Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2011 are reviewed within 420 days after the submission date.

JINAD study submissions received during FY 2011 are reviewed within 500 days after the submission date. JINAD submissions consisting of protocols without substantial data received during FY 2011 are reviewed within 290 days after the submission date.

Administrative ANADAs received during FY 2011 are reviewed within 110 days after the submission date.

FY12 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2012 are reviewed within 380 days after the submission date.

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2012 are reviewed within 340 days after the submission date.

JINAD study submissions received during FY 2012 are reviewed within 380 days after the submission date.

JINAD submissions consisting of protocols without substantial data received during FY 2012 are reviewed within 190 days after the submission date.

Administrative ANADAs received during FY 2012 are reviewed within 105 days after the submission date.

FY13 90 percent of:

Non-administrative original ANADAs and reactivations of such applications received during FY 2013 are reviewed within 270 days after the submission date.

Manufacturing supplemental ANADAs and reactivations of such supplemental applications received during FY 2013 are reviewed within 270 days after the submission date.

JINAD study submissions received during FY 2013 are reviewed within 270 days after the submission date.

JINAD submissions consisting of protocols without substantial data received during FY 2013 are reviewed within 100 days after the submission date.

Administrative ANADAs received during FY 2013 are reviewed within 100 days after the submission date.

Amending Similar Applications and Submissions

The Agency and regulated industry agree that applications and submissions to the Agency will be complete and of sufficient quality to allow the Agency's complete and timely review. The Agency will refuse to file poor quality and incomplete applications and submissions rather than allowing them to serve as ''placeholders'' in the review queue that are subsequently amended to add the missing or inadequate portions.

The Agency recognizes that there are circumstances in which a controlled amendment process can make the review of similar, pending submissions more efficient, without compromising the sponsor's responsibility for high quality submissions. Thus, starting no later than FY 2012, if the Agency requests an amendment to a non-administrative original ANADA, manufacturing supplemental ANADA, JINAD study submission, or a JINAD protocol submission (a ''CVM-initiated amendment''), or issues an incomplete letter for such an application or submission, a sponsor may request to amend other, similar applications or submissions it has pending with the Agency (''sponsor-initiated amendment(s)'') in accordance with the following criteria:

1. The amended information for these similar applications or submissions must be the same as in the CVM-requested amendment or incomplete letter; and

2. The amended information must not significantly change the pending application or submission; and

3. The amended information for these similar applications or submissions must be submitted no later than:

a. 120 days after the submission date for a pending non-administrative original ANADA, manufacturing supplemental ANADA, or JINAD study submission; or

b. 50 days after the submission date for a pending JINAD protocol.

If the Agency determines that the above criteria have been met, it will not change the user fee goal for a pending application or submission that has been amended by a sponsor-initiated amendment If the above criteria have not been met, the Agency may consider the application or submission resubmitted on the date of the sponsor-initiated amendment, thereby resetting the clock to the date FDA received the amendment.

REPUBLICAN NATIONAL CONVENTION LAW ENFORCEMENT

Mr. COLEMAN. Mr. President, I rise to express a word of enthusiastic appreciation to the thousands of courageous and principled law enforcement members who did their utmost to allow the Republican National Convention in St. Paul to proceed in an orderly fashion. I saw some of their work with my own eyes and want them to know we respect them and the vital role they play in our Nation.

It has been said that every society is defined by the boundary between each individual's right to do whatever they want and the broader community's right to peace and order. Societies without such a border disintegrate into chaos and eventually repression. That boundary is not an abstract philosophical construct, but the life's work of law enforcement personnel who enforce society's laws.

This past week we saw an extreme test of that principle as self-described anarchists, who represented a very small segment of thousands of peaceful demonstrators, sought to disrupt proceedings of the convention. Law enforcement personnel acted with professionalism, restraint and great skill in the face of serious threats to public safety. The great irony is the actions of law enforcement guarantee the future rights of protestors to protest. I only wish the small minority of violent protestors had not created a climate of fear that may have regrettably kept observers away and reduced the patronage of St. Paul businesses, that were counting on increased sales during the convention week.

The convention, the first in Minnesota since 1892, presented many logistical obstacles. St. Paul is a town of less than 300,000, not the kind of metropolis where these events are usually held. The ability of multiple jurisdictions to work together to scale up their response to the level needed was a great example of the Minnesota can-do spirit.

Many thanks are due, specifically to St. Paul chief of police John Harrington whose team was able to ensure the safety of all of our visitors, displaying Minnesota admirably in the national spotlight. Special thanks are also very much in order to the law enforcement officers who traveled from all over Minnesota and the rest of the country to assist in the security efforts.

I would also like to take a moment to express my thanks for the excellent work of a few other individuals during the convention: St. Paul assistant chief of police Matt Bostrum, Minneapolis chief of police Tim Dolan, Minneapolis deputy chief of police Rob Allen, Bloomington chief of police John Laux, Ramsey County sheriff Bob Fletcher, Hennepin County sheriff Rich Stanek, and Minnesota Department of Public Safety commissioner Michael Campion all deserve our gratitude. They, and their departments, performed with excellence in the way they did their duty and their integration with other departments.

The week of September 1, 2008, will be remembered by almost all of the thousands of visitors to Minnesota as a great week and proof-positive that our State is capable of putting on a world class event. The ability of our excellent law enforcement personnel to play defense against those who sought to disrupt the festivities allowed the people attending the convention and a worldwide audience to see an orderly process of our democratic society at its finest.

My heartfelt thanks to all the Minnesotans who worked so hard to make our dreams a reality.

IDAHOANS SPEAK OUT ON HIGH ENERGY PRICES

Mr. CRAPO. Mr. President, in mid-June, I asked Idahoans to share with me how high energy prices are affecting their lives, and they responded by the hundreds. The stories, numbering over 1,000, are heartbreaking and touching. To respect their efforts, I am submitting every e-mail sent to me through energy_prices@crapo.senate.gov to the CONGRESSIONAL RECORD. This is not an issue that will be easily resolved, but it is one that deserves immediate and serious attention, and Idahoans deserve to be heard. Their stories not only detail their struggles to meet everyday expenses, but also have suggestions and recommendations as to what Congress can do now to tackle this problem and find solutions that last beyond today. I ask unanimous consent to have today's letters printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

Thank you for this opportunity to express my concerns regarding the escalating price of living in Idaho due in large part to the ever increasing cost of energy.

I work for Alaska Airlines in Boise, Idaho. My gas bill to cover my commute has gone from $100 to $300 per month. My own industry has been heavily affected by the obscene rise in the cost of aviation fuel. Alaska Air is a profitable business. They have worked hard at putting a lot of cash in the bank. They never just spent their way into bankruptcy then emerged a few years later with

all of their debts relieved. Now in order to stay alive, in addition to raising air fares and reducing routes, they have to charge seemingly ridiculous charges for the ordinary services associated with travel. And still the cost of fuel rises. Just today we received the second corporate letter, advising us that Alaska Airlines is doing all it possibly can to reduce costs, that each of us needs to be conscious of everything we do and be as profitable as we can with each service we provide. I work in a call center. Are those the voices of Pakistani call center agents I hear at Alaska Airline's front door? So not only are some of the finest American customer service agents in danger of losing our jobs, but the least respected of all call center personnel will smudge the heretofore finest airline service in the world.

I read that you have worked on alternative fuels. This is a fine aspiration, but with what result? At present alternative fuels can not even begin to touch the huge volume it would take to replace gas and oil energy. As a result of corn-based fuels, corn-based commodities around the world have also escalated in price. Cereal, tortillas, breads, dog food, chicken and beef feed, the list goes on, are all affected by increased prices I pay every day. And in third world countries, where such commodities are staples, people are facing shortages and starvation. When the farmer cannot afford to cultivate his crops, the trucker cannot afford to pick up the crops and bring them to market, and the market has to raise the prices of staples, how far behind are we from becoming a society of haves and haves and have-nots?

Senator CRAPO, for far too long we have let the environmental movement intimidate our energy policy in this country. It started with a little bit of this and that. We stopped drilling for oil and gas off our scenic coasts and large inland tracts of land deemed environmentally sensitive. We stopped approving refineries and thereby reduced our domestic supplies of fuel, relying instead on ever-increasing foreign sources. One of the biggest environmental accidents happened near Valdez, Alaska. Environmentalists blamed big oil. Ironically the oil spilled was imported from the Middle East. Accompanying all this was the slow rise in the price consumers pay to run their cars and heat their homes. Government has played both sides of the isle with C.A.F.E standards that have not improved gas mileage so much as to drive the price of cars to the same price as a good house in the 1960's. Refineries further increase the price of fuel required to manufacture multiple blends. All of these products are heavily taxed by our government. If the oil companies are accused of making obscene profits, then can we not say the same thing about the never-mentioned windfall profits our Federal government collects?

What would I do? I would ask you to start plans to find and develop our best sources of domestic oil and natural gas resources. I would ask you to find places in this country that would just love to refine petroleum and encourage their communities to do so. Just getting the plans on the board would burst this bubble of inflationary speculation. (These suggestions, if started today would take at least 10 years to get up and running).

I would also ask that we start plans to build safe and efficient nuclear power. France and Germany possess marvelous examples we can emulate and exceed. And further we need to fend off the environmentalist's incessant legal maneuvering that subvert inflate the price of energy development.

Well, this is more than two paragraphs. But it contains in my opinion, the elements we need to address today and with haste.

Thank you.

ROBERT, *Boise.*

I would expect that I am an average Idahoan in means of monthly financial resources. The average family in my valley has 2 full-time incomes of $8/hr, totaling around $2200.00/mo. take-home after taxes. The average family also has to travel 50 miles a day—5 days a week—just for that work. The average vehicle does 20MPG. That alone is $220 in gas a month ($30.00 over most people's monthly available gas budget). Now figure that the nearest shopping mall is 50 miles away, and the nearest shopping center is 15 miles away.

The economy is and will suffer to make the difference. On-line shopping to the lowest bidder is becoming a necessity, and activities of enjoyment are on the out. Some people find themselves in a position where they can no longer afford the job they have had for decades, and others like myself are forced to close storefronts, and look for alternative methods of doing business in order to make ends meet.

I consider myself a Statesman; amateur as that may be. It is near impossible to educate and influence the general populace toward principles of freedom and free market if my means of exposure to the people is severely hampered due to extravagant and unnecessary fuel costs.

If we want so much to be like Europe that we are willing to take on their fuel costs, then we better be ready to downsize our person per square foot ratios to match theirs, otherwise we will desolate ourselves, and their 200 year wait for our failure and re-absorption back into their kingdom will be complete.

We must learn to look at what is seen, and what is not seen. We must be able to see all the impacts, and not just 5–10 years down the road. We must have 20–30 and 50–80 year plans that will cause freedom from debt and servitude to others, or we will weaken and eventually fall . . . even if that fall may take a century, we will fall if we do not change the current direction of events. Gas price recognition is merely a baby step.

We must set up forms of governing that will ensure freedom for generations, and not get caught up in the mere momentary crisis.

I beg of you . . . as do many I know . . . be true to your positions of civil servants; handle all situations with no thought for self, and every thought for generations of freedom for those you serve and represent, not bondage and slavery and misery.

Be astute in your history. Civilization has repeated cycles of growth and downfall. Must we make the same mistakes? Or is ours truly wise enough, not pompous, to overcome the challenges that face our day? Our day is truly the greatest day in history . . . for we have yet to write its annals. Victorious or victored. After all, only a small degree, or percentage caused the great chasm that made two nations of one in 1776 . . .

You are the warriors in government for us, the people. I commend every effort on your behalves to maintain and support the principles upon which our nation was founded. Be true, and be courageous. Do not let lost lives be in vain, lest that blood lie on your shoulders. I know you can, and will to help our Nation be great again. Press on!

JASON, *St. Anthony.*

It is a national security issue for our country to be energy independent. The issues outlined in the piece on your website are exactly the ideas and means I would try to implement. I feel that the environmental movement and powerful lobbyists have had too much power and influence over many Senators and Congressmen. I wish the names of the lobbyists could be widely broadcast and the bills that have been shot down could be widely circulated so people could see the total dishonesty and power grab these environmental groups have taken. It is a real disaster that we do not have more nuclear energy, more domestic oil production, more coal and of course more refineries. The massive amount of lawsuits and cost of defending many annoyance suits has cost the government and utility companies hundreds of billions of dollars if not into the trillions. We have a small business and a huge increase in cost in transportation shrinks the profit and makes cuts in other important areas necessary.

LEW, *Idaho Falls.*

Thanks for the opportunity to respond to your request for energy stories. I do not have a sad one of not being able to heat my house or whether to put gas in my SUV so I can get to work (I drive a car that gets 27 mpg and I walk a lot) or put groceries on the table. But, I have sympathy for folks who do have to make hard choices. I'm glad you are looking for answers. I think I can offer some insights for you.

My background is this: I travel a lot and have spent 11 years living abroad and 5 of those years living in various places in the Middle East. I understand our energy needs very well, having personally negotiated the delivery of $500 million dollars worth of free fuel for US/Coalition forces going into Iraq in 2003. I have spent a lot of time with guys in the petroleum industry in Kuwait. They are cranking out more than 2 million bbl a day and they consider U.S. needs their highest priority and have since 1991. From my experience I know there is not a fuel shortage, just an 8 million bbl per day shortfall in the needs of the U.S. Personally I think raising gasoline taxes will reduce waste, encourage conservation and utilization of mass transit and that might help close the gap, but I understand this might not be the popular option because we do like our power cheap and plentiful.

I have lived through the oil embargo in 1973 and the little one in 1978. I've listened to the energy companies explain that they would go after oil shale in Wyoming in 1978, but it would not be profitable unless gas prices reached $2.00 a gallon. I don't hear much about oil shale these days and gas is at $4.00 a gallon.

The EPA recently (last few years) opened new areas for drilling on the North Slope of Alaska, off the California coast and in the Gulf of Mexico that the energy companies have been asking to drill in since 1978. Those areas were protected but when an energy producer threatened to close a profitable refinery in Santa Barbara a few years ago citing ''lack of demand'' gas prices spiked to $4.00 a gallon in Phoenix, Arizona and in the Chicago area so in the interest of the national good, the EPA lifted the restrictions, so now they can get oil that was profitable at $24 a bbl in 1978—must be really low fruit at $130 a bbl in 2008. This would help explain some of the recent profits enjoyed by the energy companies and make their complaint that finding new energy is very expensive seem a bit hollow.

A Halliburton country manager told me in 2002 that Azerbaijan is awash in oil, has been for some time. A pipeline was opened in May 2005 in Azerbaijan that runs about a million bbl a day. There is more available but new pipelines are held hostage to the political process in a couple of those other countries. The Iraq fields are on the mend and they went from 200,000 bbl a day in 2006 to a reported 2 million bbl a day (but I don't believe that number yet) and they have the capability of generating 6 million bbl a day if that political situation ever stabilizes. Kazakhstan and some of the others are likewise situated, the trick has always been to

get the oil out of there. Obviously there is fuel out there and the energy companies are willing to get it—we just have to be willing to pay the price or develop alternatives. The energy companies have to spin ''doom and gloom'' so we give them a pass and do not question their methods. Political action committees and lobbyists are the point on that challenge, but you know that part already.

Sir, I don't understand the reluctance of our elected representatives to make energy independence a national priority, the same way President Kennedy made going to the moon a national priority. I do understand there is a lot of effort by the energy lobby to not encourage alternative production.

If the energy companies (gas/electric/coal) have no interest in finding alternatives, that impetus must come from the body politic.

By the way, the inside news is that banks in the Middle East are actively investing in alternative energy development, so why aren't we? They know oil will not last forever and they are getting ahead of the problem. We are not.

I will offer this. In Idaho we have a climate not unlike Seville, Spain. There they are working on a project using the sun's energy to eventually generate enough power for 600,000 homes. That would be the Treasure valley and beyond. Owyhee County is a great place to set one up. In 2007 it was already generating 11mw, enough for 6000 homes so we know the application works. It is expensive, but those costs will come down. The Spanish paid the big cost of R & D for all the rest of us. This is a place with no carbon footprint. You can see the BBC article about this effort at: http://news.bbc.co.uk/2/hi/science/nature/6616651.stm

So why is there only talk in Idaho of a nuclear power plant (very expensive, does make some waste) or a new gas fired electrical plant (very expensive, depletes resources and leaves a big carbon footprint)? Why is the battlefield being prepared by an Idaho Power rep saying recently ''the era of cheap power is over.'' Why is Idaho power (and all the other electricity providers) not championing alternative sources to generate electricity?

Why is the government not doing more to promote wind power as a source of electrical generation. I heard a story that it might affect birds. I studied a wind farm in Oklahoma recently (along the interstate). Those blades turn pretty slow and it would be a stupid bird who couldn't fly past it. We have lots of wind in Elmore County and most of Idaho along the interstate. For people concerned about birds or views, the birds will be killed the effects of global warming and the view is not worth much if our society collapses.

As an elected official and guardian to protect America from all enemies, foreign and domestic (it is in the oath) I am surprised that you (and the other elected officials) are just so stymied by this problem. It is not too hard a problem (we did figure out how to split the atom some years ago) and it cannot be too expensive since we have already spent a trillion dollars in Iraq.

You just have to want to do this.

Thanks for asking for my story. I will send this off to a couple of other Idahoans for them to share.

Respectfully,

MIKE, *Boise*.

RECIPIENTS OF THE 2008 DAVIDSON FELLOWS AWARD

Mr. GRASSLEY. Mr. President, it is my honor to pay tribute today to 20 outstanding young scholars and recipients of the 2008 Davidson Fellows Award, a scholarship granted to exceptional students to assist them in pursuing higher education. The Davidson Institute for Talent Development distributes grants to highly gifted individuals under the age of 18 who have demonstrated academically rigorous projects that demonstrate a potential to make a significant positive contribution to society. Mr. President, allow me to introduce the recipients and elaborate on their noteworthy accomplishments.

Akhil Mathew, a 16-year-old from Madison, NJ, proved a single filter, or system of weights, can decode only a finite number of rationals. Akhil's work is relevant to signal processing, analog-to-digital conversion, and representing numbers in an alternative way.

From Gaithersburg, MD, 17-year-old Sikandar Porter-Gill developed a novel process to clean wastewater and produce methane for use as an alternative form of energy by engineering bio-catalyzed microbial fuel cells to degrade organic material in wastewater. Sikandar's research is a promising step toward pursuing a cost-effective and environmentally friendly energy source.

A 17-year-old from Setuaket, NY, Christine Shrock, studied a region of the HIV protease, a protein crucial in the replication of HIV. She found that this region is a promising target for drugs to bind to change the shape of the protease, preventing it from performing its function. Christine's research is an important contribution to the development of a new class of drugs to reduce the number of infections and deaths caused by HIV.

Philip Streich, a 17-year-old from Platteville, WI, showed that carbon nanotubes are thermodynamically soluble, contradicting the generally held assumption that they were universally insoluble. He designed and custom built a unique photon-counting spectrometer that is more sensitive and precise than any commercially available. Philip's work has broad applications in the field of nanotechnology engineering.

At just 14 years old, Conrad Tao from New York, NY, has made classical music relevant to younger generations through his performances that display a vast knowledge, deep understanding, and mature interpretation of the repertoire. A composer, pianist, and violinist attending the Juilliard Pre-College Division, he has been featured on NPR's ''From the Top,'' performed at Carnegie Hall and has received five consecutive American Society of Composers, Authors and Publishers, ASCAP, Morton Gould Young Composer Awards.

Michael Cherkassky from Minneapolis, MN, compared the application of several machine learning methods to real-life medical data sets in order to understand the generalization capability of the estimated models, advancing the current predictive diagnostic model. Michael, who is 16 years old, also compared the diagnostic accuracy of two classification methods, allowing physicians to obtain more accurate diagnostic conclusions while advancing patient care.

Twelve-year-old Hilda Huang from Palo Alto, CA, has determined to change the way people feel about Johann Sebastian Bach. Performing on the harpsichord and piano, Hilda aims to bring Bach to everyone, especially young people who may be unfamiliar with his music. Her many accomplishments include performances on NPR's ''From the Top'' and at Carnegie Hall.

Jasmine Miller, a 17-year-old from Nashville, TN, examined her generation's interactions with technology and the impact of digital media on our identities. Through a one-act play, creative essays, and a novel excerpt, Jasmine explored the uncharted minds of the current generation of American youth.

At age 17, Saraswathi Shukla from Princeton, NJ, has conducted an in-depth study of sound and music in Franz-Anton Mesmer's theory of animal magnetism. Combining history, music, language, and literature, she examined the role of music in Mesmer's therapeutic seances in the context of broader changes in the popular perception of sound in pre-Revolution Paris. The importance of sound in mesmerism presents new ways to analyze scientific theories of this period.

Seventeen-year-old August Siena Thomas from Montague, MA, examined the ways in which personal and political histories are purposefully reimagined and rewritten. Through a historical novel, literary reflection, drama, and historical interpretation, August observed the manner in which interpretation of history remain fluid and reflected on how writers have used malice, ambition, flattery, and imagination through the ages to shape the way history is written.

Vijay Venkatesh, a 17-year-old from Laguna Niguel, CA, won the grand prize at the Los Angeles Music Spotlight Awards and the second prize at the Virginia Waring International Piano Solo Intermediate Competition. Vijay views music as a gift to move the world, serving as a common link to touch humanity, and believes it is his duty as a performer to assure the audience of the joy and love that transcend life's struggles.

Only 12 years old from Beaverton, OR, William Yuan invented a novel solar panel that enables light absorption from visible to ultraviolet light, doubling the light-electricity conversion efficiency. William also developed a model for solar towers and a computer program to simulate and optimize the tower parameters, providing 500 times more light absorption than commercially available solar cells and 9 times more than the cutting-edge, three-dimensional solar cell.

At age 17, Charles Zhang from Oakland Township, MI, has researched and