BIO®
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

**HEARING TESTIMONY**

**RACHEL K. KING**

**CHIEF EXECUTIVE OFFICER**
**GLYCOMIMETICS, INC.**
**ON BEHALF OF**

**THE BIOTECHNOLOGY INDUSTRY ORGANIZATION**

**HOUSE ENERGY AND COMMERCE HEALTH SUBCOMMITTEE HEARING:**

**"TREATMENTS FOR AN AILING ECONOMY: PROTECTING HEALTH CARE COVERAGE AND INVESTING IN BIOMEDICAL RESEARCH"**

**NOVEMBER 13, 2008**

Chairman Pallone, Ranking Member Deal, Members of the Subcommittee: I am Rachel King, Chief Executive Office or GlycoMimetics, Inc., and I am appearing before this subcommittee on behalf of the Biotechnology Industry Organization (BIO) where I serve on the Board of Directors and as Chair of the Emerging Companies Governing Board. It is my privilege to testify before the Subcommittee today to discuss policies Congress can implement to spur the economy and ensure the continuation of biomedical innovation in the United States. Of course one way to both spur the economy and provide support for biomedical research is increasing Federal funding of the National Institutes of Health (NIH). BIO fully supports any and all efforts to do this. But an increase in funding for NIH is just one thing the Congress can do to invigorate the economy and biomedical innovation. My testimony will also cover other recommendations the Congress should undertake to accomplish these worthy goals. While these additional proposals may not fall technically within the jurisdiction of the Committee of Energy and Commerce, it is our hope Congress will consider them as part of any stimulus package, as they would have a meaningful impact on the ability of biomedical innovation to continue during these tough economical times.

I have been the Chief Executive Officer of GlycoMimetics, Inc. located in Gaithersburg, MD since 2003 and part of the biotechnology industry for 20 years. GlycoMimetics currently has 20 employees who are developing carbohydrate mimics representing an important new class of drugs. We have developed a specialized platform technology which is producing first-in-class drug candidates with an initial focus on inflammation, cancer and infectious disease. Our lead compound, currently in Phase I clinical trials, will provide treatment for patients suffering from sickle cell disease, an area of substantial unmet medical need.

***Importance of Investing in Biomedical Research***

Biomedical research and innovation, and the development of new treatments and therapies are key economic drivers, especially as we work to strengthen our economy in the face of a recession. Life sciences R&D provides high wage jobs at both public research institutions and in the biotech companies that typically locate near centers of academic research. The indirect effects of increased research funding on the regional economy is significant. For example, sponsored biomedical research directly generates jobs in the host institutions, and indirect and induced job creation in the region amounts to additional job growth. In fact, the nation's 1.2 million bioscience jobs generate an additional 5.8 million jobs in the Unites States, resulting in a total employment impact of 7 million jobs. Additionally, wages for bioscience workers have increased 6.4% since 2001 compared with only 1.4% increase in real earnings for the average U.S private sector worker. As economic development becomes more competitive locally, regionally, and internationally, biomedical sciences that have always been intrinsically valued gain extrinsic value.

However, lack of investment by either the government or the private sector discourages the next generation of young scientists. Decreasing research and job opportunities for young scientists threatens the nation's competitive edge in the global economy – we risk losing the best new scientific minds to other fields, or research programs in other countries.

Federally-supported biomedical research builds the foundation of scientific and clinical knowledge that is widely communicated and used to improve the development of diagnostics, treatments and cures. The Federal government funds biomedical research in the United States primarily through the National Institutes of Health (NIH). An increase in NIH-supported research will yield more basic scientific findings and can also advance clinical and translation knowledge associated with the diagnosis and treatment of diseases. NIH-supported research can potentially advance the early stages of development of new biomedical products and thereby reduce the R&D burden on industry. The NIH also plays a critical role in the transfer of technology through which the fruits of NIH intramural research are transferred to industry to be developed ultimately into preventive, diagnostic, and therapeutic products that advance our ability to improve public health. Additionally, companies that market advanced laboratory

research tools also obviously benefit from and increased investment in the federal biomedical research effort.

The NIH is the nation's premier research agency for the study of human health conditions, diagnostics, and treatments. However, for the past five years the NIH budget has been flat or declining in real-dollar terms. This is happening at a time of unprecedented capacity for research, as well as an unprecedented demand for new healthcare solutions. The NIH research infrastructure is simply unable to meet the growing demand for project grants, and many important well-designed research projects are going unfunded. Moreover, there is no private sector alternative for much of the basic research that NIH supports. Adequate funding for NIH is necessary to sustain the public-private collaboration that is transforming biomedical discoveries into innovative treatments for patients.

Since completion of the doubling of the NIH budget over the five-year period, 1998-2003, annual appropriations for the agency have fallen below the rate of biomedical research inflation. Congress has been able to provide incremental funding increases, however we fall well short of the costs associated with biomedical research and technology development inflation. To maintain research grants at current funding levels, annual increases of at least 3.5-5% are required. The funding of the last 5 years has effectively resulted in a 17% decrease in spending power for the NIH. This is a serious challenge to the biotechnology industry. BIO strongly supports an additional $1.9 billion in funding for NIH. This increase in funding will put us on the track of sustainable growth that is necessary to realize our potential.

***Financial State of the Biotechnology Industry***

The biotech industry holds great promise for the future of health care, and has already delivered over 250 FDA-approved therapies, many of which address areas of unmet medical need or are first-in-class treatments. Unfortunately, though, the financial crisis facing our nation continues to have a profound impact on biotech companies and threatens biomedical innovation and U.S. competiveness. The U.S. biotech industry is the unquestioned world leader, and this is an industry that has started and been built in our country. However, the economic crisis we face is having a dramatic impact on our companies.

On average, it takes more than a decade and $1 billion to develop a new molecule for approval. As a result, biotech companies go for years without revenue, instead relying on financing from investors. Emerging biotech companies – comprising over 85% of the industry – are therefore highly dependent on well-functioning capital markets to finance their long term, capital-intensive research and development projects. Over the past 14 months, the credit markets have seized up, making less capital available for investors to put at risk; and the capital that is put at risk is dedicated to shorter-term, lower-risk options other than biotechnology. Since biotech investing

is higher-risk and longer-term in nature, while some areas of the economy have seen a slowdown, biotechnology has seen a near-freeze.

With financing generally coming from equity investments, both public and private biotechnology companies have been adversely impacted by the economic crisis. The financial markets are effectively closed for public biotech companies. Public market investors have been unwilling to participate in initial public offerings (IPOs) or follow-on (secondary) financings. Compared with 2007, IPOs for the first 9 months of 2008 have fallen 96% and follow-on/secondary offerings have fallen 50%. Without strong governmental policies, outlook for these companies remains dire at best. Ninety-nine companies are operating with less than six months' worth of cash, which accounts for 25% of all public U.S. biotech companies. Likewise, the number of public biotech companies that are presently valued at less than their cash-on-hand has risen nearly ten-fold over the past 24 months. There has been a dramatic slowdown in private investments as well, and overall, the total capital raised by the industry has fallen by a considerable 56% in the last year.

What does this mean for many emerging biotechs? The current economic crisis puts them in a precarious situation where they must continue their development projects, but are unable to attain additional financing from investors. Many of these companies, like my own, are in the development phase, do not have product revenues, and therefore are net cash burners. The bottom line is that these companies are experiencing uncertain financial situations and cannot postpone raising capital indefinitely

As other countries try to mimic the U.S. model, and make massive investments in biotech, our industry faces challenges unlike those we have seen in the past. Equally important, as this financial crisis impacts our companies, biotech companies with promising therapies are facing the need to shelve promising therapies or delay their development to conserve cash, postponing the availability of new therapeutic options for patients.

***Emerging Biotechnology Companies Face Difficult Business Decisions***

Challenged by these financial realities, many emerging biotech companies are struggling for survival and forced to continually make operational adjustments, unfortunately at an accelerating pace. Such difficult operating decisions include postponing development of new therapies or laying off employees to reduce operating expenses. In October alone, over 20 companies publicly announced layoffs. Many other companies are making programmatic adjustments, such as shelving important research to conserve financial resources to reduce cash burn rates.

***Critical Point in U.S. Biotechnology Innovation***

The economic crisis jeopardizes the current U.S. competitive edge over the rest of the world. The biotechnology industry can serve as an engine to build an innovation-based economy and help

create economic growth by (1) creating high-value, high-wage U.S. jobs; (2) continuing U.S. leadership in innovation; and (3) addressing and advancing solutions to pressing healthcare, global warming, environmental, energy security and agricultural issues.

As you look for solutions to the economic crisis, it is critical to consider legislative and regulatory policies that will improve the investment climate for the competitiveness of U.S. emerging biotech companies. Any stimulus legislation should include proposals that will help emerging companies to shore-up their balance sheets and provide incentives to attract and retain investment in our industry.

***Corporate and Investment Incentives for Emerging Biotech Companies***

While I acknowledge this Committee does not have jurisdiction over tax policy, I would like to take this opportunity to highlight some potential proposals that would infuse much needed capital into the industry at this critical juncture in innovation. Congress should consider capital formation tax provisions as part of an economic stimulus package and tax reform legislation.

Corporate tax proposals allowing loss-making companies to immediately utilize their accumulated tax assets, such as Net Operating Losses (NOLs) and research and development (R&D) tax credits, would infuse much-needed capital into emerging biotechs. Also, any reforms to the current rules limiting the use of NOLs upon a substantial change in ownership would encourage investment.

1. ***Refund of NOLs in Lieu of Other Tax Benefits to Sustain Critical R&D***

   Allowing a taxpayer to temporarily elect to receive a refund of their NOLs at a discounted rate to offset qualified research expenses and in lieu of claiming other tax benefits for those expenses, such as the R&D tax credit. This policy would extend and expand opportunities for loss-making companies. Under this proposal, a company would permanently forgo all accumulated NOLs involved in computation of a refund. Furthermore, NOL refunds would be reinvested in investments that would qualify as research expenses.

2. ***Refund of R&D Credits Modeled on Recently-Enacted R&D/AMT Provision***

   A provision in the July 2008 stimulus legislation provided for companies to claim a refund of the R&D and AMT credits in lieu of claiming "bonus depreciation" to offset capital expenditures. While this legislation was helpful for a number of biotechs, extending this provision for 2009 and 2010 and expanding the provision would allow emerging biotechs to receive much needed capital infusion for investments in U.S. employees and lab supplies. Specifically, it would also be beneficial to temporarily allow a taxpayer to claim a refund of the R&D and AMT credits in lieu of claiming "bonus depreciation" AND "qualified research expenses" at a discounted rate.

3. ***Suspension of Section 382 NOL Limitations Upon Substantial Change in Ownership***

   Another proposal that could serve to encourage mergers and acquisitions in the biotechnology industry is ensuring that the Code Section 382 limitations on the use of NOLs are not triggered by successive rounds of equity financings, or a business-driven merger of companies. Congress should look at reforming Section 382 rules at least on a temporary basis—as the Treasury Department has recently done for the financial industry during this economic crisis.

4. ***Encourage Investments in Biotechnology***

   Additionally, the enactment of certain investor tax proposals would encourage investments in the biotech industry. For example, Congress should consider short term stimuli for investments such as a zero capital gains rate, capital gains rollover, or reduced capital gains for funds invested in our industry.

***Long-Term Outlook for Biotechnology Remains Strong***

While the current crisis has substantially impacted the industry, I remain optimistic that the biotech industry will triumph by working closely with Congress and the Administration to ensure policies are enacted that will support U.S. innovation in biomedical research by increasing government investments, as well as creating financial policies that will stabilize emerging biotechnology companies and incentivize private sector investment in the industry. I believe the long-term outlook for the biotech industry remains strong.

Thank you for the opportunity to testify before you today on the very important matter of both stimulating the economy generally, and more specifically stimulating biotechnology investment. I'm happy to answer any questions you may have.

###