The APHON Advocacy Correspondent

Welcome to the Advocacy Correspondent, a quarterly offering from the Association of Pediatric/Hematology Oncology Nurses. The goal of this newsletter is to inform members about legislative and regulatory issues impacting the profession of pediatric hematology/oncology nursing and the patients we serve.

In case you missed it-November was National Marrow Awareness Month, 70% of bone marrow patients do not have a matched donor in their family; Send your health policy and advocacy news to Jordan at jwildermuth@aphon.org.

Election Roundup

As was speculated, the Republicans pulled off the victory on November 4, picking up the needed seats to gain control of the Senate. The shift in power now places Republicans in the majority in both the House and the Senate which will have an impact on what we see either happening or not happening on Capitol Hill. For those keeping score at home, Senator Mitch McConnell (R-Kentucky) is now the Majority Leader and Senator Harry Reid (D-NV) is the Minority Leader. Leadership positions did not change in the House as Rep. John Boehner was re-elected as Speaker of the House and Rep. Nancy Pelosi (D-CA) as Minority Leader. The biggest change we will see is in the make-up of the committees as new Republican chairs will be determined in the Senate and vacancies in both House and Senate committees will need to be filled. This will impact the flow of legislation and what is actually heard and voted on at the committee level before it goes to the entire chamber. Pundits believe that in the 114th Congress Republicans will have more success in legislating and avoiding Democratic filibusters.

Issues at the top of the list for Sen. McConnell and Rep. Boehner include tax reform, immigration reform, passing appropriations bills, and repealing the Affordable Care Act (ACA). Sen. McConnell has stated that it would be near impossible to repeal the entire ACA and there is not much appetite among legislators to do so. Options that may come up during the 114th Congress include repealing portions of the law including the medical device tax, restoring the 40-hour work week, and trying to eliminate the individual mandate. As we go to press, The House and the Senate passed the “CRomnibus” spending bill, which includes a continuing resolution (CR) providing funding for the Department of Homeland Security through February and complete versions of the remaining FY 2015 spending bills to fund government agencies and programs for the remainder of FY 2015. The bill now goes to President Obama for his signature.

So what does this all mean for APHON? The “CRomnibus” bill includes $231.622 million For Title VIII nursing workforce development programs, a 3.5 percent increase over the FY 2014 levels. Several Title VIII programs received increases, including Advanced Education Nursing (3.2 percent); nurse education, practice and retention (5 percent); and the nursing faculty loan program (7.9 percent). The

Nursing Workforce Diversity program was level funded at the FY 2014 level.

There are also provisions of the ACA that are beneficial to pediatric cancer patients, specifically around access to care including:

1. Prohibiting insurance companies from denying coverage on the basis of any health status-related factors
2. Mandating that plans offer essential health benefits that cover critical categories of benefits to consumers
3. Expansion of Medicaid
4. Requiring health plans to offer coverage to an insured individual's dependents up to age 26.
5. Creating the Cures Acceleration Network, a new office at the National Institutes of Health (NIH), to make grants available to help facilitate the process of turning discoveries into new therapies.

We might also see more movement than we have in the past on legislation such as the Caroline Price Walker Conquer Childhood Cancer Act. That is not to say that the chances of legislation being passed is going to increase exponentially but there is a sentiment, at least in the Senate, to bring more bills up for debate.

NIWI Scholarships

APHON is committed to being influential in decision-making affecting the care for children, adolescents, and young adults with cancer and other blood disorders and in that spirit we will be awarding two scholarships for the Nurses in Washington Internship Program (NIWI) March 15-17, 2015. NIWI provides nurses with the opportunity to learn how to influence health care through the legislative and regulatory processes. Applications are available on the APHON website and the deadline to apply is January 12, 2015.

We can all advocate for AYA!

By: Kristin Stegenga, PhD RN CPON®

We, as nurses, are advocates for our patients every day, in usual patient care situations. We are always looking out for their best interest and avoiding situations where they might not be safe or well cared for. However, advocacy can mean so much more than that. That really hit home for me in some new ways at this year's Critical Mass conference. I am one of APHON's representatives to Critical Mass, which seeks to improve care and awareness of the needs of Adolescents and Young adults (AYA) with cancer. The group which includes nurses, doctors, social workers, and advocacy groups has been working to improve issues related to AYA and their unique needs for 10 years. In that time we have made some pretty big strides. At this year's conference we honored Archie Bleyer, MD for his work in raising awareness for the needs in this area. We all know now, in great part because of his "battle cry," that AYA are not the same as our pediatric patients or older adults.

This brings me to the other awareness that has grown for me since the Critical Mass meeting. I was asked about nursing's role in helping AYA participate in clinical trials research. Participation on clinical trials in the adolescent and young adult age groups has historically been very low. The reasons are multi-factorial, some relating to where AYA receive treatment and some related to lack of clinical trials and where a trial is available, not all AYA choose to participate. This is where pediatric hematology/oncology nurses can be effective. I realized that many times we, as nurses, are

instrumental in gathering specimens, explaining protocols and medications etc. but we are in a unique position, whether staff or advanced practice nurse to do much more. We have the ability, through our unique relationship with patients (particularly AYA) to educate and influence their perceptions of clinical trial participation. We can help them understand and continue to improve their cure rates by increasing participation on clinical trials because of their trust in us. We can advocate for them by advocating for their participation in clinical trials. The next time you think that your role in research or clinical trials is simply to gather a specimen or go over a drug sheet, reconsider. You might be the key to helping increase cure rates for AYA.

APHON Signs on in Support of Fully Funding Title VIII

APHON joined other members of the ANSR Alliance in asking the chairmen and ranking members of the House and Senate Subcommittees on Labor, Health and Human Services, and Education, to fully fund the Title VIII Nursing Workforce Development Programs. Title VIII provides the main federal funding for the training of entry-level and advanced degree nurses to improve access to, and quality of, health care in underserved areas. Read the sign-on letter.

Childhood Cancer Policy Roundtable

On September 20, 2014 APHON member Kara Bryant attended a Childhood Cancer Roundtable Policy Discussion which brought together different advocacy groups to begin the process of unifying the pediatric cancer advocacy community's passions and priorities. As a result of that meeting, information was gathered on the interests and priorities of all the different advocacy groups and organized into "buckets" which included:

1. Maximizing Discovery through Research (ensure adequate funding for NIH, NCI)
2. Accelerating Development and Availability of Promising Treatments (develop and address policy that will enhance and accelerate pediatric/childhood cancer treatments)
3. Maximizing Delivery of Care, Quality of Life and Survivorship (improve care delivery through awareness, research, education)

A follow-up meeting was held on December 9, 2014 to discuss the policy goals, refine and gain consensus on a prioritized common agenda, and establish a process for concrete strategies for collective action and advocacy around childhood cancer issues. APHON continues to be involved in the endeavor and will provide updates when available.

Big Win for Children in National Cancer Institute's FY 2016 Budget

The National Cancer Institute has delivered their Annual Plan and Budget Proposal for Fiscal Year 2016 to the White House. Included in the plan is an entire section dedicated to childhood cancers which is a huge win for advocates. The entire NCI budget proposal is $5.754 billion which is an increase of $823 million from FY 2015. $100 million was allocated to research that addresses pediatric cancers including:

The Therapeutically Applicable Research to Generate Effective Treatments (TARGET) program- uses genomic approaches to catalog the full range of molecular changes in several childhood cancers to increase our understanding of their pathogenesis, improve their diagnosis and classification, and identify new candidate molecular targets for better treatments

Cancer Genome Characterization Initiative-includes genomic studies of various pediatric cancers that often do not respond well to treatment.

The Children's Oncology Group-Part of the NCI's National Clinical Trials Network (NCTN). It develops and coordinates pediatric cancer clinical trials.

Pediatric Molecular Analysis for Therapy Choice Program (Pediatric MATCH) trial-provide opportunities to test molecularly targeted therapies in children with advanced cancers and few other treatment options.

The Childhood Cancer Survivor Study (CCSS) - evaluates a long-term retrospective cohort with the twin goals of increasing our understanding of these late effects and improving the quality of life for survivors.

Pediatric Cancer Advocacy Outreach Meeting

The FDA's Office of Oncology and Hematology Products hosted a Pediatric Cancer Advocacy Outreach Meeting on November 18, 2014. Topics of discussion included background of the pediatric drug development and approval process as well as the role of the advocacy community. An important aspect of drug development is ensuring that policy is keeping pace with science and that regulatory barriers are not prohibiting innovation.

Key pieces of legislation that are leveraged in order to expedite drug approval for pediatrics includes the Pediatric Research Equity Act (PREA), the Best Pharmaceuticals for Children Act (BPCA), and the Food and Drug Administration Safety and Innovation Act which includes the Pediatric Study Plan and the Pediatric Priority Review Voucher. PREA requires that drug companies assess safety and effectiveness of certain products that specifically geared towards pediatric patients. The BPCA provides financial incentives to drug companies who conduct pediatric studies and is the primary tool used for drug approval and labeling.

Many improvements have been made to expedite drug approvals, specifically for pediatric cancer patients. The FDA is committed to early and frequent engagement among investigators and industry as well as leveraging legislative initiatives like PREA and the BPCA. The FDA also hosts quarterly meetings with representatives from the academic community and invites other stakeholders as well. As for what the landscape looks like moving forward, the FDA states that there will be many new targeted therapies, finite resources, and an increasing need for harmonization among stakeholders. For more information on the meeting visit the FDA website.

Meeting of the National Cancer Institute (NCI) Council of Research Advocates

The NCI Council of Research Advocates held a meeting on October 21, 2014 to provide an update from the NCI and discuss how advocates can advance cancer immunotherapy research. Topics of discussing included therapeutic cancer vaccines, the role of adoptive T-cell therapy, regulatory advances in immunotherapy, and ways advocates can advance cancer immunotherapy research. Minutes from the meeting are available here.

Call for Nominations

The National Cancer Institute (NCI) is pleased to invite nominations for membership on the NCI Council of Research Advocates (NCRA) starting in June 2015. The NCRA is NCI's only federal advisory board composed of advocate community leaders. The NCRA focuses on facilitating research and identifying and responding to challenges facing the Institute at the request of NCI leadership. To learn more about the NCRA, including a roster of current members and information on past meetings, visit advocacy.cancer.gov/ncra.

National Cancer Institute Launches Research Advocacy 101

NCI has launched a new video resource entitled *Research Advocacy 101* which aims to provide information about research advocacy at NCI. Some highlights of this video series include:

- A discussion of the history of advocacy
- The definition of research advocacy
- An explanation of the roles and responsibilities of research advocates at NCI
- A description of the value of advocacy in cancer research
- Information on how to become a research advocate at NCI

New Coalition Hopes to Increase Number of Nurses on Governing Boards

The Nurses on Boards Coalition was formed with the goal of putting 10,000 nurses on boards by the year 2020. The effort is a direct response to the Institute of Medicine's (IOM) report, The Future of Nursing: Leading Change, Advancing Health (2011), which recommended nurses play more pivotal roles on boards and commissions in improving the health of all Americans.

Notice of Meeting- Pediatric Oncologic Subcommittee of the Oncologic Drugs Advisory Committee

The Pediatric Oncologic Subcommittee of the Oncologic Drugs Advisory Committee met December 11, 2014. Information was presented to gauge investigator interest in exploring potential pediatric development plans for three products in various stages of development for adult cancer indications. The subcommittee considered and discussed issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion also provided information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) GANETESPIB, application submitted by Synta Pharmaceuticals Corp. (2) Etirinotecan, application submitted by Nektar Therapeutics, and (3) RO5503781, application submitted by Hoffmann-La Roche, Inc. Materials and information regarding accessing the webcast can be found here.

Online Tool Uses Natural History to Study Rare Diseases

The FDA is supporting an online tool that collects a rare disease's natural history- how a disease would progress with no treatment-to better assist scientists in developing efficient clinical trials, reducing the

length and cost of drug development and, possibly, contribute toward greater predictability of clinical development programs. The collection of studies will help scientists identify the following:

- Biomarkers, demographic, genetic, and environmental variables that correlate with the course and stages of the disease
- Identification of patient subpopulations with different characteristics and effects of the disease
- Patient perspectives on what aspects of disease are most important to treat
- How to quantify those aspects so that they can serve as useful outcome measures for clinical trials.

FDA Considers Drug Development for Sickle Cell Disease Top Priority

The FDA hosted a Patient-Focused Drug Development meeting on February 7, 2014 and posted the full meeting report online in October 2014. The 300 individuals that attended the meeting stated that there are vast health effects of Sickle Cell Disease (SCD) and an inadequate amount of medical treatments available. The FDA stated that they "consider the development of new SCD treatments a top priority" and have instituted mechanisms such as "fast track" and orphan drug designations. The "fast track" designation allows for more interaction with the FDA during the development stage, allowing for drugs to get to market faster. The orphan drug designation is for products intended to treat rare diseases affecting fewer than 200,000 individuals in the United States per year. Sponsors of an orphan designated drug or biological product can qualify for tax credits and marketing exclusivity.

Grants Issued to Boost Development of Products for Patients with Rare Diseases-Specifically Children

The FDA awarded 15 grants to in hopes of boosting the development of medical device, drug, and biological products for patients with rare diseases, with at least a quarter of the funding going to studies focused solely on pediatrics. For more information about the grant program visit the FDA website.

Panelists Discuss 21st Century Cures Initiative

Co-chairs of the 21st Century Cures Initiative, Chairman Fred Upton (R-Mich.) and Rep. Diana DeGette (D-Colo.) were on hand at the 2014 Partnering for Cures event to discuss the initiative which seeks to remake the U.S. medical research system to reflect the new realities along the research spectrum, from patients and doctors to drug and medical device developers. The main focus of the initiative is on identifying ways to expedite the approval of drugs and devices. A summary of the panel discussion can be found here.

Issues and Legislation of Interest

Below are bills that have been introduced during the current Congress that have an impact either on pediatric hematology/oncology nurses or our patients.

Access

S. 1879 Cancer Treatment Parity Act of 2013

Requires a group or individual health plan providing benefits with respect to anticancer medications administered by a health care provider to provide no less favorable coverage for prescribed, patient-administered anticancer medications

H.R. 1801 Cancer Drug Coverage Parity Act

Requires a group or individual health plan providing benefits with respect to anticancer medications administered by a health care provider to provide no less favorable coverage for prescribed, patient-administered anticancer medications

H.R. 1416 Cancer Patient Protection Act of 2013

Requires the budgetary resources sequestered for payments for drugs and biologicals under Medicare be available for obligation for drugs and biologicals furnished on or after enactment of this Act in the same amount and manner as if such order had not been issued.

H.R. 1666 Patient Centered Quality Care for Life Act

Creates a patient-centered quality of care initiative for seriously ill patients through the establishment of a stakeholder strategic summit, quality of life education and awareness initiative, health care workforce training, an advisory committee, and palliative care focused research, and for other purposes.

Research/Clinical Trials

S. 424 National Pediatric Research Network Act of 2013

Provides for the establishment of a National Pediatric Research Network.

S. 1247/H.R. 2058 Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act of 2013

Make grants to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors.

S. 1251/H.R. 2607 Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act

Reauthorizes through FY2018 cancer research programs

H.R. 225 National Pediatric Research Network Act of 2013

Provides for the establishment of a National Pediatric Research Network.

H.R. 2301 Clinical Trial Cancer Mission 2020 Act

Revises clinical trial registry data bank provisions of the Public Health Service Act to include a device or drug clinical trial whether or not it results in a positive or negative outcome.

Workforce

S. 739/H.R. 1907 National Nursing Shortage Reform and Patient Advocacy Act

Requires hospitals to implement a staffing plan that includes a minimum direct care registered nurse-to-patient ratio by unit and development of a national acuity tool.

H.R. 1821 Registered Nurse Safe Staffing Act of 2013

Requires each Medicare participating hospital to implement a hospital-wide staffing plan for nursing services furnished in the hospital.

H.R. 2986 Protecting Access to Primary Care Act

Extends to nurse practitioners, physician assistants, clinical nurse specialists, and certified nurse midwives payment for primary care services furnished in 2013 and 2014 at a rate not less than 100% of the Medicare payment rate applicable to physician for such services.

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