992 (as amended by section 503)) (referred to in this section as "tribal land").

(2) CONSULTATION.—In conducting the study under paragraph (1), the Secretaries shall consult with Indian tribes, the energy industry, appropriate governmental entities, and affected businesses and consumers.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretaries shall submit to Congress a report on the findings of the study, including—

(1) an analysis of historic rates of compensation paid for energy rights-of-way on tribal land;

(2) recommendations for appropriate standards and procedures for determining fair and appropriate compensation to Indian tribes for grants, expansions, and renewals of energy rights-of-way on tribal land;

(3) an assessment of the tribal self-determination and sovereignty interests implicated by applications for the grant, expansion, or renewal of energy rights-of-way on tribal land; and

(4) an analysis of relevant national energy transportation policies relating to grants, expansions, and renewals of energy rights-of-way on tribal land.

SEC. 1814. MOBILITY OF SCIENTIFIC AND TECHNICAL PERSONNEL.

Not later than 2 years after the date of enactment of this section, the Secretary shall transmit to Congress a report that—

(1) identifies any policies or procedures of a contractor operating a National Laboratory or single-purpose research facility that create disincentives

Exhibit G
Governor Owens' Press Release

Colorado Governor Warns of Rising Energy Costs, Says Consumers, Energy Security will be Harmed by Lack of Standards on Tribal Lands

April 18, 2006, Denver, Colorado – At a time when consumers are suffering from record-high energy prices, Colorado Governor Bill Owens today warned that energy consumers will suffer even further if objective valuation standards for energy rights-of-way are not established on tribal lands. The Governor spoke at a national energy rights-of-way public scoping meeting, hosted by the U.S. Departments of the Interior and Energy, regarding Section 1813 of the Energy Act of 2005 requiring the Departments to conduct a study on energy rights-of-way on tribal lands. **(The complete text of the Governor's remarks is below.)**

"The current standard-less environment for assessing right-of-way valuation fails everyone because it does not protect anyone," Governor Owens said. "In some cases, regulated energy transmission companies and pipelines are able to 'pass through' these additional costs directly to consumers in higher rates.

"But passing it through doesn't make it right and, in fact, harms energy consumers both on and off tribal trust lands. Even in cases where transporters cannot pass through these costs, the public will be harmed whenever projects that provide net benefits to the public are rendered unprofitable," the Governor said.

In direct contrast to tribal representatives who argue that there isn't a need for standards because this is an isolated issue involving only one tribe and one company, Governor Owens said, "The current approach to right-of-way negotiations on Indian trust land is hurting energy infrastructure development. This is an important and growing problem throughout the Western United States. It is emphatically not a mere disagreement between one or two Indian tribes and a handful of energy companies."

Governor Owens urged swift action saying, "Any delay in completion of the Section 1813 study on Right-of-Way standards is manifestly against the interests of all parties. The Congress and the President saw the necessity of identify Right-of-Way valuations standards by August of this year. I say, the sooner the better."

His comments joined the growing chorus of remarks made by U.S. Senator Wayne Allard (R-CO) and Colorado State Senator and Assistant Majority Leader Jim Isgar (D-CO), among others. Representatives of the electric utility and natural gas industries outlined case studies demonstrating that escalating rights-of-way are pervasive and that many companies responsible for natural gas and transmission delivery are negatively impacted by the lack of fair standards in determining rights-of-way fees. They cautioned that maintaining the status quo could be detrimental to consumers as many renewals are set to expire in the next five to ten years.

The meeting is being held to gather input from consumers, tribal representatives, the energy industry, and governmental entities for a study on energy rights-of-way on tribal land as mandated by Section 1813 of the Energy Policy Act of 2005. The study is due to Congress on August 7, 2006. ***For more information, please contact Nancy Ives, Executive Director of the Fair Access to Energy Coalition (FAIR) nancy.ives@faircoalition.org or 619-540-3751.***

(Please see complete text Governor Owens official remarks below)

Governor Bill Owens
Before the Joint Hearing
of the U.S. Departments of Energy and the Interior
Regarding the Energy Policy Act of 2005
Section 1813 Indian Land Rights-of-Way Study
Denver, Colorado
April 18, 2006

Good morning. Let me welcome all of you to Colorado and thank the United States Departments of Energy and the Interior for convening this important national hearing in our state.

A special greeting to our representatives from the federal government as well the leaders of the two sovereign Indian nations, the Southern Ute and Ute Mountain Ute Tribes, which call Colorado home. For more than seven years it has been my pleasure and privilege to work constructively with these two tribes on matters of mutual interest and concern. I also wish to acknowledge the leadership that Colorado's Lieutenant Governor, Jane Norton, is playing as chair of the Colorado Commission on Indian Affairs in strengthening the relationship with the Southern Ute and Ute Mountain Ute Tribes.

The genesis for today's hearing is the Energy Policy Act of 2005, which Congress passed overwhelmingly and which President Bush signed last August. Colorado and other energy-producing states especially welcomed the passage of this long-awaited legislation.

The Energy Act benefits all Americans by strengthening domestic exploration and production, thereby lessening our dependence on foreign energy sources.

The Act likewise helps consumers from all walks of life by fostering new investment in energy generation, production and transmission, and by encouraging federally-supported research and development of cleaner, more efficient technologies.

I am particularly pleased that the Indian Land Rights-of-Way Study – known as Section 1813 – was included in the final version of the Energy Act. As you all know Section 1813 calls for a study of how we approach right-of-way negotiations between tribal governments and energy-transmission providers. The study must balance the interests of the tribes, especially tribal sovereignty, and the transmission companies on behalf of the citizens we all represent.

The Section 1813 study process can lead to the establishment of clear, consistent, and fair valuation Right-of-Way standards. Such standards must balance the sometimes competing interests of tribes and transmission companies – in negotiating rights-of-way on public lands that are held in trust by the federal government for the benefit of individual tribes.

At a time when energy prices are once again approaching an all-time high, the issues that the Section 1813 study seeks to address have never been more important – or more timely. The Energy Policy Act signed last year mandates completion of this Section 1813 study by August 7th of this year.

There is no better time to ask the fundamental question that led Congress to mandate this study. Simply put, is the current approach to negotiating and assessing the value of energy rights-of-way on Indian trust lands the best we can do?

The weight of the evidence suggests we can do better – much better – than the current approach. Right-of-way negotiations between federally-recognized Indian tribes, on the one hand, and federally-approved electrical transmission providers and natural gas, crude and petroleum products pipelines, on the other – are increasingly measured not by months, but by years.

These protracted and costly negotiations stand in sharp contrast to right-of-way agreements on all other categories of public lands, whether controlled by federal, state or local governments. Everyone loses from such delays – tribal governments and the citizens they serve, energy companies and their shareholders, energy cooperatives and their members, and above all energy consumers. The public deserves better.

Congress must pay careful attention to the findings of the Section 1813 study and seek ways to work with all stakeholders to reduce and eliminate unnecessary delay and conflict – and the resulting higher costs – that the current trust land negotiating process has come to symbolize.

At the same time, the Section 1813 "study process" ought to develop credible public policy options for establishing – once and for all – truly objective standards for how trust land energy rights-of-way are valued. Here again, the current approach can result in unnecessary friction between tribes and the industry that is caused by a breakdown in federal public policy.

In the absence of objective valuation standards – such as the fair-market value appraisal that is used as the benchmark for energy-related rights-of-way across other kinds of public and private fee lands – the negotiating parties often talk past one another because there is no standard valuation method.

The current standard-less environment for assessing right-of-way valuation fails everyone because it does not protect anyone. In some cases, regulated energy transmission companies and pipelines are able to "pass through" these additional costs directly to consumers in higher rates.

But passing it through doesn't make it right and, in fact, harms energy consumers both on and off tribal trust lands.

Even in cases where transporters cannot pass through these costs, the public will be harmed whenever projects that provide net benefits to the public are rendered unprofitable.

From the tribes' perspective, the absence of a consistent and reasonable valuation standard can result in some undeniable short-term financial gains. Yet in the long run, it can sometimes have tragic unintended consequences. Lack of Right-of-Way valuation standards – and lengthy delays in negotiations – can actually encourage energy transmission companies and pipelines to bypass Indian trust land and avoid building critical energy infrastructure on Indian Reservations.

Establishing a fair and objective valuation standard would help correct this injustice and foster increased energy-related infrastructure development on Indian Reservations at a time when such public and private investments have never been more important.

Any delay in completion of the Section 1813 study on Right-of-Way standards is manifestly against the interests of all parties. The Congress and the President saw the necessity of identify Right-of-Way valuations standards by August of this year. I say, the sooner the better.

The current approach to right-of-way negotiations on Indian trust land is hurting energy infrastructure development. This is an important and growing problem throughout the Western United States. It is emphatically not a mere disagreement between one or two Indian tribes and a handful of energy companies.

The state of Colorado firmly believes that any use of another's land for public good requires fair and just compensation. And, such standards should be uniform across the country. All parties will benefit by a fair and efficient approach.

Again, I appreciate your time this morning and will be following the Section 1813 study process with great interest. Thanks again for your time this morning.

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904 CHALLENGING THE GOVERNMENT SUCCESSFULLY – WHETHER TO FIGHT, NEGOTIATE OR SETTLE

A View From Inside And Outside The Federal Government

By
Thomas L. Sansonetti
partner
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A. HOW TO INFLUENCE NEW LEGISLATION

1. Establish An Early Warning System For Learning When Legislation That May Effect Your Company is Being Considered
   - i. trade organizations
   - ii. lobbying firms
   - iii. law firms
2. If You Want New Legislation, Start Early
   - i. build a coalition of like-minded companies
   - ii. determine the most favorable committees of jurisdiction
   - iii. prepare both short and long issue papers on why the legislation is needed, its timeliness, who benefits, who does not benefit, and the financial impacts on the federal budget (if any)
   - iv. begin congressional staff visits with at least one member of your entourage who understands Capitol Hill
   - v. visit all key congressmen and their staffers, including committee staffers
   - vi. arrange for other entities who share your beliefs to do so as well
   - vii. recognize the lack of effectiveness of trade associations in representing the needs of individual companies
   - viii. draft the legislation for the Congress exactly as you would like to see it passed into law
3. Example: Small Refiners Coalition
4. Example: Abandoned Mine Land And Coal Miners' Health Benefits Coalition

B. HOW TO INFLUENCE NEW REGULATIONS

1. Establish An Early Warning System For Learning When A Regulation That May Effect Your Company Is Being Considered.

   i. trade organizations

   ii. lobbying firms

   iii. law firms

2. If You Want A New Regulation, Start Early

   i. build a coalition of like-minded companies

   ii. determine the most favorable cabinet department and agency within that department to sponsor the regulation

   iii. prepare both short and long issue papers on why the regulation is needed, its timeliness, who benefits, who does not benefit, and the financial impacts on the federal budget (if any) and burden on those complying with the new regulation

   iv. begin executive branch visits with at least one member of your entourage who has worked in the department and understands the way the bureaucracy works since each agency has its own culture

3. Example: Mining And Agricultural Industries' Attempts To Avoid Inclusion In New EPA Regulations On Fugitive Dust Standards

C. HOW TO STAND UP TO THE GOVERNMENT

1. Using The Administrative Appeal System To Seek Delays In Implementation

   i. Learn How the various Offices of Hearings and Appeals Work

   ii. The Interior Board of Land Appeals

2. Seeking Immediate Temporary Restraining Orders In Federal District Court

3. Visit With The Agencies' Litigation Arm: The Department Of Justice's Litigation Divisions

   i. the infrastructure at DOJ

   ii. gain access to the Section Chiefs

   iii. seldom start at the top with the Attorney General, Deputy Attorney General, Associate Attorney General, Solicitor General, or Assistant Attorney Generals

   iv. do visit the respective United States Attorneys on civil matters as they are more accessible

4. Intervene In Cases That Are Important To Your Industry Or Company

   i. through industry associations

   ii. by yourself if the legal issue is likely to set a precedent for your company

D. WHEN TO STAND DOWN TO THE FEDERAL GOVERNMENT

1. When Your Facts Are Deficient And Similar Cases Have Resulted In Adverse Decisions

   i. but pay attention to the circuit courts involved and where the decisions are coming from

   ii. contact the general counsels of companies already litigating

2. When 50% Or More Of Your Particular Industry Has Entered Into Consent Decrees With The Government

   i. the American Chemical Association

   ii. the Ethanol Industry

3. When You Can Settle For A Reasonable Amount Or For The Cost of Litigation

   i. DOJ would rather settle given the ratio of attorneys/cases

   ii. DOJ budgets limit the number of long-term cases

4. How To Settle With DOJ

   i. Remember that DOJ decision are final and trump the cabinet departments' general counsel's desires on how litigation is handled

   ii. the importance of the section chiefs

   iii. when to call for a meeting with the Assistant Attorney General or one of the Deputy Assistant Attorney Generals

5. Example: DuPont

   i. DOJ can play all or nothing. Can you?

ii. the Judgment Fund and how it works

6. Example: The New Source Review Cases Between The Utility Industry And EPA

i. how they got started

ii. how many settled

iii. how the litigation ended up

E. COMMENTS ON THE PRESENTATIONS BY MR. SOPER AND MR. RICHARDSON

1. What Their Respect Company Did Right And Wrong

2. What Else Their Respect Company Might Have Done

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904 Challenging the Government Successfully – Whether to Fight, Negotiate or Settle

Lessons Learned in the Trenches

By Stanley E. Soper
Vice President, Legal Affairs
Nutraceutical Corporation

1. Fighting for Changes in Proposed Legislation (Mandatory Adverse Event Reporting for Supplements and OTCs)
   a. Issue:
      i. In the process of investigating a company called Metabolife, FDA discovered what it claimed were approximately 13,000 unreported adverse event records in Metabolife's files.
      ii. Some participants in the industry petitioned FDA to adopt rules requiring the mandatory reporting of adverse events associated with dietary supplement products.
   b. Industry Response:
      i. Ultimately Senator Hatch agreed to work with Senator Durbin on legislation and drafts began circulating. See Exhibit A for the first version of the legislation circulated.
      ii. Trade associations had placed themselves in the position of promoting this new legislation and offered few if any critiques or objections to what was proposed.
   c. Our Response:
      i. Nutraceutical and a few other industry participants began pointing out issues with the drafts.
      ii. See www.nutraceutical.com/new for a summary of some of the steps taken.
      iii. Nutraceutical proposed its own alternative legislation, which would require that a 1-800 number to MEDWATCH be printed on all dietary supplement, OTC and food labels. See Exhibit B for a copy.
   d. Outcome:
      i. Neither industry participants nor congressional leaders were willing to consider Nutraceutical's proposal.
      ii. Ultimately a number of helpful changes were made to the legislation. See Exhibit C for a copy of the legislation that was ultimately introduced by Senator Hatch and others, after multiple revisions. Following are important changes that were made because a few companies spent a lot of time and money objecting and pointing out issues:

1. OTCs were included.
2. The act was revised to create true federal preemption by imposing a record-keeping requirement on all complaint records.
3. A one year limit was created on the obligation to file additional medical information and the type of information covered was narrowed.
4. Penalties were placed on individuals who file false reports.

iii. As of the date of preparing this outline, the legislation is stuck at the Senate and it is unclear whether it will proceed forward before the end of the current session.

e. Lessons Learned:
   i. Most industry participants simply went along with the proposed legislation rather than point out issues or problems, including the OTC industry and its trade associations. Unfortunately, we believe that this approach is not helpful to anyone for the following reasons:
      1. If no one is reading it with a critical eye, significant issues and problems can remain in the legislation.
      2. If the affected industry is silent and does not raise objections, its protectors in Congress have no leverage to get important changes made.
   ii. Lobbyists and trade associations don't necessarily have the same agenda as private companies that belong to them or hire them; it is important to keep a constant and close eye on their activities and to consistently involve experienced outside counsel who have a long-term and critical perspective on regulatory changes and who are willing to consider worst-case scenarios rather than always assuming that regulators will behave themselves.
   iii. Quietly accepting bad legislation in the interest of preserving relationships is usually not the right answer -- bad legislation should be fought or changed.
f. Courage and persistence are critical to achieving the best outcome.

2. Standing up to Regulatory Interpretations (Red Yeast Rice)
   a. Issue:
      i. Red yeast rice is a common Chinese food and food colorant and has been consumed for thousands of years. It is made through a fermentation of a particular variety of rice.
      ii. Red yeast rice naturally may contain some amount of lovastatin, which is the active ingredient in Mevacor, a drug for lowering cholesterol.
      iii. A company called Pharmanex marketed a product called Cholestin which contained red yeast rice that had been standardized for its lovastatin content. The labeling and marketing of this product focused on the lovastatin content.
      iv. FDA and Pharmanex engaged in litigation after FDA claimed that Cholestin was an unapproved drug. Pharmanex won at the District Court but lost at the Court of Appeals, then ended up dropping the case and withdrawing Cholestin from the market.
      v. FDA then proceeded to send warning letters to participants in the industry, telling them their products were unapproved drugs.
   b. Industry Response:
      i. Virtually every company in the industry withdrew its products from the market.
   c. Our Response:
      i. Nutraceutical did not pull its product from the market and engaged in a series of letters with FDA in which it asserted that the red yeast rice it sold was not illegal because of a number of factors, including:
         1. that red yeast rice naturally contains lovastatin and that this does not make it a drug (just as the natural presence of potassium in bananas does not make them a drug).
         2. that Nutraceutical did not specify or require that its red yeast rice contain lovastatin or any particular amount of lovastatin.
         3. that Nutraceutical's labels did not refer to lovastatin or claim any particular amount of lovastatin or any other active.
   d. Outcome:
      i. Ultimately FDA did not respond further. Other companies eventually began marketing red yeast rice again.
   e. Lessons Learned
      i. Regulators can take positions that are not supportable by underlying legislation or regulations; standing up to them if you have a reasonable basis is not an unreasonable thing to do.
      ii. Having the courage to stand up to regulators can provide a company with the opportunity to demonstrate and achieve leadership in the industry and in the marketplace.

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3. Challenging the Government in Federal Court (Ephedra)
    a. Issue
        i. Whole herb ephedra has been used in Chinese medicine for thousands of years; it is typically mixed with other herbs. It is very safe if properly used. But it contains naturally occurring ephedrine alkaloids which are the active ingredient in OTC allergy and cold medications. One potential side effect of these alkaloids can be a very minor increase in metabolism, depending on the dosage taken.
        ii. Nutraceutical began selling whole herb ephedra in capsules over 20 years ago and during that time has had virtually no reports of issues until the uproar began about ephedra a few years ago.
        iii. Many U.S. companies began selling concentrated ephedrine alkaloid products combined with caffeine as diet products; this combination seemed to work very well. The public and some companies began misusing products by taking or recommending larger doses; also, irresponsible companies began making outrageous marketing claims about the products. The result was increased attention from regulators and litigators.
        iv. Nutraceutical purchased a company that offered an Ephedra extract diet product; because Nutraceutical could see that other companies were marketing ephedra products irresponsibly, it felt there might be regulatory or other negative reaction at some point and began de-emphasizing and phasing out this product and discontinued it by 2003. However, in part because it had sold whole herb ephedra for many years, Nutraceutical continued to market its whole herb ephedra product.
        v. FDA published a series of proposed rules limiting the number of mg. of ephedrine alkaloids that could be included in products beginning in about 1997. Nutraceutical and others gave significant feedback and criticisms of the proposed levels. The entire industry expected a final rule that would limit dosage levels and require mandatory warnings.
        vi. The industry and public were surprised on December 31, 2004, when FDA announced it would ban all dietary supplements containing any ephedrine alkaloids (at any level). When the rule was finally published, it contained another surprise: it banned the alkaloids at any level based on a risk/benefit test (i.e., FDA had determined that the risks outweighed any demonstrated benefits), a concept that was not found in food or dietary supplement regulations.
    b. Industry Response
        i. Most of the industry was grateful to have the controversy and negative attention gone. No one seemed to care what the final rule said or on what basis it was decided.
    c. Our Response:
        i. Nutraceutical felt that the new use of a risk/benefit test was a real problem and could potentially allow FDA to ban any ingredient it chose to outlaw, with or without any scientific basis. Nutraceutical also felt that it was in a unique position to challenge the final rule because the administrative record contained only one reference to any evidence of any risk from whole herb Ephedra, and this was an analysis commissioned by FDA that had a number of problems.
        ii. Over the objections of many in the industry, Nutraceutical filed suit against FDA. After both parties filed summary judgment motions, the Federal District Court ruled in favor of Nutraceutical. A copy of the decision is attached as Exhibit D.
        iii. FDA subsequently appealed. The Court of Appeals ruled in favor of FDA. See Exhibit D.
        iv. Nutraceutical intends to request a rehearing and/or continue pursuing appeals and/or pursue other options.
    d. Outcome and Lessons Learned
        i. When a new regulation is proposed, reviewing the entire record is critical -- one overlooked document not objected to or countered can make all the difference.
        ii. When it appears that public opinion or regulatory headwinds are going to shift, consider carefully what changes should be made to product lines (and/or which should be discontinued) to prepare for potential changes.
        iii. Find the right lawyer to represent you in court if you plan to sue the federal government -- there are only a few with winning records and experience and with the disposition to fight the government in court.

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Exhibit A
First Draft of AER Legislation

Draft
May 27, 2004

LEGISLATIVE LANGUAGE

Drafted as an amendment to the Federal Food, Drug, and Cosmetic Act

"ADVERSE EXPERIENCE REPORTING FOR DIETARY SUPPLEMENTS

"Sec. 414. (a) IN GENERAL.--

"(1)(A) After notice and opportunity for comment, the Secretary shall by regulation establish requirements for the reporting to the Secretary of serious adverse experiences associated with the use of a dietary supplement in the United States and received by any manufacturer, packer, or distributor whose name appears on the label of the product.

"(B) A manufacturer, packer, or distributor may contract with a qualified independent person to receive and evaluate adverse experience reports and to submit to the Secretary reports of serious adverse experiences as required by this section.

"(2) The Secretary shall also receive reports of serious adverse experiences submitted from other sources.

"(b) REQUIREMENTS.--The regulation promulgated under paragraph (a)(1) shall apply to any person whose name appears on the label of the product as the manufacturer, packer, or distributor (provided that any person whose name appears on the label of the product may, by written agreement with another person who is a manufacturer, packer, or distributor of the product, designate the other person to be responsible for compliance with the requirements of this section and that all persons whose names appear on the label shall submit any report of a serious adverse experience received by them to the designated responsible person within 5 days of receipt of such report) and shall include the following provisions and requirements:

"(1) A serious adverse experience is an experience associated with the use of a dietary supplement that --

"(A) results in death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or

"(B) requires, based on appropriate medical judgment, medical or surgical intervention to prevent one of the outcomes listed above.

"(2) (A) A serious adverse experience shall be reported to the Secretary promptly, but in no instance later than 30 calendar days after initial receipt by the person required to report.

"(B) Significant additional information relating to a serious adverse experience received by the person required to report after the initial report to the Secretary shall be reported to the Secretary promptly, but in no instance later than 30 calendar days after such subsequent information is received by such person.

"(C) The Secretary may establish exemptions from the requirements of paragraphs (2)(A) and (2)(B) of this subsection.

"(3) Procedures shall be established and maintained by a person required to report under these regulations for evaluating reports of serious adverse experiences. A person required to report under this regulation shall maintain records relating to reports of serious adverse experiences received by such persons for a reasonable period of time, not to exceed 2 years.

"(4) A report or other information submitted to the Secretary under subsection (a)(1) or (a)(2) of this section or maintained under subsection (b)(3) of this section --

"(A) is a safety report under section 756, and may be accompanied by a statement about the evidence with respect to the causal relationship between the product and the serious adverse experience reported, which shall be a part of any report that is released for public disclosure whether alone or as part of a compilation or table.

"(B) is a record about an individual under the Privacy Act of 1974 and is a medical file or similar file the disclosure of which would constitute a clearly unwarrranted invasion of personal privacy under the Freedom of Information Act and shall not be publicly disclosed by the Secretary or any other person in possession of such a report unless all information that could identify individuals associated with the serious adverse experience, including any individuals identified in any reports relating to the experience, are redacted.

"(C) shall not be admissible in any product liability or related action in any state or federal court or in any arbitration or similar proceeding.

"(5) No state or local government or official shall establish or continue in effect any law, regulation, order, or other requirement that is different from or in addition to, or is otherwise not identical to, the provisions of this section.

"(c) RECORDS INSPECTION.--A manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States and any

contractor under paragraph (1)(B) of subsection (a) shall permit a person specifically authorized by the Secretary to have access to a record required to be established and maintained under this section."

Amend section 301(e) of the Federal Food, Drug, and Cosmetic Act to add "414," after "412," each time it appears.

Section 414 of the Federal Food, Drug, and Cosmetic Act shall become effective one year after the effective date of the regulations promulgated by the Secretary to implement it.

Exhibit B
Nutraceutical's Proposed AER Legislation

LEGISLATIVE LANGUAGE
Drafted as an amendment to the Federal Food, Drug, and Cosmetic Act

ADVERSE EVENT REPORTING

Sec. 414. (a) IN GENERAL -- After notice and opportunity for comment, the Secretary shall by regulation establish requirements regarding the establishment of an adverse event reporting collection system for consumers to report any adverse events that consumers believe to be potentially associated with the use of foods, dietary supplements and over-the-counter drugs.

(b) REQUIREMENTS.—(1) The regulation promulgated under this subsection shall apply to all products that are classified as a food, dietary supplement or over-the-counter drug.

(2) The regulation shall include a labeling requirement that all such products include a 1-800 phone number administered by the Department of Health and Human Services, which shall be responsible for the collection of all such adverse event reports.

(3) The regulation shall include notice to the product manufacturer, or other party responsible for the distribution of the product, of any reports of serious adverse events.

(4) The information gathered by the Secretary under this regulation shall not be deemed to constitute a determination that the product involved caused or contributed to the reported event, and shall not be admissible in any product liability or related action in any state or federal court or in any arbitration or similar proceeding.

Exhibit C
Final Draft of AER Legislation

II

109TH CONGRESS
2D SESSION

S. 3546

To amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 21, 2006

Mr. HATCH (for himself, Mr. DURBIN, Mr. HARKIN, Mr. ENZI, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Dietary Supplement and Nonprescription Drug Consumer Protection Act".

SEC. 2. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter H—Serious Adverse Event Reports

"SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

"(a) DEFINITIONS.—In this section:

"(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a nonprescription drug that is adverse, including—

"(A) an event occurring from an overdose of the drug, whether accidental or intentional;

"(B) an event occurring from abuse of the drug;

"(C) an event occurring from withdrawal from the drug; and

"(D) any failure of expected pharmacological action of the drug.

"(2) NONPRESCRIPTION DRUG.—The term 'nonprescription drug' means a drug that is—

"(A) not subject to section 503(b); and

"(B) not subject to approval in an application submitted under section 505.

"(3) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' is an adverse event that—

"(A) results in—

"(i) death;

"(ii) a life-threatening experience;

"(iii) inpatient hospitalization;

"(iv) a persistent or significant disability or incapacity; or

"(v) a congenital anomaly or birth defect; or

"(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

"(4) SERIOUS ADVERSE EVENT REPORT.—The term 'serious adverse event report' means a report that is required to be submitted to the Secretary under subsection (b).

"(b) REPORTING REQUIREMENT.—The manufacturer, packer, or distributor whose name (pursuant to section 502(b)(1)) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the 'responsible person') shall submit to the

Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

"(c) SUBMISSION OF REPORTS.—

"(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 502(x).

"(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

"(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

"(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the

requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

"(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for nonprescription drugs, and may be accompanied by additional information.

"(e) MAINTENANCE AND INSPECTION OF RECORDS.—

"(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

"(2) RECORDS INSPECTION.—

"(A) IN GENERAL.—The responsible person shall permit an authorized person to have access to records required to be maintained under this section, during an inspection pursuant to section 704.

"(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services who has—

"(i) appropriate credentials, as determined by the Secretary; and

"(ii) been duly designated by the Secretary to have access to the records required under this section.

"(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

"(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

"(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

"(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the nonprescription drug involved caused or contributed to the adverse event.

"(h) PREEMPTION.—

"(1) IN GENERAL.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for nonprescription drugs, that is different from, in addition to, or otherwise not identical to, this section.

"(2) EFFECT OF SECTION.—

"(A) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

"(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in ad-

verse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

"(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

"(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

"(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.".

(b) MODIFICATIONS.—The Secretary of Health and Human Services may modify requirements under the amendments made by this section in accordance with section 553 of title 5, United States Code, to maintain consistency with international harmonization efforts over time.

(c) PROHIBITED ACT.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by—

(1) striking ", or 704(a);" and inserting ", 704(a), or 760;"; and

(2) striking ", or 564" and inserting ", 564, or 760".

(d) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes an address or phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.".

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) MISBRANDING.—Section 502(x) of the Federal Food, Drug, and Cosmetic Act (as added by

this section) shall apply to any nonprescription drug (as defined in such section 502(x)) labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) GUIDANCE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report described under the amendments made by this Act.

SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"SEC. 761. SERIOUS ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS.

"(a) DEFINITIONS.—In this section:

"(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a dietary supplement that is adverse.

"(2) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' is an adverse event that—

"(A) results in—

"(i) death;

"(ii) a life-threatening experience;

"(iii) inpatient hospitalization;

"(iv) a persistent or significant disability or incapacity; or

"(v) a congenital anomaly or birth defect; or

"(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

"(3) SERIOUS ADVERSE EVENT REPORT.—The term 'serious adverse event report' means a report that is required to be submitted to the Secretary under subsection (b).

"(b) REPORTING REQUIREMENT.—

"(1) IN GENERAL.—The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 403(e)(1)) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the 'responsible person') shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or

within the retail packaging of such dietary supplement.

"(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 403(y).

"(c) SUBMISSION OF REPORTS.—

"(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 403(y).

"(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

"(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

"(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

"(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

"(e) MAINTENANCE AND INSPECTION OF RECORDS.—

"(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

"(2) RECORDS INSPECTION.—

"(A) IN GENERAL.—The responsible person shall permit an authorized person to have

access to records required to be maintained under this section during an inspection pursuant to section 704.

"(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services, who has—

"(i) appropriate credentials, as determined by the Secretary; and

"(ii) been duly designated by the Secretary to have access to the records required under this section.

"(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

"(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

"(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

"(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

"(h) PREEMPTION.—

"(1) IN GENERAL.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.

"(2) EFFECT OF SECTION.—

"(A) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or em-

ployee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

"(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

"(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

"(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

"(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.".

(b) PROHIBITED ACT.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by—

(1) striking ", or 760;" and inserting ", 760, or 761;"; and

(2) striking ", or 760" and inserting ", 760, or 761".

(c) MISBRANDING.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

"(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes an address or phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.".

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) MISBRANDING.—Section 403(y) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any dietary supplement labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) GUIDANCE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report as described under the amendments made by this Act.

SEC. 4. PROHIBITION OF FALSIFICATION OF REPORTS.

(a) IN GENERAL.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect 1 year after the date of enactment of this Act.

○

•S 3546 IS

Exhibit D
Ephedra Decisions

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

NUTRACEUTICAL CORPORATION and SOLARAY, INC., Plaintiffs, vs. LESTER CRAWFORD, D.V.M., Acting Commissioner, U.S. Food and Drug Administration, et al., Defendants.	ORDER Case No. 2:04CV409 TC

Plaintiffs Nutraceutical Corp. and Solaray, Inc., ("Plaintiffs") brought this action against Defendants Lester Crawford, D.V.M., Acting Commissioner of the United States Food and Drug Administration, the United States Food and Drug Administration ("FDA"), Tommy Thompson, Secretary of the Department of Health and Human Services, the Department of Health and Human Services, and the United States (collectively "Defendants"), challenging the validity of the FDA's February 2004 regulation banning all ephedrine-alkaloid dietary supplements. Plaintiffs manufacture and sell an ephedrine-alkaloid dietary supplement.

This matter is before the court on Plaintiffs' motion for summary judgment and Defendants' cross-motion for summary judgment. Plaintiffs, bringing this action under the Declaratory Judgment Act, allege that the FDA's Final Rule violates the Food, Drug and Cosmetic Act ("FDCA"), as amended by the Dietary Supplement Health and Education Act ("DSHEA"), through an improper determination of adulteration under 21 U.S.C. 342(f)[1], and also that it violates the Administrative Procedures Act ("APA").[2]

Plaintiffs seek to have the court: (1) declare the Final Rule invalid; (2) remand the matter to the FDA for further rulemaking consistent with the court's opinion; and (3) enjoin the Defendants from taking enforcement action against Plaintiffs for their sale of a dietary supplement containing 10 mg or less of ephedrine alkaloids per daily dose.

For the reasons set forth below, the court grants the Plaintiffs' motion for summary judgment and denies the Defendants' cross-motion for summary judgment

I. Background

The ephedrine alkaloids used in dietary supplements are naturally occurring stimulant compounds. Ephedrine-alkaloid dietary supplements ("EDS") have been promoted to achieve weight loss, enhance athletic performance and boost energy.

After extensive review, the FDA concluded that all EDS, regardless of the dose suggested in labeling, present an "unreasonable risk of illness or injury." The FDA regulation ("Final Rule"), published February 11, 2004, bans the distribution of all such products on the basis that they are adulterated within the meaning of the DSHEA.

Plaintiff Solaray (now owned by Plaintiff Nutraceutical), has manufactured and sold an EDS since 1988. Plaintiffs' product contains 375 mg of Ephedra sinica and the labeling

[1] 21 U.S.C. § 342 is the food adulteration provision. Subsection (f) provides the criteria for a determination that a dietary supplement is adulterated. An adulterated food or dietary supplement is not marketable under 21 U.S.C. § 333.

[2] Plaintiffs have voluntarily dismissed their claim of a categorical taking under the Fifth Amendment.

recommends one capsule taken no more than twice each day. The recommended dose yields less than 10 mg of ephedrine alkaloids per day. The Final Rule prohibits Plaintiffs from marketing and selling this product.

A. Regulatory Framework

The DSHEA, enacted in 1994 as an amendment to the FDCA, provides that a dietary supplement is adulterated if it presents "a significant or unreasonable risk of illness or injury under" the conditions of use recommended in labeling. 21 U.S.C. § 342(f)(1)(A).

Under the DSHEA, dietary supplements are regulated as a subset of foods unless the supplement producers make disease claims that bring the supplements within the definition of a drug. See 21 U.S.C. §§ 321(ff)(defining "dietary supplement), (g)(1) (defining "drug"); cf. 21 U.S.C. § 343(r)(6) (identifies claims which many be made by manufacturers of dietary supplements and those which are prohibited). Accordingly, dietary supplement manufacturers are not required to provide evidence of product safety and efficacy before marketing their products. Additionally, the DSHEA does not require dietary supplement manufacturers to comply with the post-market product safety monitoring or reporting requirements that the FDCA requires for drugs. The FDA relies on voluntary studies, voluntarily reported adverse event reports ("AERs"), and other data to identify potential safety problems associated with dietary supplements.

B. FDA's Rulemaking

On February 11, 2004, the FDA published the Final Rule declaring EDS adulterated and not legally marketable in the United States. The Final Rule became effective on April 12, 2004.

The Final Rule was the culmination of a long process beginning in the early 1990s when the FDA began receiving AERs reflecting injury and illness associated with the use of EDS. The administrative record reflecting the rulemaking process contains over 133,000 pages of scientific data, expert reviews, comments submitted by interested persons, and other materials considered.

The FDA considered evidence from three principal sources: (1) the well-known, scientifically established pharmacology of ephedrine alkaloids; (2) peer-reviewed scientific literature on the effects of ephedrine alkaloids; and (3) AERS related to the consumption of EDS. 69 Fed. Reg. 6788 (Feb. 11, 2004). The FDA also commissioned expert reviews of the scientific evidence and assessed the findings of the expert reviews. Id. at 6802, 6805 & 6814.

1. The 1997 Proposed Rule

The FDA initially published a proposed rule regulating EDS in June of 1997. Under the proposed rule an EDS was adulterated if it contained 8 mg or more of ephedrine alkaloids per serving, or if its labeling suggested or recommended conditions of use that would result in an intake of 8 mg or more during a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids. 62 Fed. Reg. 30678, 30691 (June 4, 1997). Additionally, the rule proposed to: (1) prohibit EDS labeling for claims or uses requiring long-term intake to achieve the purported effect; (2) prohibit EDS producers from combining ephedrine alkaloids with other stimulant ingredients; (3) require EDS warning statements that would alert consumers to possible drug interactions, and directing consumers not to take the product for more than seven days; (4) require EDS warning statements providing further advice for at-risk consumers; and (5) require that claims encouraging short-term excessive intake be accompanied with a statement that warned

that the recommended intake may result in serious adverse health effects. Id. at 30691-704.

Upon receiving a request from the House Committee on Science, the Government Accounting Office ("GAO") released a report entitled "Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids." 65 Fed. Reg. 17474 (Apr. 3, 2000). In this report the GAO recommended that the FDA "provide stronger evidence on the relationship between the intake of [EDS] and the occurrence of adverse reactions that support the proposed dosing level and duration of use limits." Id. at 17475. Further, the GAO noted that the FDA "should consider additional information . . . to determine whether a dietary ingredient limit, or some alternative approach, would be appropriate to regulate [EDS]." 65 Fed. Reg. at 17475.

In light of the GAO's conclusions and other comments, on April 3, 2000, the FDA partially withdrew the proposed rule. Specifically, the FDA withdrew the restrictions on dosages and directions for frequency of use and the proposed prohibition on labeling claims for uses encouraging long-term intake. The FDA also withdrew the proposed warnings advising consumers not to exceed the recommended dosages or use the product for more than seven days. The FDA retained the other warning statements and the proposed prohibition on combining EDS with other stimulant ingredients. Id. at 17475-76.

After this partial withdrawal of the proposed rule, the FDA reopened the comment period three times and considered additional evidence.

2. The 2004 Final Rule

The notice reopening the comment period on March 5, 2003, stated that the FDA intended to consider whether the "FDA should determine that [EDS] present a 'significant or unreasonable risk of illness or injury'" and sought comments on that issue. 68 Fed. Reg. 10417, 10419 (March 5, 2003) (quoting 21 U.S.C. § 342(f)(1)(A)).

The FDA published the Final Rule on February 11, 2004. The FDA concluded that when the minimal benefits of EDS are weighed against the substantial risks, all EDS present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions or use are suggested or recommended in labeling, under ordinary conditions of use. 69 Fed. Reg. at 6788. Because it found that use of EDS does not provide a benefit sufficient to outweigh the increased risk of heart attack, stroke, and death, the FDA concluded that all EDS pose an unreasonable risk and are adulterated under the DSHEA. Id. at 6789.

C. FDA's Statutory Interpretation and the Final Rule

The FDA promulgated the Final Rule under the DSHEA, which provides:

> A food shall be deemed to be adulterated–
> ***
> (f) Dietary supplement or ingredient: safety
> (1) If it is a dietary supplement or contains a dietary ingredient that–
> (A) presents a significant or unreasonable risk of illness or injury under–
> (i) conditions of use recommended or suggested in labeling, or
> (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
> . . .
> In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

21 U.S.C. §342(f)(1).

> The summary of the Final Rule closely follows the language of the statute:
>
> The [FDA] is issuing a final regulation declaring dietary supplements containing ephedrine alkaloids adulterated under the [FDCA] because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use.

69 Fed. Reg. at 6788.

The FDA concluded that the words "significant" and "unreasonable" have two separate and independent meanings. Under the FDA's statutory construction, "significant" involves an evaluation of risk alone, while "unreasonable" requires a comparison of risks and benefits. Id. at 6823 ("A risk could be significant, but reasonable if the benefits were great enough to outweigh the risks."). The Final Rule does not include a consideration of the word "significant." The record indicates that the FDA believed that evaluation of EDS under the "significant" standard was unnecessary because it is included within the statute as an alternative to "unreasonable." Id. at 6788 & 6822-23 (see also Def. Mem. Supp. Cross-Mot. Summ. J. at 31 n.14 ("Because the FDA concluded that EDS pose an unreasonable risk, it was not necessary for the agency to address DSHEA's significant risk standard.").

D. The FDA's Findings

EDS have been promoted to help achieve weight loss, enhance athletic performance, increase energy levels, ease breathing, and for other similar uses. The FDA determined that these effects are temporary, of modest benefit, and do not improve health if they occur at all. 69 Fed. Reg. at 6822 & 6826. The FDA found that although there is evidence to support modest, short-term weight loss, the FDA could not determine whether that weight loss results in improved health outcomes. Specifically, the FDA could not determine whether EDS have a positive effect on cardiovascular risk factors associated with being overweight. Id. at 6789, 6818-21, 6825-26.

The FDA found that EDS, generally, increase the risk of serious adverse events, including heart attacks, stroke, and death. Id. at 6789, 6800-04. An evaluation of single-dose studies showed that EDS cause an increase in heart rate and blood pressure in healthy subjects. A multiple-dose study demonstrated a higher blood-pressure measurement after one month of continued exposure to a combination of EDS and caffeine. Id. at 6801-02. The FDA also reviewed studies observing increased mortality in people with congestive heart failure who were treated with substances similar to EDS. Id. Additional evidence of the negative effects of EDS was obtained through 3,000 AERs submitted directly to the FDA and 16,000 reports from records maintained by Metabolife, one of the largest distributors of EDS.

Plaintiffs' product is labeled with a recommended daily dose of approximately 10 mg of ephedrine alkaloids. Therefore, the key evidence is that which the FDA contends shows a significant or unreasonable risk of illness or injury at recommended dosages of 10mg per day or less. The FDA points the court to 69 Fed. Reg. 6788, References 84-87 ("Reference") as the relevant sections.

References 84 and 85 are a series of letters between the FDA and Dr. Mario A. Inchiosa written between May and July of 1999. The letters are a response by Dr. Inchiosa to a request from the FDA that he conduct a scientific review on the effects of ephedrine alkaloids. The letters contain Dr. Inchiosa's conclusions derived from the examination of various studies of intake of

substances similar to ephedrine. Dr. Inchiosa performed a pharmacokinetic analysis[3] comparing epinephrine to ephedrine. According to Dr. Inchiosa, epinephrine and ephedrine alkaloids produce similar effects in the human body, but at different potencies.[4] He also used studies of the effects of injections of epinephrine to derive conclusions about the effects of ephedrine alkaloids. Acceptance of Dr. Inchiosa's conclusions depends on the acceptance of a mathematical model used to compare doses of epinephrine to ephedrine.

Dr. Inchiosa specifically refers to a study performed by W.E. Clutter, et al., ("Clutter Study"), in which the administration of epinephrine increased heart rate and blood pressure. See W.E. Clutter, et al., Epinephrine plasma metabolic clearance rates and physiologic thresholds for metabolis and hemodynamic actions in man, 1980 J. Clin. Invest. 66, 94-101 (cited in Reference 84 at 4 & 6). Dr. Inchiosa's mathematical model demonstrates that a "chronic ephedrine dose of 1.5 mg every four hours"would produce the same effects as epinephrine did in the Clutter Study. Reference 84 at 4. Dr. Inchiosa concluded that: "In the absence of a clinical indication, it would not be possible to recommend a safe dose of ephedra." Id. Other than the conclusions about ephedrine drawn from the Clutter Study on the effects of epinephrine, there is no evidence in the administrative record pertaining specifically to doses of ephedrine at the ephedrine- alkaloid levels recommended by Plaintiffs, that is, 10 mg per day.

References 86 and 87 are excerpts from the transcript of the FDA's Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids Meeting held on August 26-27, 1996. The transcript demonstrates that several physicians and researchers were unable to conclude that there is a safe dosage level for EDS. For example, Dr. Georgitis stated, "I obviously cannot identify [a safe level]. There's no scientific data which shows that 1 milligram is any better than 5, which is any better than 10, which is any better than 30, and that goes both for the ephedrine alkaloid and for ephedrine itself." Reference 86 at 136. Dr. Ricaurte noted that part of the difficulty in identifying a safe level of EDS is that "[t]here is uncertainty . . . [in] the available data with regard to the ephedrine alkaloids themselves[.]" Id. at 221. Dr. Marangell expressed concern regarding "the serious adverse events in the 1- to 5- milligram range. . . . [W]e don't have a lot of data on that, and perhaps for many people that's fine, but . . . individual variation is going to play as much of a role as a particular dose level is." Id. at 229. Reference 87 duplicates much of what is discussed in Reference 86.

In sum, those present at the meeting concluded that it is difficult or impossible to identify any safe recommended dosage level for EDS.

II. Analysis

The parties' motions ask the court to determine whether the Final Rule banning all EDS violates 21 U.S.C. 342(f). To resolve this issue the court must answer: first, whether the FDA's use of a risk-benefit analysis is appropriate under the DSHEA; and second, whether the FDA has provided sufficient evidence to support the conclusion that EDS containing 10 mg or less per day of ephedrine alkaloids pose a significant or unreasonable risk of illness of injury.[5]

[3] A pharmacokinetic analysis is one which examines the bodily absorption, distribution, metabolism, and excretion of drugs. Webster's New Collegiate Dictionary 852 (G. & C. Merriam 1979).

[4] In Reference 84, Dr. Inchiosa indicates that various studies have shown that epinephrine is between 41 and 69 times more potent than ephedrine. These potency ratios serve as the basis of his analysis. Reference 84 at 4-5.

[5] Because of the court's answers to these two questions, it need not determine whether the FDA properly omitted the term "significant" from its construction of the statute or whether it complied with the notice and comment procedures of the APA.

A Scope of Review

While styled as cross-motions for summary judgment, this is actually an appeal from the decision of an administrative agency. Accordingly, the court must apply the standards for an appeal. See Olenhouse v. Commodity Credit Corp., 42 F.3d 1560, 1580 (10th Cir. 1994); Southern Utah Wilderness Alliance v. B.L.M., 147 F.Supp. 2d 1130, 1135-36 (D.Utah 2001). In a review of an administrative decision under the APA, the parties are typically not permitted to supplement the evidence in the administrative record. See e.g., Roberts v. Morton, 549 F.2d 158, 160 (10th Cir. 1976) ("Such review is confined to the agency record or such portions of it which the parties may cite, and additional evidence is not to be admitted.") (citing Nickol v. United States, 501 F.2d 1389, 1390 (10th Cir. 1974)).

B. Deference

The final sentence of 21 U.S.C. §342(f) provides that: "The court shall decide any issue under this paragraph on a de novo basis." The parties agree that this provision requires the court to examine all factual determinations on a de novo basis. The parties do not agree, however, on whether the court should review the FDA's statutory construction de novo or whether the court should accord the FDA's conclusions deference under Chevron USA, Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984). The court, reviewing the Final Rule under Chevron, need not reach the question of whether the FDA's statutory construction should be reviewed de novo.

Under Chevron, a court must first determine whether Congress has spoken to the precise question at issue. Chevron, 467 U.S. at 842; see also FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000); Pharmanex v. Shalala, 221 F.3d 1151, 1154 (10th Cir. 2000). If Congress' intent is clear and unambiguous, the analysis is complete and Congress' intent controls. "In a statutory construction case, the beginning point must be the language of the statute, and where the statute speaks with clarity to an issue[,] judicial inquiry into the statute's meaning . . . is finished." Estate of Cowart v. Nickols Drilling Co., 505 U.S. 469, 475 (1992).

"As a general rule of statutory construction, a statute is ambiguous if it is 'capable of being understood in two or more possible senses or ways.'" Houghton ex. rel. Houghton v. Reinertson, 382 F.3d 1162, 1169 (10th Cir. 2004) (quoting Chickasaw Nation v. United States, 534 U.S. 84, 90 (2001)); see also, Allen v. Geneva Steel Co., 281 F.3d 1173, 1178 (10th Cir. 2002) ("[A]mbiguity exists when a statute is capable of being understood by reasonably well-informed persons in two or more different senses.") (quotation omitted). The ambiguity of a statute is determined "by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." Houghton, 382 F.3d at 1169 (citing Robinson v. Shell Oil Co., 519 U.S. 337, 341 (1997)).

If a court finds that the statute is silent or ambiguous as to the specific issue, the question is whether the agency's answer is "based on a permissible construction of the statute." Chevron, 467 U.S. at 842-43. Under Chevron, a court must accord deference to an administrative agency's reasonable interpretation of a statute. Chevron, 467 U.S. at 843-44 & n.11; see also United States v. Mead Corp., 533 U.S. 218, 229 (2001) ("reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular statutory ambiguity simply because the agency's resolution seems unwise") (citations omitted). A court must "give effect to the agency's interpretation unless it is arbitrary, capricious, or manifestly contrary to the statute." Pharmanex, 221 F.3d at 1154. The decision as to what a statute means, however, is "the

quintessential judicial function." BATF v. FLRA, 464 U.S. 89, 98 (1983). The question of statutory interpretation ultimately rests with the court. Chevron, 467 U.S. at 843 n. 9.

With these principles in mind, the court turns to the questions at issue.

C. Was the FDA's use of a risk-benefit analysis appropriate under the DSHEA?

In promulgating the Final Rule, the FDA relied upon a risk-benefit test to determine whether the risk presented by EDS is unreasonable and argues that this is a proper construction of the statute. 69 Fed. Reg. at 6788. Plaintiffs have asserted that the application of this test is an improper interpretation of the statute because it adds language not intended by Congress and has the effect of shifting the burden of proof from the government to the manufacturers of EDS contrary to Congress' intent to harmonize the treatment of dietary supplements with that of food generally. The plain language of the DSHEA does not require a comparison of benefits and risks.

The pertinent portion of 21 U.S.C. 342(f) states that a dietary supplement shall be deemed adulterated if it "presents a significant or unreasonable risk of illness or injury." 21 U.S.C. 342(f)(1)(A). The FDA contends that the plain meaning of the term "unreasonable" in the statute requires a risk-benefit analysis: "In the absence of a sufficient benefit, the presence of even a relatively small risk of an important adverse health effect to a user may be unreasonable." 69 Fed. Reg. at 6788. The FDA argues that this construction is consistent with Congress' definition of the term "unreasonable risk" in other parts of the same statute and other portions of similar statutes. Specifically, the FDA refers the court to the provisions of the FDCA governing medical devices and also the Toxic Substances Control Act ("TSCA"). See 21 U.S.C. §360c(a)(1); H. Rep. 94-853, 94th Cong. 2d Sess. 19 (1976) ("the requirement that risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against the benefits of use."); 15 U.S.C. §2605(a); H. Rep. 94-1341, 94th Cong., 2d Sess. 14 (1976) (defining "unreasonable risk" in the context of the TSCA as "balancing the probabilities that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture").

Defendants' reliance on the medical device provisions of the FDCA to justify the inclusion of a risk-benefit test for dietary supplements is misplaced. The provision governing the safety and effectiveness of medical devices specifically calls for a risk-benefit analysis:

> For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined--
>
> . . .
>
> (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. § 360c(a)(2) (emphasis added). The DSHEA contains no such provision. Unlike medical devices and drugs, dietary supplements are not classified on the basis of a risk-benefit analysis. Cf. 21 U.S.C. §§ 355(b) (requiring that an application for a new drug show that it is effective for its intended use); 360c(a)(1)(A),(B) & (C) (all three classes of medical devices have effectiveness requirements).

The FDCA, in defining dietary supplements, states: "Except for the purposes of section 201(g), a dietary supplement shall be deemed a food within the meaning of this Act." 21 U.S.C. § 321(ff). A brief look at the legislative history of the DSHEA indicates that Congress generally intended to harmonize the treatment of dietary supplements with that of foods when it added the dietary supplement subsection to the food adulteration provision. Sen. Rep. No. 103-410 at 21

("Section 402 [of the FDCA] is the provision that establishes the grounds upon which the [FDA] may deem a food (including a dietary ingredient) to be adulterated"). "Under present law, a dietary supplement, as with any food, is presumed to be safe." Id. at 22 (emphasis added). Food producers are not required to establish a benefit before sale.[6]

The FDA's imposition of a risk-benefit analysis places a burden on the producers of EDS to demonstrate a benefit as a precondition to sale, and that is contrary to Congress' intent. Congress unequivocally stated that "[i]n any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. 342(f). Proof of adulteration is the sole responsibility of the FDA: "[A dietary supplement, as with any food,] may be lawfully marketed, unless and until the FDA, by a preponderance of the evidence, shows that the supplement is 'injurious to health.'" Sen. Rep. No. 103-410 at 21. The imposition of a risk-benefit analysis requires the producer of an EDS to establish a benefit and alleviates the burden Congress placed squarely on the government to demonstrate the existence of a significant or unreasonable risk.

For the above reasons, the court concludes that the FDA's requirement that EDS demonstrate a benefit is contrary to the clear intent of Congress. For those same reasons, the FDA's definition of "unreasonable" entailing a risk-benefit analysis is also improper.

D. Has the FDA provided evidence to support the conclusion that EDS containing 10 mg or less per day of ephedrine alkaloids pose a significant or unreasonable risk of illness of injury?

Under 21 U.S.C. §342(f), "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." The government must establish that EDS pose a significant or unreasonable risk by a preponderance of the evidence. See Sen. Rep. No. 103-410 at 36 ("By the last sentence of [§342(f)], it is intended to codify current law that the government bear the burden of proving dietary supplements adulterated. The government must produce the preponderance of the evidence as to the harmful effects from the dietary supplement when used as recommended and suggested in the labeling." (citing United States v. 71/55 Gallon Drums of Stuffed Green Olives, 790 F. Supp. 1379 (N.D. Ill. 1992)).[7]

The statute reads that the government's burden is met only if it has demonstrated the presence of a risk "under conditions of use recommended or suggested in labeling." 21 U.S.C. §342(f)(1)(A)(i). The plain language of the statute requires a dose-specific analysis. Legislative history also confirms Congress' intent to require that a finding of adulteration be dose-specific: "a safety finding cannot be entered against a supplement based upon a dosage not recommended to consumers in the labeling." Sen. Rep. No. 103-410 at 36.

Simply stated, to declare all EDS adulterated, as it has done, the FDA must prove that any dose amount, no matter how small, presents a significant or unreasonable risk of illness or injury. Specifically, because the Plaintiffs' suggested dosage recommends no more than 10 mg of ephedrine alkaloids per day, the proper focus here is on the evidence the FDA presented regarding the risks of low-dose EDS. To this end, the Defendants have directed the court specifically to 69

[6] As pointed out by Plaintiffs, if food producers were required to show a benefit as a precondition to sale, the sale of foods such as potato chips might be prohibited.

[7] The courts have long required the FDA to prove adulteration by a preponderance of the evidence. See United States v. 5 Cases More of Less Containing 'Figlia Mia Brand', 179 F.2d 519, 524 (2d Cir. 1950) ("This is a civil proceeding in which the usual rule as to burden of proof [preponderance of the evidence] prevails."); 71/55 Gallon Drums of Stuffed Green Olives, 790 F. Supp. at 1382 ("The burden of proof rests on the government to establish by a 'fair preponderance of the evidence' that the article of food is adulterated within the meaning of §342(a)(3)." (citation omitted)); see also United States v. Tins of Strawberries, 175 F. Supp. 694, 699 (D.Ark. 1959); United States v. Anderson Seafoods, Inc., 447 F. Supp. 1151 (N.D.Fla. 1978) ("A preponderance of the evidence shows that some unquantified portion of the mercury in swordfish is attributable to the acts of man.").

Fed. Reg. 6788, References 84, 85, 86, and 87.

Reference 84, the Inchiosa review, concludes that "a chronic ephedrine dose of 1.5 mg every 4 hours" (a daily dose of 9 mg) would cause "increases in heart rate and systolic blood pressure." Reference 84 at 4. This conclusion, contained in one six-page letter to the FDA, is the only specific reference in the administrative record to the effects of low-dose EDS. The Inchiosa review derives the potential physiological effects of orally ingested ephedrine from data obtained regarding intravenous injections of epinephrine. He used a hypothetical mathematical model to perform a pharmacokinetic analysis of the effects of ephedrine alkaloids. There is no specific data involving the oral ingestion of 10 mg per day of EDS.[8]

Dr. Inchiosa's conclusions rest on a comparison of potency rates between epinephrine and ephedrine alkaloids. Dr. Inchiosa reviewed studies indicating that epinephrine is between 41 and 69 times more potent than ephedrine. Id. at 1-2. The data and its application to ephedrine alkaloids are applicable only upon acceptance of Dr. Inchiosa's mathematical model. In Reference 85, however, Dr. Inchiosa also states that the onset of the effects of ephedrine alkaloids would vary depending on the source of the alkaloids and the actual rates of absorption which weakens his general conclusions regarding the intake of low-dose EDS. Reference 85 at 1-2. Dr. Inchiosa's conclusion that 9 mg per day of ephedrine alkaloids produces negative health effects is based upon chronic intake, which is not the condition of use suggested on the labeling of Plaintiffs' product. This evidence cannot, on its own, support a conclusion that a recommended dose of 10 mg per day of EDS presents a significant or unreasonable risk.

Dr. Inchiosa also states that he cannot determine a safe level of EDS intake. This sentiment is echoed throughout the transcript of the FDA's Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids Meeting held on August 26-27, 1996 (References 86 and 87). Several of the meeting's attendees made comments that a safe level could not be determined. There was, apparently, not enough evidence to support the conclusion that there is a safe level of intake for EDS.

A negative inference is different from the affirmative proof required by 21 U.S.C. 342(f). The statute requires an affirmative demonstration of "significant or unreasonable" risk at a particular dose level to support a finding of adulteration. There is not sufficient evidence in the administrative record to establish that the risks identified by the FDA are associated with the intake of low-dose EDS. The statement that a safe level cannot be determined is simply not sufficient to meet the government's burden. To find otherwise would be to place the burden on the manufacturers of EDS to show that their recommended dosages are safe. This would be directly contrary to the statutory language placing the burden of proof on the government and to the intent of Congress in regulating dietary supplements as food.

The FDA, by failing to prove by a preponderance of the evidence that a dosage of 10 mg or less of ephedrine alkaloids presents a significant or unreasonable risk of illness or injury, has failed to give effect to the dose-specific language of 21 U.S.C. §342(f)(1)(A)(i).

[8]The only dose-specific data provided by Dr. Inchiosa pertaining to low-dose EDS is that the harmful effects of ephedrine would be felt with a "chronic ephedrine dose of 1.5 mg every four hours." Reference 84 at 4. This data was derived not from a study involving the oral ingestion of ephedrine alkaloids, but from a derivative analysis relying on Dr. Inchiosa's mathematical model.

ORDER

Accordingly, Plaintiffs' motion for summary judgment (Dkt. 7) is GRANTED and Defendants' cross-motion for summary judgment (Dkt. 14) is DENIED.

The court remands to the FDA for further rulemaking consistent with this Order and enjoins Defendants from taking enforcement action against Plaintiffs for their sale of a dietary supplement containing 10 mg or less of ephedrine alkaloids per daily dose.

SO ORDERED this 13 day of April, 2005.

BY THE COURT:
Tena Campbell
TENA CAMPBELL
United States District Judge

F I L E D
United States Court of Appeals
Tenth Circuit

August 17, 2006

Elisabeth A. Shumaker
Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

NUTRACEUTICAL CORPORATION; SOLARAY, INC.,

Plaintiffs-Appellees,

v.

ANDREW VON ESCHENBACH, Acting Commissioner, U.S. Food and Drug Administration; UNITED STATES FOOD AND DRUG ADMINISTRATION; MICHAEL O. LEAVITT, Secretary of the Department of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES OF AMERICA,

Defendants-Appellants.

No. 05-4151

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
(D.C. No. 2:04-CV-00409-TC)

Christine N. Kohl, Attorney (Peter D. Keisler, Assistant Attorney General, Paul M. Warner, United States Attorney, Jeffrey Bucholtz, Deputy Assistant Attorney General, and Douglas N. Letter, Attorney, Department of Justice, Washington, D.C., and Paula M. Stannard, Acting General Counsel, Sheldon T. Bradshaw, Associate General Counsel, Eric M. Blumberg, Deputy Chief Counsel, and Claudia J. Zuckerman, Associate Chief Counsel, Office of General Counsel, U.S. Department of Health & Human Services, Food and Drug Division, Rockville, Maryland, with her on the briefs), for Defendants-Appellants.

Jonathan W. Emord (Andrea G. Ferrenz with him on the brief), Emord & Associates, P.C., Reston, Virginia for Plaintiffs-Appellees.

Before **KELLY, TYMKOVICH**, Circuit Judges and **EAGAN**,[*] District Judge.

EAGAN, District Judge.

Defendants-appellants, Andrew von Eschenbach, M.D., Acting Commissioner of the U.S. Food and Drug Administration, the United States Food and Drug Administration ("FDA" or "the agency"), Michael O. Leavitt, Secretary of the Department of Health and Human Services, the Department of Health and Human Services, and the United States, appeal from a judgment of the district court denying their motion for summary judgment and granting the cross-motion of plaintiffs-appellees for summary judgment. Nutraceutical Corp. v. Crawford, 364 F. Supp. 2d 1310 (D. Utah 2005). Plaintiffs-appellees, Nutraceutical Corporation and its wholly-owned subsidiary, Solaray Corporation (collectively, "Nutraceutical"), manufacture and sell Ephedra, a product containing ephedrine-alkaloid dietary supplements ("EDS"). In 2004, the FDA issued a regulation which banned all EDS sales in the United States market. Nutraceutical brought this action challenging the regulation as unlawful. The district court agreed with Nutraceutical. Id. at 1321. Our jurisdiction arises under 28 U.S.C. § 1291, and we reverse.

Background

In its published decision, the district court determined that the risk-benefit analysis employed by the FDA to support an EDS ban was contrary to the intent of Congress and that the FDA had failed to prove by a preponderance of the evidence that EDS pose an unreasonable risk of illness or injury at 10 milligrams ("mg") or less a day. Nutraceutical, 364 F. Supp. 2d 1310. It accordingly entered summary judgment in favor of Nutraceutical, enjoined the FDA from enforcing its proscription against Nutraceutical for the sale of products with a recommended daily dosage of 10 mg or less of EDS,[1] and remanded to the FDA for new rule-making.

The issues raised by this appeal are: (1) whether the FDA correctly interpreted the relevant statute to require a risk-benefit analysis in determining if a dietary supplement presents an "unreasonable risk of illness or injury"; and (2)

[*] The Honorable Claire V. Eagan, District Judge, United States District Court for the Northern District of Oklahoma, sitting by designation.

[1] To the extent that we recognize Nutraceutical's product as recommending less than 10 mg of ephedrine alkaloids per day, Nutraceutical's Motion to Correct Oral Argument Record, filed on May 11, 2006, is granted.

whether the FDA satisfied its burden of proving that dietary supplements containing EDS present an unreasonable risk of illness or injury when doses of 10 mg or less per day are suggested or recommended in labeling.

Nutraceutical alleges that the FDA lacked statutory authority to promulgate and enforce a ban of all EDS. The FDA argues that it acted pursuant to the broad authority delegated to it by the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, et seq., to regulate dietary supplements for safety. The FDCA provides the FDA with broad authority to regulate food, drug, and dietary supplement products in order to ensure public health and safety. Id. In 1994, Congress amended the FDCA with the Dietary Supplement Heath and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994). Under DSHEA, the FDA regulates vitamins, minerals, herbs, amino acids, and other dietary substances. Dietary supplements are generally regulated in a manner similar to food and the FDA is authorized to prevent adulterated products from entering the market. See 21 U.S.C. § 331(a), (b), (c), (k) (adulteration and distribution of adulterated food are prohibited acts). Congress declared that a dietary supplement is "adulterated":

> If it is a dietary supplement or contains a dietary ingredient that--
> (A) presents a significant or unreasonable risk of illness or injury under--
> (i) conditions of use recommended or suggested in labeling, or
> (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use; . . .

21 U.S.C. § 342(f)(1). The FDA argues that EDS are adulterated and points to the "unreasonable risk of illness or injury" provision of DSHEA as the primary source of statutory authority for its EDS ban. 21 U.S.C. § 342(f)(1)(A).

Ephedrine alkaloids are a class of structurally-related chemical stimulants that occur naturally in some botanicals. In the 1980s and 1990s, manufacturers promoted the sale of EDS for weight loss and athletic performance enhancement. In the 1990s, the FDA received numerous Adverse Event Reports ("AERs") which documented harmful side effects, including heart attacks, strokes, seizures, and death, associated with EDS intake.[2] Based on the circumstantial evidence of the AERs, the FDA began to investigate the effects of EDS. The investigation included a literature review of scientific studies and a Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids Meeting held on August 26-27, 1996 ("1996 Food Advisory Committee"). In 1997, the agency proposed a regulation which would have required specific warnings and established a dosage regimen. 62 Fed. Reg. 30,678 (June 4, 1997).

The FDA's 1997 proposed regulation of EDS faced substantial opposition, including from the General Accounting Office ("GAO"). The GAO determined that the FDA had not been thorough in its investigation and requested further

[2] The FDA established the MedWatch program to monitor AERs associated with nutritional products, including dietary supplements. This program relies on voluntary reporting from public health agencies, health professionals, and consumers. See FDA MedWatch Home Page, http://www.fda.gov/medwatch/.

research. See GAO, Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids 11 (1999). Responding to the GAO's concerns, the FDA withdrew the 1997 proposed regulation. 65 Fed. Reg. 17,474 (Apr. 3, 2000).

The FDA continued to receive AERs and compile scientific literature regarding EDS. Given the fact that dietary supplement manufacturers are not required to submit scientific data on their products, the body of scientific literature on EDS was limited. Among the studies on which the FDA relied was a report commissioned by the National Institutes of Health. To further supplement the record, the agency hired Mario A. Inchiosa, Jr., Ph.D.,[3] to conduct further research on the health effects of EDS in 1999. During the public notice and comment period, Nutraceutical submitted to the FDA several requests for an exemption of low-dosage EDS, to no avail. The administrative record grew to over 130,000 pages, approximately 19,000 AERs were collected,[4] and extensive public notice and comment resulted in over 48,000 comments.

After seven years of investigating EDS, the FDA adopted a regulation which banned EDS at all dosage levels from the national market. Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788 (Feb. 11, 2004) ("Final Rule"). In the Final Rule, the FDA concluded that "[t]he best clinical evidence for a benefit . . . supports only a modest short-term weight loss, insufficient to positively affect cardiovascular risk factors or health conditions associated with being overweight or obese." Id. at 6789. Based on this risk-benefit analysis, the FDA determined that all EDS present an "unreasonable risk of illness or injury" under all ordinary or recommended conditions of use. Id. at 6788. As such, the Final Rule classified EDS adulterated within the meaning of DSHEA.

The district court held that "the FDA's requirement that EDS demonstrate a benefit is contrary to the clear intent of Congress" and found the agency's definition of "unreasonable" as entailing a risk-benefit analysis to be improper. 364 F. Supp. 2d 1310, 1319. The district court also found that the FDA failed "to prove by a preponderance of the evidence that a dosage of 10 mg or less of ephedrine alkaloids presents a significant or unreasonable risk of illness or injury." Id. at 1321. Based on these findings, the district court granted summary judgment for plaintiffs and denied summary judgment for defendants.

[3] Professor of Pharmacology, New York Medical College.

[4] The AERs which were voluntarily submitted to the FDA were supplemented with 16,000 complaints received by Metabolife, one of the largest distributors of EDS. 364 F. Supp. 2d at 1315; see GAO, Dietary Supplements: Review of Health-Related Call Records for Users of Metabolife 356 (GAO-03-494) (2003).

Discussion

Standard of Review

The district court's conclusions as to whether the FDA had acted pursuant to congressionally delegated authority in promulgating a rule is reviewed de novo. However, the parties dispute the appropriate standard of review of the administrative decision. DSHEA provides that: "The court shall decide any issue under this paragraph on a de novo basis." 21 U.S.C. § 342(f). The district court did "not reach the question of whether the FDA's statutory construction should be reviewed de novo." 364 F. Supp. 2d at 1317. In the interest of clarity and consistency, we now reach this question.

Courts are to review agency actions under DSHEA using the "traditional tools of statutory construction." Pharmanex v. Shalala, 221 F.3d 1151, 1154 (10th Cir. 2000). The de novo standard, under section 342(f), applies to enforcement actions by the United States against manufacturers of dietary supplements. Such enforcement actions may result in imprisonment or monetary fines. 21 U.S.C. § 333; see United States v. Park, 421 U.S. 658 (1975). Reading the statute as a whole, it is clear that the de novo standard applies when courts "decide" matters rather than when they "review" administrative decisions. As such, it is appropriate to limit the de novo standard of review, which affords the FDA no deference, to enforcement proceedings. Challenges by private parties to FDA rules promulgated under DSHEA are reviewed pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and "the normal rules for judicial deference regarding agency action apply." NVE, Inc. v. HHS, 436 F.3d 182, 196 (3rd Cir. 2006). "Had Congress intended to supplant the well-established procedures for APA challenges, it would have been clearer about its objective." Id. at 194.

Chevron Analysis

A court reviewing the FDA's construction of the FDCA must determine: whether Congress has directly spoken to precise question at issue; and if not, then whether agency's construction of statute is permissible one. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). In reviewing the FDA's interpretation of DSHEA under Chevron, we ask two questions:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress [Chevron step 1]. But if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. If Congress has explicitly or implicitly delegated authority to an agency, legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute [Chevron step 2].

Seneca-Cayuga Tribe of Oklahoma v. National Indian Gaming Com'n, 327 F.3d 1019, 1037 (10th Cir. 2003) (citations omitted).

The APA reflects the principles of Chevron and "provides that agency action must be set aside if the action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements." Valley Cmty. Pres. Comm'n v. Mineta, 373 F.3d 1078, 1084 (10th Cir. 2004) (internal quotation omitted) (citing 5 U.S.C. § 706). "When we review an agency's decision under the arbitrary, capricious or abuse of discretion standard [of the APA], our review is narrow and deferential; we must uphold the agency's action if it has articulated a rational basis for the decision and has considered relevant factors." Slingluff v. Occupational Safety & Health Review Comm'n, 425 F.3d 861, 866 (10th Cir. 2005) (citing Mountain Side Mobile Estates P'ship v. Sec'y of HUD, 56 F.3d 1243, 1250 (10th Cir. 1995)). Under the APA, regulations are presumed to be valid, and review is deferential to the government agency.

"Unreasonable Risk"

In this case, we must determine whether Congress unambiguously manifested its intent to restrict the FDA from weighing benefits when determining the risk posed by a dietary supplement. The district court was correct to proceed under Chevron step one in deciding the question of whether the FDA properly used a risk-benefit analysis in determining whether EDS pose an "unreasonable risk." Chevron, 467 U.S. at 843. We nevertheless reverse the district court after finding that Congress unambiguously required the FDA to conduct a risk-benefit analysis under DSHEA.

In 1994, Congress enacted DSHEA to clarify that dietary supplements, absent declarations promoting the supplements as drugs, would be regulated in a manner similar to food products. Accordingly, in the interest of public health, Congress imposed a duty on the FDA to keep adulterated dietary supplements off the market. 108 Stat. at 4326 (instructing the FDA to "take swift action against [dietary supplements] that are unsafe or adulterated."). DSHEA classifies a dietary supplement as adulterated if it "presents a significant or unreasonable risk of illness or injury." 21 U.S.C. § 342(f)(1). The FDA understood "[t]he plain meaning of 'unreasonable' . . . [to] connote[] comparison of the risks and benefits of the product." 69 Fed. Reg. 6788, 6823 (2004). We agree. The plain language of the statute directs the FDA to restrict distribution of dietary supplements which pose any risk that is unreasonable in light of its potential benefits. See Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (unanimously finding that "unreasonable risk," as used in another FDCA provision, 21 U.S.C. § 355(i)(3)(B)(I), "involves a comparison of the risks and the benefits . . . .").

Congress enacted DSHEA in an effort to improve public access to dietary supplements based on the belief that there may be a positive relationship between dietary supplement use, reduced health-care expenses, and disease prevention. See Pharmanex, 221 F.3d at 1158-59 ("It is true that DSHEA was enacted to

alleviate the regulatory burdens on the dietary supplement industry, allowing consumers greater access to safe dietary supplements in order to promote greater wellness among the American population.") (citation omitted). The FDCA should not be read too restrictively but in manner consistent with the statute's overriding purpose to protect public health. See 21 U.S.C.A. § 301 et seq.; United States v. Rx Depot, Inc., 438 F.3d 1052, 1061 (10th Cir. 2006) ("The FDCA's primary purpose is to protect the public health.") (citing United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969)). Accordingly, DSHEA should receive a liberal construction where the FDA has taken remedial steps in response to a perceived public health problem.

According to the district court, by injecting a risk-benefit analysis, the FDA required Nutraceutical to make a showing of the benefits of its product. However, at no time has the FDA required manufacturers of EDS to provide data on the benefits of their products. Rather, the FDA has assumed its responsibility of gathering data, soliciting comments, and conducting the risk-benefit analysis.[5]

[5] The district court compared the language of DSHEA to the statutory language governing medical devices and drugs and concluded that, unlike manufacturers of medical devices and drugs, manufacturers of dietary supplements do not need to prove effectiveness prior to taking their product to market. 364 F. Supp. 2d at 1318 ("A brief look at the legislative history of the DSHEA indicates that Congress generally intended to harmonize the treatment of dietary supplements with that of foods when it added the dietary supplement subsection to the food adulteration provision."). The district court is correct. However, the district court confused effectiveness with safety. The FDA did not ban EDS for failing to deliver promised health gains or for ineffectiveness; the FDA banned EDS because they were determined to be unsafe.

Congress expressly placed the burden of proof on the government to determine whether a dietary supplement is adulterated. Accordingly, EDS were allowed to enter the market without findings of safety or effectiveness. The FDA did not impose a pre-market requirement for the sale of EDS. For example, Nutraceutical has been selling EDS since 1988. As dictated by the statutory scheme, the FDA assumed the duty of post-market surveillance and imposed the EDS ban following numerous AERs, public notice and comment, and significant scientific review. See 69 Fed. Reg. 6788. Based on the record, we disagree with the district court and find that the FDA did not shift the burden of proof to manufacturers. The risk-benefit analysis is conducted by, and at the expense of, the agency. Id. at 6798 ("the agency performs a risk/benefit analysis to ascertain whether the risks of the product outweigh its benefits."). Despite Nutraceutical's characterization of the process, the agency did not "require[] proof of a substantial benefit to counterbalance risk as a condition precedent to lawful sale of EDS." Appellee's Brief, at 5. The burden remains on the agency to show that risks associated with a dietary supplement outweigh benefits and are, therefore, unreasonable. Thus, a risk-benefit analysis does not undermine congressional intent by improperly shifting the burden of proof onto manufacturers of dietary supplements.

Under the rules of statutory construction, courts consider the whole act and evaluate terms in context. Pharmanex, 221 F.3d at 1154 ("we examine the statutory provision in context."). The rule against surplusage encourages courts

to give meaning to every word used in a statute to realize congressional intent. In effect, this rule embodies the belief that Congress would not have included superfluous language. Thus, in DSHEA, an "unreasonable risk" has a meaning independent from a "significant risk." The plain meaning of a "significant risk" is a great danger. "Unreasonable risk" is a distinct term and requires more than evaluation of the significance of risk. "A risk could be significant but reasonable if the benefits were great enough to outweigh the risks." 69 Fed. Reg. at 6823. In other words, an "unreasonable risk" is relative to the circumstances; the potential risk is more "unreasonable" if the potential benefit is smaller. See Castrignano v. E.R. Squibb & Sons, Inc., 900 F.2d 455, 459 (1st Cir. 1990) (upholding jury instructions which define "unreasonable" as the "balance between the expected beneficial effects of the [product] as opposed to its harmful effects, if any."). The district court erred by conflating the terms "significant" and "unreasonable," thereby rendering "unreasonable" superfluous. In contrast to "significant risk," "unreasonable risk" accounts for whether the benefits justify the risks. The use of "unreasonable" to qualify risk in addition to "significant" makes it clear that Congress intended to integrate a risk-benefit analysis in the former. Thus, because we find the statute is clear, we now review the FDA's absolute prohibition of EDS under the APA.

"Conditions of Use"

Under DSHEA, the government bears the burden of proof to show that, "under conditions of use recommended or suggested in labeling," a dietary supplement is adulterated. 21 U.S.C. § 342(f)(1)(A)(i). It is undisputed that the FDA must consider the dosage recommended in a dietary supplement's labeling when making an adulteration determination under section 342(f)(1)(A). The district court held that the FDA failed "to prove by a preponderance of the evidence that a dosage of 10 mg or less of ephedrine alkaloids presents a significant or unreasonable risk of illness or injury, [and] has failed to give effect to the dose-specific language of [] § 342(f)(1)(A)(I)." 364 F. Supp. 2d at 1321.

In determining that EDS pose an "unreasonable risk of illness or injury," the FDA found that the weight loss and other health benefits possible from the use of EDS were dwarfed by the potential long-term harm to the user's cardiovascular system. The agency went on to enact a complete ban on the product after making a finding that any amount of EDS had negative ramifications on the cardiovascular system and, based on the FDA's analysis, EDS provided no benefits so great as to justify such risk.

The preponderance of the evidence standard[6] requires the party with the burden of proof to support its position with the greater weight of the evidence.

[6] Congress did not prescribe the quantum of proof required under DSHEA. Accordingly, the standard traditionally applied in administrative cases, the preponderance of the evidence standard, governs. See Steadman v. SEC, 450 U.S. 91, 95, 102 (1981).

See Metropolitan Stevedore Co. v. Rambo, 521 U.S. 121, 137-38 n.9 (1997) (explaining that the preponderance of the evidence standard "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence . . . .") (citation omitted); Vesper Const. Co., Inc. v. Rain for Rent, Inc., 602 F.2d 238, 242 (10th Cir. 1979) ("by the greater weight of the evidence or, as it is sometimes called, the preponderance of the evidence."). The evidence relied on by the FDA to enact its ban of EDS covers over seven years of agency review, public notice and comment, peer-reviewed literature, and scientific data. It is the purview of the FDA to weigh the evidence, including the evidence submitted by Nutraceutical and other manufacturers during public notice and comment.

It is noteworthy that Nutraceutical relies on the 1999 GAO report to support its contention that the Final Rule lacks support. However, the GAO has since updated its findings and arrived at conclusions in support of the Final Rule. See GAO, Dietary Supplements: Review of Health-Related Call Records for Users of Metabolife 356 (GAO-03-494) (2003). Based on scientific data and AERs, the GAO concluded that EDS pose a significant risk of cardiovascular and nervous system effects among consumers who are young to middle-aged. See GAO, Dietary Supplements Containing Ephedra, Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives (July 23, 2003); 69 Fed. Reg. at 6818 (GAO found that AERs "were consistent with . . . the scientifically documented pharmacological and physiological effects of ephedrine alkoids.").

The FDA hired Dr. Inchiosa to study the effects of EDS on human health in 1999. Dr. Inchiosa used principles of pharmacokinetics[7] to examine the effects of ingestion of EDS on the human cardiovascular system. Dr. Inchiosa found that ephedrine would be expected to produce the same adverse cardiovascular effects (increased heart rate and blood pressure) as a comparable dose of the pharmacologically-related drug, epinephrine,[8] and that, consequently, no dose of ephedrine can be considered safe. Nutraceutical raises objections to Dr.

[7] A pharmacokinetic analysis is one which examines the bodily absorption, distribution, metabolism, and excretion of drugs. Merriam Webster's Collegiate Dictionary 871 (10th ed.1994).

[8] To reach his conclusions, Dr. Inchiosa relied on a peer-reviewed study of the effect of epinephrine in humans. William E. Clutter, et al., Epinephrine Plasma Metabolic Clearance Rates and Physiologic Thresholds for Metabolic and Hemodynamic Actions in Man, 66 J. Clin. Invest. 94 (July 1980). The Clutter study revealed significant increases in heart rate and blood pressure from epinephrine infusion at the rate of 0.5 µg/minute.

Inchiosa's study and methodology which it did not raise during the rulemaking.[9] Nutraceutical argues that Dr. Inchiosa's work is irrelevant to the effect of its low-level dosage EDS product because his study examined the impact of continuous injection of epinephrine into the bloodstream rather than ingestion of pills containing 10 mg or less of EDS.[10] The district court rejected the "mathematical model used [by Dr. Inchiosa] to compare doses of epinephrine to ephedrine." 364 F. Supp. 2d at 1315. To account for the different potency levels of ephinephrine and ephedrine, Dr. Inchiosa factored the greater potency of ephinephrine into his calculations. Dr. Inchiosa's work indicates that he exaggerated margins of error in order to come to a conservative conclusion that the cardiovascular effects produced by a dose of 9 mg of EDS daily may be dangerous.

[9] Although Nutraceutical did not specifically object to Dr. Inchiosa's study and methodology during rulemaking, it did not thereby waive its objection. In a review of the decision of an administrative agency, a party waives its right to appeal an issue if it fails to object through comments or documents in the record. New Mexico Environmental Imp. Div. v. Thomas, 789 F.2d 825, 835 (10th Cir. 1986) (when agency solicited comments on the very issue being challenged, party "was obligated to make its record before the agency."); American Frozen Food Institute v. Train, 539 F.2d 107, 134 (D.C. Cir. 1976) ("What the industry failed to present to the Administrator during rulemaking procedures when specifically asked to comment cannot now be urged [as] a basis for invalidation [of the rule]."); see also Fuel Safe Washington v. F.E.R.C., 389 F.3d 1313 (10th Cir. 2004); Kennecott Copper Corp. V. E.P.A., 612 F.2d 1232, 1245 (10th Cir. 1979) ("it is well settled that industry must first utilize the opportunity for comment [on an agency regulation] before it may raise issues on appeal."). While Nutraceutical did not object to Dr. Inchiosa's study on the record, it did advance dissatisfaction with the scientific evidence relied on by the FDA during the rulemaking. Appellee's App., at 159-60 ("Nutraceutical submits these comments to show that there is absolutely no basis for concluding that [] whole-herb ephedra supplement products present a significant or unreasonable risk . . . ."). The FDA solicited comments on "new scientific evidence . . . concerning health risks associated with the use of dietary supplements containing ephedrine alkaloids." 68 Fed. Reg. 10417 (March 5, 2003). Dr. Inchiosa's study was not among the evidence referenced in the FDA's March notice. Id. Given that the FDA did not specifically ask for comments on Dr. Inchiosa's study and Nutraceutical did object to the new scientific evidence generally, it is appropriate for us to consider Nutraceutical's objections to Dr. Inchiosa's study in particular.

[10] Nutraceutical's conclusory allegation that there is insufficient science to support the FDA's conclusion that increased heart rate and blood pressure correlate to increased risk of cardiovascular disease is contrary to the vast scientific evidence in the administrative record.

Further, the FDA did not rely on Dr. Inchiosa's work alone.[11] The FDA's investigation also considered the findings of the National Institutes of Health, the GAO, and the 1996 Food Advisory Committee, among others. See also 364 F. Supp. 2d at 1320-21 ("Dr. Inchiosa . . . states that he cannot determine a safe level of EDS intake. This sentiment is echoed throughout the transcript of the [1996 Food Advisory Committee]. Several of the meeting's attendees made comments that a safe level could not be determined. There was, apparently, not enough evidence to support the conclusion that there is a safe level of intake for EDS."). The review of scientific literature is properly in the province of the FDA, to which this Court grants deference based on its expertise. See Weinberger v. Bentex Pharms., Inc., 412 U.S. 645, 653-54 (1973) (The FDA is "peculiarly suited" to evaluate conflicting scientific reports, a matter "not . . . well left to a court without chemical or medical background," because it "necessarily implicates complex chemical and pharmacological considerations.").

The majority of data in the administrative record suggests that EDS pose an unreasonable threat to the public's health. The FDA:

[11] The FDA relied on multiple studies which demonstrated that EDS raise blood pressure and increase heart rate. The agency considered evidence from the well-known, scientifically established pharmacology of ephedrine alkaloids; peer-reviewed scientific literature on the effects of ephedrine alkaloids; and AERs of occurrences following consumption of EDS. 69 Fed. Reg. 6788. In its call for comments, the FDA specifically cited to the following peer-reviewed studies: Stephen Bent, et al., The Relative Safety of Ephedra Compared with Other Herbal Products, 138 Ann. Intern. Med. 468-72 (March 2003) (finding that EDS accounted for 64% of all adverse reactions to herbs in the United States, despite representing only 0.82% of herbal product sales); Paul G. Shekelle, et al., U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, Assessment No. 76, Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects (Feb. 2003) (concluding that the use of ephedrine and/or the use of ephedra or ephedrine plus caffeine is associated with two to three times the risk of nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations); Lewis B. Morgenstern, et al., Use of Ephedra-Containing Products and Risk for Hemorrhagic Stroke, 60 J. Neurology 132-35 (2003) (concluding that ephedra is not associated with increased risk for hemorrhagic stroke, expect possibly at higher doses); David Samenuk, et al., Adverse Cardiovascular Events Temporally Associated With ma huang, an Herbal Source of Ephedrine, 77 Mayo Clinic Proceedings 12 (2002) (concluding that ephedra use is temporally related to stroke, myocardial infarction, and sudden death; underlying heart or vascular disease is not a prerequisite for ephedra-related adverse events; and the cardiovascular toxic effects associated with ephedra were not limited to massive doses); Christine Haller, et al., Pharmacology of Ephedra Alkaloids and Caffeine After Single-dose Dietary Supplement Use, 71 Clinical Pharmacology and Therapeutics 421-32 (June 2002) (after assessing the pharmokinetic effects of a single dose of EDS plus caffeine in eight healthy adults and finding that the mean heart rate response reached a maximum change of 15 beats/minute above the baseline, the authors concluded that dietary supplements that contain ephedra and caffeine can produce significant cardiovascular responses after a single dose); C. Boozer, et. al. Herbal Ephedra/Caffeine for Weight Loss: a 6-month Randomized Safety and Efficacy Trial, 26 Int'l J. Obesity Related and Metabolic Disorders 593-604 (2002) (concluding that dietary supplements that contain ephedra and caffeine promote weight and fat loss without the expected decrease in blood pressure); C. Boozer, et al., An Herbal Supplement Containing Ma Huang-Guarana for Weight Loss: A Randomized, Double-blind Trial, 25 Int'l J. Obesity and Related Metabolic Disorders, 316-24 (2001) (concluding that dietary supplements that contain ephedra and caffeine promote short-term weight and fat loss, but that safety with long-term use requires further investigation). The FDA also relied on an (continued...)

[11](...continued)
investigation by the GAO which withdrew its earlier criticism of the FDA's 1997 proposed regulation of EDS after linking EDS use with heart attacks, strokes, seizures, death, and cardiac arrest. In addition, Dr. Inchiosa's study discussed the relationship between EDS and epinephrine in a transparent manner. Ephedrine alkaloids are members of a family of pharmacological compounds called sympathomimetics, which mimic the effects of epinephrine in the human body. 69 Fed. Reg. at 6789. Dr. Inchiosa extrapolated data on epinephrine to draw conclusions about EDS, but he did so using peer-reviewed data and generally accepted principles of pharmacology.

> looked at the seriousness of the risks and the quality and persuasiveness of the totality of the evidence to support the presence of those risks. [It] then weighed the risks against the importance of the benefits and the quality and persuasiveness of the totality of the evidence to support the existence of those benefits . . . giv[ing] more weight to benefits that improve health outcomes, especially in the long term, than to benefits that are temporary or rely on subjective measures such as feeling or looking better.

69 Fed. Reg. at 6799. The agency expressed that it would not deem EDS adulterated based on "risks that are insignificant and reasonable in light of the benefits from the supplement . . . ." Id. at 6825. The evidence in the administrative record was sufficiently probative to demonstrate by a preponderance of the evidence that EDS at any dose level pose an unreasonable risk. The greater weight of the evidence supports the FDA's ban on EDS, thus satisfying the agency's burden.

The FDA's extensive research identified the dose level at which ephedrine alkaloids present unreasonable risk of illness or injury to be so minuscule that no amount of EDS is reasonably safe. The FDA reasonably concluded that there is no recommended dose of EDS that does not present an unreasonable risk. Id. at 6829 ("dose limitations cannot change the unfavorable risk-benefit ratio of [EDS]"). The FDA was not arbitrary or capricious in its Final Rule; the FDA met its statutory burden of justifying a total ban of EDS by a preponderance of the evidence.

We find that the FDA correctly followed the congressional directive to analyze the risks and benefits of EDS in determining that there is no dosage level of EDS acceptable for the market. Summary judgment for plaintiffs was therefore improper, and summary judgment for defendants should have been entered. Accordingly, the district court's decision is reversed, and we remand for entry of judgment in favor of defendants. As noted above, Nutraceutical's Motion to Correct Oral Argument Record is granted.

REVERSED AND REMANDED.