



## **CMPI TO HOST HILL BRIEFING ON FOLLOW-ON BIOLOGIC DRUGS FOR CONGRESSIONAL STAFF AND MEDIA WITH REPS. ESHOO AND ROGERS**

### *Event Focused on Ensuring Patient Safety is Top Priority of Follow-on Biologic Legislation Currently Being Debated on Capitol Hill*

**Capitol Hill (July 15)** – The Center for Medicine in the Public Interest today hosted a briefing followed by a question-and-answer session for media and Congressional Staff entitled: "A Follow-On Biologics Legislation Update; Congressional Leaders and Medical Experts Discuss Patient Safety." The event will be co-hosted by two high-ranking members of the House Energy and Commerce Committee, Congresswoman Anna Eshoo (D-CA) and Congressman Mike Rogers (R-MI). The Representatives are lead sponsors of bipartisan legislation to modernize the regulatory pathway for Food and Drug Association approval of follow-on biologics.

Representative Eshoo's legislation: H.R. 1548, the Pathway for Biosimilars Act ensures that new standards for testing will make certain that follow-on biologic drugs are both safe and effective. The bill currently has 108 cosponsors and has the broadest bipartisan support of any legislation designed to regulate follow-on biologics.

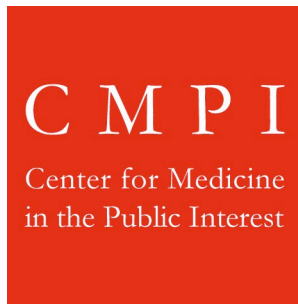
“CMPI applauds Representatives Eshoo's and Rogers' commitment to ensuring patient safety is the top-priority for follow-on biologics legislation,” said Robert Goldberg of CMPI. “The next few weeks are going to be a pivotal time in Congress as health care takes top billing in the House and the Senate. It is critical that advocates for safe and effective follow-on biologics do all they can to support Representative Eshoo's legislation. Representatives Eshoo's and Rogers' dedication to ensuring FDA takes the appropriate steps to ensure the safety of patients could mean the difference between health and illness for millions of Americans.”

Also speaking at the event will be former Congressman Mike Ferguson; Dr. Geno Merli, Senior Vice President & Chief Medical Officer, Thomas Jefferson University, and Director, Jefferson Center for Vascular Diseases; and John F. Crowley, President and Chief Executive Officer of Amicus Therapeutics. All three will help highlight the importance of balancing cost reduction and the well-being of patients in the follow-on biologics debate, bringing their unique experiences and perspectives directly to Hill staffers.

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### About CMPI

The Center for Medicine in the Public Interest, a non-profit public policy group dedicated to research-based free market reforms for the health care industry.



## **CMPI July 15<sup>th</sup> Capitol Hill Briefing**

*“A Follow-On Biologics Legislation Update;  
Congressional Leaders and Medical Experts Discuss Patient Safety”*

### **Event Program**

- Noon:** Official start time for event
- 12:05pm:** **(5 minutes)** Opening remarks and introductions by The Honorable Mike Ferguson (R-NJ), former Member, U.S. House of Representatives, Senior Fellow, CMPI
- 12:10pm:** **(10 minutes)** Legislation update and patient safety remarks from Congresswoman Anna Eshoo (D-CA)
- 12:20pm:** **(10 minutes)** Legislation update and patient safety remarks from Congressman Mike Rogers (R-MI)
- 12:30pm:** **(7 minutes)** Patient safety remarks by Dr. Geno Merli, M.D., Senior Vice President & Chief Medical Officer, Thomas Jefferson University, and Director, Jefferson Center for Vascular Diseases
- 12:37pm:** **(7 minutes)** Patient safety remarks by John F. Crowley, President and Chief Executive Officer of Amicus Therapeutics, and Founder, CrowleyFamily5.com
- 12:44pm:** **(2 minutes)** Closing remarks by The Honorable Mike Ferguson (R-NJ), former Member, U.S. House of Representatives, Senior Fellow, CMPI
- 12:46pm:** **(Open-ended)** Question-and-answer session for panelists

**John F. Crowley, J.D., M.B.A.**

Mr. Crowley became president and CEO of Amicus in January 2005, having served as a director since 2004. Previously he was founding president and CEO of Orexigen Therapeutics. Preceding Orexigen, Mr. Crowley was senior vice president at Genzyme Therapeutics, a position he assumed after overseeing the sale of Novazyme Pharmaceuticals to Genzyme in September 2001. Mr. Crowley was the founding president and CEO of Novazyme that was developing a novel treatment for Pompe disease. He previously served in several senior management roles with the Bristol-Myers Squibb Company (BMS), including director of the Executive Committee for the U.S. Medicines Group, director of Business Strategy for the U.S. Pharmaceuticals Group, and director of U.S. Area Marketing for the Neuroscience and Infectious Disease Division. Preceding his experience at BMS, Mr. Crowley worked as a business strategy consultant for Marakon Associates. Mr. Crowley began his professional career as a litigation associate in the Health Care Practice Group of the Indianapolis-based law firm of Bingham, Summers, Welsh & Spilman.

Mr. Crowley is involved with several charitable and community organizations, including serving as president of the National Tay-Sachs and Allied Diseases Association. He is also on the Research Advisory Board of the national Muscular Dystrophy Association and the Board of Directors of St. Peter's University Hospital. Mr. Crowley's involvement with biotechnology stems from the 1998 diagnosis of two of his children with Pompe disease - a fatal neuromuscular disorder. Mr. Crowley and his family have been featured on the cover of The Wall Street Journal and on The Today Show, CNBC and The Paula Zahn Show.

Mr. Crowley is a commissioned officer in the United States Navy Reserve (active). Mr. Crowley earned his B.S. degree in Foreign Service from Georgetown University's School of Foreign Service, his J.D. from the University of Notre Dame Law School and his M.B.A. from Harvard Business School.

## **Anna Eshoo**

Anna G. Eshoo was first sworn in as a Member of the United States House of Representatives in 1993, after serving on the San Mateo County Board of Supervisors for 10 years. For more than a decade in Congress she has defended consumers, promoted American competitiveness and innovation, fought for access to health care for families and children, and protected the environment.

Rep. Eshoo has served on the powerful House Energy and Commerce Committee since 1995 and is a member of the Subcommittee on Telecommunications and the Internet and the Subcommittee on Health. The Energy and Commerce Committee is responsible for legislation affecting Medicare, Medicaid, telecommunications, energy, the Internet, health-based environmental laws, children's health, biotechnology, high technology, water resources, bioterrorism, homeland security, interstate commerce, gun safety, consumer protection, and food and drug safety.

Rep. Eshoo was appointed to the House Permanent Select Committee on Intelligence in January 2003. In the 110th Congress, Rep. Eshoo chairs the Subcommittee on Intelligence Community Management, which focuses on policies and management challenges affecting all 16 agencies that comprise the nation's Intelligence Community. She has authored legislation to protect our national security and our civil liberties, as well as legislation to require that any surveillance or intelligence gathering be conducted in accordance with the law, requiring court warrants based upon probable cause. Her legislation has also been directed at reforming the Intelligence Community, and increasing human intelligence to better meet the security challenges of the 21st Century.

In addition, Rep. Eshoo co-chairs the Congressional E-911 Caucus and the House Medical Technology Caucus, and serves as Vice Chair of the 21st Century Health Care Caucus.

Rep. Eshoo has sponsored legislation aimed at "cleaning up the House" to restore the confidence of the American people in their government. She has co-sponsored numerous reform bills to require more transparency and accountability in lobbying, as well as a fairer and more open legislative process. This year, the House passed a bill authored by Rep. Eshoo that would invest in research and support services for the 46.3 million Americans living with arthritis. In the 110th Congress Eshoo introduced legislation that would modernize the medical records system and protect the privacy of patients. Eshoo also introduced legislation to protect national forests, federal lands and wildlife refuges from aggressive logging practices.

Rep. Eshoo has authored landmark legislation that has:

- Created the use of electronic signatures, making legally binding digital documents possible and allowing online commerce to flourish;
- Given discounts to schools and libraries to increase public Internet access;
- Provided emergency call centers with funding to obtain the necessary technology to locate mobile phone users when they call 911;
- Promoted better labeling and testing of pharmaceuticals for children;
- Exempted FEMA mitigation grants from income taxes, saving homeowners from being required to pay the government for vital damage prevention;

- Ensured that low-income women who are diagnosed with breast and cervical cancer receive treatment, and requires insurance companies to pay for reconstructive surgery for cancer patients.

In 2005, Rep. Eshoo led House Democrats in introducing The Innovation Agenda - A Commitment to Competitiveness to Keep America #1. This comprehensive policy plan was developed in conjunction with leaders from the high technology, biotechnology, academic and venture capital communities.

The Agenda makes a bold and critical national commitment to achieve energy independence for America within the next decade. It calls for legislation to increase investment in research and development to promote sustainable biofuels and hybrid technology. The Agenda calls for the creation of the Advanced Research Projects Agency for Energy, a new laboratory within the Department of Energy to engage in high-risk, high-reward experimentation to yield discoveries of new sustainable energy sources.

Education is a key element of the Innovation Agenda, with a national commitment to:

Educate 100,000 new scientists, engineers, and mathematicians in the next four years;  
Place a highly qualified teacher in every math and science K-12 classroom;  
Tuition assistance to talented undergraduates;

Pay for competitive salaries to established teachers working in the fields of math and science;

Create a special visa for the best and brightest international doctoral and postdoctoral scholars in science, technology, engineering and mathematics;

Make college tuition tax-deductible for students studying math, science, technology, and engineering.

Rep. Eshoo's work has earned the approval of a wide range of organizations. She consistently receives an 'A' rating from the League of Conservation Voters and recently received a 100% rating from the American Association of University Women for her work to protect educational funding and women's rights. In 2008 she received an 'A' rating from the Iraq and Afghanistan Veterans of America. She was honored with the 2006 Government Leadership Award from the Semiconductor Equipment Manufacturing Industry, and the 2006 Inaugural Congressional Award from the American Institute for Medical and Biological Engineering.

## **Mike Ferguson**

The Honorable Mike Ferguson is chairman and CEO of Ferguson Strategies LLC, a government affairs and business consulting firm based in Washington, D.C. The Honorable Mike Ferguson served in the U.S. House of Representatives from 2001-2009, representing New Jersey's 7th District.

In the House, Ferguson served as a member of the House Energy and Commerce Committee, which has wide jurisdiction over the health care, telecommunications and energy industries. He served as vice chairman of the panel's Health Subcommittee, as a member of the Telecommunications and the Internet Subcommittee, and as a member of the Oversight and Investigations Subcommittee.

While in Congress, Mike Ferguson also served as a member of the House Financial Services Committee, the Transportation and Infrastructure Committee, and the Small Business Committee.

Before entering the House, Mr. Ferguson was an educator and small business owner. He founded an education consulting firm that advocated school reform and scholarship programs. He taught history and coached basketball at a high school in the Bronx, New York and was an adjunct instructor of political science at a college in New Jersey.

A graduate of Delbarton School in Morristown, New Jersey, Mike Ferguson attended the University of Notre Dame, where he received a bachelor's degree in government. He received a master's of public policy degree with a specialization in education policy from Georgetown University in Washington, D.C. He and his wife Maureen have four children.

## **Robert Goldberg, PhD**

Robert Goldberg is co-founder and vice president of the Center for Medicine in the Public Interest. (CMPI) Along with Peter Pitts, Dr. Goldberg hosts the popular and controversial blog on the pharmaceutical industry and healthcare, [www.drugwonks.com](http://www.drugwonks.com).

Prior to founding CMPI, Goldberg was Director of the Manhattan Institute's Center for Medical Progress and Chairman of its 21st Century FDA Task Force which examined the impact of the FDA's Critical Path Initiative on drug development and personalized medicine.

He has written for The Wall Street Journal, The Washington Post, the Los Angeles Times, National Review Online, The Chicago Tribune, The Philadelphia Inquirer, The New York Sun and writes regularly for The Washington Times, the New York Post and The Weekly Standard.

He is an expert on Medicare reform, comparative effectiveness and FDA's Critical Path Initiative. He is author, with Peter Pitts of "Keeping Medicine Personal: A Critical Path for Comparative Effectiveness," a recent CMPI white paper, The Impact of Medicare's Anemia Drug Coverage Decision On Cancer Patients: Comparative Effectiveness vs. Patient Centered-Care, Insta-Americans: The Empowered (and Imperiled) Health Care Consumer in the Age of Internet Medicine, and with John Vernon, "Alzheimer's Disease and Cost-effectiveness Analyses: Ensuring Good Value for Money?"

Dr. Goldberg lives in Springfield NJ. He has a daughter Sara, age 24 and a son Zach, age 21. He received his PhD from Brandeis University in 1984 and is a Yankees fan.

## **Geno J. Merli, M.D., FACP**

Dr. Geno Merli is the Ludwig A. Kind Professor of Medicine, Director of the Division of Internal Medicine, and Vice Chairman of Clinical Affairs, Thomas Jefferson University in Philadelphia, Pennsylvania. Dr. Merli received his medical degree in 1975 from Jefferson Medical College. He completed his residency in both rehabilitation medicine and internal medicine at Thomas Jefferson University Hospital.

Dr. Merli is a nationally recognized expert in the areas of prophylaxis and management of deep vein thrombosis and pulmonary embolism (DVT/PE), as well as in the area of medical consultation of surgical patients. He is co-editor of “Medical Management of the Surgical Patient” and co-chairs a national course on the perioperative care of the surgical patient with medical problems.

Dr. Merli’s research interests have focused on prophylaxis for deep vein thrombosis and pulmonary embolism and on management of deep vein thrombosis in acute spinal cord injury, total joint replacement, trauma, and high-risk cancer patients.

## **Peter J. Pitts**

Peter Pitts is President and co-founder of the Center for Medicine in the Public Interest and Partner/Director Global Healthcare, Porter Novelli. Prior to founding CMPI, Pitts was a Senior Fellow for healthcare studies at the Pacific Research Institute.

From 2002-2004 Peter was FDA's Associate Commissioner for External Relations, serving as senior communications and policy adviser to the Commissioner. He supervised FDA's Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, Office of Executive Secretariat, and Advisory Committee Oversight and Management. He served on the agency's obesity working group and counterfeit drug taskforce.

His book, *Become Strategic or Die*, is widely recognized as a cutting edge study of how leadership, in order to be successful over the long term, must be combined with strategic vision and ethical practice. He is the editor of the new book, *Coincidence or Crisis*, a discussion of global prescription medicine counterfeiting.

He has served as an adjunct professor at Indiana University's School of Public and Environmental Affairs and Butler University.

## **Mike Rogers**

U.S. Rep. Mike Rogers is serving his fifth term as a member of the U.S. House of Representatives, representing Michigan's 8th District. Rogers serves on the House Energy and Commerce Committee and on the Subcommittee on Health as well as the Telecommunications Subcommittee. He also serves on the House Permanent Select Committee on Intelligence and is the Ranking Member on the Subcommittee on Terrorism.

A Michigan native, Rogers graduated from Adrian College, Adrian, Michigan in 1985, earning a bachelor's degree in Criminal Justice and Sociology. He served in the United States Army from 1985 to 1989; worked as a Special Agent with the Federal Bureau of Investigation in its Chicago office, specializing in organized crime and public corruption cases, 1989–1994; and was a member of the Michigan State Senate, 1995–2000, serving as majority floor leader, 1999–2000. He is also a former small business owner.

In Congress, Rogers has been a leader on health care policy. He has spearheaded efforts to expand access to affordable health insurance, promote health information technology, crack down on counterfeit drugs, and strengthen bio-medical countermeasures development. Rogers has authored legislation to improve the quality of America's cancer care, increase access to children's medical devices, strengthen medical innovation, and make seniors' prescription drugs more affordable.

Rogers also has developed legislation to make America energy independent. His plan focuses on increased use of nuclear energy, greater funding for research and development of alternative fuels, and the opening up of more domestic sources of oil. He believes an effective energy plan will provide economic security, national security and environmental security for the nation.

Rogers is the youngest of five sons. His father was a public school teacher-administrator-football coach and his mother was the director of a local Chamber of Commerce. He has two children and resides in Howell, Michigan.

Eshoo drug legislation better than Waxman alternative bill

The Hill

June 30, 2009

By Robert M. Goldberg

An important part of the healthcare debate is the two competing pieces of House legislation that give the Food and Drug Administration the authority to create modernized pathways for the creation of generic forms of biologic medicine drugs.

Known as follow-on biologics, or biosimilars, the FDA currently cannot approve these important medicines because of safety concerns over the difficulty in replicating these types of drugs.

House Energy and Commerce Committee Chairman Henry Waxman (D-Calif.) believes the language in his follow-on biologic bill should be included in the broader healthcare legislation in order to reduce the cost of one of President Obama's top policy agenda items.

On the other hand, Rep. Anna Eshoo (D-Calif.) believes her legislation should go through the standard process of committee markup and onto the House floor on its own, allowing for full vetting and debate on one of the key healthcare reforms of this generation.

Both pieces of legislation have their merits and both members should be commended for their willingness to take a lead on this important issue, but Eshoo's bill has the right prescription for getting follow-on biologics to the market.

First, the Eshoo legislation puts a priority on patient safety by requiring appropriate and stringent clinical trials and testing. This is necessary because biologic drugs are created from living organisms such as proteins and carbohydrates, and are not as simple to replicate as traditional drugs like aspirin and antihistamines.

Second, by protecting adequate data exclusivity, innovator companies will not be forced to charge more for their biologic treatments.

Third, Eshoo's legislation rewards new biologic innovation by drug companies because it grants them a longer period of data exclusivity to continue research and development to fight other diseases.

Fourth, Eshoo's legislation gives hope to those suffering from rare diseases or conditions. If drug companies think they will have a short time before a generic version of their product is on the market, they will only focus on the drugs for major diseases and conditions, potentially ignoring ailments that are less common, but equally as serious, to those suffering.

Follow-on biologic legislation must be about balancing patient safety and cost reduction. To ignore either one — or to unnecessarily rush creating this pathway — will only hurt those patients who depend on follow-on biologics the most.

Editorial: Congress must preserve medical research incentives in quest for health care reform

Mercury News Editorial  
June 24, 2009

Stem-cell research has gotten lots of attention, and billions of dollars, because it could produce treatments and cures for stubborn diseases from Parkinson's to Alzheimer's. But there's another line of biotech research that holds great promise for developing breakthrough drugs.

It's called biologics, and it involves large, complex, genetically engineered molecules. Legislation in Congress could determine whether this research goes forward or stalls in Silicon Valley and other biotech centers.

The issue is essentially patent protection: the length of time companies have to at least try to recover the \$1 billion or more in investment it can take to bring one of these drugs to market. For each biologic breakthrough, other companies are waiting to introduce biosimilars — basically, generics — at lower prices.

The dilemma goes to the heart of President Barack Obama's goal for comprehensive health care reform: Can the nation continue to spark health care innovation at the same time it guarantees access to affordable medical care, including medication? Can it save the billions of dollars a year we know is wasted in the current system without undercutting incentives for excellence?

Health care reform will fail if it stalls research and medical progress. When Congress takes up regulation of biosimilars later this year, it needs to shore up the incentive for promising biologics research.

A bill by Rep. Anna Eshoo, D-Palo Alto, takes the right approach. It's smart, science-based legislation that puts a premium on patient safety and encouraging further innovation. It essentially offers 12 years for companies to recover their investments before others can use their clinical trial and related data to substantiate the safety of a biosimilar.

She has dozens of co-sponsors for the bill, but she's going up against the powerful Democratic Rep. Henry Waxman of Los Angeles, who chairs the House Energy and Commerce Committee that the bill must clear. Waxman would offer just five years' protection and would facilitate making cheaper alternatives. Holding down cost is a worthwhile goal, but these medicines won't exist in the first place if research dries up, or if safety issues crop up with the biosimilars.

Biologics aren't cheap. Treatments involving some cancer-fighting drugs can cost up to \$2,000 a month. But as their use increases and more new drugs come onto the market to attack debilitating diseases, savings will kick in. Medical experts estimate that as the biosimilars come into use, savings could range from \$7-10 billion a year over current costs of these types of medicines.

People want drugs to be less expensive, but they also want to know that if they become seriously ill, they'll have access to the best treatment science can provide. The academic and research communities, biotech companies, venture capitalists and patient safety

advocates support Eshoo's legislation, which would maintain the incentive for research. Congress should, too.

Congress must light the way for biologic drugs' approval

The Hill

April 21, 2009

By David B. Nash, M.D., and Geno Merli, M.D., Thomas Jefferson University Hospital

Medical science and legislation are colliding in Congress over the development of biologic drugs. The debate pits the hope of lower-cost “follow-on biologics” (FOBs), which would be available to more patients, against the complex science of using living tissue to create new treatments.

Biologics are made from organic material such as animal tissue and microorganisms, and are among the most effective medicines for treating diabetes, cancer and other diseases. Biologic drugs provide treatments for debilitating illnesses that hitherto were unavailable. But how FOBs are approved presents a clear case of legislation catching up with science. Unlike Europe, there is no standard approval process for FOBs in the U.S. Instead, the Food and Drug Administration examines FOB applications on a case-by-case basis.

There are competing bills in Congress to create an approval process for FOBs. Some policy makers embrace the proposal by Rep. Henry Waxman (D-Calif.), chairman of the House Energy and Commerce Committee. Others back the bill drafted by Rep. Anna Eshoo (D-Calif.). They differ primarily on how long companies could market their drugs before FOBs could be manufactured — Waxman’s bill would allow five years while the Eshoo version provides 12 years. In the upper chamber, Sen. Charles Schumer (D-N.Y.) has introduced a companion to the Waxman proposal and Sen. Edward Kennedy (D-Mass.) plans to reintroduce his FOB bill, which is similar to Eshoo’s blueprint.

The relative merits of each bill notwithstanding, the issue of drug safety must be addressed. Biologics are far more complicated than traditional chemical-based drugs. These drugs can be safely manufactured and, provided they are properly synthesized with the right chemicals, result in a generic that is identical to the original drug.

This is not so with biologics. Complex genetic engineering is required to produce biologics. Even minor changes in how biologics are made can result in significant changes involving the drug’s efficacy and safety. The nature of biologics means FOBs can be very similar to the original drug, but it’s not possible to be identical. FOBs may even be effective for use but they are not interchangeable with the original because they are not identical.

This is true of both carbohydrate-based and protein-based biologics and the risk of not including both varieties of biologics in pending legislation could significantly jeopardize patient health and safety. As legislation advances through Congress, it’s important that the final version of any bill provide a comprehensive approval pathway for carbohydrate- and protein-based FOBs.

Americans spend more than \$40 billion annually on biologic drugs and the goal of more affordable medicine is a national health priority — one that is a critical component of healthcare reform. But paramount in medicine is the health and safety of the patient, which demands a thoughtful and comprehensive approach to FOB approval including clinical testing.

This debate will have far-reaching implications with regard to safety, access, cost and therapeutic impact for thousands of patients with serious diseases and it is critical that the approval process for FOBs applies to all biologics, not just some.

Philadelphia