Testimony of

Lonna J. Williams
CEO of Ridge Diagnostics

on behalf of CONNECT

Before the

U.S. House of Representatives

Committee on Oversight & Government Reform Committee

Subcommittee on TARP, Financial Services and

Bailouts of Public and Private Programs

Hearing on

"America's Innovation Challenge: What Obstacles do Entrepreneurs Face?"

November 2, 2011

Good Morning Congressman McHenry and Members of the Committee. It is an honor to appear before the committee today and testify on the challenges those of us raising capital for early stage, innovative new companies face in this financial and regulatory environment. I commend you for acknowledging that sources of capital today are uniquely limited, thus creating a serious problem that greatly impacts innovation and job creation in this country. I am pleased to know you are exploring means to remedy the situation and proposing new legislation to loosen regulations and free new sources of capital for privately held companies.

I am Lonna Williams, CEO of Ridge Diagnostics. Ridge is an early stage Life Sciences company with the mission of developing objective, diagnostic and therapy management blood tests for neuropsychiatric disorders. Neuropsychiatric disorders include Depression, known clinically as Major Depressive Disorder, Bipolar Disorder, Schizophrenia and others. Our testing also includes monitoring the efficacy of

medications like antidepressants and antipsychotics. None of these types of testing has been available for patients and health care providers before Ridge.

There are several aspects limiting entrepreneurs and early stage companies today which are perhaps creating a near perfect storm for early stage Life Science or medical product innovations in our country. I will focus on Ridge today, but realize it is an example of many companies, all of whom are facing the same growing issues which are deterring financiers, such as FDA hurdles, a slow U.S. Patent and Trademark Office and an unknown path to reimbursement.

About Ridge Diagnostics

Ridge Diagnostics was founded in 2006 by three scientists from Research Triangle Park, North Carolina, and San Diego, California. Their innovation, and Ridge's first commercial product, is the first blood test to aid in diagnosing depression. It is currently being marketed to psychiatrists in pilot regions in the US. The testing is performed in our laboratory in Research Triangle Park, NC. Our technology, the first to provide biologically based results in the area of mental health medicine, is a break-through, first-in-class innovation that could positively change the management of mental health disorders, including to the underserved, create a substantial number of jobs considering the size and scope of this issue, and importantly, dramatically bend the health care cost curve in this sector of medicine. I ask you not to underestimate the size and scope of this particular area of medicine and the problems to be solved. With approximately 20 million adults and 6 million teens suffering from depression each year in the US, more than AIDS, cancer or cardiovascular disease, the cost to employers currently exceeds $43 billion dollars a year in lost or compromised work hours and the cost to health insurers exceeds the employers' loss per patient due to the high level of consumption of services through mis-diagnosis and excessive resource utilization related to the trial and error associated with diagnosis, medication selection and treatment options. Over the last several years, antidepressants were in the top three most often prescribed drug

class annually in the US, and the most commonly used drug among people aged 18-44. According to a recent report issued from US Centers for Disease Control and Prevention's National Center for Health Statistics, the use of antidepressants jumped nearly 400% between 2005 and 2008 and are now being used by more than one in ten Americans. This is approaching a health care crisis in our country.

Although the wide spread use of antidepressants exists, there are no objective tools to accurately diagnose depression. In fact, it has been published that over 50% of the actual cases of depression are missed by primary care providers. It has also been published that over 50% of initial prescriptions fail and that an effective course of therapy is only found through trial and error. Up to three to eight different drugs may be prescribed over years before a safe and effective course of treatment is established. Yet, a proven blood test, independently evaluated at top academic institutions, including the Massachusetts General Hospital/Harvard University and Vanderbilt University, cannot get financed by venture capitalists in today's environment. This is the case despite the fact that our technology will aid those who are undertrained in the diagnosis of depression, including primary care physicians, and is one of the most sought after blood tests by both physicians and patients.

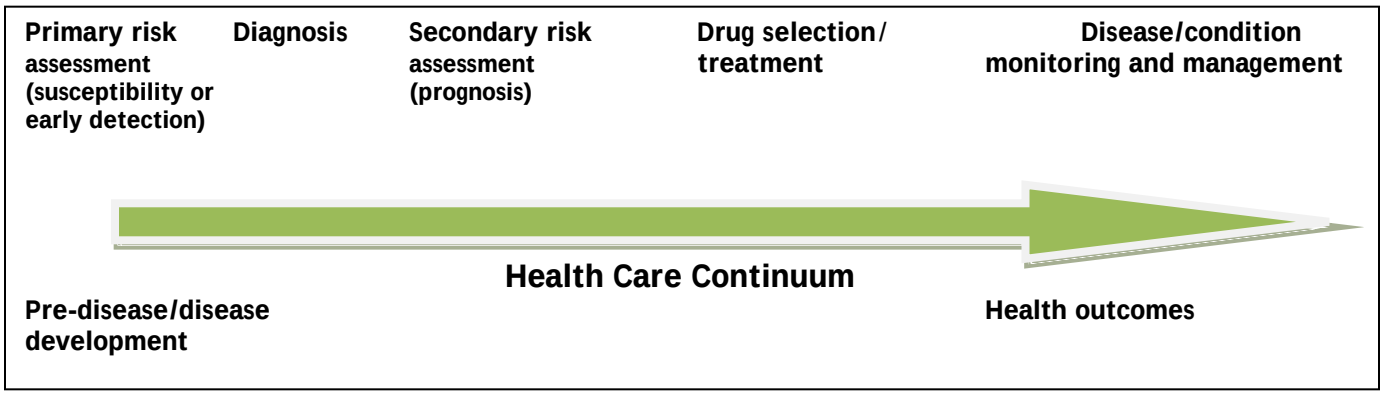
This challenge also exists with the military. We have had a research proposal before the Army for over a year to test active duty servicemen and servicewomen in hopes of detecting depression in these stoic individuals who do not talk about their feelings so that we can assist in reducing the extraordinarily high suicide rate associated with this war. Unfortunately, priorities were focused elsewhere within the military and the proposal is still awaiting funding, countless and unnecessary suicides later. The financing environment needs to be changed as we are depriving physicians, patients and payers, and our soldiers, the benefit of this valuable and cost effective heath assessment tool.

The management team and Board of Directors at Ridge Diagnostics are seasoned professionals; all are serial entrepreneurs in the pharmaceutical, biopharmaceutical and

clinical diagnostics sectors of health care. During our careers, we have been associated with large multi-national companies, as well as founded or managed over 20 start-up companies in the aggregate since the mid-1980's. Today, we are facing a financial climate critically restricting traditional means of capital formation for new, innovative biotech and life sciences companies. We have not witnessed challenges of this magnitude in our professional history and are seeking alternative sources to further finance this company's commercialization plan and research programs. Additionally, Ridge is a graduate of San Diego's innovators industry organization, CONNECT's Springboard Program, which aids entrepreneurs toward funding and was also a finalist in CONNECTS' Most Innovative New Product competition in 2010.

Challenges associated with Capital Formation for Early Stage *In vitro* Diagnostic Companies

Clinical diagnostic tests, or *In vitro* Diagnostics, are those blood tests we have all had from time to time and some routinely. In their simplest form, they are tests that may be preventative in nature, like routine cholesterol testing, or diagnostic for a particular disease or disorder, like strep throat. Today's advances now allow for prenatal testing, the early screening for cancers and cardiovascular risk and the determination of the right cancer drugs for the right patient. The Lewin Group, in a report prepared for The Advanced Medical Technology Association (AvaMed) in July of 2005, encapsulated the value of clinical diagnostic testing to health care. Diagnostics play a role along the disease management continuum.



Extracted from Levin Group report to AvaMed July 2005

Lewin's reports emphasize that diagnostic methods enable accurate detection of health risks and disease at earlier stages and improve treatment and disease management, while diminishing subsequent health problems and their associated costs. *Sixty to seventy percent of medical decisions are influenced by some type of diagnostic testing, yet diagnostics accounts for only a tiny fraction or 2.3% of national health care spending and 1.6% of total Medicare expenditures*. Our system is paying for treatment, but underpaying for diagnosis or prevention. Regulator and financial support for of this type of testing could dramatically reduce treatment costs. Emerging and high need areas of diagnostics, such as personalized medicine, therapeutic management and objective diagnostics for neuropsychiatric disorders, such as those developed and commercialized by Ridge, have the potential to fundamentally alter clinical practice. These technologies are intended to match the "right patient with the right treatment at the right time." As such products become more widely available, patients and physicians will be able to assess the risks and benefits of their care options and customize health management strategies to optimize health and quality of life.

Why would such valuable and economical tools for health care providers and patients prove difficult to finance?

From the mid-1980's to 2008, for companies like Ridge, capital was initially available through angel investors, friends and family and government sponsored grant programs, such as the SBIR NSF, which Ridge received, to assist the company to achieve measureable, financeable milestones. Achieving the key milestones triggered the need for larger amounts of capital, typically an institutional financing, such as a Series A offering of company stock. At this point, Venture Capital funds came into play and hence have had a significant role in the development of new technologies. Over the last three years, VC resources for Series A investments in life sciences have waned. Sources of capital have diminished forcing VC partners to reduce their risk profiles and limit or even eliminate new, early stage investments. Instead, VCs are investing in later stage, lower risk, companies, including buying undervalued stocks in the public market. Venture Capitalists have been forced to retain a higher percentage

of their funds to support their existing portfolio companies and the lack of liquidity of their portfolio companies due to the lagging IPO market have also left them with limited cash available for new investments. Angels and friends and family have also fallen victim to the financial crisis and are holding onto cash, while government resources are limited and slow.

It is truly a financing crisis for health care innovation. Because of the limited access to capital for early stage companies, those few financiers with resources to invest are heavy handed and insist on taking a larger percent of the company for a smaller investment, which, not surprisingly, is a disincentive for those with innovative new concepts to step out and establish a company to exploit it. Additionally, in my opinion, full government control of medicine and health care in the US will not help these companies nor stimulate entrepreneurs. For the benefits of innovative products to move health care forward and be widely available, a reasonable reimbursement structure must exist. Without a reasonable financial opportunity for each stakeholder involved from product conception, to funding, commercialization and utilization, innovation will be stifled.

Why is it critical to seek new sources of capital for clinical diagnostics? Why is the clinical diagnostic sector important to all aspects of medicine, including thoughtful reform?

In a 2009 report for the American Clinical Laboratory Association and AdvaMed, The Lewin Group stated:

Innovation, demonstrated clinical benefit, and appropriate use of laboratory *screening and diagnostic tests are essential for achieving the goals of health system reform. Clinical laboratory testing is integral to evidence-based improvements in health care quality, patient outcomes, efficiency, and accountability.*

Examples of existing, state-of-the-art laboratory screening and diagnostic tests that can contribute to health system value are presented in the table below:

Right Diagnosis

- **Cardiac enzyme marker tests,** which are released after a heart attack and identify heart damage
- **Fragile X syndrome** tests for inherited developmental delay, to determine appropriate management and risk of familial recurrence.

Early Detection and Treatment

- ***BRCA1* and *BRCA2*** test to identify increased risk of breast cancer and ovarian cancer in the absence of tumor
- **Prenatal and newborn screening** for inherited disorders, to enable initiation of treatment and to reduce adverse effects
- **IAI test,** a non-invasive cervical-vaginal fluid to diagnose intra-amniotic infection, a condition that is 80-90% asymptomatic

Right Treatment to the Right Patients

- **HER-2/*neu* (**human epidermal growth factor receptor 2, for patients with breast cancer who will benefit from targeted treatment with Herceptin
- ***KRAS* gene mutation testing** for patients with metastatic colorectal cancer distinguishes who are most unlikely or likely to benefit from cetuximab
- ***BCR/ABL* oncogene testing** for patients with chronic myelogenous leukemia who will benefit from treatment with imatinib (Gleevec)

Fewer Mistakes and Repeats in Treatment

- **HIV viral load test** to determine disease progression and whether the drug is working
- **Emphysema gene test** to identify likelihood of liver disease in emphysema patients without biopsy and allows early intervention

Fewer delays in the Care Delivery Process

- **Rapid molecular MRSA testing** for *mecA* identify within two hours, antibiotic-resistant *S. aureus* infections to guide drug selection and timely hospital control measures
- **Point-of-care tests**

extracted from Lewin 2009

Impact on Job Creation

Today, our options as entrepreneurs are limited, thus we are forced to turn to mid to large size corporations, now rich with cash, to partner with or fund our companies at a much earlier stage than in the past. This financing strategy may ultimately be helpful

and accelerate availability of our new products to patients, but typically, the outcome is the opposite, and at a much higher cost in terms of autonomy, innovation associated with autonomy, and importantly, job creation. Most large companies absorb the technology into their existing departments, limiting the job growth otherwise associated with the smaller company growing and hiring. Large, publically traded companies frequently move at a glacial pace relative to start-ups and are much more risk adverse.

Consider some facts associated with this situation. I would like to recognize the Kauffman Foundation, Cameron Cushman and Carl Shramm, for providing this data. According to the Kauffman Foundation's Fast Facts, published March 2011, *from 1980 to 2005, firms less than five years old accounted for all net job growth in the US.* Another fact, New *Firms add an average of 3 million jobs in their first year, while older companies loose 1 million jobs annually.* In the diagnostic industry, jobs typically are held by college graduates and have been reported to pay far higher salaries than the US average. At Ridge alone, we expect to generate over 300 jobs, with appropriate levels of financing, in approximately five years. Kauffman also reported from a Poll on Entrepreneurship, January 2010 which said 71% of entrepreneurs did not expect to create new jobs in 2010. More than 1/3 said it was because the economy had taken a toll on their businesses.

New or alternative methods to finance private companies promise to alter the trend of flat to negative job growth realized by companies like Ridge.

Summary

I appreciate the opportunity to provide this information to the Committee and summarize by emphasizing that new sources of capital for early stage life sciences companies are highly necessary. Making new resources available will enable the following:

- Critical, cost effective and timely health care delivery tools brought efficiently to patient care
- The bending of the cost curve down by minimizing trial and error and rapidly and accurately diagnosing disorders and selecting and monitoring treatments

- The creation of new, higher paying jobs
- Accurately and efficiently service the underserved with objective measures and without specialist intervention

Appropriate use of diagnostics is integral to high quality health care, including informing earlier, more targeted health care interventions and averting adverse health outcomes and unnecessary costs. To continue to make these valuable tools available, alternative sources of capital for early stage, privately held companies is critical.

Thank you.

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Lonna J. Williams

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2008. Include the source and amount of each grant or contract.

Ridge Diagnostics CEO

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

See attached

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2008, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

L Williams 10/31/2011

I certify that the above information is true and correct.
Signature: Date:

Lonna J. Williams

Lonna J. Williams, CEO of Ridge Diagnostics, has over 25 years of experience in marketing, sales and business development in the field of medical diagnostics and devices. Lonna's clinical laboratory background has aided in her success bringing over 25 new products to market including successfully commercializing 4 novel technologies. Her expertise resides in identifying and developing new markets and unique channels for novel technologies and health care products. Lonna has held senior management positions in both large, multinational companies and startup organizations including Johnson and Johnson, Hybritech/Eli Lilly, GenProbe Inc. Quidel, Prometheus and Viking Systems prior to joining Ridge. She has been involved in corporate acquisitions and technology licensing and has created business plans, integration and commercialization plans for mergers and acquisitions. As President of MarketMarketSolutions she consulted with a variety of companies and organizations including university enterprise development groups analyzing opportunities for emerging technologies. Lonna previously served as President and CEO of LifeGen, Inc. a neurotechnology and nutrigenomics startup company. She joined Ridge in 2008 and became CEO and director in December