Hagan's TREAT Act Moves Forward, Accelerating Access to Treatments for Rare & Life Threatening Diseases

Tuesday May 1, Hagan to hold NC Impact Event at the N.C. Children's Hospital in Chapel Hill to Discuss the TREAT Act

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WASHINGTON, D.C. – U.S. Senator Kay R. Hagan (NC) today commented after the Health, Education, Labor and Pensions Committee passed the Food and Drug Administration Safety and Innovation Act (FDASIA), which includes important provisions of her Transforming the Regulatory Environment to Accelerate Access to Treatments (TREAT) Act were incorporated into FDASIA. Now that FDASIA has been approved by the Health, Education, Labor, and Pensions (HELP) Committee it will next move to the Senate floor for consideration.

"I am thrilled that the TREAT Act is moving forward and has been incorporated into the Food and Drug Administration Safety and Innovation Act," said Senator Hagan. "The TREAT Act will get innovative treatments to patients quicker, without lowering the FDA's standards for safety and effectiveness. For patients suffering from diseases for which there are no current treatments, medical advances supported by the TREAT Act can't come fast enough."

Also today, the Biotechnology Industry Organization honored Senator Hagan as their Legislator of the Year for her work on the TREAT Act. For a photo of Hagan accepting the award from BIO president and CEO Jim Greenwood and NCBIO President Sam Taylor, please click here.

Next Tuesday, May 1, Senator Kay Hagan will be in Chapel Hill to discuss the TREAT Act.

WHAT: Hagan to Discuss TREAT Act Impact on NC at the N.C. Children's Hospital
WHEN: Tuesday, May 1, 2012; 9:45-10:15 B-roll opportunity Tour N.C. Children's Hospital; 11:00-11:30 AM Press Avail in the Play Atrium.

WHERE: N.C. Children's Hospital
101 Manning Drive, Chapel Hill, NC 27514
For a map of the hospital facility, please click here.
RSVP to Jack_Pfeiffer@Hagan.Senate.gov to request complimentary parking.

Background on the TREAT Act

To date, the FDA's accelerated approval pathway has been successfully used for the approval of therapies to treat HIV/AIDS and cancer, but has been inconsistently applied to other diseases, including rare diseases.

In fact, a 2011 report by the National Organization for Rare Disorders compared the approval process for 135 non-cancer orphan therapies (rare disease therapies) approved by FDA from 1983 through June 2010. The report found that 45 went through the conventional approval process; 32 were approved with some sort of administrative flexibility; and 58 were approved on a case-by-case flexibility process. This report illustrates that while FDA does have the authority to approve treatments with some flexibility, but there does not appear to be uniformity or consistency in employing it.

The TREAT Act will provide a consistent pathway to encourage the development of innovative treatments, and will send a clear message to the FDA that the accelerated approval pathway is to be used for the approval of treatments for rare diseases. Of 7,000 known rare diseases, fewer than 250 currently have FDA-approved therapies.

For additional background on Senator Hagan's TREAT Act, please click here.

Below is a list of 35 patient advocacy groups that have voiced their support for Senator Hagan's TREAT Act:

1. Alliance for Patient Access
2. American Autoimmune Related Diseases Association
3. American Institute for Medical and Biological Engineering
4. American Society of Clinical Psychopharmacology (ASCP)
5. Californians for Cures
6. Celiac Disease Center at Columbia University
7. Colon Cancer Alliance
8. Crohn's and Colitis Foundation of America

9. Digestive Disease National Coalition
10. EveryLife Foundation for Rare Diseases
11. HealthHIV
12. Hope4Bridget Foundation
13. Huntington’s Disease Society of America
14. Inspire
15. International Cancer Advocacy Network (ICAN)
16. Lung Cancer Alliance
17. Lupus Foundation of America
18. MLD Foundation
19. Muscular Dystrophy Association
20. National Family Caregivers Association
21. National MPS Society
22. National Venture Capital Association
23. NBIA Disorders Association
24. New Jersey Association for Biomedical Research
25. Parkinson’s Action Network
26. Polycystic Kidney Disease Foundation
27. RARE Project
28. Sickle Cell Disease Association of America, Inc.
29. Student Society for Stem Cell Research
30. The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA)
31. Tuberous Sclerosis Alliance
32. US Against Alzheimer’s
33. Veterans Health Council
34. Vietnam Veterans of America
35. ZERO - The Project to End Prostate Cancer

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