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DIFFERENT APPLICATIONS FOR GENETICALLY MODIFIED CROPS

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SUBCOMMITTEE ON RURAL ENTERPRISES, AGRICULTURE & TECHNOLOGY

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DIFFERENT APPLICATIONS FOR GENETICALLY MODIFIED CROPS

WEDNESDAY, JUNE 29, 2005

HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON RURAL ENTERPRISES, AGRICULTURE AND TECHNOLOGY
COMMITTEE ON SMALL BUSINESS
Washington, DC

The Subcommittee met, pursuant to call, at 2:04 p.m. in Room 311, Cannon House Office Building, Hon. Sam Graves presiding.

Present: Representatives Graves, Sodrel, Barrow, Udall, Case

Mr. GRAVES. We will go ahead and call this hearing to order. We have kind of got a little dilemma here. We have got to vote at any second now. It was supposed to be about 10 minutes ago, and obviously it has been delayed, for whatever reason, but I think we are going to go ahead and proceed forward. We can get some of the opening statements taken care of by some of the Members and move forward from there.

But I would like to welcome everybody to the Rural Enterprises, Agriculture and Technology Subcommittee, part of the overall Small Business Committee, and today we are going to be looking at different applications for genetically modified crops. Again, I want to thank everybody here today, our audience, and those who are participating in the hearing. Some of you have come from a long ways, and I appreciate you coming out to testify today.

As a farmer by trade myself, I truly believe genetically modified crops are the future of American agriculture. As agriculture markets become more competitive worldwide, it is imperative that the United States keep an edge by offering continued superior quality product. Genetically modified crops allow agribusiness to increase profits and continue to uphold the United States' representation for excellence in agriculture.

For centuries, farmers have been modifying crops to improve their growth rates and yields. We have seen technology, not only improve these yields, but also to create varieties resistant to pests and diseases. Such modifications have previously been made through cross-breeding plants with desirable traits and through hybridization. Thomas Jefferson himself was renowned for his work in cross-pollination and hybridization at Monticello.

Already in this country, 85 percent of all of the soybeans we grow have been modified, followed closely by 75 percent of all of the cotton and half of the corn. Thirteen different plants in the U.S. today have been approved to be genetically modified, and, in fact, some

60 percent of all of the food that we grow and consume is genetically modified. Continued developments and research hold great promise for traditional agriculture not only when it comes to feeding the world but also to produce crops for medical purposes.

Through advanced technology, scientists can modify specific genes for desired qualities and grow them within the plants. Commonly referred to as "biofarming," this method of retrieving certain enzymes holds limitless potential and will allow the United States to retain its leadership role within the medical research community.

Worldwide, genetically modified crops offer hope, incredible hope, as a matter of fact, for overpopulated countries when it comes to feeding and treating the people in a much more efficient and a much more effective way. I am greatly concerned that current regulations and a lack of knowledge for this science will not only hamper growth in this industry but will also allow other countries to surpass the United States' position as a world leader within the agriculture business industry.

We have to continue to make policy decisions based on sound, scientific facts and help businesses to expand in this industry. I think we have a great potential to not only revitalize rural business communities but also offer an incredible product to consumers throughout the United States and throughout the world.

Again, I am looking forward to hearing what all of the witnesses have to say—this is going to be a great hearing to talk about the great things when it comes to genetically modified crops—and learning more about this expanding industry. I am pleased to recognize now Ranking Member Barrow for his opening statement, and good to have you.

[Chairman Graves' opening statement may be found in the appendix.]

Mr. BARROW. Thank you, Mr. Chairman. Mr. Chairman, the agricultural sector has always played a central role in the success of the United States economy, and as the representative for Georgia's 12th District, I know how important agricultural interests are not only to my area of the country but to the entire country, and it is important for us to remember that farming and rural communities are a critical component of the history and landscape of our nation. Generations of Americans have relied on the strength of our agriculture through the hard work, dedication, and innovation of our farmers.

The importance of the agriculture and farming industries has continued to evolve with the growth of our nation. From early farming techniques, such as crop rotation and irrigation systems, to 19th century inventions, such as the steel plow and the cotton gin, farmers have always looked for ways to increase productivity and maximize crop yields.

Today, small family farms and other agriculture-related businesses help to meet our needs and contribute to local and national economies. With farmers having such a strong presence in my district, I know how important their success is to economic development. In Georgia, agriculture is our largest industry, contributing over $57 billion, or 16 percent of the state's $350 billion annual

economic output. In fact, in many parts of my district, the farm economy is the economy.

As we make our way through the early years of this century, biotechnology and genetic engineering our some of the advances leading the way in agriculture innovation. These methods may hold the promise to ensure the continued success of the farming industry, even as we face increased demands and especially as fewer people in each generation turn to farming as a profession. High-technology applications and improved crop yields are extremely important to the U.S. agricultural economy and the rural economy because they will help us meet the challenges facing the small farmer and reduce the risk to crops and the land itself.

Today's hearing will give us an opportunity to learn more about genetically engineered crops and the scientific gains that are leading us in this direction. It will also provide an overview to the barriers that we face in bringing this science on line in the face of resistance around the world. This is an instance, Mr. Chairman, where scientists, businesses, and farmers need to work together to grow their own future.

Genetically engineered crops were first introduced in 1996 for commercial production. They are now planted on 167 million acres of farm land around the world. Of this, the U.S. accounts for nearly two-thirds of all biotechnology crops planted worldwide, including soybeans, cotton, corn, canola, tomatoes, potatoes, papaya, and squash. According to the Biotechnology Industry Organization group, 70 percent of all processed foods on our shelves today contain products enhanced by biotechnology. By selecting specific genes from one organism and transferring these desired traits to another, scientists have been able to produce new varieties that are stronger, more resistant, and better equipped to handle harsh weather conditions and withstand insects and other pests. American farmers, large and small, have been able to take advantage of our technology agriculture, and that is what is keeping the U.S. the world's leader in the field.

This is an important hearing for the folks you represent, Mr. Chairman, and for mine. For farmers in Georgia and across the nation, it is important to hear what to expect in the future in terms of research and production of genetically engineered crops.

I look forward to hearing all of the testimony of today's witnesses, particularly Tommy Dollar, a Georgia farmer who is the president and owner of Dollar Farm Products and the Decatur Gin Company. Thank you, Mr. Chairman.

Mr. GRAVES. Thank you, Mr. Barrow.

Mr. Udall?

Mr. UDALL. I do not have anything, Mr. Chairman. I look forward to hearing from the witnesses. Thank you very much.

Mr. GRAVES. Mr. Case?

All right. We will move forward, then, and it looks like we had a vote through voice vote. It is not going to be recorded, so that is good news. We can continue forward. I do want to make it clear that all of the statements made by the witnesses and the members will be placed in the record in their entirety. Also in front of you, you will notice that you have a little box. It is green. I think everybody has five minutes, and then it goes to yellow with one minute

left, and it is red after that. Do not worry about it. If you have got something to say, I want to hear it, and do not pay too much attention to it. It is just, for the most part, to keep us on track and moving forward, so if it turns red, do not be too alarmed.

We are going to start, and what I am going to do is I will introduce you as we move through. I will let everybody give an opening statement, and then we will come back through with the questions.

First off, we have got Sam Huttenbauer, who is the CEO of Agragen in Cincinnati, Ohio. We have actually got both Sams here, senior and junior, I assume. I am a junior, so I understand how that is. We are looking forward to hearing your testimony, and please go ahead.

STATEMENT OF SAM HUTTENBAUER, AGRAGEN

Mr. HUTTENBAUER. Good afternoon, Mr. Chairman and members of the Committee. Thank you for giving me the opportunity to participate in this panel.

My name is Sam Huttenbauer, and I am the president of Agragen, Inc., a biotech company working on the development of plant-made pharmaceuticals, otherwise known as "PMPs." We are located in Cincinnati, Ohio, and are opening up a laboratory facility in Grand Forks, North Dakota, where we plan to grow and process our pharmaceuticals.

I am pleased to testify today at this hearing regarding the future potential of PMPs and their tacit economic impact towards bolstering America's agricultural economy.

Agragen was started three year ago with the express purpose of manufacturing pharmaceuticals utilizing the natural protein-manufacturing capability of plants. The company has also concentrated since its inception on selecting molecular targets that require substantial agricultural acreage. Agragen is one of the new breed of agribusiness companies combining conventional agriculture with high-tech science. As such, it will work with farmers, employing their agronomic expertise and existent land. With America's agriculture undergoing change in the competitive world arena, Agragen and companies like it present one opportunity to move our country's great food-and-fiber skills into a more profitable and stable system.

Plant-made pharmaceuticals are the new, ultra-high-value farming for the 21s century. What are "plant-made pharmaceuticals?" PMPs are the result of the breakthrough application of biotechnology to plants to enable them to produce therapeutic proteins that will be used by the medical community to combat life-threatening illnesses. In this process, plants themselves become factories that manufacture therapeutic proteins. These proteins are then extracted, refined, and used in pharmaceutical production. These plants are grown under highly regulated conditions in defined growing environments and are strictly regulated by the U.S. Department of Agricultural, its animal and plant health inspection service, and by the Food and Drug Administration.

Why do we want to use PMPs? Well, as the world's scientific technology increases, more and more drug therapies rely on recombinant proteins and less on traditional combinatorial chemistry. While this represents monumental breakthroughs in healing, it

also presents significant problems of economics, efficiency, and safety. Consider this: Over 14 percent of treatments in clinical trials today require recombinant proteins. It takes five to seven years to build a biotech plant capable of producing recombinant proteins versus one to three years for a conventional pharmaceutical plant. And just four molecules currently consume 75 percent of the existing capacity to make recombinant proteins. Over 100 new, protein-based medicines are now in late-stage clinical trials.

There are also many challenges to current recombinant production methodologies. From an economic standpoint, current biotech plants require five to seven years to construct, cost 250 to $450 million, and must be individually approved and certified by the FDA prior to full-scale operation. From a supply standpoint, despite increased therapeutic use of recombinant proteins, there is a global shortage of production facilities, less than 12 worldwide for these new proteins. This greatly limits the movement of these proteins into therapeutic use, and from a safety standpoint, there is the possibility of cross-contamination with human or mammalian contaminants utilizing the current production methodologies.

Plants provide a number of advantages over other production methods of biomedical materials. Cost, for instance. Plant vaccines and proteins are inexpensive to produce relative to the cost of traditional vaccines and proteins.

From a safety standpoint, the use of plants for the production of biomedical materials eliminates the possibility of cross-contamination with human and animal pathogens.

From an economic standpoint, farming is already an important and established part of our global economy, and from a practicality and flexibility standpoint, because one plant can express several antigens simultaneously, vaccines against a variety of pathogens can be produced in a single plant. In addition, plants producing therapeutics can be rapidly scaled up as demand increases simply by planting more acres.

The industry needs a cheaper, more effective way to manufacture today's and tomorrow's pharmaceuticals. PMPs offer this alternative. Plants approved for the use of biotechnology can produce the essential building blocks or therapeutic proteins for innovative treatments for diseases such as Alzheimer's; cancer; chronic, obstructive pulmonary disease; Crohn's disease; cystic fibrosis; diabetes, and many others at a fraction of the cost of current manufacturing methods.

Agragen is not currently what might be classified as a drug-discovery company, having chosen to focus on established therapeutics that are market limited, either due to extreme production costs or limited production capacity. Once we have established our production platform, this will lead to additional pharmaceuticals that will also require large acreage. The overall thrust of our technology is to insert genes into the plant, thereby permitting the plant to make and store the protein of interest in the seed where it can be stored indefinitely until it is purified.

From a business standpoint, plant-made pharmaceuticals represent a means to reduce the production costs and to increase the availability of many new drug therapies with the downstream ef-

fect of dramatically reducing costs to consumers and allowing life-saving therapies to find their way into the hands of many patients who would not have access, either due to cost or availability.

Agragen has selected two products for the initial stages of production and several additional candidate proteins. These initial products are in line with the company's goals, which are the utilization of a large amount of acreage and the passing of value-added agricultural profits back to the farmers, for three reasons.

First, both represent $1 billion-plus, underserved and growing markets; second, both targets will ultimately require large acreage, in the neighborhood of 100,000 acres-plus, and spawn meaningful infrastructure in the areas where they are developed; and, third, both molecules are currently being utilized in the marketplace, which will reduce both clinical test costs and time to market. As recombinant-protein science becomes an increasingly important technique for the formation of new therapeutics, manufacturing capabilities must keep pace.

Agragen is one of a number of companies that understands the capabilities and cost efficiency of plants serving as pharmaceutical factories. In addition, plants offer genetic mechanisms that may allow discovery and creation of molecules that cannot be constructed from any other source.

To be truly beneficial for small rural business, plant-made pharmaceuticals must be tied to open-field production. PMPs utilizing plants created in laboratories or in greenhouses have little or no connection to the agribusiness system. While these operations can utilize plants' natural production mechanisms to produce life-saving therapeutics, they do not provide an opportunity for the American farmer.

Large PMP farms, similar to what Agragen is creating, can be established around the country utilizing a large number of acres, either supplementing lost state farming acreage or establishing new growth. In many cases, there will be the opportunity for both. Farmers benefit from the production of PMP-producing crops via their provision of steady employment of their fields and by their greater cash-to-crop yield than is available via the current agricultural industry.

In addition to supplying farmers with a new, high-value crop, Agragen envisions further rural economic involvement by potential farmer ownership of PMP processing and manufacturing facilities. Agragen's business model offers farmers and rural economies the opportunity to participate firsthand in this new, value-added family of crops. The goal of this novel form of agribusiness is to bring the farmer into the process of partner, which specifically means allowing operators to share in the profitability of what they are manufacturing.

Agragen believes that it can double or possibly triple the bottom line of its partners with a market price that is far more stable than typical focused commodities. Furthermore, Agragen's impact will be felt in equipment sales, transportation and processing jobs, real estate values, et cetera. Facilities to handle the transformation of the large biomass from field crop to pharmaceutical will have to be located within proximity to actual growing areas. This means millions of dollars in construction and additional opportunities for

skilled employees in rural locations. Our own initial projections allow—our first two output products show close to $80 million infused in the economy of the state that we will operate in.

We see an instant opportunity to utilize American agronomic skills to help replace some farm products that might be rendered marginal by rapidly developing worldwide agricultural production. PMPs offer the possibility for the small farmer businessman to share in a potentially large profit market while providing tangential benefits to rural economies that would not be subject to new investment otherwise.

However, being immersed in the standard farming arena is not without its problems. Typical agricultural challenges, such as weather and parasites, can be mitigated by the use of multiple growing regions and protein development in seeds which allow for long-term storage and thus the capability to stockpile. But the greatest immediate threat comes from public perception. Field production pits PMP companies against GM antagonists, organic farmers, particularly those who may have an interest in the crop species being transformed.

There has been a call for all PMP crops to exclude any plants currently used for food or feed. Unfortunately, while many plants possess the potential for protein production, certain species are better matched with specific targeted proteins. Some plants may serve as excellent converters, i.e., tobacco, but require too high economic inputs or extraordinarily expensive processing procedures. The need to utilize the production capacity of food crops will be necessary, but these crops are solely used as a factor and will never enter the food chain.

Unlike former GM plant transformations, including the now-notorious Starling corn, where crops basically enter a side-by-side handling and distribution system and one where the possibility of interchange with non-GM materials is always present, PMPs will never have the opportunity to mix with their commodity counterparts. PMPs must adhere to a close-loop system that will include dedicated equipment, transportation, storage, processing, and waste handling.

Still, public perception issues exist. Chief among them is the fear that PMP crops will contaminate non-PMP fields vis-a-vis pollen drift. This is not an insurmountable issue. A major step forward occurred recently in Missouri where government officials played a large role in resolving a similar PMP-related controversy. In Missouri, the problem was untangled by diverse separation, essentially using large distances to keep PMP crops away from that being produced for the food system.

Distance is an effective means to mitigate crop commingling; however, it might not always be enough. In addition to distance requirements, the USDA mandates that all PMPs must be grown using a tight, closed-loop system with dedicated equipment, shipping trucks, and plant material and pollen to prevent them from mixing.

In Agragen's case, because of the ultimate magnitude of the acres projected, the solution might only be temporary. Other methods are being developed to take a more proactive approach to containing the PMP agriculture. For example, Agragen is hard at work devel-

oping novel, gene-control mechanisms that will make mixing with other plants a statistical improbability.

In conclusion, Mr. Chairman, I want to reiterate that by working with established control mechanisms under the guidance of the USDA and other organizations, by working with state and local officials, and by incorporating the knowledge of the farmers themselves, PMPs can be safely grown throughout the states.

According to a report by a consultancy, Frost & Sullivan, released in December 2004, the U.S. market for plant-made pharmaceuticals could be worth $2.2 billion by 2011, with the first products reaching the market by 2005-2006. Agragen believes that from that point, its growth will be restrained only by discovery science not keeping pace. This can translate into direct economic growth for U.S. agriculture as companies utilize more and more acres for PMP production.

PMPs offer not only the promise of cheaper, more abundant pharmaceuticals but the establishment of a new, ultra-high-agricultural venue for today and tomorrow's farmer. Agragen, by bringing the farm community into its business system, feels that it will economically benefit rural areas and individuals who otherwise would have no connection to the biotech revolution. Thank you, Mr. Chairman.

[Mr. Huttenbauer's testimony may be found in the appendix.]

Mr. GRAVES. Thank you. Next, we are going to hear from Dawn Parks. Dawn is public, industry, and government affairs manager for ArborGen in Summerville, South Carolina. Did I get that right?

Ms. PARKS. Yes, you did. Thank you.

Mr. GRAVES. I look forward to hearing what you have to say.

STATEMENT OF DAWN W. PARKS, ARBORGEN

Ms. PARKS. Thank you. Good afternoon, Mr. Chairman, members of the Committee, ladies and gentlemen. I am Dawn Parks. I am the director of public and government affairs for ArborGen.

I am privileged to be here this afternoon on behalf of ArborGen, as well as on behalf of our trade organization, the Biotechnology Industry Organization. BIO represents more than 1,100 companies, academic institutions, state biotech centers, and related organizations across the United States and in 31 other nations. BIO members are actively involved in the research and development of new medicines, food, and industrial and environmental products to benefit the lives of people and the environment.

I would like to thank Chairman Graves and members of the Committee for the opportunity to be with you today and for organizing this hearing. I would also like to thank you, Mr. Chairman, for your leadership on the Small Business Innovation Research program. Specifically, I want to take this opportunity to publicly express BIO's and BIO's member companies' appreciation for your introduction of H.R. 2943, the Save Biotechnology Innovative Research Act of 2005. This important legislation preserves venture capital-backed biotechnology small businesses' access to vital Small Business Administration grants.

In this tenth year of growing crops enhanced through biotechnology, global acceptance continues to increase at a rapid pace. According to the International Service for the Acquisition of Agr-

Biotech Applications, in 2004, global biotech crop plantings continued to grow at a sustained double-digit rate of 20 percent, compared with 15 percent in 2003. The estimated global area of approved crop plantings was more than 200 million acres in 2004.

The United States is the world leader in the development and planting of these crops, and rural America is one of the chief beneficiaries. In 2004, American farmers chose to plant 85 percent of the soybeans, 76 percent of cotton, and 45 percent of corn with seeds improved through biotechnology that allow the plants to protect themselves from insects and disease and promote better weed management. The United States has also approved for commercial planting biotech varieties of canola, chicory, flax and linseed, melon, papaya, potatoes, rice, squash, sugar beets, tobacco, and tomato. The annual R&D investment of the six largest companies in this sector is $2.7 billion, or 10.8 percent of sales.

The rapid adoption of this technology by U.S. farmers is a testament to the solutions it provides to problems on the farm. Biotechnology enables farmers to reduce input costs and improve yields.

My company, ArborGen, is a small business, but the research and development we are doing at our headquarters in Summerville, South Carolina, holds potential to improve forestry on a national and international scale. Forestry, of course, is a rural business that supports millions of jobs across America.

Our goal at ArborGen is to use breeding techniques, including biotechnology, to improve the sustainability of forestry. According to the Food and Agriculture Organization, about one-third of the harvested wood is supplied from industry-owned, highly managed tree plantations. The rest comes from landowners that utilize a wide variety of management techniques, including natural forest management.

As the worldwide population increases, so does the demand for wood and paper products. Rather than expanding the forested acreage under management to meet these wood and paper requirements in the future, we are developing faster-growing trees that will improve the productivity of forest plantations, and by producing more wood on less land, people can build the homes and buy the products they desire without cutting down our natural forests, which will be conserved for wildlife, recreation, biodiversity, and beauty.

ArborGen also is developing trees with modified lignin. Lignin is a component of wood fibers that is removed during the pulping process to obtain the cellulose needed to make paper. The process involves intensive use of chemicals and energies. Reducing lignin content in the trees intended for pulp, or by making it easier to remove the lignin during the manufacturing process, will provide important environmental benefits.

The area of forestry biotechnology has potential to bring many other benefits, and several institutions around the world are developing really exciting products that have significant social, environmental, and economic benefits. One key potential benefit is the production of cleaner burning fuels. Wood produced for ethanol or used directly as fuel by power companies would be a clean, renewable, and cost-effective energy resource.

Phyto-remediation of Superfund sites or other toxic lands is another very promising possibility. Instead of spending billions of dollars removing and sterilizing impaired soils, it may be feasible to plant modified trees that can absorb and neutralize hazard wastes and heavy metals.

Biotechnology can also help restore endangered species, such as the American chestnut, American elm, flowering dogwood, and the California oaks. A single disease-resistance gene added to chestnut could allow for these beautiful species to withstand the blights that have nearly obliterated them from the landscape. Field trials with American elm are underway now, and chestnut trials should begin soon.

Another possibility is trees that can grow in harsh conditions, such as arid climates or salty soils. In areas where trees are an important part of the landscape, this technology could halt further encroachment of the desert and allow trees to grow in areas where they are now unable to grow. And the ability to grow important hardwoods more quickly on managed lands could halt the black market harvesting of these species in natural forests.

Forest biotechnology is in its infancy, but it holds unlimited possibilities that would take generations to produce through traditional cross-breeding. Instead of waiting for trees to grow to sexual maturity so they can be cross-bred with one another, forest biotechnology can identify a desirable gene and transfer it to a tree. The success of failure of the transfer can be seen almost immediately. Then through high-production, multiplication systems, we can mass produce plantlets and introduce large numbers of the improved trees to supply plantation foresters so they can begin to provide benefits to this generation of citizens and into the future. Perhaps adults living today will be able to stand beneath the shade of a spreading chestnut tree, just as their great-grandparents did.

Mr. Chairman, I hope you can understand from my testimony how excited I am to be part of this emerging industry. There are, however, threats to the continued success of the research I have just described, the most daunting being the exclusion of companies such as ArborGen, with majority private funding from companies, from participating in SBIR programs.

While BIO does represent companies in the industry, the vast majority of its members, over 85 percent, are small, emerging companies with less than 500 employees. In fact, more than 50 percent of the companies in our industry have fewer than 50 employees. In our case, a company with 70 employees, it strikes us as unthinkable that we would be considered ineligible for an SBIR grant because we receive private funding for our core projects.

Under the current interpretation of the eligibility, we are concerned ineligible because, as a start-up company, we did what virtually all early stage start-up companies do to continue their research: We received funding for early research and development projects from corporate investors. Funding partners often support the development of the critical platforms, technologies, and protocols that will lead to products for a particular kind of industry. But, for example, as we develop products designed for improving forest management and manufacturing efficiencies, we have identi-

fied genes that can provide significant values to industries outside of paper making and lumber.

The SBIR program is ideally suited for this purpose because the company, our company, has already demonstrated that it can successfully raise follow-on financing, one of the key criteria in evaluating an SBIR Phase II grant proposal.

To remove this barrier to participation in the SBIR program, BIO has urged SBA to revise the SBIR eligibility requirements and issue a proposed rule that reflects Congress's original intent to encourage awards to small businesses that have successfully attracted outside investors.

The approach proposed by SBA in its December 3, 2004, advanced notice of proposed rulemaking to disregard affiliation is a step in the right direction. However, it does not address the fundamental obstacle, which is SBA's requirement that small businesses be majority owned and controlled, directly or indirectly, by individuals. The SABIR Act, however, clarifies that biotechnology small businesses receiving venture capital funding are, in fact, eligible for SBIR Phase II grants. We thank you so much, Mr. Chairman, for your leadership on this very important issue.

Mr. Chairman, we appreciate your leadership on these issues and look forward to continuing to work towards a resolution. Thank you for giving me the opportunity to provide this information to you today. I look forward to answering any questions that you may have.

[Ms. Parks' testimony may be found in the appendix.]

Mr. GRAVES. Thank you, Ms. Parks, and thank you for mentioning the venture capital issue that we have got up. I actually testified on that yesterday in another Committee, and we are going to have a hearing on it in this Committee in about a month. So we might ask you for your input on that, too.

I will let Mr. Barrow introduce our next witness.

Mr. BARROW. Thank you, Mr. Chairman. I am pleased to introduce to the Committee Mr. Thomas Dollar. Mr. Dollar is a third-generation Georgia farmer. In addition to growing over 3,000 acres of cotton and peanuts, he is the president of both the Decatur Gin Company and the Miller County Gin Company. Both businesses gin about 56,000 acres of cotton each year.

Mr. Dollar sells materials and supplies to farmers. He is a grower and crop producer, and he is a crop processor as well. He is here to talk about the impact that agricultural genetic engineering is having on agriculture in my part of the country.

Mr. Dollar, thank you for being here today.

STATEMENT OF THOMAS H. DOLLAR, II, DOLLAR FARM PRODUCTS COMPANY, DECATUR GIN COMPANY

Mr. DOLLAR. Thank you very much. Thank you, Chairman Graves, Ranking Member Barrow, and members of the Subcommittee. I am very grateful to be asked to speak to you on different application benefits of genetically modified crops. You have described myself tremendously. I appreciate the accolades, and I will not go through that on my speech, but I will go ahead and proceed to the next paragraph.

I come before you today speaking as a producer and to speak for my producer customers about the benefits of growing genetically modified crops, namely, cotton. The general practice of growing crops of cotton has dramatically changed in the last 15 years. Since I started ginning consulting for the gins in 1988, the customary practices of growing cotton have changed in three major ways.

During the 1988 growing season, it normally took five or six applications of residual-type herbicide to control weeds in cotton during the growing season. We sprayed 10 to 14 applications of worm spray to control bollworms, budworms, and armyworms. Then we typically sprayed five to six applications of insects for boll weevils. The end result was 20 to 25 applications of chemical on a cotton field in any given year. Many trips to the field were required, costing me and my other growers time and money.

Now we use genetically modified cotton with the Roundup Ready and BT genes. Roundup Ready cotton has been genetically enhanced to provide herbicide tolerance that allows Roundup herbicide to be applied directly over the top of cotton in the field. Weeds that can negatively infect the field are killed while the cotton plants live. Because of this technology, Roundup has replaced the multiple herbicides I used to use. I also use Bollgard cotton, which contains the BT gene to control bollworms and budworms that can devastate a cotton crop.

This year, in contrast to what I did in 1988, I will only apply two to three applications of Roundup, a nonresidual herbicide, spray two to three times for armyworms, which are not currently controlled by genetically modified cotton varieties suited to my region. Because of the success of the boll weevil eradication program, I will not have to apply any organophosphates that can be deadly to nontargeted pests. The result is four to six applications of a pesticide on any given field versus the 20 to 25 applications required in 1988.

The benefits to me as a grower and to the community as a whole are significant. First, I have experienced cost reductions. I have reduced total sprays by approximately 15 applications since 1998. These chemicals cost approximately $7 per application, and the cost of applications covering things like fuel and labor and aerial application is $4.15, for a total of $11.15 per acre per application. Over the course of 15 applications, that is a savings of approximately $167 an acre. While growers such as myself have to pay a technology fee for biotechnology traits that we use, I calculate that my savings are still more than $100 an acre, not to mention reduced wear and tear on my equipment and the time I save.

The biotech cotton varieties I use require a refuge area of 5 percent to ensure that pests do not become resistant to the technology, so 95 percent is biotech cotton. Over my 2,500 acres, that means I save a total of $237,500.

This reduced cost is helping my bottom line in an ever-competitive cotton market. Globalization, a new farm bill, Brazil's WTO case, the World Trade Organization case against U.S. cotton programs and broader World Trade Organization negotiations continue to bring enormous uncertainties to my future business planning. But given all of these uncertainties, at least I know that my

ability to adopt the latest agricultural technology, such as new biotech traits, will help me compete in these changing times.

Reduced pesticide applications are providing a positive environmental impact. As I mentioned, I have switched from a variety of herbicides to using primarily just Roundup on my crops. Unlike many other herbicides that I have used in the past, Roundup is nonresidual. I have also seen a resurgence in fire ants in my fields because I am using fewer broad-spectrum insecticides. While that might not seem like a positive impact from biotech crops, it is actually a good thing for me. You see, fire ants eat eggs from other pests in cotton, which means less damage to my crops and even fewer pesticide sprays.

The results on my farm are not unusual. Many other farms in the United States and the world have experienced similar positive results. A study by the National Center for Food and Agricultural Policy found that six biotech crops—corn, canola, cotton, papaya, soybeans, and squash—lifted growers' income by $1.9 billion and reduce agricultural chemical use by 46.4 million pounds of active ingredients. Additionally, this study found crop yields increased 5.3 billion pounds. This is money in the pockets of U.S. farmers.

Even more exciting for me is the prospect of new biotech crops yet to come. I traveled to Australia in January 2005 and saw growers there using Bollgard II on their cotton plants. This technology is on the market in the United States but is not currently in very many of the varieties that I use. Next season, this technology will be available to varieties suited to my region and will be stacked with the latest Roundup Ready technology. This new product will address the armyworm problem that currently requires two to three sprays per season in my area.

I look forward to utilizing Bollgard II technology in varieties that are high yielding, specifically adopted for my growing area, and brought to me by U.S. seed companies such as Delta and Pineland Seed. This technology will reduce my pesticide sprays even more, making more a more efficient and cost-effective grower.

In closing, I would like to note that we are experiencing extremely high fuel and fertilizer costs this year, and if it were not for genetically modified crops, many farms simply could not be profitable. In addition to agricultural biotechnology, I am using tools, such as strip till to weed cover crops on 100 percent of my acres, verberate soil sampling for fertilizer and lime application to most efficiently apply these inputs, aerial imagery to show extreme growth and lack of in crops which cannot be detected by the ground, and yield monitors to monitor yield variances in the field.

While you can see that genetically modified crops are not the only strategy I use in my farming operation to reduce costs and improve my efficiency and bottom line, biotechnology is a key component of my operation. Without biotech cotton, I would have faced a tremendous shortfall in my operation. Therefore, continuing to encourage the development of new biotech traits for agriculture, continuing to seek global acceptance of these crops, and continuing to support the rigorous regulatory system that we currently have in place to ensure the safety of biotech crops that make their way to the market are critical to the success of my operation and of American agriculture.

As you can see, I do not mind embracing new technologies or ideas. The day I do not adopt or try a new technology and ideas will be the day I retire. In fact, I think we have only seen the tip of the iceberg in agricultural biotechnology. I look forward to future products that can make me more efficient or help me address some of my most pressing problems, such as a aflatoxins in corn and peanuts and soybeans. I also understand that products that could help growers across the United States, such as drought-resistant corn and soybeans, are currently being researched.

I encourage this Committee and Congress as a whole to promote new technology and to promote new ideas as we move forward in an ever-competitive, global, agricultural environment. Innovation is the key to the United States remaining competitive, and we need to be sure that we are aware of innovations so that new technologies continue to flow to farmers such as myself. The future of U.S. agriculture's ability to feed and clothe the world depends on it.

Chairman Graves, Ranking Member Barrows, and members of the Subcommittee, thank you again for this opportunity to speak on the benefits provided to growers by agricultural biotechnology. I look forward to answering any questions you and the Committee have.

[Mr. Dollar's testimony may be found in the appendix.]

Mr. GRAVES. Thank you, Mr. Dollar.

Next, we are going to hear from Mr. Scott Deeter, president and CEO of Ventria Bioscience in Sacramento, California. Scott, thanks for being here.

STATEMENT OF SCOTT E. DEETER, VENTRIA BIOSCIENCE

Mr. DEETER. Good afternoon, Chairman Graves, Mr. Barrow, members of the Committee, ladies and gentlemen. It is a pleasure to be here.

My name is Scott Deeter. I am president and CEO of Ventria Bioscience, the company that I am representing today in this testimony. I appreciate the opportunity to address the Committee to describe some of the different applications of genetically modified crops. I will briefly describe the company, our technology, and our products in development, and I would be happy to answer any questions following the testimony.

First, let me provide an introduction to Ventria Bioscience. Ventria was founded with the support and guidance of several leaders in biotechnology and agribusiness who formed the company's board of directors. Our chairman is Tom Urban, who was former chairman and CEO of Pioneer Hi-Bred. Other board members include Bill Rutter and Pablo Valenzuela, who were co-founders of Chiron, one of the early biotechnology companies in the U.S.; and Hank Rutter, and entrepreneur and attorney by training. Also, Bill Crouse is a limited partner of Healthcare Ventures; Dean Hubbard, president of Northwest Missouri State; and Mel Booth, who was the previous president of Human Genome Sciences and MedImmune.

These industry leaders have committed their resources, their time, their talents to realize the vision of improving health care on

a global basis utilizing the tools of modern biotechnology combined with the industrial might of American agriculture.

Ventria Bioscience is a plant-made pharmaceutical company. We utilize rice and barley as a factory to produce these biologic products. Ventria's initial products provide human health benefits; however, the company's technology has the potential to address many challenges faced by other sectors of the economy, including animal health, energy, food processing, and industrial processing.

The company's core technology is a highly efficient and unsurpassed method of producing biological products in the seed of self-pollinating rice and barley. The technology was discovered in collaboration with the University of California, as well as other leading research institutions in the United States. Ventria believes this technology will lead to more affordable medicines for a broader patient population than what is possible today with conventional technology.

Our technological innovation results in a substantial improvement in the economics of biopharmaceutical production. For instance, the capital investment required for Ventria to produce 500 kilograms of product per year is $4 million. To compare, to produce that same amount using conventional technology, such as mammalian cell culture, would cost $125 million, a more than thirtyfold increase. In addition, the operating costs of Ventria's technology are less than one-tenth of conventional technology.

Now, there are several reasons why this technological and economic advantage exists. First, we have been able to achieve extraordinarily high yields of the product in the seed of rice and barley.

Second, barley and rice are self-pollinating. They can easily achieve the necessary geographic isolation from their food crop counterparts to eliminate any concerns of cross-contamination with the food supply.

Third, since processing cost is the primary component of cost of goods for biologic products, Ventria's technology has the advantage versus many other systems because it can achieve higher utilization rates for the processing facility. That makes the processing facility much more efficient. The reason for this improvement in efficiency is that these crops can be stored in ambient conditions for up to two years without degrading the protein or the biologic in the seed. By storing the grain and processing on a continuous basis, this allows for high processing capacity utilization and reduced cost of goods.

And, fourth, because rice and barley are safe for human consumption, they are ideal for products that can be delivered orally, thereby eliminating the need for expensive separation technology that is required by conventional systems to remove infectious or toxic contaminants.

These advantages paved the way for a paradigm shift in biopharmaceutical production for the benefit of patients worldwide.

As an illustration of the strength of Ventria's technology, I would like to describe some of the human health products in development. Ventria's first two health products are proteins called Lactiva and Lysomin. These two proteins are found naturally in mother's milk, saliva, tears, and they contribute to the improved health status

that has widely been reported for breast-fed children when compared to their infant formula-fed counterparts. These proteins are part of the reason why breast feeding is the best form of nutrition for infants and is highly recommended by pediatricians.

Now, using Ventria's technology, we can produce these proteins cost effectively and incorporate them into a variety of products for improved human health. We currently produce Lactiva and Lysomin in the seed of rice through contract relationships with selected and well-trained growers. Ventria's field production is regulated under permits issued by the USDA Animal and Plant Health Inspection Service. In fact, last year alone, Ventria's field location was inspected eight times by APHIS inspectors with no compliance infractions. Once harvested, the seed is pulverized to a powder and transported to a dedicated facility where the final product is processed into either a concentrate or an isolate.

The U.S. FDA has regulatory authority over Ventria's products for human health. As part of our premarket activity, we reviewed the safety of Lactiva and Lysomin with a panel of scientific and medical experts who have unanimously concluded that these products are generally recognized as safe for use in functional and medical foods. The results of the panel review were summarized and submitted to FDA where they are currently awaiting clearance prior to commercial sale for human health.

Ventria has several products under development that will incorporate Lactiva and Lysomin. One product has been developed for children suffering from acute diarrhea. The World Health Organization estimates 1.9 million children under the age of five die every year due to diarrhea. To address this crisis, Ventria added Lactiva and Lysomin to an oral rehydration solution, which is a common therapy given to children suffering from diarrhea. By adding Lactiva and Lysomin, Ventria believes it can improve the recovery rate, reduce the severity, as well as the duration of the disease in these children.

This hypothesis is the basis of a recently completed study and Peru with 150 children suffering from this disease. Ventria expects the results of this study to be published shortly.

Our production technology enables the cost-effective addition of Lactiva and Lysomin to oral-rehydration solution for the benefit of millions of children worldwide.

Ventria is also exploring the use of Lactiva and Lysomin for the prevention of diarrhea in the military. During Operation Iraqi Freedom, 70 percent of the deployed troops suffered a diarrheal attack, and 43 percent reported decreased job performance as a result of this attack. During the Vietnam War, it has been reported that hospitalizations due to diarrhea were four times more prevalent than malaria. This is a silent enemy attacking American troops.

Ventria has set its goal to reduce the attack rate by 50 percent with the preventive administration of Lactiva and Lysomin. If we achieve our objective, it would improve military morale, efficiency, and manpower. In terms of manpower productivity alone, this may pay for itself due to the cost effectiveness of Ventria's technology. Incidentally, this is a similar problem to that experienced by the millions of Americans who travel overseas.

Another use of Lactiva that is being developed is for the management of inflammatory bowel disease, or IBD. IBD afflicts over one million Americans and over four million people worldwide. IBD is an extremely debilitating disease that causes severe abdominal pain, weight loss, poor absorption of nutrients, and chronic gastrointestinal ulcers. Ventria is testing the potential of Lactiva to improve the quality of life for the millions with this disease.

Ventria is also working with the University of Cincinnati to develop a treatment for chronic lung infections caused by Pseudomonas, which is the leading cause of death for patients suffering from cystic fibrosis. Ventria and our collaborators have already shown successful inhibition of this infection, and we are jointly planning a preclinical program to further develop this product.

Recently, Ventria was the recipient of an SBIR grant from the National Institutes of Health, National Institute on Aging, related to the use of one of Ventria's products to inhibit biofilms constructed by pathogenic bacteria. These types of infections affect more than 10 million Americans annually. Infections that are protected by biofilm are 100 to 1,000 times more resistant to antibiotics. So it is important to inhibit the formation of these biofilms before they can establish themselves in a wound site.

Ventria has worked with scientists from the University of Iowa and Howard Hughes Medical Institute to develop a natural human protein that has been shown to inhibit the ability of pathogens to construct these biofilms. Using its plant-made pharmaceutical technology, Ventria produced and purified the protein and shown the effective inhibition. With the SBIR grant, Ventria will further develop this product, with the goal of improving patient recovery by reducing the establishment of biofilm infections.

This concludes my testimony on behalf of Ventria Bioscience to describe some of the different applications of genetically modified crops. As you can see, combining the tools of biotechnologies with the capabilities of modern agriculture, we are able to make a significant difference to human health on a global basis.

I would like to thank Chairman Graves, Mr. Barrow, and Committee members for your kind attention and the opportunity to testify. I would be happy to answer any questions following the testimony.

[Mr. Deeter's testimony may be found in the appendix.]

Mr. GRAVES. Thank you, Mr. Deeter. I apologize for the interruption. Everybody should be happy to know that if we do have an attack in Washington, that our system is working well.

Next, I am going to turn it over to Mr. Case to introduce our next witness.

Mr. CASE. Thank you, Mr. Chair. Thank you for the courtesy, and also thank you for, first of all, highlighting through this forum something that is obvious to all of us but not so obvious sometimes outside of the Capitol, and that is that small business is agriculture, and agriculture is small business; in this country, most of agriculture is small business. Also, thank you for the subject matter of the hearing where I think legitimate concerns are often overshadowed by the wrong information and other concerns.

I am really happy to introduce Delan "Rusty" Perry from my own home state, my constituent. Delan was born and raised on the island of Oahu and graduated from the University of California at Berkeley with a degree in political science. He immediately made two very good decisions. The first decision was to abandon the political track and go into agriculture. The second decision was to move to my home island, the island of Hawaii, where he went into agriculture 30 years ago now, focusing in the very rich, volcanic soil of east Hawaii on the island of Hawaii, which, if anybody knows that area, is literal a volcanic zone. In fact, where he grows papaya and other crops, I actually went down at eight years of age from the town of Hilo to watch the volcano erupt in 1960.

He has owned Kapoho Grown, a diversified ag. farm, for 30 years now. He grows a number of different crops as part of the diversified agriculture industry of our Hawaii. Papaya is his specialty. Papaya is our eighth-largest crop at the moment. By the way, if you want to get into some of the history, the four largest crops in Hawaii are pine sugar; seed corn, which is clearly intensive in the genetic engineering area; macadamia nuts, all of which have a very heavy component.

He is the past president of the Big Island Farm Bureau. He is the president of the Hawaii Papaya Industry Association. He is the president also of the Big Island Banana Growers Association. We do a little bit of everything there, and I think he has a real story to tell about the reality of genetic engineering, and I am looking forward to your sharing the story with us. Thank you for being here.

Mr. GRAVES. Mr. Perry, I, too, want to thank you for being here and appreciate the fresh papayas that you brought with you. It is not something we get in Washington or Missouri very often, and I do appreciate that. Very good.

STATEMENT OF DELAN PERRY, HAWAII PAPAYA INDUSTRY ASSOCIATION

Mr. PERRY. Okay. Thank you very much, Mr. Chairman. Thank you, Representative Case, and thank you, members of the Committee. I am really honored to be here, although it is a little ways to come. Aloha and good afternoon.

My name is Delan Perry. I have been a papaya grower on the Big Island since 1974, and I am here today representing the Hawaii Papaya Industry Association, which is a state-wide, voluntary association of growers, packers, shippers, of which I have been president for the last seven years.

I am always happy to share our experience in commercializing virus-resistant papayas. We call it "The Papaya Story." I am proud of the success that we have had using this new technology that was brought to our crop. We certainly did not choose to have papaya ringspot virus come into our farm and almost put us out of business, but we are happy that some visionary scientists recognized the potential for this technology in the late 1980's and that by the time this fatal papaya virus came to our major growing area, a transformation had been proven to be highly resistant. I also believe our experience can be useful to other specialty crops, both in the United States and throughout the tropics and subtropics.

In 1992, as chairman of the Papaya Administrative Committee's Research and Development Subcommittee, it became my job to take a research project and find a way to put it into our growers' hands before everyone went out of business. The need of literally several hundred pounds of seeds, not hundreds of thousands of pounds of seeds, meant that there was really, in reality, little economic incentive for anyone else to do the job. Being farmers, we figured, yeah, we can do this.

The period between 1992, when the virus moved to Puna, which is a district on the Big Island, and 1998, when the United States deregulation as well as licensing of the relevant intellectual properties was completed, was a very hard time for my farm, as well as hundreds of others of affected papaya growers. Our employees went from 17 to one, and I took a job managing an agricultural supply co-op for 27 months. I counted the months. We did not plant papayas for two years. If the transgenic papaya had not been in the works, I would never have gone back to growing papayas.

One of the things, I think, that differentiates our experience with genetically modified crops is that our grower association, at that time, the Papaya Administrative Committee, which was a federal marketing order, and its successor, Hawaii Papaya Industry Association, with the help of a dedicated group of researchers, took all of the steps to bring this elegant solution to a fatal virus to our growers through several things: licensing the appropriate intellectual properties; deregulation with USDA, EPA, and FDA; production of seed—we got in the seed business; very importantly, demonstrating to both the growers and the wider community the efficacy and the need for the technology; development of a distribution plan; development of a marketing plan that had to come; and later, deregulating our papayas with Health Canada, so we deregulated into Canada, and now we are finishing up the deregulation process in Japan, a very important export market.

Today, almost 60 percent of Hawaii's papayas have a resistant gene in several varieties chosen for their special micro-climates and markets. Over 200 growers have received a sublicense from our association to grow transgenic varieties. An important issue, segregation of varieties for the market, and the issue of pollen flow are related issues and an area that we continue to do research in. We believe an important future of our industry is to be able to market a variety for every taste. Papaya is also marketed as a whole food, which sort of sets it apart from other transgenic crops. It is not going to be blended.

Thus, keeping varieties separate is an important key to market expansion. Also, Japan, for instance, has a zero tolerance for nonderegulated, transgenic products. For these reasons, segregation of varieties has become much more important. The Hawaii Papaya Industry Association, together with the Hawaii Department of Agriculture, developed and implemented an identity preservation protocol. Since implementation over two years ago, over 800 acres of nontransgenic papayas have been certified, and with careful handling requirements, no transgenic papayas have been shipped to Japan. Upon deregulation, we will expect the zero tolerance to be relaxed, but we have shown that it is achievable.

We have also found that growers, especially inexperienced ones, have made mistakes in obtaining seeds or, in the case of organic growers, wanted tolerances less than five percent, which is the industry standard. Since our ongoing research shows that cross-pollination is very limited, I believe that, talking to your neighbor and using simple and reasonable practices, all papaya growers will be able to grow different varieties side by side without problems.

We will have the scientific basis to make recommendations before long on optimal distances between varieties to ensure varietal integrity. In fact, most growers already successfully grow two or more varieties side by side to support new markets and hedge their virus risk. On our farm, we grow three different varieties.

Papayas are a very important crop throughout the tropics and subtropics. Papaya ringspot virus is, likewise, a nasty problem most places. Many countries in South America, the Caribbean, Africa, and South and Southeast Asia are working on their own transgenic papayas using local scientists, local strains of papaya ringspot virus for protection of their local papaya varieties.

The Hawaii papaya story is told in many places. Just in the last few months, we have had visitors from Thailand, the Philippines, and Vietnam wanting to see for themselves how well the technology has worked and what challenges we have overcome.

Though consumer acceptance has been very good in Hawaii and the rest of the U.S. and in Canada, we will have a different challenge in Japan when deregulation is finished because of the labeling requirement. Even though transgenic and non-transgenic papayas are substantially equivalent, I want to acknowledge the great help of the Foreign Agricultural Service that has been providing market research, map and task funds, and much other support as we approached this challenge.

Surprisingly, one of the most important consequences of our successful commercialization of transgenic papayas has been the attention of the scientific community on papaya research other than genetic engineering. It is particularly exciting that the Hawaii Papaya Genome Project will sequence the whole papaya DNA. Sometime next year, they will be completed. Not only has this sped up the answering of regulatory questions on molecular biology, but we will soon discover new neutriceuticals hidden in the genome that will be the basis for more papaya usage in the future.

I want to leave you with two thoughts. As a commercial crop for domestic and export sales, Hawaii papayas would not have survived without this technology. And I hope you will agree that our papaya can be a model for other small specialty crops which need to overcome a similar challenge. I believe we have demonstrated this. Papayas are once more a growth industry seeking new premium markets.

Thank you for this opportunity to testify on this important issue. I will be happy to answer any of your questions.

[Mr. Perry's testimony may be found in the appendix.]

Mr. GRAVES. Thank you, Mr. Perry.

We will start with questions, and I actually have one for all of you, and just to give you a little bit of background on one of the reasons why I am so fascinated with this and one of the reasons I am so interested in this is this is actually my area. My degree

was in plant physiology, and I had every intention after I got out of college—obviously, I went back to the farm, and I had every intention of getting a master's and possibly a doctorate in this field, in plant chemistry. Unfortunately or fortunately, however you want to look at it, I got sidetracked into politics, and that is where I am today. That was not my original track, but it is where I am going, and now I have an opportunity to see and help foster some of the advancements that are coming at us.

When I was in school, which was in the early eighties, we were just talking about—in fact, Mr. Deeter touched on protieomics and breaking it down at the protein level and some of the wonderful opportunities of marrying plant science and human science together. And, of course, a protein, it does not matter if it comes from a plant or a human; it is the same thing.

But I would be interested in knowing from your respective areas, and you are all experts and very knowledgeable in your areas, and it does not matter whether it is production outcomes you are looking for or human health outcomes or whatever the case may be; I would like to know what you think out there as to what is going to knock the public's socks off, what is one of the wonderful things that is going to happen? It may be production, it may be human health, but tell me what is fascinating on the horizon today, and, Mr. Huttenbauer, we will start with you.

Mr. HUTTENBAUER. Thank you. From our standpoint, obviously, as a plant-made pharmaceutical company, the thing that we hope will ultimately knock the public's socks off is the ability to really produce high-quality and low-cost health care. But in particular, some of the targeted proteins that we are looking into are proteins that cannot be created in the abundance that they are needed to be created to address certain health care needs.

I have one example of approach that we are working on. It is a disease that afflicts about 50,000 people worldwide, and because of current production constraints, and this is a particular blood protein, only about 14,000 patients can be treated on a yearly basis. In addition to that, the actual costs of those treatments are in excess of $30,000 per patient.

So one of the advantages plant-made pharmaceutical has is to not only allow for the entire 50,000 patients to be treated but also to dramatically lower the cost of the health care. For some people, they just simply could not afford it even if it was available, and I think that is one of the greatest advantages that we can bring to the future.

Mr. GRAVES. Ms. Parks?

Ms. PARKS. People, in general, have an extraordinarily personal relationship with forests, and they do not realize the number of products that actually derive from forests and all of the downstream products that come from the manufacturing processes. And I think one of the most exciting things that could be available for the public is if they could actually maintain that really strong personal relationship with the forest and have a mechanism to be able to produce a lot more wood on a lot less land so they could have the products that they want and be able to have the personal experience with the forest on a regular basis or whenever it is that they want that experience.

Mr. GRAVES. Mr. Dollar?

Mr. DOLLAR. One thing you say that would knock the socks off of biotech—I am in the rain belt, the southeast United States, but we do not get rain when we need it, so we have to have irrigation. I have 26 irrigation systems running most of the time when we need it. But water issues are becoming bigger and bigger, so if we could develop plants that are more water tolerant and do not have to have as much water, I think that would be one big item that would affect everybody.

Mr. GRAVES. Mr. Deeter?

Mr. DEETER. Well, my socks are already off. I am impressed with the papaya story. Actually, that, to me, is a major story that really is not out there, quite frankly. You do not hear about that in the press, that we would not be eating papayas today, but that knocks my socks off.

But I would say that I think there is another item, and that is I am reminded when the human insulin gene was cloned, biotechnology—this was 20 years ago—biotechnology was a scary idea, and there was a lot of concern about biopharmaceuticals. But when we cloned the human insulin gene and were able to produce insulin for diabetics, all of a sudden we had a real product for real patients to solve a real, life-threatening problem. And I think that is the same for plant-based biotechnology, that as we have a story like the papaya industry, something that was saved by biotechnology, to me, that is important. But when we also have a mother that can stand up and say that my child is alive today because of plant-made pharmaceuticals, and that I could neither maybe afford that product before, or I did not have that product before, to me, that is when the public stands up and says that is amazing.

Now, in order to get there, we have to have a science-based, regulatory process, and we have to have the research and development because, from the data that I am aware of, it takes 10 years to get to that point, from the time you start until you actually achieve it. So that is what I see as the knock-your-socks-off application in plant biotechnology.

Mr. GRAVES. Mr. Perry?

Mr. PERRY. Well, I think, from a papaya grower's standpoint, having a papaya in every kitchen would be really great. But looking at the larger picture, I think, in our industry, the thing that is most exciting to me is the potential for not necessarily our industry but solving the papaya ringspot virus in places like Bangladesh where they really need an easy-to-grow crop full of Vitamin C to supplement their diet, and they cannot do it now because they have a virus, and this is something that they will be able to commercialize in the foreseeable future.

And the same thing goes for Thailand where papaya is a very important fruit. They got ringspot in there, I think, 15 years ago, and now it is really hard to grow, and this is the same story you will find in a lot of places. In Brazil and Thailand, papaya farmers run into virgin forests, chop them down,—you have heard this before—running away. This is not something that has to be happening in the future for papayas anyhow.

Mr. GRAVES. Thank you. I have got a lot of questions, but I am going to let some of the members ask theirs. Mr. Case?

Mr. CASE. Thank you very much Mr. Perry. Let me just ask you a couple of questions, going back to Hawaii ag., and I would like to have a few more questions after you, Mr. Chair, on some other aspects.

You and I both know that in Hawaii we are doing some of the most advanced tropical and subtropical agricultural research in the world, whether it be the papaya story or other crops, through the USDA, which has major facilities in Hawaii, including the Pacific Agricultural Research Center right now in Hilo. Can you just outline perhaps some of the other applications of genetically engineered solutions in Hawaii, whether it be from a disease-resistance perspective or from a crop-yield perspective or, for that matter, the cotton water-tolerant analysis? What are the other things that we are doing in GE?

Mr. PERRY. You may know the list better than I do. The ones I am familiar with are there is some work on sugar cane. I do not know exactly what they are looking for. In pineapple, they are looking for nemintode resistance, which is a serious problem that utilizes a whole lot of chemicals that is accomplishable using genetic engineering. Right now, there is some work on orchids, and in that area, they are looking at a nice, dark-blue orchid that has a gene that is not available in the regular population. The seed corn industry, as I think you mentioned, is a huge part of our agricultural sector now, and there are a number of companies doing a lot of developing new varieties using our multiseason growing conditions.

Mr. CASE. And then to go back, just briefly, to the comments you were making about the ringspot virus situation, the solution to that, as well as these other GE applications, is done in conjunction with the federal research facilities, USDA. Could you just talk a little bit about the relationship between the private sector and the federal government's agricultural research and scientific facilities?

Mr. PERRY. Well, we have been working with various research, USDA research, in the past. I think the ground breaking just last week for the facility in Hilo is a great opportunity to house everybody together in potentially a large facility serving not only Hawaii but the whole Pacific Basin. The director, Dennis Gonsalves, is the person that actually made the cassette that was inserted into the papaya back in Cornell in the eighties. He is one of these visionary scientists that I was talking about. We maintain a continuing, really good relationship with them. They have helped us out enormously in coming up with the microbiological research to finish our deregulation process in Japan.

Mr. CASE. Just so I can be clear on deregulation, "deregulation" refers to the fact that they are going to let the product in and allow it to be marketed. Right? Is that essentially what that is?

Mr. PERRY. Well, you know, if you ask them, they say it is a safety review. We say it is deregulation, but that is what it is. Every country has their own set of rules that you have to go through, and, in some cases, they require extra research, things that we did not have to do for FDA, looking at different aspects, and that is what we think we have completed in Japan. So getting all of the safety information or data that they think is necessary to say, yeah, this something we want our people to eat.

Mr. CASE. Thank you.

Mr. GRAVES. Mr. Sodrel?

Mr. SODREL. I heard a little bit earlier about the crop separation and making sure the genetically engineered crops did not get mixed in with other crops. What is the worst-case scenario, if they do get mixed together?

Mr. HUTTENBAUER. To properly answer that question, I would have to say it would depend somewhat on what the actual output product is that is being engineered. The worst-case scenario in the two targeted outputs that we are going after would be that an organic flax farmer, for instance, would not be able to indicate that they actually had organic crops. The actual molecules themselves are completely harmless if ingested, so that would not be an issue in terms of contamination.

I think it is interesting that even though there have been some instances of crop contamination that have been highly publicized, and I referred earlier to the Starlink corn, there has not been a single case of anyone being harmed from a genetically modified crop in the entire history that they have been developed. I think regulations are in existence that are doing a pretty good job of keeping that from happening. I think they are advancing.

As technology advances, things such as gene containment can further advance that crop separation, but I cannot say that there is not something that is being devised right now in a plant that if it did get into a food system could not be harmful, but that is also why the systems for containment exist.

Mr. SODREL. So it is fair to say it is more a perception problem than it is a reality problem.

Mr. HUTTENBAUER. I would say greatly so. In my experience, the Starlink corn gets brought up time and time again, and, you know, it was an unfortunate incident, and one of the problems perhaps with corn, because of the pollen transfer, and also the folks from Ventria mentioned that the use of self-pollinating crops is one way to mitigate that containment issue, as we go forward there are lots of new ways to do this well. But I would say, largely, it is a self-perception issue versus the reality of the dangers there.

Mr. SODREL. Thank you, Mr. Chairman.

Mr. GRAVES. Thank you, Mr. Sodrel.

My next question is probably for Mr. Deeter and Mr. Huttenbauer. Can you talk a little bit about how your technologies might be used in other areas of agriculture, animal agriculture, for instance? Go ahead, Mr. Deeter.

Mr. DEETER. Sure. In fact, that is an interesting question because Ventria has been looking at the opportunity to replace antibiotics that are used in production agriculture today with a natural and a microbial protein that could be produced in the seed of barley, for instance. These could essentially eliminate the need for antibiotics in confined animal feeding operations.

Now, today, antibiotics are used broadly, of course, because they not only promote growth, but they also keep at bay the pathogenic infections that can be devastating for a confined animal feeding program. But if we could deliver in the barley, ground, pulverized powder, say, of barley that contains an antimicrobial protein and eliminate the need for the antibiotic, that would be significant not only for animal health, but there is a significant impact to human

health because these same antibiotics that are used in animal production agriculture can potentially cause resistance to develop in the human population and make the antibiotics that we use for human health less effective.

So if we can eliminate pathogenic infections and do that without a loss of the benefits of antibiotics, that would be significant.

Mr. HUTTENBAUER. Along with animal antibiotics, one of the things that we have been looking at in terms of the effects on animals is essentially enhancing animals' health effects on humans consuming them. One of the things that we have undertaken is a study of cattle being fed using DHA-enhanced flax in a feed program which ultimately translates the health benefits of the Omega 3's into the cattle so that humans downstream consuming them could take advantage of those healthy benefits which currently are basically limited to fish or fish oil supplements. As well, we have looked at programs involving chicken feed and the healthy benefits being imparted on the eggs as well, again, really around Omega 3. So that is one avenue in terms of animal health that could be applied with this.

Mr. GRAVES. I am curious, real quick, Mr. Perry. You mentioned possible markets,—Europe, China, Korea—and Europe has traditionally resisted GMOs considerably, and it has been a little bit of an education process, but we are still not there yet. I know you are look at those as potential markets. Do you have any ideas on how you are going to combat that or work through that or what you are going to do to try to get them to overcome their fears, you might say?

Mr. PERRY. Well, to start with, one of the things that we have relied on is voluntary researchers, and that has slowed the process down a little bit, and for that reason, we are chewing these deregulation issues off country by country, one by one, and after we finish Japan, we do sell papayas to the EU. I think this is something that we believe we will have all of the basic research that they will ask for, and the same would be true of China and Korea.

The future for us is looking at premium markets. We cannot compete with some of the South American countries for price because of our costs, but we can look at premium markets, and these, because it is so difficult to grow nonvirus-resistant papayas, these are things that the countries are going to have to look at, going through the same deregulatory process.

Mr. GRAVES. Mr. Case, did you have a follow-up? If you have got a follow-up, go ahead, Mr. Sodrel.

Mr. SODREL. I just have a question. Ms. Parks, in my district, about 20,000 people make their living out of forest products, so trees are of great interest. The ash borer in Central Park in New York; they have got smoke jumpers crawling up the trees trying to find the trees that are infected.

You talked a lot about growing the trees faster and the makeup of the tree, the pulp content and so on. Can we also look for disease-resistant or insect-resistant trees as well?

Ms. PARKS. Absolutely. ArborGen is currently not working on disease or pest resistance because we are working with more commercial species in the southern United States and in Brazil, but there are quite a few universities who are actually looking at different

ways to manage pest and disease resistance, and, in fact, Syracuse University and the State University of New York are also looking at how can they expand their programs to try to address some of those issues as well.

Mr. GRAVES. Mr. Case?

Mr. CASE. Thank you. Since we are in the Small Business Committee, let me ask you some questions related to federal programs available to small business. I have a suspicion that I have never actually checked out—perhaps it is just more anecdotal—that agriculture small businesses may tend to access our federal government programs at a lower rate than perhaps other kinds of small businesses, technology or whatever else.

I do not know if it is true or not; it just occurs to me that it might be true, and I am not talking about USDA scientific because I think agriculture has been able to access that just fine, at least from my perspective. But I am talking about things like the EDA and the SBA and USDA rural development. Have each one of your companies utilized those programs of the federal government in the small business area for venture capital, start-up loans, basic advice, and how is it going from that perspective? I will just go right down the list. If you could just briefly give me a quick picture.

Mr. HUTTENBAUER. From our standpoint, we have not utilized them, and the reasons were twofold. One was, as I think you alluded to, the relatively small size of the potential contribution, and, secondly, because we are dealing in biotech, and there is a degree of secrecy in what we are doing, the initial thoughts were to maintain some of the secrets, if you will, of what we were developing, so we chose not to go that route for initial funding.

Ms. PARKS. We have only just begun exploring some of those programs. In the first place, we started this with the SBIR and discovered that, at this point in time, those funds are not available to us. But forestry in general and forest biotechnology is very underfunded at this point in time, so we are trying to look at a lot of different options that we could approach the government for funding.

Mr. DOLLAR. We currently do not use anything. We have looked at some SBA loans when we have had some hurricanes come through, and we were ineligible for those SBA loans. When we did start the first cotton gin in 1988, we used FHA business and industry loans, and other than about eight inches' worth of paperwork, they were very helpful for our gin because there had not been a gin in our county since 1922. So our bankers were a little reluctant to put a gin in without a little back-up help, so we were able to secure a business and industry loan from FHA in '88.

Mr. DEETER. We have received recently an SBIR grant, Phase I, for $100,000, which is really our first foray into a collaborative program with the federal government, but that is something that we believe, especially with the case of the prevention of military diarrhea, that is obviously something for benefit for DARPA, so we will explore that opportunity. We will also explore other SBIRs. I think that is something that we have not done a lot of. We are only 15 employees today, but it is something that we would really like to do going forward.

I must say, it does take some time. It takes the time of some of your best people, and the process to receive that type of funding is fairly significant. I think the first phase is $100,000. Of course, it can be larger than that going down the road. To put that in perspective, to date, our investors, which are all individuals, have invested $35 million in Ventria to get us to where we are. So $100,000 out of $35 million is the share.

Mr. PERRY. Well, I think I mentioned earlier that we have a very good relationship with the Foreign Agricultural Service, and we have utilized their programs for our papaya administrative Committee before and now the Hawaii Papaya Industry Association. Two years ago, we got a task grant to help us complete some of the research for our Japan deregulation

Mr. CASE. Thank you. Very helpful.

Mr. GRAVES. Dovetailing on talking about the small business aspects, and I do want to change gears just a little bit, and this may be more for Ventria and Agragen, but as far as developing your technology, growing your technology, you might talk a little bit about the aspects of utilizing farmers, contracting with farmers to do that. Are you planning on doing that yourself? You just might explain what is happening there. Mr. Dollar, you may have some experience with that, too, but go ahead.

Mr. DEETER. Actually, our technology, we use today contract growers that grow, and these are growers that have been certified, trained growers. They are monitored. There is quite an auditing process and inspection process. We will expand that grower base as the company grows and as our products develop and commercialize.

Our first two products, Lactiva and Lysomin, represent tens of thousands of acres, so it is not millions of acres initially, but it is a start. We seek growers that have the skills and capabilities, and most importantly, the desire to learn the skills and capabilities for our type of production because this is a very different type of production than commodity food production, a totally separated, totally dedicated type of production with new skills, new capabilities.

What is the payoff? We expect these growers will make double what they could make with their best alternative commodity production, so they will make two times what they can make with their next best alternative. They will not only make more money, but they will be trained in new areas, and those skills and capabilities will also, we believe, have value down the road.

To put this in perspective, once we are fully commercialized, we expect the first two products that we are developing to increase, and this is an increase over what they could make in their best alternative—it will increase their income by $10 million every year. Now, this is, again, tens of thousands acres; it is not millions of acres. It will be very significant for those growers who elect to participate, but, again, our first products will not be millions of acres. That is really not our plan.

I want to also mention, the amount of federal crop subsidies that Ventria receives is zero. These crops are not subsidized at all, so it is a 100-percent benefit to the grower.

Mr. GRAVES. That is a good point.

Mr. HUTTENBAUER. I think a lot of what we are doing is mirrored with Scott's commentary, and I should also point out that they are

further down the road than we are. We are looking at also going with the contract grower system. We have commitments now for roughly the first 16,000 acres when we get to the stage when we are actually planting. Again, the importance of establishing a contract grower system, because of the closed-loop network of how this has to be contained and the regulatory environment, it is almost essential to have a preestablished network of farmers.

As I pointed out in our testimony, we are truly looking at large-scale agriculture. The first two components that we are going to be making are upwards in the neighborhood of 100,000 acres, so the potential for a rather large contract grower network exists.

As PMPs advance, I can certainly see a lot of the learning that is derived from some of these initial companies being passed down and farmers forming actual PMP growing networks, if you will, going forward that are established exclusively for PMPs because there will be some isolation to that, and you could get to the stage where a certain portion of a state may be set aside for specific PMP farming.

Mr. GRAVES. In agriculture, as profit margins get squeezed narrower all of the time, and that is happening all of the time, you know, we are obviously looking for more opportunities to make agriculture work. Unfortunately, we are price takers on both sides. We do it a little bit different than other industries. We buy everything retail and sell everything wholesale, so we are price takers at both ends, and we have to find opportunities, and I think these are wonderful opportunities to be looking at. Mr. Case, do you have any more?

Mr. CASE. Just a quick question. The federal government obviously regulates genetically engineered crops through a tripartite regulation structure. Last year, the secretary of agriculture opened up a docket to take comments on the potential revision of those regulations. Did any of you participate or make submissions on that docket or, through your trade industries, make any recommendations, and what were they if you did it?

Mr. DEETER. We have been involved through the Biotechnology Industry Organization. First of all, as, I think, the history of mankind shows, when technologies like plant biotechnology first enter the public domain, there is often a violent and very emotional reaction, and it has been true for biotechnology in general, not only plant biotechnology but biotechnology in general. I would say, thanks to a scientifically driven, regulatory process, we have allowed the differences of opinion to surface. We have been able to consider the scientific facts, and we are not swayed as much by the emotional arguments that are really meant to stymie the innovator and arrest progress in these important areas.

I think that we have got to keep steadfast in the science-driven regulatory process, and with BIO's help,—Ventria is a small company, and we do not have a team that can spend a lot of time working with new types of regulations, so we work mostly through BIO—we have been able to improve upon the base of regulatory structure. We have been working with new regulations related to advantageous presence so that it is more of a scientifically sound approach.

The member asked the question, what would happen if there was a contamination? Well, I cannot speak for every product, but I can speak for Ventria's products. You know, it is in mother's milk. These proteins are in saliva. They are in our tears. What would happen? You might be healthier.

So I think we need to remove the emotion, focus on the scientifically driven, regulatory process and do not put in regulations that serve no other purpose if there is really no scientifically valid reason for it.

Ms. PARKS. ArborGen participated on behalf of ArborGen and as part of BIO and as part of a coalition that was developed for perennial and specialty crops, and our position had been, when we spoke with APHIS, is that the current regulations obviously demonstrate that there is a lot of safety in the way the regulations are currently enforced and that any new regulations should still continue to be developed so that decisions are made on a case-by-case basis based on the product, the trait, species of interest, and that APHIS should have the opportunity to streamline processes where the biology of the plant is well understood and where the application of the plant in the field is well understood.

And so we have, in our conversations with APHIS, just strongly encouraged them not to create any kind of overburdensome regulations based on a particular type of plant or the nature of the plant as in a perennial crop simply because they are gaining experience with how that product or that crop works because the system to date has worked very well, and we would fully like to have our products go in under the current system or with modifications made for the specific trait or species of interest that we have.

Mr. GRAVES. Mr. Barrow?

Mr. BARROW. Thank you, Mr. Chairman. I apologize for my absence, but my other Committee is meeting and marking up a bill today, and so I had to be running back and forth, and I appreciate your indulgence and that of the witnesses.

I would like to ask Mr. Dollar a couple of questions, if I can, that are matters that I do not think have been covered. First of all, I will preface this by saying, I am sure that the farmers here who farm for a living and some of the old hands on this Committee do not need an education in all of this stuff, but I am fascinated to learn the impact that biotechnology is having in such matters as fighting weeds in crop production.

So, Mr. Dollar, for those of us who are not all that well versed, either by background or experience, could you help us have a better understanding of just exactly what biotechnology is helping you all do and making it easier for you all to manage crop production dealing with weeds?

Mr. DOLLAR. Well, before Roundup Ready crops, we used several different methods, most of them called Blue Steel, which you had to have a good tractor operator and a good piece of equipment, and you would plow the fields, but you could not get all of the crops. Then with the advent of 24D's and atrizenes, we had not hard chemicals, so to speak, but chemicals that left a residual, and they would show up a couple of weeks later or may interfere with a crop that is planted in a rotation behind the crop that you are planting at a certain time.

So with the advent of Roundup Ready crops, we do not have any residual left over, so we can plant a vegetable crop. In south Georgia, we are 20 miles from the Florida line, so we will have sweet corn following cotton, or we will have snap beans following cotton, or we will have peanuts following cotton. So with the advent of those crops following the crops that we are growing, we do not want to put a harsh or long-residual chemical out there that may show up in a nontarget crop.

So the Roundup has been efficient for that for us, and also sometimes you would have to spray a multitude of chemicals to kill a grass, to kill a broad leaf, certain types of monocot plants or dicot plants, you would have to use several different herbicides, and those would be very cost prohibitive on a low-input crop like soybeans or field corn, and Roundup has leveled the playing field, so to speak.

Mr. BARROW. In some of the testimony we heard earlier today, folks were talking about trying to segregate or keep new, innovative crops and products of biotechnology away from the larger population for a variety of reasons. That brought to mind something I wanted to discuss with you, and that is how are you in the industry, how are farmers and the folks who are supplying you all with biotechnology, how are you all responding to the concerns that folks have about growing a generation, if you will, of pests that have increased tolerance for the things we are engineering into the plants to make them resistant to the pests? What are you all doing to deal with that because I know that is a concern on the part of folks generally?

Mr. DOLLAR. Well, in cotton, the crops, what we will do is we will have a 20-percent rule or a 5-percent rule that when we are planting a non-BT or non-Roundup Ready crop that we will basically let that crop go to waste so that, say, on BT cotton, we will not spray it with any type of chemicals so it will host a generation of pests or insects that may be tolerant at one time or another to BT, but then it will decrease its vulnerability to be more tolerant over the long term.

Monsanto, which developed a lot of this technology, along with the EPA, mandate what we do as farmers and how much land we leave out and plant to a host crop so we will not have a problem later on down the line. We are very keenly aware of how beneficial this crop has been to us from the advent, so we, as farmers, adhere to those rules, the 100 percent, and Monsanto is also developing some crops. Bollgard II, that was a new type of crop that will work better on armyworm complex, and then eventually they will phase out the Bollgard I altogether so we will not build up any resistance.

Mr. BARROW. It sounds to me like what you are saying is you will sacrifice, you will, by design and by practice, by good management practice, sacrifice a percentage of your crop for the greater good of making sure that you do not evolve or grow a whole generation of pests that will be able to overcome that engineering.

Mr. DOLLAR. Correct.

Mr. BARROW. Two questions as a follow-up to that. One, are you still able to make more? Does the increase in productivity, despite that sacrifice, still make it a good deal for you all? And, secondly, is this something you all are just doing on the buddy system, on

the honor system, or is this something that is mandated and actually policed to make sure that these best-management practices are actually followed?

Mr. DOLLAR. It is mandated by EPA, and then Monsanto and—

[Loudspeaker announcement.]

Mr. BARROW. To return to my question, the concern I had was that while it is a good idea for everybody to do that in order to make sure that you do not grow up a generation of pests that have an increased tolerance of this, how are they making sure that everybody is doing that so that nobody is going to opt out of that system in order to get that extra 5 or 20 percent of capacity out of their crop ?

Mr. DOLLAR. Monsanto and EPA; we have spot checks. They will come by and check fields randomly for the BT gene in the cotton plant. Probably the biggest policing person we have is your neighbor because your neighbor does not want you to get an edge up on him. So I think there has been more farmer-to-farmer tattle telling when there have been instances or occasions than the greater good that Monsanto or EPA can do because everybody wants to be treated the same, and everybody wants to make sure they get treated the same.

Mr. BARROW. I understand. I appreciate that. And, finally, something you touched on in your testimony earlier, I want to return to, and that is the subject of what some folks refer to as the technology fees, the research and development costs, that are passed along for the products of biotechnology. Can you give us your assessment of whether or not they are reasonable in light of the benefits?

Mr. DOLLAR. Well, in light of the testimony of the people to my right and the people to my left in talking about funding from other sources to try to develop this, developing technology is a very expensive way to make a living, and with that in mind, the technology that we pay as farmers is always too much. Anything we have got as farmers is too much fee, but with the farmers in mind and the amount of money that we spent prior to the 1988 or prior to 1995, when we started going to Roundup Ready and BT crops, it is a value. There is a lot of value. We are saving $167 an acre, and our technology fee is not even a third of that.

It is grumbling when you look at your end of the year, your P&L, and you say, I paid X number of dollars to a technology fee, and that bothers you. It is like you look at the end of the year, and you see how much money you spent on groceries or anything else, and when you itemize it up, you say it is a lot of money, but if you turned around and itemized how many bills you would have had spraying all of these different chemicals and all of these application costs, you do not have that to look at now, so you tend to forget about it, and you tend to complain.

Mr. BARROW. Thank you, Mr. Dollar.

Mr. DOLLAR. Thank you.

Mr. GRAVES. I apologize for the interruption again. Stay away from the Hart Building and welcome to post-9/11 Washington, D.C., unfortunately. Sometimes we have those a lot; sometimes we do not. Unfortunately, that is part of the process today.

I want to thank all of the witnesses for being here again. All of the statements made by members and the witnesses will be included in the record in their entirety. I do appreciate some of you came a long ways to be here, and I do appreciate it.

I want to introduce one individual who is here, State Senator David Clint from Missouri, who is a leader in biotechnology as both a producer and as a member of the state Senate in Missouri. I am very pleased that he came out here to hear this hearing. David, thank you for being here.

I also want to make sure everybody knows we are having a reception in this hearing room at 5 o'clock for all of the witnesses who are here, if you can stick around, and for the audience to know, too, if you can stick around, please come back and attend that. It will be right here in this hearing room on the balcony, if you can make it. I hope you will be here.

Thank you all for coming, and I appreciate it very much. Very enlightening. This is cutting-edge technology, and it fascinates me, and I am looking forward to moving forward with it. Thank you.

[Whereupon, at 3:49 p.m., the Subcommittee was adjourned.]

Different Applications for Genetically Modified Crops
Rural Enterprises, Agriculture and Technology Subcommittee
June 29, 2005

Good Afternoon and welcome to the Rural Enterprises, Agriculture and Technology Subcommittee. Today we will be looking at "Different Applications for Genetically Modified Crops." I want to thank everyone for participating in this hearing. As a farmer by trade, I truly believe Genetically Modified Crops are the future for American Agriculture. As Agricultural markets become more competitive world-wide, it is imperative that the United States keep its edge by offering a continued superior quality product. Genetically Modified Crops also allow agribusinesses to increase profits and continue to uphold the United States' reputation for excellence in agricultural products.

For centuries, farmers have been modifying crops to improve their growth rates and yields. We have seen technology not only improve these yields, but also create varieties resistant to pests and diseases. Such modifications have previously been made through crossbreeding plants with desirable traits and through hybridizations. Thomas Jefferson was renowned in this area for his experimentation at his Monticello plantation.

Already in this country, 85 percent of the soybeans have been genetically modified, followed closely by 75 percent of cotton and half of all corn. In all, thirteen different plants in the U.S. have been approved to be genetically modified. In fact, some 60 percent of all our food has been genetically modified.

Continued developments in research hold great promise not only for traditional agricultural crops to feed the world, but also crops for medical purposes. Through advanced technology, scientists can modify specific genes for desired qualities and grow them within plants. Commonly referred to as "Biopharming" this method for retrieving certain enzymes hold limitless potential and will allow the United States to retain its leadership role within the medical research field.

Worldwide, genetically modified crops offer hope for over-populated countries to feed and medicate their people in a much more effective, efficient manner. I am greatly concerned that current regulations and the lack of knowledge for this science will not only hamper growth within this industry, but also will allow other countries to surpass the United States position as a world leader within the agriculture business industry. We must continue to make policy decisions based on sound scientific facts and help businesses to expand in this industry. We have great potential to not only re-vitalize rural business communities, but also offer incredible products more resourcefully to the consumer.

I am looking forward to hearing from all of the witnesses today and learning more about this expanding industry and its incredible potential.

Prepared Remarks of Mr. Sam Huttenbauer
President Agragen, Inc.

Good afternoon Mr. Chairman and members of the Committee. Thank you for giving me the opportunity to participate in this panel. My name is Sam Huttenbauer, and I am the president of Agragen, Inc., a biotech company working on the development of plant made pharmaceuticals (PMPs). We are located in Cincinnati, Ohio and are opening up a laboratory facility in Grand Forks, North Dakota where we plan to grow and process our pharmaceuticals. I am pleased to testify today at this hearing regarding the future potential of PMPs and their tacit economic impact toward bolstering America's agricultural economy.

Agragen was started three years ago with the express purpose of manufacturing pharmaceuticals utilizing the natural protein manufacturing capability of plants. The company has also concentrated, since its inception, on selecting molecular targets that required substantial agricultural acreage. Agragen is one of a new breed of agribusiness companies combining conventional agriculture with high tech science. As such it will work with farmers employing their agronomic expertise and existent land. With America's agriculture undergoing change in the competitive world arena, Agragen and companies like it present one opportunity to move our country's great food and fiber skills into a more profitable and stable system. Plant made pharmaceuticals are the new ultra-high value farming for the 21st century.

What are plant made pharmaceuticals[1]

Plant-made pharmaceuticals (PMPs) are the result of a breakthrough application of biotechnology to plants to enable them to produce therapeutic proteins that will be used by the medical community to combat life-threatening illnesses. In this process, plants themselves become "factories" that manufacture therapeutic proteins. These proteins are then extracted, refined and used in pharmaceutical production.

These plants are grown under highly regulated conditions in defined growing environments and are strictly regulated by the U.S. Department of Agriculture (USDA), its Animal and Plant Health Inspection Service (APHIS) and by the Food and Drug Administration (FDA).

Why use PMPs?

As the world's scientific technology increases, more and more drug therapies rely on recombinant proteins[2] and less on traditional combinatorial chemistry. And while this represents monumental breakthroughs in healing, it also presents significant problems of economics, efficiency and safety:

Consider This:

- Over 14% of treatments in clinical trials today require recombinant proteins
- It takes 5 – 7 years to build a biotech plant capable of producing recombinant proteins vs. 1 – 3 years for a conventional pharmaceutical plant
- Just 4 molecules consume 75% of the current existing capacity to make recombinant proteins– over 100 new protein-based medicines are now in late stage clinical trials

There are many challenges to current recombinant production methodologies:

- **Economic** - Current biotech plants require 5-7 years to construct, cost $250 million to $450 million and must be individually approved and certified by the FDA prior to full-scale operation
- **Supply** - Despite increased therapeutic use of recombinant proteins, there is a global shortage of production facilities (<12 worldwide) for these new proteins. This greatly limits the movement of these products into therapeutic use
- **Safety** - There is the possibility of cross-contamination with human pathogens or other mammalian contaminants utilizing current production methodologies

Plants provide a number of advantages over other production methods of biomedical materials:

1) Cost: Plant vaccines and proteins are inexpensive to produce relative to the cost of traditional vaccines and proteins
2) Safety: The use of plants for the production of biomedical materials eliminates the possibility of cross-contamination with animal or human pathogens

3) Economic Implications: Farming is already an important and established part of our global economy

4) Practicality and Flexibility: Because one plant can express several antigens simultaneously, vaccines against a variety of pathogens can be produced in a single plant. In addition, plants producing therapeutics can be rapidly scaled-up as demand increases simply by planting more acres

The industry needs a cheaper, more efficient way to manufacture today's and tomorrow's pharmaceuticals. PMPs offer this alternative; plants improved through the use of biotechnology can produce the essential building blocks (therapeutic proteins) for innovative treatments for diseases such as Alzheimer's disease, cancer, chronic obstructive pulmonary disease (COPD), Crohn's disease, cystic fibrosis, diabetes, and many others at a fraction of the cost of current manufacturing methods.

About Agragen

Agragen is not currently what might be classified as a drug discovery company, having chosen to focus on established therapeutics that are market limited either due to extreme production cost or limited production capacity. Once we have established our production platform, this will lead to additional pharmaceuticals that will also require large acreage. The overall thrust of our technology is to insert genes into the plant thereby permitting the plant to make and store the protein of interest in the seed, where it can be stored indefinitely until it is purified. From a business standpoint, plant made pharmaceuticals represent a means to reduce the production costs and to increase the availability of many new drug therapies, with the downstream effect of dramatically reducing costs to consumers and allowing life-saving therapies to find their way into the hands of many patients who would not have access either due to cost or availability.

Agragen has selected two products for the initial stages of production and has several additional candidate proteins. These initial products are in line with the Company's goals - the utilization of a large amount of acreage and the passing of value added agricultural profits back to the farmers- for three reasons:

1. First: They both represent $1 billion plus underserved and growing markets

2. Second: Both targets will ultimately require large acreage (100,000+) and spawn meaningful infrastructure

3. Third: Both molecules are currently being utilized which will reduce both clinical test costs and time to market

As recumbent protein science becomes an increasingly important technique for the formation of new therapeutics, manufacturing capabilities must keep pace. Agragen is one of a number of companies that understands the capabilities and cost efficiency of plants serving as pharmaceutical factories. In addition plants offer genetic mechanisms that may allow discovery and creation of molecules that can not be constructed from any other source.

Benefit to the rural farmer

To be truly beneficial for small rural business, plant made pharmaceuticals must be tied to open field production. PMP operations utilizing plants created in laboratories or in green houses have little or no connection to the agribusiness system. While these operations can utilize plants' natural production mechanisms to produce life-saving, valuable therapeutics, they do not provide an opportunity for the American farmer.

Large PMP farms, similar to what Agragen is creating, can be established around the country utilizing a large number of acres, either supplementing lost state farming acreage or establishing new growth. In many cases there will be opportunity for both. Farmers benefit from the production of PMP producing crops via their provision of steady employment of their fields and by their greater cash to crop yield than is available via the current agricultural industry.

In addition to supplying farmers with a new high-value crop, Agragen envisions further rural economic involvement by potential farmer ownership of PMP processing and manufacturing facilities. Agragen's business model offers farmers and rural economies the opportunity to participate first hand in this new value added family of crops.

The goal in this novel form of Agribusiness is to bring the farmer into this process as a partner which specifically means allowing operators to share in the profitability of what they are manufacturing. Agragen believes that it can double or possible triple the bottom line income of its partners with a market price that is far more stable than typical focused commodities.

Further more, Agragen's impact would be felt in equipment sales, transportation and processing jobs, real estate values, etc. Facilities to handle the transformation of the large biomass from field crop to pharmaceutical will have to be located within close proximity to actual growing areas. This means millions of dollars in construction and additional opportunities for skilled employees in rural locations. Our own initial projections following our first two output products show close to eighty million dollars infused into the economy of the state that we will operate in.

We see an instant opportunity to utilize American agronomic skills to help replace some farm products that might be rendered marginal by rapidly developing world-wide agriculture production. PMPs offer the possibility for the small farmer businessman to share in a potentially large profit market while providing tangential benefits to rural economies that would not be subject to new investment otherwise.

Challenges

However, being immersed in the standard farming arena is not without its problems. Typical agricultural challenges such as weather and parasites can be mitigated by the use of multiple growing regions and protein development in seeds which allow for long-term storage and thus the capability to stockpile. The greatest immediate threat comes from public perception. Field production pits PMP companies against GM antagonists and organic farmers, particularly those who may have an interest in the crop species being transformed.

There has been a call for all PMP crops to exclude any plants currently used for food or feed. Unfortunately, while many plants possess the potential for protein production certain species are better matched with specific targeted proteins. Some plants may serve as excellent converters, i.e., tobacco, but require too high of economic inputs or extraordinarily expensive processing procedures. The need to utilize the production capacity of food crops will be necessary, but these crops are used solely as a factory and will never enter the food chain.

Unlike former GM plant transformations including the now notorious 'Starlink' corn, where crops basically entered a side-by-side handling and distribution system- one where the possibility of interchange with non-GM materials is always present, PMP's will never have the opportunity to mix with their commodity counterparts. PMPs must adhere to a closed loop system that will include dedicated equipment, transportation, storage, processing, and waste handling.

Still, public perception issues exist; chief among them is the fear that PMP crops will contaminate non PMP fields vis-à-vis pollen drift. This is not an insurmountable issue. A major step forward occurred recently in Missouri where governmental officials played a large role in resolving a similar PMP related controversy. In Missouri the problem was untangled by diverse separation, essentially using large distances to keep PMP crops away from that being produced for the food system.

Distance is an effective means to mitigate crop commingling, however it might not always be enough. In addition to distance requirements the USDA mandates that all PMPs must be grown using a closed loop system. Dedicated equipment and shipping

trucks are employed to keep seeds, plant material and pollen from mixing. In Agragen's case, because of the ultimate magnitude of the acres projected, this solution might only be temporary. Other methods are being developed to take a more proactive approach to containing the PMP agriculture. For example, Agragen is hard at work developing novel gene control mechanisms that will make mixing with other plants a statistical improbability.

Conclusion

Mr. Chairman, I want to reiterate that by working with established control mechanisms under the guidance of the USDA and other organizations, by working with State and local officials, and by incorporating the knowledge of the farmers themselves, PMPs can be safely grown throughout the states.

According to a report by consultancy Frost & Sullivan released in December 2004, the US market for plant made pharmaceuticals could be worth $2.2 billion by 2011 with the first products reaching the market by 2005/2006. Agragen believes that from that point its growth will be restrained only by discovery science not keeping pace. This can translate into direct economic growth for US agriculture as companies utilize more and more acres for PMP production.

PMPs offer not only the promise of cheaper more abundant pharmaceuticals, but the establishment of a new ultra-high agricultural venue for today and tomorrow's farmer. Agragen, by bringing the farm community into its business system, feels that it will economically benefit, rural areas and individuals who otherwise would have no connection to the biotech revolution.

Thank you, Mr. Chairman.

Notes:

1) Source- Bio.org 2004
2) **Recombinant** proteins are proteins that are produced by different genetically modified organisms following insertion of the relevant DNA into their genome. As this *recombines* the DNA of two different organisms, the word *recombinant* is used to refer to this process.Many peptide hormonemedications (including insulin), and vaccines are the product of recombinant processes. The organism most commonly used is Escherichia col (E.coli)

WRITTEN TESTIMONY

DAWN W. PARKS
DIRECTOR, PUBLIC AND GOVERNMENT AFFAIRS
ARBORGEN, LLC

BEFORE THE
COMMITTEE ON SMALL BUSINESS SUBCOMMITTEE ON RURAL ENTERPRISES, AGRICULTURE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES
REGARDING DIFFERENT APPLICATIONS FOR GENETICALLY MODIFIED CROPS

June 29, 2005

Good morning Mr. Chairman, Members of the Committee, Ladies and Gentlemen. I am Dawn Parks, Director, Public and Government Affairs of ArborGen, LLC.

I am privileged to be here this afternoon on behalf of ArborGen as well as on behalf of our trade association, the Biotechnology Industry Organization (BIO). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in 31 other nations. BIO members are actively involved in the research and development of new medicines, foods, and industrial and environmental products to benefit the lives of people and the environment.

I would like to thank Chairman Graves and members of the committee for the opportunity to be with you today, and for organizing this hearing. I would also like to thank you Mr. Chairman for your leadership on the Small Business Innovation Research (SBIR) program. Specifically, I want to take this opportunity to publicly express BIO's, and BIO's member companies', appreciation for your introduction

of H.R. 2943, the Save Biotechnology Innovative Research Act (SABIR) of 2005. This important legislation preserves venture capital-backed biotechnology small businesses' access to vital Small Business Administration grants

Agricultural biotechnology is celebrating two significant milestones in 2005. First, this year marks the 10th anniversary of commercialized biotech crop plantings, and second, last month we marked the planting of the one billionth acre of biotech crops. These two points clearly demonstrate that agricultural biotechnology is the most rapidly adopted technology in the history of agricultural production.

In this tenth year of growing crops enhanced through biotechnology, global acceptance continues to increase at a rapid pace. According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), in 2004, global biotech crop plantings continued to grow at a sustained double-digit rate of 20% compared with 15% in 2003. The estimated global area of approved crop plantings was more than 200 million acres in 2004.

These crops were grown by approximately 8.25 million farmers in 17 countries, up from 7 million farmers in 2003. But most notably, 90% of the beneficiary farmers were resource-poor farmers from developing countries, whose increased incomes from biotech crops contributed to the alleviation of poverty.

Closer to home, the United States is the world leader in the development and planting of these crops and rural America is one of the chief beneficiaries. In 2004, American farmers chose to plant 85% of soybeans, 76% of cotton and 45% of corn with seeds improved through biotechnology that allow the plants to protect themselves from insects and disease and promote better weed management. The United States has also approved for commercial planting biotech varieties of canola, chicory, flax and linseed, melon, papaya, potatoes, rice, squash, sugar beets, tobacco and tomato. The annual R&D investment of the six largest companies in the sector is $2.7 billion, or 10.8 percent of sales.

The rapid adoption of this technology by U.S. farmers is a testament to the solutions it provides to problems on the farm. Biotechnology enables farmers to reduce input costs and improve yields.

Agricultural biotechnology contributes to increasing the health of farm animals enabling the production of safer and more nutritious meat, milk and eggs. It also keeps our family pets healthy. There are over 100 licensed vaccines and diagnostic tests developed through biotechnology that significantly reduce disease in both farm and companion animals. In addition, biotechnology can be used to detect desirable genes in livestock populations. This new tool can improve breeds, help select the healthiest animals for feedlot management and provide consumers with a certification of meat quality.

Biotech companies are developing soybean and canola varieties with healthier profiles, reducing or eliminating harmful trans-fat and saturated fat. Foods are in development which will have higher levels of nutrients, protein and essential amino acids as well as extended shelf-life. And because biotechnology researchers have identified the allergenic proteins in many foods and are developing varieties that delete or disable those proteins, we can look forward to allowing those with allergies to enjoy a fuller diet without fear of an allergic reaction.

Biotechnology has a long track record for using innovative techniques to solve long standing problems.

My company, ArborGen, is a small business, but the research and development we are doing at our headquarters in Summerville, South Carolina, holds potential to improve forestry on a national and international scale. Forestry, of course, is a rural business that supports millions of jobs across America.

Our goal at ArborGen is to use breeding techniques, including biotechnology, to improve the sustainability of forestry. According to the Food and Agriculture Organization (FAO), about one-third of harvested wood is supplied from industry-owned highly managed tree plantations. The rest comes from landowners that utilize a wide variety of management techniques, including natural forest management. As the worldwide population increases, so does the demand for wood and paper products. Rather than expanding the forested acreage under management to meet these wood and paper requirements in the future, we are developing faster-growing trees that will improve the productivity of plantations. By producing more wood on less land, people can build the houses and buy products they desire, without cutting down our natural forests, which will be conserved for wildlife, recreation, biodiversity and beauty.

ArborGen also is developing trees with modified lignin. Lignin is a component of wood fibers that is removed during thr pulping process to obtain the cellulose needed to make quality paper. The process involves intensive use of chemicals and energy. Reducing lignin content in trees intended for pulp or making it easier to remove lignin during manufacturing processes, will provide important environmental benefits.

The area of forestry biotechnology has potential to bring many other benefits, and several institutions around the world are developing exciting products that have significant social, environmental and economic benefits. One key potential benefit is the production of cleaner burning fuels. Wood produced for ethanol or used directly as fuel by power companies would be a clean, renewable, and cost-effective energy source.

Phyto-remediation of Superfund sites or other toxic lands is another very promising possibility. Instead of spending billions of dollars removing and sterilizing impaired soils, it may be feasible to plant modified trees that can absorb and neutralize hazardous wastes and heavy metals.

Biotechnology can also help restore endangered species such as the American chestnut, American elm, flowering dogwood and California oaks. A single disease-resistance gene added to chestnut could allow these beautiful species to withstand the blights that have nearly obliterated them from our landscape. Field trials with American elm are under way now, and chestnut trials should begin soon.

Another possibility is trees that can grow in harsh conditions, such as arid climates or salty soils. In areas where trees are an important part of the landscape, this technology could halt further encroachment of the desert and allow trees to grow in areas where they are now unable to grow. And the ability to grow important hardwoods more quickly on managed lands could halt the black market harvesting of these species in natural forests.

Forestry biotechnology is in its infancy, but it holds unlimited possibilities that would take generations to produce through traditional cross breeding. Instead of waiting for trees to grow to sexual maturity so they can be cross bred with other trees, forest biotechnology can identify a desirable gene and transfer it to a tree. The success or failure of the transfer can be seen immediately.

Then, through high-production multiplication systems, we can mass produce plantlets and introduce large numbers of the improved trees to supply plantation foresters so they can begin to provide benefits to this generation of citizens and into the future. Perhaps adults living today will be able to stand beneath the shade of a spreading chestnut tree, just as their great-grandparents did.

Mr. Chairman, I hope you can understand from my testimony how excited I am to be a part of this emerging industry. There are, however, threats to the continued success of the research I have just described. The most daunting being the exclusion of companies, such as ArborGen with majority private funding from companies, from participation in the SBIR programs.

While BIO does represent established companies in the industry, the vast majority of its members, over eighty-five percent, are small, emerging companies with less than 500 employees. In fact, more than fifty percent of the companies in our industry have fewer than 50 employees.

In our case, a company with 70 employees, it strikes us as unthinkable that we would be considered ineligible for an SBIR grant because we receive private funding for core projects .

Under the current interpretation of eligibility, we are considered ineligible because as a start-up biotechnology company we did what virtually all of our early-stage member companies must do to continue their research; we received funding for early research and development projects through corporate investors. Funding partners often support the development of critical platforms, technologies, and protocols that will lead to products for a particular industry. For example, as we develop products designed for improving forest management and manufacturing efficiencies, we have identified genes that can provide significant value to industries outside of papermaking and lumber.

The SBIR program is ideally suited for this purpose, because the company has already demonstrated that it can successfully raise follow-on financing, one of the key criteria in evaluating an SBIR Phase II grant proposal.

To remove this barrier to participation in the SBIR program, BIO has urged SBA to revise the SBIR eligibility requirements and issue a proposed rule that reflects Congress' original intent to encourage awards to small businesses that have successfully attracted outside investors. The approach proposed by SBA in its December 3, 2004 Advanced Notice of Proposed Rulemaking to disregard affiliation is a step in the right direction. However, it does not address the fundamental obstacle which is SBA's requirement that small businesses be majority owned and

controlled, directly or indirectly, by individuals. The SABIR Act, however, clarifies that biotechnology small businesses receiving venture capital funding are in fact eligible for SBIR Phase II grants. We thank you so much, Mr. Chairman, for your leadership on this very important issue.

Mr. Chairman, we appreciate your leadership on these issues and look forward to continuing to work towards a resolution. Thank you for giving me the opportunity to provide this information to you today. I look forward to answering any questions that you may have.

The Testimony of Mr. Thomas H. Dollar II
Dollar Family Farms, GP
President and CEO
Dollar Farm Products, Inc.
Decatur Gin Company, Inc.
Miller County Gin Company, Inc.

Before the Subcommittee on Rural Enterprises, Agriculture and Technology
House Small Business Committee

June 29, 2005

Thank you, Chairman Graves, Ranking Member Barrow and Members of the Subcommittee. I am very grateful to have been asked to speak to you today on the different applications and benefits of genetically modified crops.

First, I would like to briefly tell you about myself. I am a third generation agri-businessman from Southwest Georgia. Currently, I am a producer of 2,500 acres of cotton and 900 acres of peanuts. Additionally, I oversee the sale and application of chemicals and fertilizer at Dollar Farm Products for 40,000 acres of cotton, 10,000 acres of sweet corn and 20,000 acres of peanuts in general trade for three counties in Southwest Georgia. I am also President of Decatur Gin in Bainbridge, Georgia and Miller County Gin in Colquitte, Georgia. Decatur Gin gins approximately 26,000 acres of cotton annually, and Miller County Gin gins approximately 30,000 acres of cotton annually. My businesses employ more than 125 people in my community in Southwest Georgia.

I come before you today to speak as a producer and to speak for my producer-customers about the benefits of growing genetically modified crops, namely cotton. The general practice of growing cotton has changed dramatically in the past 15 years. Since I started

ginning and consulting for other gins in 1988, the customary practices of growing cotton have changed in three major ways. During the 1988 growing season:

- It normally took 5 or 6 applications of a residual-type herbicide to control weeds in cotton during the growing season.
- We sprayed between 10 and 14 applications of worm spray insecticides to control bollworms, budworms and armyworms.
- We sprayed 5 to 6 applications of insecticides for boll weevils.

The end result was 20 to 25 applications of chemicals on a cotton field in any given year. Many trips through the field were required, costing me and other growers time and money.

Now I use genetically modified cotton with the Roundup Ready and Bt genes. Roundup Ready cotton has been genetically enhanced to provide herbicide tolerance that allows Roundup herbicide to be applied directly over the top of the crop in the field. Weeds that can negatively impact yield are killed, while the cotton plants live. Because of this technology, Roundup has replaced the multiple herbicides I used to use.

I also use Bollgard cotton, which contains the Bt gene to control the bollworms and budworms that can devastate a cotton crop. In 2005 I will:

- Apply 2 to 3 applications of Roundup, a non-residual herbicide.
- And spray 2 to 3 times for armyworm, which is not currently controlled by genetically modified cotton varieties suited to my region.
- Because of the success of the Boll Weevil Eradication Program, I will not have to apply any organophosphate chemicals that can be very deadly to non-targeted pests.

The result is 4 to 6 total applications of pesticide on any given field, versus the 20 to 25 applications required in 1988. The benefits to me as a grower and to the community as a whole are significant.

First, I have experienced significant cost reductions. I have reduced total sprays by approximately 15 applications since 1998. These chemicals cost approximately $7 per acre per application. The cost of the application run itself – covering the cost for things such as fuel and labor – is approximately $4.15 per acre for a total cost of $11.15 per acre per application. Over the course of 15 applications, that is a savings of $167.25 per acre!

While growers such as myself have to pay a technology fee for the biotech traits that we use, I calculate that my savings is still more than $100 per acre – not to mention reduced wear and tear on my equipment and the time that I save.

The biotech cotton varieties that I use require a refuge area of 5% to ensure that pests do not become resistant to the technology, so 95% of my farm is biotech cotton. Over my 2,500 acres, that means I have a total savings of $237,500.

This reduced cost is helping my bottom line in an ever-competitive cotton market. Globalization, a new Farm Bill, Brazil's WTO case against the US cotton programs, and broader WTO negotiations continue to bring enormous uncertainties to my future business planning. But given all of these uncertainties, at least I know that my ability to adopt the latest agricultural technologies such as new biotech traits will help me compete in these changing times.

Reduced pesticide applications are also providing a positive environmental impact. As I mentioned, I have switched from a variety of herbicides to using primarily just Roundup on my crops. Unlike many other herbicides that I have used in the past Roundup is non-residual.

I have also seen the resurgence of fire ants in my fields because I am using fewer broad-spectrum insecticides. While that might not sound like a positive impact from biotech crops, it is actually a very good thing for me. You see, fire ants eat eggs from other pests in cotton, which means less damage to my crops with even fewer pesticide sprays.

And the results on my farm are not unusual. Many other farms in the United States and around the world have experienced similarly positive results. A study by the National Center for Food and Agriculture Policy (NCFAP) found that six biotech crops – corn, canola, cotton, papaya, soybeans and squash – lifted grower incomes by $1.9 billion and reduced agricultural chemical use by 46.4 million pounds of active ingredients. Additionally, this study found crop yield increases of 5.3 billion pounds. This is money in the pockets of US farmers.

Even more exciting to me is the prospect of new biotech crops yet to come. I traveled to Australia in January 2005 and saw growers there utilizing Bollgard II. This technology is on the market in the United States, but is not currently in very many varieties. Next season this technology should be available in varieties suited to my region and will be stacked with the latest Roundup Ready technology. This new product will address the armyworm problem that currently requires 2 to 3 sprays per season in my area. I look forward to utilizing Bollgard II technology in varieties that are high yielding, specifically adapted for my growing area and brought to me by US seed companies such as Delta Pineland. This technology will reduce my pesticide sprays even more, making me a more efficient and cost-effective grower.

In closing, I would like to note that we are experiencing extremely high fuel and fertilizer costs this year, and if it were not for genetically modified crops, many farms simply could not be profitable. In additional to agricultural biotechnology, I am using tools such as:

- Strip till into a wheat cover crop on 100% of my acres.
- Variable rate soil sampling for fertilizer and lime applications to most efficiently apply these inputs.
- Aerial imagery to show extreme growth and lack of growth in crops, which cannot always be detected from the ground.

- And yield monitors to monitor field yield variances and adjust input applications as necessary.

While you can see that genetically modified crops are not the only strategy I use in my farming operation to reduce costs and improve my efficiency and bottom line, biotechnology is a key component of my operation. Without biotech cotton, I would have faced a tremendous shortfall in my operation. Therefore, continuing to encourage the development of new biotech traits for agriculture, continuing to seek global acceptance of these crops, and continuing to support the rigorous regulatory system that we currently have in place to ensure the safety of the biotech crops that make their way to the market is critical to the success of my operation and of American agriculture.

As you can see, I do not mind embracing new technologies or new ideas. The day I do not adapt to or try new technology and ideas will be the day I retire. In fact, I think we have only seen the tip of the iceberg in agricultural biotechnology. I look forward to future products that could make me more efficient or help me address some of my most pressing problems, such as aflatoxins in corn and soybeans. I also understand that products that could help growers across the United States, such as drought resistant corn and soybeans, are currently being researched.

I encourage this committee and Congress as a whole to promote new technology and to promote new ideas as we move forward in an ever-competitive global agricultural environment. Innovation is key to the United States remaining competitive, and we need to be sure that we are rewarding this innovation so that new technologies continue to flow to farmers such as myself. The future of US agriculture and our ability to feed and clothe the world depend on it.

Chairman Graves, Ranking Member Barrow and Members of the Subcommittee, thank you again for this opportunity to speak on the benefits provided to growers by agricultural biotechnology. I look forward to answering any questions you and the Committee have.

DRAFT ***6/28/2005***

Ventria Bioscience Testimony

Committee on Small Business

Subcommittee on Rural Enterprises, Agriculture and Technology

U.S. House of Representatives
June 29, 2005

Given by:
Scott E. Deeter
President & CEO
Ventria Bioscience

Good afternoon Chairman Graves (R-MO), Members of the Committee, Ladies and Gentlemen. My name is Scott Deeter and I am President & CEO of Ventria Bioscience. I appreciate the opportunity to address the Committee on behalf of Ventria Bioscience. I will briefly describe the company, our technology and our products and would be happy to answer any questions.

First, let me provide an introduction to Ventria Bioscience. Ventria Bioscience is a plant-made pharmaceutical company that utilizes rice and barley as a factory to produce biologic products. Ventria's initial products provide human health benefits, however the Company's technology has the potential to address many challenges faced by other sectors of the economy including animal health, energy and industrial processing.

Ventria was founded with the support and guidance of several leaders in biotechnology and agribusiness who form the Company's Board of Directors. Ventria's Chairman is Thomas N. Urban, Jr. former Chairman and CEO of Pioneer Hi-Bred International. Other Board members include William J. Rutter, Ph.D. and Pablo Valenzuela, Ph.D., who were Co-Founders of Chiron; William H. Rutter, an attorney by training and an entrepreneur; William W. Crouse, a limited partner of Healthcare Ventures; Dean Hubbard, Ph.D. President of Northwest Missouri State University and Melvin D. Booth, former President of MedImmune, Inc. and Human Genome Sciences, Inc. These industry leaders have committed

contaminants. These advantages pave the way for a paradigm shift in biopharmaceutical production for the benefit of patients worldwide.

As an illustration of the strength of Ventria's technology, I would like to describe some of the human health products in development. Ventria's first two human health products are proteins called Lactiva™ and Lysomin™. These two proteins are found naturally in mother's milk, saliva and tears and they have been suggested to contribute to the improved health status that has been widely reported for breast fed children when compared to their bottle fed counterparts. These proteins are part of the reason why breast feeding is the best form of nutrition for infants and is highly recommended by most pediatricians.

Ventria currently produces Lactiva™ and Lysomin™ in the seed of rice through contract relationships with selected and well trained growers. Ventria's field production is regulated under a permit that is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS"). In fact, last year alone, Ventria's field location was inspected eight times by APHIS inspectors. Once harvested the seed is pulverized into a powder and transported to the processing facility where the final product is isolated into either a concentrate or isolate.

The United States Food and Drug Administration ("FDA") has regulatory authority over Ventria's products for human health. As part of Ventria's pre-market activities, we reviewed the safety of Lactiva™ and Lysomin™ with a panel of scientific and medical experts that have unanimously concluded that these products are Generally Recognized as Safe ("GRAS") for human consumption. The results of the panel review were summarized and submitted to FDA where they are awaiting clearance prior to commercial sales for human health.

There are several products being developed by Ventria that will incorporate Lactiva™ and Lysomin™. One product has been developed for children

Ventria is also working with University of Cincinnati to develop a treatment for chronic lung infections caused by Pseudomonas, which is the leading cause of death for patients suffering from Cystic Fibrosis. Ventria and our collaborators have shown successful inhibition of this infection and we are jointly planning a pre-clinical program to further develop this product.

Recently, Ventria was the recipient of an SBIR grant from National Institutes of Health, National Institute on Aging relating to the use of one of Ventria's products to inhibit biofilms constructed by pathogenic bacteria. These types of infections affect more than 10 million Americans annually. Infections that are protected by biofilms are 100 to 1,000 times more resistant to antibiotics, so it is important to inhibit the formation of these biofilms before they can establish themselves at the wound site. Ventria has worked with scientists from University of Iowa and Howard Hughes Medical Institute to develop a natural human protein that has been shown to inhibit the ability of pathogens to construct these biofilms. Using its plant -made pharmaceutical technology Ventria produced and purified this protein and has shown the effective inhibition of biofilm formation. With the SBIR grant, Ventria will further develop this product with the goal of improving patient recovery by reducing the establishment of biofilms that lead to antibiotic resistant pathogens.

This concludes my testimony on behalf of Ventria Bioscience. I would like to thank Chairman Graves and the Committee members for your kind attention and would be happy to answer any questions you may have.

Testimony

Honorable Sam Graves
Chairman, Subcommittee on Rural Enterprises, Agriculture, ans Technology

Regarding: Hearing on "Different Applications for Genetically Modified Foods" June 29, 2005.

Dear Mr. Graves and committee members:

I am honored to be given a chance to testify on what we call our Papaya Story. This is story of the spread of a disease fatal to papayas to the major production area of Puna in 1992

For decades, papayas have been grown in Hawaii and have come to be accepted as a basic part of Hawaii's tropical experience and diet. Papayas are grown in abundance on all the islands and pineapples are the only fruit that is produced in larger volume in Hawaii. Papayas, in contrast with Pineapples, are primarily grown on hundreds of family farms. Papayas have achieved this place in our diet and economy because they are not only sweet and flavorful, but very high in Vitamins C and A, and have many folk uses such as easing digestion, good early food for babies, good food for recovering from upset stomach, and good food for regularity.

Papayas have been exported out of state for nearly 50 years after quarantine treatment for Fruit flies.

Background :

The papaya ringspot virus (PRSV) was discovered in Puna in 1992 where 95% of Hawaii's papaya was grown. Previously, PRSV had decimated the growing areas of Oahu, and a small outbreak on Kauai had been eradicated. In 1995 the PRSV was widespread in Puna and the total Hawaii papaya production fell from a peak production of 58.2 million lbs in 1993 to 35.6 million lbs in 1998, a decrease of 39%., but the decrease in Puna was greater at 52%. During the period between 1992 and 1998 Puna growers used several strategies to survive: Rogue out infected trees by cutting them down (This worked in areas that had limited disease pressure and were isolated); move to new areas far removed from Puna's traditional growing areas (This worked for about two years until PRSV found its way to the new areas, but quality and yields due to different soils and climates was decreased.); give up and find new crops or jobs (In the job market at that time, many farmers were severely impacted. From my personal perspective, I took a job as a co-op manager and didn't plant papayas for two years). One result of the moving echoed the experience of growers in Thailand, Brazil and many other areas: marginal land, sometimes in native forests, were cleared, only to become infected in a short time, often within the first crop cycle of 3.5 years. The effect on our

growers had a significant impact on the economy of the whole Island and the State. Papayas had been the biggest business in Puna.

Luckily for the Papaya Industry, visionary scientists had begun looking at new biotech ways of developing disease resistant plants. The transgenic papaya developed by Dr. Dennis Gonsalves, then at Cornell University and currently at the Hilo US Department of Agriculture Pacific Basin Agriculture Research Center (PBARC), and University of Hawaii researchers, Richard Manshardt and Maureen Fitch, was released in Puna in 1998. The transgenic papaya was transformed in 1991 but it took seven years to get through the US regulatory system and into the fields. During the pre-commercialization period between 1991 and 1998, the groundwork was laid for the cooperative effort that led to the successful

1) licensing of the intellectual properties;
2)deregulation with USDA, EPA, and FDA;
3) production of seed;
4)demonstration to both growers and the wider community of the efficacy of the technology;
5) development of a distribution plan;
6) development of a marketing plan.

When the licensing issue came up in 1991, the University of Hawaii turned the process over to the Papaya Administrative Committee (PAC). The PAC was a Federal Marketing Order founded in 1971. The PAC, helped by the mandatory assessment program, and the Hawaii Papaya Industry Association (HPIA), which had preceded the PAC and remained primarily engaged in education and lobbying, both understood early on that this technology was a potential solution to the anticipated spread of PRSV. Both of these Statewide associations worked hard to support the research projects and take the information to growers and the community. PAC identified, first by itself and later with the help of a patent attorney, just who had the underlying patents and should be approached for licenses. Fortuitously, the four entities that were identified turned out to be very generous in the conditions deemed necessary for granting licenses. Certainly, the unique position of a small agricultural industry meeting a local problem with a local disease, utilizing research provided by land grant universities was to our benefit. PAC subsequently developed sub-licensing agreements of growers and homeowners primarily to insure good resistance management and prohibit export of seed outside Hawaii.

Deregulation of the transgenic papaya in the United States, and later in Canada and Japan, fell to the same group of researchers who had developed the transgenic papaya. While the licensors had much of the data for the underlying genes, the many safety and horticultural aspects specific to the Papaya were researched and data submitted by what still remains our mostly voluntary research team.

The PAC undertook contracting out seed production with availability corresponding to the date all licensing and deregulation issues had been resolved. The industry was dying, and timeliness of seed availability has a high priority. Initially, under the marketing order, all seed was deemed already paid for by growers and distributed free, in a complex formula to ascertain fairness of access, to all growers. Upon turnover of this function to the HPIA in 2002, seed cost to growers was closely tied to seed production cost, and represents 1-2% of first year planting costs for members in good standing.

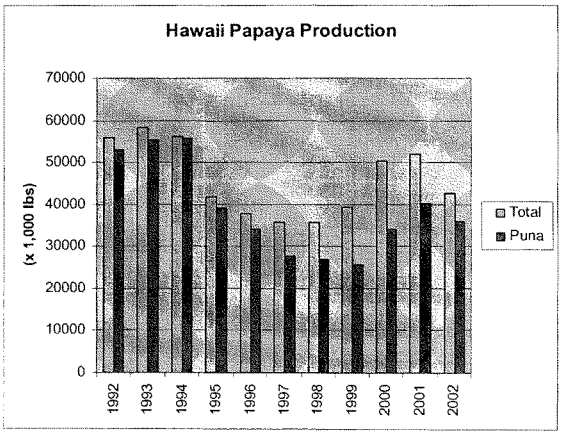
A critical part of our successful commercialization of Transgenic Papaya, was the openness of the development of the technology, first to growers through the PAC and HPIA, and later to the wider community and State. There was no secret that there was a serious disease problem and that the impacts on both growers and consumers would be significant. Many media stories, meetings, and field trips, de-mystified the technology, often in the most practical ways. Growers were believers when they could see, touch, and taste the new varieties. Hundreds visited the very successful field trial .Consumers acted much the same way.

The development of a marketing plan flowed from those early experiences. See it, touch it, taste it: it was hard to resist buying it. Whatever the breeding technology used, it was very clear that this was still very much a papaya. Consumer acceptance was as quick as grower acceptance. Early on after transformation, the papaya industry knew that the end product needed to be a yellow flesh papaya. Hawaiian papayas were seen in the US marketplace as yellow flesh. Since the transformed variety ended up to be a red flesh variety (Sunup), our research team came up with what turned out to be an excellent hybrid cross, later named Rainbow, that was a light orange flesh similar enough to the traditional yellow flesh "Kapoho" that it fit the correct flesh color expectation. Additionally, the new hybrid blended the characteristics of it's parents to produce a variety much better that either of it's parents

Unlike most other genetically modified foods , Fresh Papaya is a whole food. While there is no blending, varietal segregation is very important. Certainly, in non-deregulated markets such as Japan, at present, segregation is critical. HPIA has developed, with the Hawaii Department of Agriculture, a certification program for Identity Preservation (IPP). This very effective program with over 800 acres certified for several hundred growers has been responsible for complying with the zero tolerance for non- deregulated foods in Japan for over 2 years. From the marketing standpoint, keeping varieties segregated means broadening consumer demand by supplying a taste for every palate, much like the Apple industry has succeeded in doing. The Papaya Industry is presently developing a marketing plan for Rainbow in Japan. Here the situation will be somewhat different because there will be a labeling

requirement. We have hired a marketing specialist and are working closely with FAS to expand our market with a new papaya taste in Japan.

The technology used is based on the concept of Pathogen Derived Resistance (PDR), that holds that by incorporating a small particle of, in this case, the coat protein of the PRSV in the DNA of the papaya, resistance is conferred. This had been shown earlier on Squash. This method was chosen because there were no papayas any where that had resistance to PRSV. In fact PRSV is widespread in the tropical and subtropical countries of the world and has devastated production in many countries.



Milestones:

- **1992- PRSV discovered in Puna where 95% of Hawaii's papaya was grown**
- **1995- PRVS widespread in Puna**
- **1998- Transgenic papaya (Rainbow and SunUp) released in Puna**
- **2002- Decline in production adverse weather , disease and reduced marketing**

There is no doubt that the transgenic papaya saved the papaya industry in Hawaii and now constitutes about 60% of all papayas grown in Hawaii.. Oahu is also recovering from the PRSV disaster that started for them in the 1940's. That virus problem had led to the growth of the Papaya Industry on the Big Island. Furthermore, these transgenic papaya have been used as a genetic source to produce new varieties that are especially suited for growing on Oahu.

Currently, the transgenic papaya can be marketed to Canada and the mainland USA. However, it cannot be marketed to Japan, which is a major market for the Hawaiian papaya. Japan represents a premium market and presently takes about 5 million pounds of non transgenic Kapoho a year. We estimate that upon deregulation, the Japan market will grow to 10 million pounds a year within 3 years. The Japan market pays the kind of premium which makes up for the higher labor and other growing costs found in Hawaii. Thus, efforts to get the transgenic papaya deregulated in Japan were taken up by the Hawaii papaya industry with the aid of local scientists that had developed the transgenic papaya. Although progress had been made in obtaining information for getting the transgenic papaya deregulated in Japan, some key areas in sequencing of the transgenic papaya were required, and needed to be done in a timely manner. Recent breakthrough efforts by the University of Hawaii Center for Genomics, Proteomics and Bioinformatics Research Initiative (CGPBRI) and the Hawaii Agriculture Research Center (HARC) in sequencing of the genome of the transgenic papaya will provide indispensable technical information for deregulating the transgenic papaya in Japan. If all goes well the deregulation will be completed by the end of this year.

The efforts to sequence the papaya genome and deregulate the transgenic papaya will benefit Hawaii in a number of other practical ways. First, it adds essential technical information for the deregulation process leading to marketing transgenic papaya in Japan. Second, after the approval of the transgenic papaya in Japan, Hawaii needs to develop sound and expanded marketing strategies for Japan. Third, mainland China has already expressed keen interest in importing the Hawaiian transgenic papaya. However, like Japan, the transgenic papaya needs to be deregulated in mainland China. The necessary information to get the transgenic papaya deregulated in mainland China will be quickly obtained by the ability of the Hawaiian consortium (UH CGPBRI, HARC) of scientists to get the necessary sequencing and other information that is required. Korea and Europe are also potential markets for the Hawaiian transgenic papaya. The Hawaii Papaya Industry must develop these and other premium markets if it is to grow. This interest in the scientific community is one of the additional benefits that our successful use of agricultural biotechnology has brought to further build our future.

Today, the Hawaiian transgenic papaya is the only commercially available transgenic papaya in the world. The transgenic papaya is a interest to the US government in marketing 'minor' transgenic products outside of the US. In many ways, it is a test case for the US. The success of Hawaii's efforts will certainly be a very positive example of how a state as small as Hawaii and a small industry can lead the way in such an important field of biotechnology development and marketing. The benefits to Hawaii will be enormous in attracting local and out of state students to come to Hawaii to study this exciting field. The benefits of such an influx of intellectuals are self-evident.

The ability for Hawaii to attract major grants in biotechnology and commercial partners will also be of great benefit to the economy of Hawaii.

Lastly, a major goal of the scientific efforts that will have a long term impact to Hawaii and the world is the study of the genomics of the papaya. HARC has related the papaya to such fundamental discoveries of incipient sex chromosome evolution development in all species has the interest of the entire world . The excitement that these major discoveries will create will make Hawaii a major player in the field of functional genomics which can hardly be measured and will open the entire field. The application of compounds discovered in the papaya genome can benefit fields as diverse as medical research and food science. It is indeed rare to have such a combination of basic science melding with the practicality of a biotechnology product such as the transgenic papaya located in Hawaii. Successes such as these will bring untold benefits to Hawaii.