FOR IMMEDIATE RELEASE

Candlelighters
Childhood Cancer Foundation

Candlelighters®
Childhood Cancer Foundation

DATE: April 19, 2007

Contact: Ruth Hoffman 1-800-366-2223

Candlelighters Endorses Expedited Approval Path For Breakthrough Cancer Therapies

Bill Would Expand Access to Life-Saving Drugs Today, While Protecting Development of Tomorrow's Cures

Declaring biotech drugs, "The Pipeline of Hope for children with cancer and their families," Executive Director Ruth Hoffman announced the endorsement of the Candlelighters Childhood Cancer Foundation for The "Patient Protection and Innovative Biologic Medicines Act of 2007" introduced by Congressman Inslee.

"This important legislation strikes the necessary balance between expanding access and incentivizing innovation for millions of Americans with cancer and other life-threatening diseases" said, Hoffman, whose organization's 100,000 members advocate for children with cancer and their families.

"Biologic drugs have proven to be the most effective weapons in the war on cancer, and the most promising for the future. Because conventional chemotherapy and radiation treatments are so dangerous to children, young cancer patients are depending on innovative biotech companies to continue to developed more effective and targeted treatments in the future.

"At the critical moment when targeted therapies are finally bearing the fruit of decades of research and providing new hope for cancer patients and their families, "The "Patient Protection and Innovative Biologic Medicines Act of 2007" would speed and expand access to life-saving biologics, while encouraging the development of future treatments.

"The combination of affordable access and data protections included in this bill will continue to kindle the fires of biotech innovation, ensuring a future of hope and healing for millions of young people living with cancer."

"On behalf of our 100,000 members nationwide, I thank Rep. Jay Inslee for introducing "The "Patient Protection and Innovative Biologic Medicines Act of 2007", and I urge its speedy passage.

Interamerican College of Physicians & Surgeons

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Tel (202) 467-4756 * Fax (202) 467-4758 * tierney@icps.org

April 19, 2007

STATEMENT

The Interamerican College of Physicians and Surgeons is the largest association of Hispanic physicians in the nation. We focus on improving the health of Hispanic communities, reducing the incidence of communicable diseases, providing educational and leadership opportunities, and encouraging Hispanic youth to pursue careers in healthcare.

We are writing today in support of Congressman Inslee's introduction of the "Patient Protection and Innovative Biologic Medicines Act of 2007". This proposal establishes a science-focused, patient-centered, responsible process through which the FDA will be able to approve and track safe and effective lower cost versions of biologic treatments in the U.S

In many ways, the Hispanic community is unique when it comes to healthcare, with its own unique incidence of illnesses and health conditions. Over the past 20 years, innovation in biotechnology has led to treatments for a wide range of diseases that profoundly affect the Hispanic community, including diabetes, HIV/AIDS, heart disease, cancer and asthma.

Congressman Inslee's "Patient Protection and Innovative Biologic Medicines Act of 2007" makes these life saving developments available to more people. Follow-on biologic products are a natural evolution of biotechnology, and offer the promise of making medical miracles available to more people. For patients to gain the greatest possible benefits, we completely agree that biologics with patent protections that have expired should be subject to competition from safe and effective follow-on versions.

We welcome the introduction of follow-on biologic medicines, and we welcome the balanced approach of the "Patient Protection and Innovative Biologic Medicines Act of 2007", which will provide

access to life saving medicines for all patients, while continuing to incentivize innovative biotech companies to bring new and better therapies to patients.

The EU experience shows that a science-based, patient-focused pathway works. "The Patient Protection and Innovative Biologic Medicines Act of 2007" follows the example of the EMEA – the European Medicines Evaluation Agency – by testing both the structural and functional features of the follow-on biologic medicine, with an emphasis on identifying difference from the innovator. Congressman Inslee's bill would require that follow-on biologics undergo robust clinical testing in order to identify potential differences in clinical efficacy, undesired immunogenicity or other adverse events.

As physicians, we rely on the science to keep our patients safe and we applaud Congressman Inslee for helping us to do just that.

Sincerely,

Rene F. Rodriguez, M.D.
President

LUPUS RESEARCH INSTITUTE
National Coalition
The Patient Voice for Lupus Research

Dear Congressman Inslee:

The Lupus Research Institute National Coalition is the advocacy network of state and local lupus organizations and other supportive groups united to promote increased education and awareness of the seriousness of lupus and the need for increased research; and advocate for the eradication of lupus through a vigorous public and private-supported research effort.

The National Coalition supports the Lupus Research Institute (LRI), a national, non-profit organization that is leading the advance of new science in lupus by supporting top scientists across the country in the search for new treatments, prevention and a cure.

Lupus is a devastating disease – a chronic, systemic autoimmune disease that can attack virtually any organ or bodily system at any time. Lupus affects an estimated 1.5 million Americans, mostly women, and is a leading cause of kidney disease, stroke, and cardiovascular disease in young women.

Currently, there is no cure for lupus, and the FDA has not approved a new treatment for lupus for over 40 years.

We are writing to you today to applaud your introduction of the "**The Patient Protection and Innovative Biologic Medicines Act of 2007**"

Your proposal establishes a science-focused, patient-centered, responsible process through which the FDA will be able to approve and track safe and effective lower-cost copies of biologic treatments in the U.S.

Despite the mysterious nature of lupus, advances in science, medicine, research and technology are shaping a future of hope for those with this devastating disease. The LRI is at the forefront of this new world, encouraging and funding young scientists to combine new thinking with these advances to push the envelope in scientific research and therapy.

The "Patient Protection and Innovative Biologic Medicines Act of 2007" makes these breakthrough developments available to more people. Follow on biologic products are a natural evolution of biotechnology, and offer the promise of making medical miracles available to more people with lupus. For patients to gain the greatest possible benefits, we agree that biologics with patent protections

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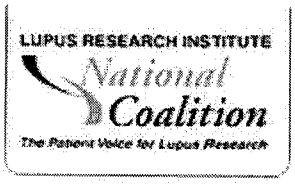
www.lupusresearchinstitute.org



that have expired should be subject to competition from safe and effective follow-on biologics.

We welcome the introduction of follow on biologic medications, and we welcome the introduction of "The Patient Protection and Innovative Biologic Medicines Act of 2007" , which will provide access to life saving medications for all patients through a patient focused and science based application of a logical, open and rational process.

The EU experience shows that a science based, patient-focused pathway works. "The "Patient Protection and Innovative Biologic Medicines Act of 2007" truly follows the example of the European Medicines Evaluation Agency (EMEA) by testing both structural and functional features of the follow-on biologic medicine, with an emphasis on identifying differences from the innovator. It would require that follow-on biologics undergo robust clinical testing so that we can identify potential differences in clinical efficacy, undesired immunogenicity, and other adverse events. Science and experience show that non-clinical assays are not sufficient – there is no assay as sensitive as the human body.

To protect the most vulnerable among us, the "The Patient Protection and Innovative Biologic Medicines Act of 2007" would require careful post-marketing studies. It would also introduce appropriate naming conventions to distinguish follow-on biologics from the innovator so that we can accurately track safety, efficacy, and immunogenicity in the larger population.

We must get the science right. We are finally reaping the rewards of two decades of innovation, and those with lupus and their loved ones depend on all of us to get the science right. "The Patient Protection and Innovative Biologic Medicines Act of 2007" does that by offering all of us a responsible regulatory pathway to making safe and effective follow-on biologics available to more patients – without putting patient safety at risk.

Sincerely,

Margaret G. Dowd
Representative
The Lupus Research Institute National Coalition

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www.lupusresearchinstitute.org

April 19, 2007

Dear Congressman Inslee:

On behalf of the Celiac Sprue Association, the nation's largest celiac patient support organization, we are writing to you today to applaud your introduction of the "**The Patient Protection and Innovative Biologic Medicines Act of 2007**". I am also writing to commend you for your leadership on public health issues and for your commitment to ensuring that people with autoimmune diseases such as celiac disease have timely access to safe and effective drugs and biologics.

Celiac disease, or gluten intolerance, is a genetic autoimmune disease that affects 1 of every 133 people in the United States. The research indicates that celiac is twice as common as Crohn's disease, ulcerative colitis and cystic fibrosis combined.

Currently, there are no drugs or biologics to treat celiac disease and there is no cure. The Celiac Sprue Association supports efforts by both government and private industry to develop treatments and hopefully, a cure for celiac disease.

The "Patient Protection and Innovative Biologic Medicines Act of 2007" makes these breakthrough developments available to more people. Follow on biologic products are a natural evolution of biotechnology, and offer the promise of making medical miracles available to more people with lupus. For patients to gain the greatest possible benefits, we agree that biologics with patent protections that have expired should be subject to competition from safe and effective follow-on biologics.

We welcome the introduction of follow on biologic medications, and we welcome the introduction of "The Patient Protection and Innovative Biologic Medicines Act of 2007" , which will provide access to life saving medications for all patients through a patient focused and science based application of a logical, open and rational process.

The EU experience shows that a science based, patient-focused pathway works. "The Patient Protection and Innovative Biologic Medicines Act of 2007" truly follows the example of the European Medicines Evaluation Agency (EMEA) by

Evaluation Agency (EMEA) by testing both structural and functional features of the follow-on biologic medicine, with an emphasis on identifying differences from the innovator. It would require that follow-on biologics undergo robust clinical testing so that we can identify potential differences in clinical efficacy, undesired immunogenicity, and other adverse events. Science and experience show that non-clinical assays are not sufficient – there is no assay as sensitive as the human body.

To protect the most vulnerable among us, "The Patient Protection and Innovative Biologic Medicines Act of 2007" would require careful post-marketing studies. It would also introduce appropriate naming conventions to distinguish follow-on biologics from the innovator so that we can accurately track safety, efficacy, and immunogenicity in the larger population.

We must get the science right. We are finally reaping the rewards of two decades of innovation, and those with lupus and their loved ones depend on all of us to get the science right. "The Patient Protection and Innovative Biologic Medicines Act of 2007" does that by offering all of us a responsible regulatory pathway to making safe and effective follow-on biologics available to more patients – without putting patient safety at risk.

Sincerely,

Mary Schluckebier
Executive Director
Celiac Sprue Association

AMERICAN PAIN FOUNDATION®
A United Voice of Hope and Power over Pain

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For Immediate Release: April 18, 2007

Contact: Will Rowe

American Pain Foundation Supports Legislation to Broaden Access to Biologics for Chronic Pain

Bill Would Reduce Costs, Increase Access and Foster Continued Innovation

(BALTIMORE, MD) – Citing the importance of biologic drugs in the war on pain, the American Pain Foundation (APF) today endorsed "The Patient Protection and Innovative Biologic Medicines Act of 2007" legislation introduced by Congressman Inslee which is designed to create a safe and abbreviated approval path for "follow-on" biologics. The bill would make these life-enhancing drugs more broadly available to patients in pain, while ensuring that research and development of innovative biotech drugs continues to thrive.

"APF welcomes this legislation, because it balances the priority unmet needs of patients in chronic pain," said APF Executive Director Will Rowe. "It offers patients safe, affordable access to the pioneering medications of today, as well a hopeful outlook on the breakthrough therapies of tomorrow."

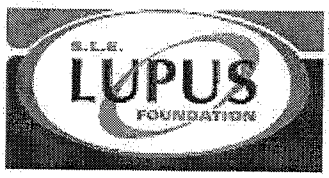
Biologics have proven to be among the most effective and promising therapies for a range of diseases, including cancer and certain chronic pain syndromes. As genomic research matures, more and more of these targeted biotech medications are emerging from the R&D pipeline. Unfortunately, many of these biotech drugs are so expensive that they remain beyond the reach of many patients in need.

As patent protections expire for branded biologics, non-branded or so-called "biosimilar" drugs hold the promise of more affordable access. But unlike conventional chemical compounds, biologics are made from living cell tissues; therefore, currently existing approval pathways for generic versions of chemical drugs don't apply to so-biosimilar or "follow-on" biologics.

The "Patient Protection and Innovative Biologic Medicines Act of 2007" will create an expedited approval pathway for "follow-on" biologics that will provide the FDA the science-based guidance necessary to ensuring patient safety – as well as sufficient data exclusivity to incentivize continued innovation on the part of pioneering biotech companies.

"Innovation is the raw fuel for medical breakthroughs," said Rowe, "and a beacon of hope for people living in pain. On behalf of our 90,000 members and the millions of people suffering from chronic pain, we welcome this forward-thinking legislations."

The American Pain Foundation is the nation's leading nonprofit organization serving people with pain through information, education and advocacy. APF offers the public, including its 90,000 members, educational materials, a toll-free information line, and an award-winning website (www.painfoundation.org.)



Dear Congressman Inslee:

The S.L.E. (Lupus) Foundation, Inc., is dedicated solely to providing services for people with lupus and their families, educating and informing the public about the disease; and encouraging and supporting lupus research. To fulfill this mission, the S.L.E. Foundation, Inc. developed the Lupus Cooperative of New York to demonstrate that an integrated network of existing professional and community services can effectively coordinate and improve the care and quality of life for lupus patients and their families in under-served inner city communities. The S.L.E. Foundation does not charge any fees for the services provided.

Lupus is a devastating disease – a chronic, systemic autoimmune disease that can attack virtually any organ or bodily system at any time. Lupus affects an estimated 1.5 million Americans, mostly women, and is a leading cause of kidney disease, stroke, and cardiovascular disease in young women.

Currently, there is no cure for lupus, and the FDA has not approved a new treatment for lupus for over 40 years.

We are writing to you today to applaud your introduction of "The Patient Protection and Innovative Biologic Medicines Act of 2007". This proposal establishes a science-focused, patient-centered, responsible process through which the FDA will be able to approve and track safe and effective lower-cost copies of biologic treatments in the U.S.

Despite the mysterious nature of lupus, advances in science, medicine, research and technology are shaping a future of hope for those with this devastating disease. A sister organization of the SLE (Lupus) Foundation, the Lupus Research Institute, is at the forefront of this new world, encouraging and funding young scientists to combine new thinking with these advances to push the envelope in scientific research and therapy.

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The EU experience shows that a science based, patient-focused pathway works. "The Patient Protection and Innovative Biologic Medicines Act of 2007" truly follows the example of the European Medicines Evaluation Agency (EMEA) by testing both structural and functional features of the follow-on biologic medicine, with an emphasis on identifying differences from the innovator. It would require that follow-on biologics undergo robust clinical testing so that we can identify potential differences in clinical efficacy, undesired immunogenicity, and other adverse events. Science and experience show that non-clinical assays are not sufficient – there is no assay as sensitive as the human body.

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We must get the science right. We are finally reaping the rewards of two decades of innovation, and those with lupus and their loved ones depend on all of us to get the science right. "The Patient Protection and Innovative Biologic Medicines Act of 2007" does that by offering all of us a responsible regulatory pathway to making safe and effective follow-on biologics available to more patients – without putting patient safety at risk.

Sincerely,

Margaret G. Dowd
Representative
The S.L.E. (Lupus) Foundation, Inc.

For more information about the S.L.E. Lupus Foundation,
Visit our website at www.lupusny.org

Colon Cancer Alliance

THE VOICE OF SURVIVORS

April 19, 2007

Patient Protection and Innovation Biologic Medicines Act of 2007

The Colon Cancer Alliance was started in 1999 by a group of people affected by colorectal cancer—the second leading cause of cancer deaths in the United States. The Alliance has focused its efforts on providing a robust and diverse network of support for people with colorectal cancer and their caregivers. We now have over 50,000 members and 100 chapters across the country.

At the time of our founding only one treatment option was available for patients whose cancer had metastasized from the colon into other organs of the body, and the five-year survival rate for those diagnosed in these later stages was depressingly low.

In recent years additional new therapies have come onto the market, providing greater hope for the more than 150,000 people diagnosed with colorectal cancer each year. The new therapies with the largest impact are biologics, and the use of these therapies has made a significant difference in the life of our community.

One of the early volunteers and subsequent member of the staff for the Colon Cancer Alliance was diagnosed with Stage IV cancer when her son was a toddler. She was told she had only months to live. For her, the most tragic aspect of that diagnosis was her very real fear that her son would not to remember her. This courageous woman recently succumbed to her cancer, but only after surviving more than eight years with the disease. Her son, now 11, will go through his life with clear memories of his mother. The primary difference between her initial diagnosis and her final outcome was the impact of biologics on the disease.

As "the voice of survivors" the Colon Cancer Alliance has a strong interest in new treatments for colorectal cancer. We are keenly aware that bringing new weapons into the fight requires a balance between factors that are, to some extent, contradictory. We are interested in ongoing innovation, in products that are safe, and in affordability. These interests are reflected in our discussion groups and chat room for survivors.

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Colon Cancer Alliance™

THE VOICE OF SURVIVORS

They want to know what new options are available, what the side effects of those options are likely to be, and how they can have access to the therapies.

The Patient Protection and Innovation Biologic Medicines Act of 2007 demonstrates a thoughtful approach to all three of these factors. We support this act, and applaud Congressman Inslee for submitting this legislation.

Sincerely,

Tim Turnham, PhD
CEO

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