

As the Ranking Member and former Chairman of the House Subcommittee on the Western Hemisphere, I have visited many Caribbean countries and have learned the importance of the region to the United States and the entire Western Hemisphere. In fact, last year I wrote an amendment, which passed the Foreign Affairs Committee unanimously, urging the State Department to place U.S. Embassies in five Caribbean countries that are without a permanent diplomatic post. I strongly believe that bolstering U.S.-Caribbean relations needs to be a priority, and opening these embassies would benefit U.S. ties with the entire region. I also had the honor of joining President Obama earlier this year at the Summit of the Americas where we reinforced our dedication to the Caribbean and, last year, had the unique experience of traveling with a delegation of Caribbean ministers to Israel.

My time spent with my Caribbean American constituents and in the great countries that make up the Caribbean has helped me to truly appreciate the influence of Caribbean culture on the U.S. This June, I am pleased to take this opportunity to commemorate Caribbean Americans Heritage Month, and look forward to a future of working closely with the Caribbean American community ensure positive cross-cultural relations.

#### HONORING ISRAEL SOTO, LEADING EDUCATOR

#### HON. CHARLES B. RANGEL

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, June 5, 2012*

Mr. RANGEL. Mr. Speaker, today I rise to recognize a great force in the education of our children, Israel Soto, principal of PS/MS 57. He is retiring after a long career in public service. Mr. Soto got his start in education teaching in Washington Heights, in my congressional district. As a Puerto Rican immigrant, he has taken an active role in bilingual education, having served as a school Bilingual Coordinator and Assistant Director of Bilingual Education.

In 1999, Mr. Soto ascended to principal of PS/MS 57, a pre-K-8 school in East Harlem. Last year, 67 percent of enrollees were Hispanic or Latino. Mr. Soto's expertise in bilingual education and the fact that his second language was English, like many of the school's students, made him an ideal choice for principal. His talents extend to all facets of education, however. Under his leadership, PS/MS 57 has gone from a near-failing school to one that received a grade of "A" in its latest Progress Report and is ranked in the 93rd percentile of all New York City K-8 schools.

Mr. Soto has deservedly received numerous awards during his tenure as principal. In 2001, he was named "Principal of the Month" in his school district and in 2004 was recognized as the "Educator of the Week" by Channel 41. He has also been inducted into the "Calm Fellows Program for Distinguished Principals" at Columbia University as well as being honored by Children 4 Children, the YMCA of New York, the New York Post and El Diario La Prensa.

Mr. Soto's work at PS/MS 57 serves as a model for current and future educators. He has built strong partnerships with teachers,

parents, community organizations and the private sector while keeping his focus internal, on his students. This outreach has significantly increased the academic resources available to his students and demonstrates the supreme importance of an active and charismatic principal such as Mr. Soto.

Mr. Speaker, I ask that you and my colleagues join me in honoring a great man and an impassioned educator who, first and foremost, believes in all of our extraordinary children.

#### MELANIE KURTZ

#### HON. ED PERLMUTTER

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, June 5, 2012*

Mr. PERLMUTTER. Mr. Speaker, I rise today to recognize and applaud Melanie Kurtz for receiving the Arvada Wheat Ridge Service Ambassadors for Youth award. Melanie Kurtz is an 8th grader at Oberon Middle School and received this award because her determination and hard work have allowed her to overcome adversities.

The dedication demonstrated by Melanie Kurtz is exemplary of the type of achievement that can be attained with hard work and perseverance. It is essential students at all levels strive to make the most of their education and develop a work ethic which will guide them for the rest of their lives.

I extend my deepest congratulations to Melanie Kurtz for winning the Arvada Wheat Ridge Service Ambassadors for Youth award. I have no doubt she will exhibit the same dedication and character in all her future accomplishments.

#### TO AMEND THE NATIONAL COMMUNITY SERVICE ACT OF 1990 TO MAKE CERTAIN UNITED STATES TERRITORIES ELIGIBLE FOR NONPROFIT CAPACITY BUILDING GRANTS UNDER THAT ACT

#### HON. GREGORIO KILILI CAMACHO SABLAN

OF THE NORTHERN MARIANA ISLANDS

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, June 5, 2012*

Mr. SABLAN. Mr. Speaker, today, I am introducing legislation that will amend the National and Community Service Act, as amended by the Edward M. Kennedy Serve America Act, to make the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands eligible for the Nonprofit Capacity Building Grants under that Act.

The Nonprofit Capacity Building Grant Program awards intermediary nonprofit organizations with funding to provide development training to small and mid-sized nonprofits on best practices, financial planning, grant writing, and compliance with applicable tax laws.

In my district, we have hard working nonprofit organizations and advocates who commit themselves to truly noble causes. Whether it is the protection of families from domestic violence or raising funds to find a cure for cancer, nonprofits work tirelessly for the greater

good of all members of our community. The technical correction I offer here today would allow organizations in the Northern Marianas and other U.S. territories an equal opportunity to apply for federal funds to increase the effectiveness of nonprofits and to expand their impact within their communities.

I urge my colleagues to support this bill and allow the U.S. territories an equal opportunity to compete for this program.

#### FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012

SPEECH OF

#### HON. CLIFF STEARNS

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, May 30, 2012*

Mr. STEARNS. Mr. Speaker, the Food and Drug Administration Reform Act, H.R. 5651, is based on user fee negotiations between FDA and the prescription drug, generic drug, biologic, and medical device industry. This reauthorization of the FDA user fees will provide stability with FDA's new product review as companies submit new and innovative devices and drugs for approval.

In codifying the User Fee Agreement, this committee has included additional provisions designed to address some of the defects of the regulatory structure and overreach by the FDA. Under my Chairmanship of the Oversight and Investigation Subcommittee, we held a hearing into FDA's regulatory efforts in the medical device space. During our hearing, many of the witnesses talked about the reluctance of FDA to approve devices and how FDA continually moved the goalposts for approval. I am glad that Title VII of this bill includes a significant number of reform provisions designed to bring certainty to the medical device field.

In addition to reforming approaches to medical devices through Title VII, the FDA's approach to rare diseases must also be modernized. I'm happy the Committee included the Faster Access to Specialized Treatments Act, FAST Act, H.R. 4132, which I introduced with my friend and colleague, Representative ED TOWNS. FAST updates and modernizes Section 506 of the Food, Drug & Cosmetic Act, and updates the Accelerated Approval statute to reflect two decades worth of medical sciences that has occurred since Accelerated Approval was first created. FAST will help FDA implement broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases by using modern scientific tools.

The use of surrogate endpoints may result in fewer, smaller or shorter clinical trials without compromising FDA's existing high standards for safety or efficacy. Surrogate and clinical endpoints only need to be reasonable predictors of clinical benefit to support accelerated approval. They do not need to be validated or proven first. The changes made to current law permitting the Secretary to require validation of surrogates following accelerated approval is not intended to change FDA's long history of granting accelerated approval based on unvalidated, but predictive, surrogate endpoints.

Additionally, FAST includes explicit language for FDA to think about the challenges of rare diseases when developing their guidance and gives the rare disease community an opportunity to publically comment on FDA's draft guidance. FAST ensures that the voices of the 30 million Americans with a rare disease will be heard by FDA. There are about 7,000 rare diseases and only about 250 have any treatment. FAST will save lives, and give a voice to the voiceless; and I am glad it is in the bill.

Lastly, the committee included the Expanding and Promoting Expertise in Review of Rare Treatments, EXPERRT Act, H.R. 4156, a bill my fellow Co-Chairs of the Cystic Fibrosis Caucus and I introduced. EXPERRT will have the FDA consult with experts in rare diseases. This will ensure that FDA has access to the knowledge needed when dealing with drug approvals for diseases where FDA may lack subject matter expertise. As one of the Co-Founders of the Cystic Fibrosis Caucus, I am glad that we are giving this tool to the FDA.

I'd like to submit this letter of support for FAST signed by over 150 rare disease groups into the RECORD.

H.R. 5651 is a good bill that will help new drugs and new medicines get into the market and be available to patients. I support passage of the FDA Reform Act.

MARCH 23, 2012.

Hon. CLIFF STEARNS,  
*House of Representatives, Rayburn House Office Building, Washington, DC.*

Hon. EDOLPHUS TOWNS,  
*House of Representatives, Rayburn House Office Building, Washington, DC.*

DEAR CONGRESSMEN STEARNS & TOWNS: On behalf of patients, physicians, and other members of the health advocacy community we are writing to express our support for H.R. 4132, the Faster Access to Specialized Treatments (FAST) Act. This legislation will modernize and expand the FDA's Accelerated Approval pathway to encompass a broader range of diseases and leverage 21st century drug development tools and strategies. This reform will speed the approval of much-needed therapies and cures to patients who are facing serious and life-threatening conditions, including Alzheimer's disease, autoimmune diseases, multiple sclerosis, Parkinson's disease, neuromuscular disease and hundreds of rare diseases that remain untreated.

We commend you for championing legislation that maintains the FDA's high standard for approval while at the same time ensuring the Agency can help facilitate the development of new and novel therapies to patients in a more timely manner. In many cases our patients have no available treatment for their diseases, or they are using a therapy that is older and may not work as effectively and safely. This is not acceptable. We believe that this legislation will ensure patients receive the best, modern treatment as soon as possible and we applaud your efforts on their behalf.

Thank you for your leadership on this important bill and we look forward to working with you as it moves forward.

Sincerely,

Abigail Alliance for Better Access to Developmental Drugs; Advocacy for Patients with Chronic Illness, Inc.; Affiliated American CSA Foundation; Alliance for Aging Research; Alliance for Patient Access; American Autoimmune Related Diseases Association; American Brain Tumor Association; American Childhood Cancer Organization; American College of Medical Genetics;

American Institute for Medical and Biological Engineering; American Society of Clinical Psychopharmacology; Batten Disease Support and Research Association; Break Through Cancer Coalition; Californians for Cures.

Celiac Disease Center at Columbia University; Celiac Sprue Association; Charcot-Marie-Tooth Association (CMTA); Children's Cardiomyopathy Foundation, Inc.; Chinese American Association of Greater Chicago; Coalition Duchenne; Coalition for Pulmonary Fibrosis; Colon Cancer Alliance; Cooleys Anemia Foundation; Crohn's and Colitis Foundation of America; Cryoglobulinemia Vasculitis Organization; CureDuchenne; CurePSP; Digestive Disease National Coalition; Erik Metzler Foundation.

EveryLife Foundation for Rare Diseases; Fabry Support & Information Group; Georgia PKU Connect; GIST Support International; Hadley Hope Fund; Hannah's Hope Fund; Hayden's Batten Disease Foundation Inc.; HealthHIV; Hope4Bridget Foundation; ICE Epilepsy Alliance; I Have IHH; In Need of Diagnosis, Inc. (INOD); Inspire; International Cancer Advocacy Network (ICAN); Jacob's Cure, Inc.

Jain Foundation Inc.; Jonah's Just Begun—Foundation to Cure Sanfilippo Inc. LAM Treatment Alliance; LGS Foundation; Liddy Shriver Sarcoma Initiative; Little Miss Hannah Foundation; Lung Cancer Alliance; Lupus Foundation of America; Lymphangiomatosis & Gorham's Disease Alliance (LGDA); Lymphatic Malformation Institute (LMI); Macular Degeneration Support, Inc. Madisons Foundation; Midwest Asian Health Association (MAHA); MLD Foundation; Mpdsupport.org—Myeloproliferative Disease Support; Muscular Dystrophy Association.

National Family Caregivers Association; National MPS Society; National MS Society; National Niemann-Pick Disease Foundation, Inc.; National PKU Alliance; National Tay-Sachs & Allied Diseases Association; National Venture Capital Association; NBIA Disorders Association; New Jersey Association for Biomedical Research; NKH International Family Network; Noah's Hope—Batten Disease Fund; Oxalosis and Hyperoxaluria Foundation; Pachyonychia Congenita Project.

Parkinson's Action Network; Parry-Romberg Syndrome Resource, Inc.; Partnership for Cures; Polycystic Kidney Disease Foundation; RARE Project; Russell-Silver Syndrome Support; Scleroderma Research Foundation; Sickle Cell Disease Association of America, Inc.; Society for Women's Health Research; Solving Kids' Cancer; Student Society for Stem Cell Research; Sudden Arrhythmia Death Syndromes (SADS) Foundation; Taylor's Tale.

The Association for Frontotemporal Degeneration (AFTD); The Children's Medical Research Foundation, Inc.; The Erythromelalgia Association; The Focus Foundation; The Manton Center for Orphan Disease Research, Children's Hospital Boston; The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA); The Stop ALD Foundation; Tuberous Sclerosis Alliance; Veterans Health Council; VHL Family Alliance; Vietnam Veterans of America; ZERO—The Project to End Prostate Cancer.

IN RECOGNITION OF "HAND IN HAND"

HON. FRANK PALLONE, JR.

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Tuesday, June 5, 2012

Mr. PALLONE. Mr. Speaker, I rise today to congratulate the efforts of the Hand in Hand organization, as its members gather to honor its outstanding teen volunteers. Hand in Hand continues to cultivate friendships and build life long relationships between local teen volunteers and special needs children. Hand in Hand teen volunteers will be recognized for their outstanding service to the community at an awards dinner on June 5, 2012. Aimee and Gerald Ostrov and Nona and Dennis Drazin will serve as Guests of Honor. Their faithful service and dedication to the community is worthy of this body's recognition.

Hand in Hand is a local volunteer based organization founded in 2006 under the direction of Chabad of the Shore. The organization is dedicated to building friendships between children with special needs and teen volunteers. Students involved in the Hand in Hand organization remain fully exposed to a wide variety of Jewish activities and social experiences. Teen volunteers learn to become effective friends and mentors while children learn to interact and build social skills. The interaction has helped build eye opening experiences and strong, life long relationships. The unending generosity demonstrated by the Hand in Hand teen volunteers has undoubtedly touched many lives and has helped countless people throughout central New Jersey.

Hand in Hand volunteers and children have also benefited from the steadfast leadership and mentoring of Rabbi Laibel Schapiro and the Chabad of the Shore staff. Rabbi Schapiro received his rabbinical ordination from the Central Chabad Yeshiva in Brooklyn, New York. He has directed the Chabad of the Shore of Monmouth County since 2002 and is a powerful presence in the Monmouth County Jewish community. Rabbi Schapiro's steadfast leadership and contributions to Chabad of the Shore, the Hand in Hand organization and Jewish community are an inspiration to future generations throughout Monmouth County, New Jersey.

The 2012 Annual Hand in Hand Dinner will also recognize four outstanding individuals who will serve as the Guests of Honor. Aimee and Gerald Ostrov are residents of Long Branch, New Jersey and Herzliya Pituch, Israel. Aimee served the Hadassah organization for 30 years and has served in numerous prominent positions including President of the East Brunswick Chapter, President of the Southern New Jersey Region and National Board and Executive Committee. She is an alumna of Cornell University and completed a dietetic internship at Massachusetts General Hospital. Aimee worked as a dietitian in hospitals and nursing homes before dedicating her time exclusively to family and philanthropy. Jerry is an alumnus of Cornell University and earned his Masters in Business Administration from Harvard Business School. He has spent most of his career at Johnson & Johnson where he was later promoted to Company Group Chairman. After a short retirement, he returned to work as Chairman and CEO of Bausch & Lomb. He currently serves on several Boards and provides guidance for start-up