contagious. It makes one realize how important history is and we do not want to lose these experiences.—Garrett Tollelle

The tributes, memories, and lives of those who serve or have served in the armed forces must be exalted and above all else never forgotten. Thanks to this interview of United States Marine Corps Major John Lauder, I have first hand insight on the life of a true patriot. Major John Lauder went from only a Cadet, to Captain, 1st Lieutenant, 2nd Lieutenant all the way to where he is now at Major. As I listened to the memories and experience of Major Lauder, it occurred to me the massive amount of courage, dedication, and perseverance it takes to serve. As a marine he has served four tours of duty thus far and is still an honorable member of the Marines. It is to him I owe my understanding of the true hardships that one must take on as a Marine. I hold people like Major John Lauder responsible for my feelings of security and pride in such a beloved country.

The memories of our men in service and veterans are important ones. They are memories that should not be lost. These people have put their lives on the line and triumphed over all odds. I proudly say that Major John Lauder is one of these people. While serving, Major Lauder has truly excelled as a Marine. earning awards such as Iraqi and Afghan campaign medals as well as being decorated for valor. Not only those, but he has also received the Global War on Terrorism Service medal, expeditionary medals, along with a combat action ribbon. Major John Lauder is a truly exemplary person and I give thanks to God for people like him.—Amanda Dees

Colonel James E. Gilliland grew up in a changing time throughout the tides of war and peace. He entered the Air Force as the Korean War had ended, but answered the call to defend his country during the Vietnam War, flying 100 vital reconnaissance missions over North and South Vietnam war zones in a very short amount of time. The dangerous missions which he completed helped to contribute to the key strategies during the war, saving countless American lives. Throughout his tour in enemy skies, he was a highly decorated RF–4C pilot in the United States Air Force, which includes the Silver Star, Distinguished Flying Cross, Legion of Merit, Bronze Star and Air Medals. Even after his combat tours in Vietnam, Colonel Gilliland continued to hold senior command and staff positions in Saigon, Hawaii, Colorado, Texas, England, and eventually Belgium. Not only was this man a hero throughout his career with the Air Force, but he is also my grandfather, a man I hold in the highest regard. Hearing his story, which even now is hard for him to tell, has helped me to better understand just how much he has sacrificed for his country.—Trevor Ede

What Corbett Reagan accomplished was a 6 month tour (1990–1991) of duty in Iraq during Operation Desert Storm where he specialized in anti-tank gunning. He was the recipient of the Meritorious Unit Award, the Valorous Unit Citation, and the Kuwait Liberation Medal. What I gained from this interview experience was how committed Corporal Reagan was to his country. It was part of his heart and soul to be a Marine and serve our nation, particularly growing up in a military family. I also was struck by the influence the Marines and his overall service in Kuwait/Iraq during Operation Desert Storm had in molding him into a man of character. Being in the Marines shaped his life in many ways, particularly in helping him understand the issues of life and death, obtaining his education, the importance of family and friends, as well as gaining an appreciation for what it means to live in this great nation of ours.—Lauren Hill

Lieutenant Colonel Richard Castle was born in 1946 in Rochester, New York. His decision to join the Army was voluntary but also influenced by his family. His grandfather had served in the Navy during WWI while his own father had been a captain in the air corp. Even his brother had served in the United States Army during the Vietnam War. Richard served in the Vietnam War as a logistics officer. During his entire military career. Richard reached the position of 5th corp commander under a three star general. At the end of his military career, he reached the position of lieutenant colonel for his incredible service. The things I learned from Lieutenant Colonel Richard Castle were so astounding and intriguing. He seemed like a man who genuinely cared about his country and had loved serving in the Army. It made me gain a much greater appreciation for the men and women in the service right now. Talking on the phone with him. I realized how much of an ordinary person Mr. Castle was. Yet for him to have done so much for the Army is absolutely amazing. His story truly shows that anyone can serve the country and be an inspiration.—Lisa Hu

Colonel Vernon David Gores was born on December 27, 1929 in Bisbee, North Dakota. He grew up exposed to the agricultural environment of North Dakota, in addition to the small city life of Fargo, North Dakota. Vern Gores graduated from North Dakota State University with a degree in civil engineering in 1951. While there he attended ROTC, then entered the United States Air Force as a second lieutenant and attended flight school. Vern served in several capacities for the Air Force. For most of his Air Force career, Vern served as a pilot for transport (C–46) and reconnaissance aircraft (EC–121). He also advised an ROTC unit. He held positions of operations officer, commander advisor to the National Guard, and inspector general. Vern lived across the nation and internationally during his career. After North Dakota he lived in Alabama, Oklahoma, Illinois, Vermont, California, Massachusetts, Florida, and Ohio. He also served in several foreign countries: Japan, South Korea, Libya, Vietnam, and Thailand. Vern served in the Korean conflict and Vietnam. He remembers the Cuban Missile Crisis and the ''ongoing'' Cold War.

Vern retired from the Air Force at the rank of Full Colonel in 1979 at Wright-Patterson AFB, Ohio after 28 years of service. He has been awarded the Legion of Merit, Air Medal, and Bronze Star recognitions. Today Colonel Gore lives in the Villages of Lady Lake, Florida with his wife Colleen. They have been married for more than fifty years. They have one son, two daughters, and five grandchildren. His family is very proud of his accomplishments. He served with untiring effort, superior intellect, and uncompromising values of honesty, integrity, and loyalty. The nation and our family are fortunate to be associated with him.—Garrett McDaniel

PERSONAL EXPLANATION

HON. HILDA L. SOLIS

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, March 13, 2008

Ms. SOLIS. Madam Speaker, during rollcall vote No. 120, on motion to adjourn, I was unavoidably detained. Had I been present, I would have voted ''no.''

INTRODUCTION OF THE PATHWAY FOR BIOSIMILARS ACT

HON. ANNA G. ESHOO

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, March 13, 2008

Ms. ESHOO. Madam Speaker, the field of biotechnology is the future of medicine. Scientists and doctors are just beginning to scratch the surface of the potential to harness the extraordinary power of biology and the astounding natural processes which occur in the human body, in animals, and in other living organisms to advance breakthrough medical discoveries and treatments. While ordinary pharmaceuticals primarily treat the symptoms of a disease or illness, biotechnology products—''biologics''—can be manipulated to target the underlying mechanisms and pathways of a disease.

Through the study of biotechnology, we will develop effective treatments for cancer and AIDS, many of which are already saving lives. We will cure diabetes. We will prevent the onset of deadly and debilitating diseases such as Alzheimer's, heart disease, Parkinson's, multiple sclerosis and arthritis. We will save millions of lives and improve countless more.

The development of biologics is expensive and extremely risky. Bringing a biologic to market can require hundreds of millions of dollars in research and development costs and can take several years. For every successful biologic, there are another 10 or 20 that do not pan out, making the incentives for investment in this field extremely sensitive to any changes in the regulatory structure for biologics.

In the relatively young industry of biotechnology, many of the original patents on biologics are beginning to expire and it's appropriate for Congress to consider how ''follow-on'' biologics or ''biosimilars'' are considered and approved by the FDA, and the impact these products will have on patient health and safety, health care costs, and incentives for innovation.

As a primary matter, it's important to recognize that traditional ''small-molecule'' pharmaceuticals and biologics are fundamentally different in their development, their manufacture and their chemical makeup. A traditional small-molecule drug is manufactured through synthesis of chemical ingredients in an ordered process, and the resulting product can be easily identified through laboratory analysis. A biologic is a large, complex molecule, which is ''grown'' in living systems such as a microorganism, a plant or animal cell. The resulting protein is unique to the cell lines and specific process used to produce it, and even slight differences in the manufacturing of a biologic can alter its nature. As a result, biologics are difficult, sometimes impossible to characterize, and laboratory analysis of the finished product is insufficient to ensure its safety and efficacy.

The pharmaceutical drug production process is easily replicated and a ''generic'' drug product is virtually identical to the original innovative product, so generic drug manufacturers are permitted to reference the original testing data submitted by the innovator companies when the original drug is submitted to the FDA for approval. With biologics, the manufacturing process is unique to each biologic and is not

generally disclosed as part of the published patent. A biosimilar manufacturer would have to have intimate knowledge of these proprietary processes in order to ''duplicate'' the biologic product, and even then it is extremely difficult—no two living cell lines are identical, so no two biologics manufacturing processes have identical starting materials or proceed in the same way.

It's also important to note that because biologics are produced with cells from living organisms, many of them can cause an immune reaction which is normally benign and does not affect safety. However, some of these reactions can negate the effectiveness of the biologic or even cause side effects that are more dangerous. Most of these reactions can only be observed through clinical trials with real patients.

Any expedited regulatory pathway for biosimilars must account for all these factors and I'm proud to join with the Ranking Member of the Energy and Commerce Committee, Rep. JOE BARTON, to introduce the Pathway for Biologics Act. Our bill builds on the significant progress the Senate, led by Senators KENNEDY and ENZI, has already made, as well as the significant level of consensus we have heard on our Committee about this issue. The Pathway for Biologics Act will establish a new statutory pathway for biosimilars guided by three principles:

1. Legislation to facilitate the development of biosimilars should promote competition and lower prices, but patient safety, efficacy and sound science must be paramount.

2. We must preserve incentives for innovation and ensure that patients will continue to benefit from the groundbreaking treatments biotechnology alone can bring.

3. We must strive to protect the rights of all parties and resolve disputes over patents in a timely and efficient manner that does not delay market entry and provides certainty to all parties.

The regulatory pathway set forth in the Pathway for Biologics Act embodies each of these principles and sets forth a sensible, scientifically sound process for approval of biosimilars. The legislation allows for input from all interested parties and provides FDA appropriate flexibility to protect patient health by requesting analytical, animal and clinical studies to demonstrate the safety, purity and potency of a biosimilar. The FDA will be empowered to require the tests and data it deems necessary, but the results of clinical testing for immunogenicity will always be required as part of this data unless the FDA has published final guidance documents advising that such a determination is feasible in the current state of science absent clinical data and explaining the data that will be required to support such a determination. Since biologics are derived from human and animal products, immune reactions are a major concern for any new biologic product and are now impossible to detect without actual human testing.

Our legislation also addresses the important issue of interchangeability of biosimilars for the reference product. Some legislative proposals would allow the FDA to permit pharmacists and insurers to substitute a biosimilar for a physician's prescription for an innovator biologic product even when they cannot be demonstrated to be identical in their composition or effectiveness. Interchangeability of generic pharmaceuticals for brand name drugs is entirely appropriate since traditional generic drugs are chemically identical to the reference product. However, if the state of science is such that a complex molecule cannot be fully characterized and a precursor biologic cannot be adequately compared to a proposed biosimilar, then the biosimilar should not be fully substitutable for the precursor product without a physician's direction. The Pathway for Biologics Act makes it clear that the FDA cannot make a determination that a biosimilar is interchangeable with a reference product until it has published final guidance documents advising that it is feasible in the current state of scientific knowledge to make such determinations with respect to the relevant product class and explaining the data that will be required to support such a determination. This requirement is consistent with the recommendations of the Secretary of Health and Human Services.

An essential element of any new regulatory scheme for the biotech industry is a careful balancing of incentives for innovation and opportunities for new entry by competitors. To preserve incentives for innovation, the Pathway for Biologics Act provides 12 years of data exclusivity for new biologic products, which ensures that biosimilar applications that rely on the safety and efficacy record of existing biologic products will not be permitted to enter the market for 12 years following the approval of the innovator product. The 12-year exclusivity period is meant to preserve existing protections biotech companies receive from patents. The Congressional Budget Office has found that the effective patent life for pharmaceuticals is about 11.5 years, so a data exclusivity period of 12 years is consistent with that finding. Data exclusivity is necessary to provide additional protections and incentives for biologics because biosimilars—unlike generic drugs—will not be chemically identical to the reference product and will be less likely to infringe the patents of the innovator.

The legislation also includes incentives for additional indications and pediatric testing. New indications are critical for biologics and are often more significant than the indications for which approval was granted. Incentives for continued testing on new indications must be included to promote access to new treatments and cures, and this bill provides an additional 2 years exclusivity for new indications. I also believe it's important to provide incentives similar to those given traditional pharmaceuticals under the Best Pharmaceuticals for Children Act to biologics, so the legislation provides an additional 6 months of data exclusivity for testing for use in pediatric groups.

In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before the expiration of the data exclusivity period, the Pathway for Biosimilars Act establishes a simple, streamlined patent resolution process. This process would take place within a short window of time—roughly 6–8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large. The legislation also preserves the ability of third-party patent holders such as universities and medical centers to defend their patents.

Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patent's validity or applicability. All information exchanged as part of this procedure must be maintained in strict confidence and used solely for the purpose of identifying patents relevant to the biosimilar product. The patent owner will then have two months to decide whether to enforce the patent. If the patent owner's case is successful in court, the final approval of the application will be deferred until the patent expires.

Madam Speaker. I believe the Pathway for Biosimilars Act sets forth a straightforward, scientifically based process for expedited approval of new biologics based on innovative products already on the market. This new biosimilars approval pathway will promote competition and lower prices, but also ensure that patients are given safe and effective treatments that have been subjected to thorough scrutiny and testing by the FDA. The Pathways for Biosimilars Act will also protect the rights of patent holders and preserve incentives for innovation in the biotechnology sector to develop the next generation of life-saving, life-changing therapies.

I strongly urge my colleagues to support the Pathway for Biosimilars Act.

RECOGNIZING MARCELLA POTTHOFF OF INDIANOLA, IOWA, AS THE GOOD SAMARITAN SOCIETY'S 2007 VOLUNTEER OF THE YEAR

HON. TOM LATHAM

OF IOWA

IN THE HOUSE OF REPRESENTATIVES

Thursday, March 13, 2008

Mr. LATHAM. Madam Speaker, I rise today to recognize and congratulate Marcella Potthoff of Indianola, Iowa, as the Good Samaritan Society's 2007 Volunteer of the Year.

Marcella volunteers three days every week at the Indianola Good Samaritan Center. She performs a variety of tasks for residents, which includes making food, pushing wheelchairs and playing games. She especially enjoys bingo. According to Trudie Wood, the activity director and volunteer coordinator at the Good Samaritan Center, Marcella's eagerness to serve, and her patience and availability at short notice is what makes Marcella deserving of this award.

Marcella has dedicated her life to improving her community. Her past volunteer work includes teaching Sunday school, hosting a Bible study, helping with youth activities, leading a Girl Scout troop, and being an active member in a quilt club and a singles club. She is a great example for her community, and I commend her on her enduring commitment.

I consider it an honor to represent Marcella Potthoff in Congress. I commend Marcella's willingness to volunteer and I wish her all the best in her future endeavors.