



**Statement of The Hemophilia Alliance for
The Committee on Energy and Commerce, Subcommittee on Health
Hearing on Examining the 340B Drug Pricing Program
March 5, 2015**

The Hemophilia Alliance is pleased to provide this statement for the Subcommittee on Health's Hearing on "Examining the 340B Drug Pricing Program." The Alliance is a non-profit organization comprised of hemophilia treatment centers (HTCs) across the United States that provide patients with hemophilia and other bleeding and clotting disorders with comprehensive specialized diagnostic and treatment services. HTCs directly provide hemophilia treatments (clotting factor) to their patients. The Alliance also serves as a group purchasing organization for its HTC members that are listed in the Office of Pharmacy Affairs database with the hemophilia treatment center (HM) designation.

About Hemophilia, Bleeding Disorders, and Hemophilia Treatment Centers

Hemophilia is a rare, chronic bleeding disorder affecting about 20,000 people in the US, who require life-long infusions of high-cost clotting factor therapies that replace missing or deficient blood proteins to prevent and treat debilitating and life-threatening internal bleeding. Individuals with hemophilia are trained to assess their needs and self-infuse their clotting factor at home since rapid time-to-treatment is critically important to prevent complications. The average annual cost of treatments for the 80% of the hemophilia population with the severe form of the disease is around \$300,000. However, the development of an inhibitor (immune intolerance to regular treatment), bleeding from trauma or surgery, and other complications can elevate the annual cost to \$1 million or more. Currently, there is no cure for hemophilia. Individuals may require lifelong infusions of replacement clotting factor therapies manufactured from human plasma or using recombinant technology.

In 1974, Congress authorized and funded the national network of hemophilia treatment centers (HTCs) within the Health Resources and Services Administration (HRSA) Maternal and Child Health's (MCH) Special Projects of Regional and National Significance. Since then, the MCH Hemophilia program's patient-centered, multi-disciplinary care provided by HTCs has been a model for patients with special needs. The Veterans Health Care Act of 1992 (PL 102-585) designated HTCs as original covered entities eligible to participate in the 340B program. The 340B program provides significant value to HTC patients by enabling access to lower cost prescriptions that have reduced out-of-pocket spending and allowed patients to maintain insurance and has increased patient access to the medical, dental, and support services and educational programs that HTCs are able to provide through 340B savings.

Over seventy-five percent of the hemophilia population receives specialized care at HTCs and many receive their medications through the HTCs' 340B drug delivery programs. The treatment centers bring together a multi-disciplinary team of providers including hematologists, nurses, physical therapists, social workers, and pharmacists to provide highly specialized care to assess and provide treatment for the long-term complications of hemophilia including inhibitors, liver disease and HIV/AIDS. The HTC comprehensive care model is patient-centered and trains individuals with hemophilia to recognize and quickly treat life-threatening internal bleeding episodes to prevent complications. Studies have shown that mortality and hospitalization rates are 40% lower for people who use HTCs than in those who do

not, despite the fact that more severely affected patients are more likely to be seen in HTCs. The HTCs have been recognized as a model system of high quality, cost effective care.

HTCs participating in the 340B program directly provide hemophilia treatments (clotting factor) to their patients. Clinical and pharmacy services are totally integrated at the HTC and are a critical component of comprehensive hemophilia care. HTCs coordinate the provision of pharmacy services as part of their comprehensive care program, providing constant monitoring of bleeds and clotting factor utilization to allow for quick response to needed changes in treatment.

The Importance of the 340B Programs to Hemophilia Treatment Centers

The 340B program is essential to maintaining patient access to the broad set of HTC services. HRSA grants to HTCs are small - only \$4.9 million in federal grant funding is provided by MCH for services not covered by insurance, which is spread among the 140 federally-funded HTCs nationwide. An additional \$5 million in grants from the Centers for Disease Control and Prevention is awarded to HTCs, but these funds must be used for surveillance and research.

The HTCs participating in the 340B program use program revenues to meet the needs of their patient population and to carry out the mission stipulated in their grants. HTCs comply with significant Federal reporting requirements and limitations on the use of 340B program income funds as defined in HRSA/MCH grant guidance. 340B revenues enable HTCs to stretch scarce Federal dollars to reach more patients and provide more comprehensive services. Simply put, most HTCs would not be able to provide the full array of comprehensive services to their patients without the 340B program.

Like the HIV/AIDS 340B providers, there are a limited number of centers that participate in the 340B Drug Pricing Program and they serve a patient population easily defined by their patients' diagnoses. There is little opportunity for diversion of 340B clotting factor to non-patients as they are seen at the clinic, and the HTCs have many Medicaid patients and work closely with State Medicaid so the chance of any duplicate discount are almost non-existent. HTCs do not have multiple clinic sites, and do not use multiple contract pharmacy arrangements which have been the subject of much Congressional concern. Additionally, the HTCs' participation in the 340B program is strongly supported by the majority of manufacturers of hemophilia clotting factor therapies as the attached letters demonstrate.

In conclusion, the Hemophilia Alliance encourages the Subcommittee on Health to support the 340B program and to ensure its long term viability for HTCs and other providers of services for vulnerable populations. The Alliance anticipates the release of 340B program guidance and regulations later this year to strengthen 340B program operations. The Alliance supports these efforts, but will seek to ensure that any proposed changes do not prevent HTCs from meeting the needs of the patients they serve.

For further information, contact Joseph Pugliese, President of the Hemophilia Alliance at 215-439-7173 or joe@hemoalliance.org.

February 04, 2015

The Hemophilia Alliance Board of Directors
1758 Allentown Road #183
Lansdale, PA 19446

Dear Board of Directors,

Baxter International Inc. is committed to ensuring that patients obtain the most appropriate treatment based on their individual healthcare needs. This includes access to the full range of FDA approved hemophilia clotting factors and comprehensive hemophilia treatment centers, as well as choice of experienced pharmacy providers, including pharmacy programs administered by hemophilia treatment centers as part of the 340B drug discount program.

Hemophilia treatment centers are federally recognized facilities that provide a comprehensive model of care for people with bleeding disorders. Patients receive coordinated care within one facility which is typically comprised of a multi-disciplinary team of experts in hemophilia including hematologists, pediatricians, nurses, social workers and physical therapists. Research at the Centers for Disease Control and Prevention documented a decrease in mortality and bleed-related hospitalization in men who visited a hemophilia treatment center.¹

Hemophilia treatment centers are included in a specific category of HRSA grantees that participate in the 340B drug discount program. The 340B program has served as a source of funding for comprehensive hemophilia care and has helped hemophilia treatment centers provide access to high quality hemophilia care to all patients, both insured and uninsured.

Baxter continues to believe each patient has the right to select the hemophilia clotting factor and medical and pharmacy provider to meet their individual needs. Pharmacy programs administered by 340B eligible hemophilia treatment centers are an option that should be available to all patients.

Sincerely,



Peter O'Malley
Vice President, Market Access
Baxter BioScience, North America

Baxter Healthcare Corporation
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T 847.948.2000

¹ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449458/>

September 30, 2014

Board of Directors
The Hemophilia Alliance
1758 Allentown Road #183
Landsdale, PA 19446

Dear Board Members,

Biogen Idec is pleased to support the work of the Hemophilia Alliance in ensuring that people with hemophilia have access to the health care specialists, services, and treatments they need to lead active and productive lives.

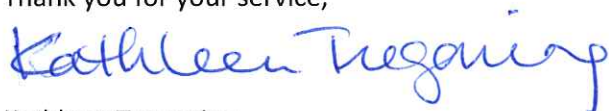
Hemophilia Treatment Centers (HTCs) are comprehensive care facilities, recognized for providing cost effective high quality health care to people with a rare, serious, and complicated medical condition. HTCs serve as the medical home and conduit for guaranteeing that those with hemophilia receive the best care, both directly, and through their participation in the Alliance. Biogen Idec supports the Alliance's work toward creating an environment where people with hemophilia can tailor the care they receive to meet their individual needs by having access to:

- Providers of their choice,
- Affordable medicines and services,
- Health plans that include HTCs in their networks, and
- A wide range of products included in health plan formularies.

HTCs exemplify the type of health care facility that the federal government envisioned should be eligible to participate in the 340B drug discount program when it was established in 1992.

Although Biogen Idec is new to the hemophilia community, we recognized early on that HTCs are indispensable contributors to hemophilia care and also bring significant value to the larger U.S. health care system. As more and more innovative products are created to better treat this serious disorder and the health care delivery system continues to evolve, HTCs and the Alliance will become increasingly important in helping to shape policies that will improve hemophilia care.

Thank you for your service,



Kathleen Tregoning
Vice President
Public Policy & Government Affairs

CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

CSL Behring

October 8, 2013

Board of Directors
Hemophilia Alliance Board of Directors
1758 Allentown Road #183
Lansdale, PA 19446

Dear Board Members,

CSL Behring is committed to working with all providers of therapies to ensure that patients with bleeding disorders have access to these life-saving therapies. One major source for patients to access blood clotting factors is the hemophilia treatment center.

The federally funded hemophilia treatment center network managed through the Maternal Child and Health Bureau in partnership with the Centers for Disease Control and Prevention has been a vital tool for treating individuals with bleeding disorders in the United States. Medical literature demonstrates that individuals with bleeding disorders who visit their local hemophilia treatment center for an annual check-up see a potential 40% reduction in morbidity and mortality. In fact, the treatment center network combined with the technological advancement in treatment therapies has resulted in the average life span of a person with bleeding disorders increase significantly to the point of where it is now comparable to the average life span of a "healthy" individual.

CSL Behring is a partner with the bleeding disorders community and we continue to support the federally funded treatment center network and the comprehensive care they provide. To that end we ensure that people with bleeding disorders have access to these life-saving blood clotting factors through a variety of options, whether it be specialty pharmacy, mail-order pharmacy or directly through the hemophilia treatment center network.

CSL Behring recognizes and supports the vital role that safety net providers like hemophilia treatment centers play in providing access to life-saving therapies. We also support the hemophilia treatment centers ability to purchase products for these patients through the 340B Public Health Service Pricing Program should the center choose to participate in the program. For those centers that make this decision, we do provide therapy as one outlet for making product available for their eligible patients. Treatment centers participating in the 340B program provide one valuable resource in the options available to ensure that patients with bleeding disorders receive proper care.

CSL Behring is a company of CSL Limited.

Thank you very much for the work that you do to ensure that hemophilia treatment centers have access to blood clotting factors and we look forward to our continued collaboration.

Sincerely,

A handwritten signature in black ink that reads "Patrick Collins". The signature is written in a cursive style with a large initial "P".

Patrick Collins
Director, US Healthcare Policy and External Affairs

May 1, 2014

Board of Directors
Hemophilia Alliance
1758 Allentown Road, No. 183
Lansdale, Pennsylvania 19446

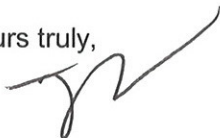
Dear Board Members,

Octapharma USA is pleased to provide its input into an important issue regarding continuing access to life-saving blood coagulation factor for Florida Medicaid beneficiaries. As a relatively recent entrant into the U.S. coagulation market, Octapharma is committed to the core principle of ensuring access to all approved therapies for patients who need them. As applied to the specific case of Florida Medicaid, we believe that patients with bleeding disorders would benefit from having multiple providers of factor whether from a hemophilia treatment center or from specialty pharmacy.

Octapharma USA recognizes the importance of all providers and market participants who pay a role in delivering factor products to the patients who need them. Chief among the providers is the federally-funded hemophilia treatment (HTC) network – a jointly managed program of the Maternal Child and Health Bureau and the Centers for Disease Control and Prevention. Over the years CDC data has shown that hemophilia treatment centers are responsible for a 40% decline in mortality and morbidity for HTC patients, *i.e.*, patients who visit the hemophilia treatment center at least once annually.

As it continues to expand its repertoire of coagulation therapies available to patients in the U.S., Octapharma USA looks forward to working with the bleeding disorders community and with providers such as the HTC network. Together, we will work towards the goal of ensuring that patients with bleeding disorders have access to their life-saving therapies irrespective of source be it a specialty pharmacy or directly through a hemophilia treatment center.

Yours truly,



Flemming Nielsen
President, Octapharma USA, Inc.
Member of the Board, Octapharma A.G.

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The Hemophilia Alliance
Board of Directors
1758 Allentown Road #183
Lansdale, PA 19446

Dear Board of Directors of the Hemophilia Alliance:

We are writing to affirm Pfizer's belief that patients living with hemophilia should have access to providers who are experts in treating this serious and complex disease.

The National Hemophilia Foundation (NHF) back in 1973 launched an initiative to establish Hemophilia Treatment Centers (HTC) to bring the comprehensive care needed by hemophilia patients into one facility. The comprehensive care provided by Hemophilia Treatment Centers (HTCs) has been shown in studies to have a positive effect on patient outcomes.

In order for a patient to access the full range of services provided by the HTC they need health insurers to include HTC's in the provider networks.

Pfizer has a long history of supporting the hemophilia community. We understand the medicines and resources we provide are one part of the effort needed to support patients with hemophilia and their families. The comprehensive care that patients receive from the HTC helps them lead a more normal life. In order for patients to continue to benefit from this care it is critical that insurance providers include HTC's in the provider networks.

Sincerely,

A handwritten signature in black ink, appearing to read "Karen Boykin-Towns".