

March 12, 2014

**Legislative Update
for the
Clinical Trials and Translational Research Advisory Committee**

**Activities of the 113th Congress-
Second Session**

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I. Appropriations

On January 17th, the President signed Consolidated Appropriations Act of 2014 into law following Congressional passage of the omnibus funding bill with a House vote of 359-67 on 1/15/14, and a Senate vote of 72-26 on 1/16/14. Despite efforts to move the bill before the continuing resolution (CR) expired on January 15th, Congress was unable to do so and therefore needed to pass an emergency three-day Continuing Resolution (CR) to continue funding the government through January 18th.

This “omnibus” appropriations act contains funding for all 12 Congressional Appropriation bills, including Labor-HHS-Education. It provides a \$1 billion increase for NIH over the post-sequester funding level of FY2013 (\$29.9 billion for FY2014 for NIH, including \$4.92 billion for NCI). While this is an increase over the FY2013 funding level, the bill funds NIH and NCI at a level lower than FY2012, as well as lower than FY2011 and FY2010 levels.

The funding levels provided by the omnibus bill are based on spending levels established by the Bipartisan Budget Act, an agreement reached between House Budget Chair Paul Ryan and Senate Budget Chair Patty Murray (House amendment to H.J.Res. 59/P.L. 113-67; passed by the House and Senate and signed into law by the President in December 2013). The budget act restored a portion of sequestration cuts, providing an additional \$63 billion in discretionary spending authority (\$45 billion FY2014, \$18 billion FY2015, split evenly across defense and non-defense). This is offset by \$85 billion in cuts to mandatory programs and non-tax revenue increases (which provides an additional \$23 billion in deficit reduction).

Additionally, the Labor-HHS section of the appropriations act includes language directing each agency or operating division with research and development expenditures in excess of \$100,000,000 per year to develop a Federal research public access policy to provide for free online access to peer-reviewed manuscripts supported in whole or in part by federal funds, within 12 months of publication. This effectively directs the Centers for Disease Control, the Agency for Health Research and Quality, and the Department of Education to implement a public access policy similar to NIH. The omnibus bill also continues existing government-wide conference and travel restrictions, specifically, executive agencies must submit detailed reports to their Inspector Generals about conferences costing over \$100,000, and the head of the agencies must also report within 15 days details about any conference costing more than \$20,000. All travel and conference activities must continue to be in compliance with the guidance memo issued by the Office of Management and Budget on 5/11/12.

Conference report language accompanying the appropriations bill, called the Joint Explanatory Statement, includes additional policy directives for NIH, NCI, and other institutes. For example, the NIH Director is directed to conduct an NIH-wide review of how the priority-setting process affects program goals and the overall NIH research portfolio, and that of each IC. The NIH Director is also expected to develop an NIH-wide process to reduce duplication across communications activities – to consolidate and improve efficiencies, improve coordination of messages, and generally reduce costs in this area. Language specific to the NCI encourages certain pediatric brain tumor research efforts (biospecimen collection, genetic models, xenograft models), and requests more information regarding the use of bioinformatics in pediatric cancer research.

As noted above, the Bipartisan Budget Act also set discretionary spending levels for FY2015 and House and Senate Appropriators will use these figures to begin planning for the FY2015 appropriations process. The release of the President’s FY2015 budget began on March 4, and included summary information for the budgets of agencies such as the Department of Health and Human Services. This budget includes \$30.4 billion for NIH, an increase of \$211 million over FY2014. It is important to note that, while the proposed NIH budget is an increase relative to FY2014, it is less than the NIH FY2012 appropriation of \$30.86 billion. The FY2015 proposal includes approximately \$4.93 billion for NCI. Like NIH, this proposed budget is an increase (\$8 million) relative to FY2014, however it is less than the NCI FY2012 appropriation of approximately \$5.07 billion.

II. Special Topics

E-cigarettes: Ongoing Congressional Interest

Sen. Tom Harkin (D-IA), Chairman of the Senate Health, Education, Labor, and Pensions Committee, and Chairman of the Senate Appropriations Subcommittee on Labor-HHS-Education, indicated in a recent press interview that encouraging FDA regulation of electronic cigarettes is among his top priorities before he retires at the end of this year. Sen. Harkin is one of a number of members of Congress who continue to express concerns over electronic cigarette marketing and regulation.

Currently, E-cigarettes are not regulated by the U.S. Food and Drug Administration (FDA) as a tobacco product, although the FDA has indicated that it intends to issue a proposed rule extending its tobacco product authorities to include regulation of e-cigarettes. There is broad agreement that there are many important research gaps regarding these products. The NCAB December 2013 Legislative Update included a summary of congressional interest in e-cigarette use and regulation, including in response to a September 2013 Centers for Disease Control and Prevention report that e-cigarette use doubled among middle and high school students from 2011-2012.

Along with Sen. Harkin, Senators Barbara Boxer (D-CA), Richard Blumenthal (D-CT), Sherrod Brown (D-OH), Richard Durbin (D-IL), and Ed Markey (D-MA) wrote to the Federal Trade Commission (FTC) in December 2013, calling on the FTC to investigate e-cigarette marketing practices, particularly false, deceptive, or misleading advertising and marketing toward children and teens. The Senators asked the FTC to include e-cigarettes in its annual reports on tobacco product sales, advertising, and promotion – the FTC currently issues reports on cigarettes and smokeless tobacco products.

This group of Senators, along with a few House colleagues, continue to focus on e-cigarettes in the new year. Rep. Henry Waxman (D-CA) joined his Senate colleagues in writing to the House Office Building Commission and the Senate Committee on Rules asking that the ban on smoking on Capitol grounds be extended to include e-cigarettes. Additionally, after e-cigarettes were featured during the opening skit of the televised Golden Globe Awards, Senators Durbin, Blumenthal, Brown, and Markey wrote to the Hollywood Foreign Press Association and NBC Universal asking that future ceremonies refrain from intentionally featuring e-cigarettes.

Most recently Senator Harkin, Rep. Waxman, and Rep. Peter Welch (D-VT) wrote to their states' Attorneys General urging them to classify e-cigarettes as cigarettes under the Tobacco Master Settlement Agreement (a 1998 settlement between the Attorneys General of 46 states and tobacco companies; in addition to a financial settlement, terms include restrictions on marketing tobacco products to youth). Harkin, Waxman, and Welch write, "We believe e-cigarettes meet all the criteria for the definition of cigarette (and tobacco product) in the Master Settlement Agreement. In fact, the MSA contemplated that novel products -- like e-cigarettes -- would later meet the definition of cigarette. Inclusion of these products in the definition of cigarette is consistent with the MSA's overarching goal of protecting America's youth from the harms of tobacco use. . . . By taking action to apply the MSA to e-cigarettes, you could make a giant stride in protecting kids from a lifelong addiction to nicotine."

Oral Chemotherapy Parity: State and Federal Legislation

Recent laws and current proposals

Twenty six states and the District of Columbia have enacted laws that require insurance plans that provide coverage for intravenous (IV) or injected chemotherapy treatments to provide coverage for orally administered chemotherapies at the same cost. Oregon was the first state to do so in 2008, and in the past year alone seven states signed similar bills into law. In the current Congress, a number of legislators have expressed interest in a more consistent application of this policy and have introduced legislation to accomplish this at the federal level.

Traditionally, insurance plans have covered IV or injected chemotherapy as a medical benefit, meaning that a patient would be billed for a doctor's office visit, often a co-payment in the range of twenty to thirty dollars. Oral

chemotherapies, however, are usually classified as prescription drugs, and therefore covered under an insurance policy's prescription benefit, if the policy includes one. Prescription benefits are often structured as co-insurance, or cost sharing, where a patient would be required to cover a percentage of the cost of the oral chemotherapy. Many oral chemotherapies are newly approved drugs, with no equivalent generic alternative, and therefore can result in high out-of-pocket costs for patients with a cost sharing prescription benefit, or with an insurance plan that does not include a prescription benefit. For example the drug crizotinib, recently approved for the treatment of ALK-positive small cell lung cancer, is only available in the U.S. as brand-name Xalkori, and is considered a specialty medication. The price for a typical daily dose (two 250 mg pills) is approximately \$384, and patients continue on this dosage until disease progression or until the drug is no longer tolerated. Results from the international Phase III trial that crizotinib's FDA approval was based upon indicate that patients taking crizotinib had on average 7.7 months of progression-free survival. A 7.7 month supply of crizotinib costs approximately \$89,000.

The current national picture of the way oral chemotherapies are treated by payers is quite patchy. While a majority of states now require private insurance plans to cover all chemotherapies equally to eliminate high out-of-pocket costs for patients taking oral chemotherapies; more than 20 states do not have policies in place, although some have legislation pending. At the federal level, Medicare Part B currently covers any oral chemotherapy drug that is identical to an IV chemotherapy drug as a medical benefit. Oral chemotherapies that do not have an identical IV chemotherapy are covered under the Medicare Part D prescription plan.

Federal companion bills, introduced in the House by Rep. Brian Higgins (D-NY) and in the Senate by Sen. Al Franken (D-MN), were designed to substitute a consistent national standard of oral chemotherapy parity for the current status of comparable coverage required only in states with individual state laws. In addition, the federal proposals include provisions calling for a study to assess how closing the Medicare Part D "donut hole" (a gap in Medicare prescription drug coverage) affects Medicare coverage for orally administered anti-cancer medications. A summary of the Cancer Treatment Parity Act of 2013 (S.1879) and the Cancer Drug Coverage Parity Act of 2013 (H.R. 1801) is included in the "Legislation of Interest" section of this update.

Oral anti-cancer drugs: examples and ongoing research

The U.S. Food and Drug Administration (FDA) approved the first oral chemotherapy in 1998, the drug capecitabine (Xeloda) to treat patients with metastatic colorectal and metastatic breast cancer. Since that time the FDA has approved a growing number of oral anti-cancer drugs, including the first generic formulation of capecitabine, in September 2013 (the patent on capecitabine expired in December 2013, allowing generic formulations to enter the market). A typical two-week cycle of Xeloda costs approximately \$2,500 and patients often undergo up to eight cycles. A two-week cycle of generic capecitabine costs approximately \$1,475.

Advances in cancer genomics are identifying potential therapeutic targets across various cancer types, and continue to inform the development of targeted therapies, including those that are commonly administered orally. Many cancer immunotherapy agents, another area of promising research, are also oral medications. For example, a number of immunotherapies used to treat the blood cancer multiple myeloma are administered orally, including lenalidomide (Revlimid, approved for the treatment of multiple myeloma in 2006). A 25 mg dose of Revlimid is usually taken on days 1-21 of a 28 day cycle. Revlimid is associated with a median progression-free survival of 25.5 months. The cost for a 21-day supply is approximately \$9,500 (the cost of a 25.5 month supply of Revlimid is approximately \$252,000).

Anti-cancer targeted therapies known as small molecule inhibitors, which interfere with specific molecules known to drive a cancer's growth and progression, are usually orally administered drugs. Examples include imatinib (Gleevec), approved in 2002 for the treatment of chronic myeloid leukemia and advanced or metastatic gastrointestinal stromal tumor, and more recently crizotinib (Xalkori), mentioned above, approved in 2013. In the case of both imatinib and crizotinib, clinical trials demonstrated significantly prolonged progression-free survival with these targeted therapies as compared to existing chemotherapies. Gleevec is scheduled to come off patent in 2015, and until that time imatinib is only available in the U.S. as brand-name Gleevec. The starting dose is 400 - 600 mg per day, although some patients may be prescribed up to 800 mg per day. Most patients take Gleevec daily to

control their cancer, and continue to do so for years without disease progression. A daily dose of 400 mg costs approximately \$270. Generic pricing is not yet available.

Since the approval of capecitabine in 1998, the FDA has approved more than 50 oral anti-cancer drugs, with more oral therapies in development – estimates indicate that 25 to 30 percent of oncology drugs in the pipeline are oral medications.

Breast Density Reporting: State and Federal Legislation and Policy

Recent laws and current proposals

Breast density reporting legislation is gaining momentum at the state level, and interest is building at the federal level as well, from both a legislative and regulatory perspective. Breast density, which varies with the proportions of fat, glandular, and connective tissue in the breasts as seen on a mammogram, can cause difficulty in detecting breast cancer through the use of mammography. A breast with high density would yield a mammography image that is uniformly white throughout, making it difficult to distinguish normal tissue from tumors, which also appear white, due to the lack of contrast. Recent bills and regulatory actions would require that measures of breast density, and explanations about possibly related breast cancer risk, be reported to patients receiving mammogram results.

Representative Rosa DeLauro (D-CT), an ovarian cancer survivor, introduced the Breast Density and Mammography Reporting Act of 2013 on 10/20/13. Rep. DeLauro has introduced and co-sponsored similar proposals in past sessions of Congress; however the bills saw little activity. Rep. DeLauro's bill would amend the Mammography Quality Standards Act (MQSA) of 1992, which established quality standards for mammography facilities, and requires mammography facilities to provide patients with a report, in lay language and within 30 days, that summarizes the exam results. Rep. DeLauro's proposal would require the lay summary report to also include: (1) the patient's relative breast density, (2) their relative risk of developing breast cancer associated with their level of breast density, and (3) information communicating that individuals with more dense breasts may benefit from supplemental screening. Specific measures of breast density and language regarding relative risk and supplemental screening are to be determined by the HHS Secretary in consultation with leading experts and based on current scientific knowledge and medical practice. The bill also includes a clause specifying that, if passed, the federal legislation would not preempt any state requirements regarding breast density reporting. Upon the bill's introduction, Rep. DeLauro commented, "By providing this simple piece of information, we can help women and their doctors make more informed decisions about their risks for developing breast cancer, helping improve their chances for early detection and survival."

At the same time- and independent of Rep. DeLauro's proposal - the FDA scheduled a Notice of Proposed Rule Making for a breast density reporting amendment to the MQSA for December 2013, however the notice has yet to be issued. The abstract indicated that "FDA is taking this action to address changes in mammography technology and mammography processes, such as breast density reporting, that have occurred since the regulations were published in 1997." Currently the MQSA requires that breast density reporting is sent to the referring clinician, but not the patient.

At the state level, often in response to concerns from patient advocates, and in an effort to address some of the inherent challenges in screening for breast cancer in women with dense breasts, thirteen states have enacted laws requiring that women be notified of their breast density as part of standard reporting of mammography results. Similar laws are pending in 8 states, with efforts underway in additional states. The laws generally require that the mammography lay summary inform patients of their relative breast density, notify them of the association between dense breast tissue and cancer risk, and inform them of the limitations of mammography in patients with dense breast tissue and the possible benefit of additional screening tests (often specified as MRI or breast ultrasound). However, the specific reporting language, and who is responsible for the reporting, varies from state to state, and the provisions often do not include language addressing insurance coverage for any additional

screening tests. Many state laws indicate that breast density reporting categories be based on the American College of Radiology (ACR) classification scale, but some laws do not indicate a specific measurement and scoring system. The ACR classification is based on a 1-4 rating system, with type 1 indicating less than 25% fibroglandular tissue (almost entirely fat), type 2 indicating 26-50% fibroglandular tissue (scattered area of fibroglandular density), type 3 indicating 51-75% fibroglandular tissue (heterogeneously dense), and type 4 indicating more than 75% fibroglandular tissue (extremely dense).

Responses from the medical and patient advocacy communities

Legislative proposals at the state and federal level have elicited varying responses from professional associations and patient advocates. For example, the American College of Radiology has issued a position statement indicating that while it “is not opposed to including breast parenchymal information in the lay summary, we urge strong consideration of the benefits, possible harms and unintended consequences of doing so.” ACR urges caution in considering legislative proposals, and suggests that it might be valuable to review the experience of Connecticut, the first state to enact breast density reporting requirements, to evaluate the outcomes and effects of the law.

The advocacy organization “Are You DENSE?” has led grassroots efforts in support of state and federal breast density reporting legislation, and “Susan G. Komen for the Cure” affiliates have also advocated in support of state breast density reporting requirements.

Most recently, the *Journal of the American College of Radiology* published a special issue on imaging and screening in December 2013. The issue included two articles focusing on breast density – a summary of state laws and pending legislation, as well as a commentary from the Research Advocacy Network, a patient advocacy organization focused on advancing cancer research. The commentary addressed challenges in implementation of breast density legislation across states, calling for additional research and emphasizing the importance of patient-physician conversations on this issue. It identifies variability in breast density measurement as a particular challenge, noting that breast density is currently measured using various qualitative methods, and that the quantitative ACR classification system described above (which is identified most frequently in state legislation as the recommended or required measurement) relies on the expertise of individual radiologist readers, introducing a degree of variability to how results are interpreted.

Breast density and cancer research

Many characteristics may be associated with an increased risk for developing breast cancer, including mammographic breast density, history of atypical breast disease, a number of factors associated with reproduction, use of hormone replacement therapy, alcohol consumption, and body weight and physical activity, although the precise roles of these factors in cancer development is not fully understood. Research on risk prediction models that have entered many of these factors have generally found that breast density may contribute most to the prediction of risk. Breast density-associated risk is of most concern in women whose breast density persists into older age, even after menopause when breast density usually decreases. Dense breast tissue and age are both significant risk factors for breast cancer; therefore, postmenopausal women who have persistent breast density, which makes it harder to detect cancer through mammography, are at a higher risk for breast cancer. Additionally, research has shown that high breast density may not increase a woman’s risk of dying from breast cancer.

While mammography remains the current standard of care for breast cancer screening, NCI continues to support research on a wide variety of other technologies that may in the future serve to complement or even replace conventional mammography. These methods aim to improve sensitivity and specificity compared with screening methods currently in clinical practice. For example, Cone Beam Computed Tomography (CBCT) is currently under development for diagnosis of breast abnormalities and has a higher resolution than mammography, particularly in women with dense breasts. Another relatively new technology, Digital Breast Tomosynthesis (DBT), has shown in some studies to result in a lower recall rate than conventional mammography for women with dense breasts and may allow for more accurate viewing of dense breast tissue. In addition, ultrasound is currently used, on an as-needed basis, in conjunction with mammography, particularly for women with radiologically dense breast tissue or a high risk for developing cancer. Most ultrasound technology research is focused on increasing the resolution of

the images produced and on developing computer-aided detection programs similar to those used for conventional mammography. NCI is supporting the development and validation of 3D ultrasound technology and examining its potential for screening both high-risk women and the general population. However, at this time there is not sufficient evidence to recommend that women with high breast density receive any of these new types of screening as part of their routine breast cancer screening.

III. Congressional Briefings and Visits

NIH IC Directors Met with Rep. Joe Pitts (R-PA) (2/3/14): Various NIH IC Directors, including Dr. Harold Varmus, Director, NCI, participated in a roundtable discussion on the NIH campus with Congressman Joe Pitts (R-PA), Chair of the House Energy and Commerce Committee's Subcommittee on Health. Rep. Pitts and a number of his committee and personal staff toured the NIH Clinical Center and visited a National Heart Lung and Blood Institute lab.

NIH IC Directors Met with Sen. Richard Durbin (D-IL) (2/3/14): Various NIH IC Directors, including Dr. Harold Varmus, Director, NCI, participated in a roundtable discussion on the NIH campus with Senator Richard Durbin (D-IL), Assistant Majority Leader in the Senate, and member of the Senate Appropriations Committee, Labor-HHS Subcommittee. Sen. Durbin and his staff also visited labs at the National Heart Lung and Blood Institute and the National Institute of Neurological Disorders and Stroke.

Sen. Barbara Mikulski (D-MD) Tours NCI Lab and Hosts Press Event at NIH (2/24/14): Senator Barbara Mikulski (D-MD), Chair of the Senate Appropriations Committee, visited the NIH and hosted a press event focusing on the federal workforce and budget. During her visit she toured the lab of Dr. Marston Linehan, Chief of the Urologic Oncology Branch in NCI's Center for Cancer Research. Sen. Mikulski also met with a patient participating in a clinical trial led by Dr. Linehan's research team.

IV. Legislation of Interest

The following resolutions and bills were selected for inclusion in this update due to anticipated interest among the CTAC membership. More detailed information about these bills and others are available on our website under Legislative Topics: <http://legislative.cancer.gov/topics>

Selected Bills With Recent Activity or Interest (113th Congress)

Consolidated Appropriations Act of 2014 (H.R. 3547/P.L. 113-67)

- The act contains funding for all 12 Congressional Appropriation bills, including Labor-HHS, and provides a \$1 billion increase for NIH over the post-sequester funding level of FY2013 (\$29.9 billion for FY2014 for NIH, including \$4.92 billion for NCI).
- The Labor-HHS section of the appropriations act includes language directing each agency or operating division with research and development expenditures in excess of \$100,000,000 per year to develop a Federal research public access policy to provide for free online access to peer-reviewed manuscripts supported in whole or in part by federal funds, within 12 months of publication. This effectively directs the Centers for Disease Control, the Agency for Health Research and Quality, and the Department of Education to implement a public access policy similar to NIH.
- The bill also continues existing government-wide conference and travel restrictions, specifically, executive agencies must submit detailed reports to their Inspector Generals about conferences costing over \$100,000, and the head of the agencies must also report within 15 days details about any conference costing more than \$20,000. All travel and conference activities must continue to be in compliance with the guidance memo issued by the Office of Management and Budget on 5/11/12.
- The bill was originally introduced by Rep. Lamar Smith (R-TX) on 11/20/13, and was amended to reflect the omnibus appropriations proposal agreed to by House and Senate Appropriators on 1/15/14. The House

passed the act by a vote of 359-67 on 1/15/14, and the Senate passed the act by a vote of 72-26 on 1/16/14, and **the President signed the bill into law on 1/17/14.**

PEPFAR Stewardship and Oversight Act of 2013 (S.1545/H.R.3177; P.L. 113-56)

- The bill would extend authorities related to global HIV/AIDS and promote oversight of the United States Programs. The reported version of the bill would add to the requirement for an annual report a description, globally and by country, of specific efforts to address co-infections and comorbidities of HIV/AIDS, including the number and percent of people in HIV care or treated who started tuberculosis treatment; and the number and percentage of eligible HIV positive patients starting isoniazid preventative therapy.
- The Senate Committee Report indicates that the description of efforts to limit co-morbidities should include a discussion on AIDS-related cancers, including trends with respect to cervical cancer, and efforts to address such cancers.
- The Act was introduced by Sen. Robert Menendez (D-NJ) on 9/24/13 and was reported favorably out of the Senate Committee on Foreign Relations on October 2, 2013. The Act was introduced in the House by Rep. Eliot Engel on September 25, 2013, and was referred to the House Committee on Foreign Affairs. The Act passed the Senate on 11/18/13 and the House on 11/19/13, and the **President signed it into law on 12/2/13.**

Drug Quality and Security Act (H.R. 3204; P.L. 113-54)

- The bill aims to clarify laws related to human drug compounding, and to strengthen the drug supply chain.
- Regarding drug compounding, the bill:
 - Distinguishes compounders engaged in traditional pharmacy practice from those making large volumes of compounded drugs without individual prescriptions.
 - Allows compounders who prefer to practice outside the scope of traditional pharmacy practice to register as outsourcing facilities. Compounders who choose to remain traditional pharmacies will continue to be primarily regulated by State Boards of Pharmacy as they are in current law.
 - Defines the FDA's role in oversight of outsourcing facilities, with these facilities subject to FDA oversight in much the same way as traditional manufacturers.
 - Gives providers and patients the option of purchasing products from outsourcing facilities that comply with FDA quality standards.
 - Requires the FDA to list FDA-regulated outsourcing facilities on its website, requires detailed labeling on compounded drugs, and prohibits false and misleading advertising.
 - Clarifies current federal law regarding pharmacy compounding by resolving the patchwork of current federal regulation and applying a uniform standard nationwide.
- Regarding a "track and trace" system for prescription drugs, the bill:
 - Replaces the current state product tracing laws with a uniform standard, in an effort to implement electronic, interoperable unit-level product tracing throughout the country over a ten year implementation period.
 - Requires, over seven years, that the major sectors of the pharmaceutical supply chain share and track key information about each drug's distribution history. Within ten years, supply chain stakeholders will be required to participate in electronic, interoperable product tracing.
 - Strengthens licensure requirements for wholesale distributors and third-party logistics providers. In addition, the bill would require the FDA to keep a database of wholesalers that will be available to the public through the FDA's website.
 - Establishes nationwide drug serial numbers, to be implemented by four years after the date of enactment.
- The Act was introduced by Rep. Fred Upton (R-MI), Chairman of the House Energy and Commerce Committee, on 9/28/13 and passed in the House by a voice vote on 9/28/13. The Senate passed H.R. 3204 on 11/18/13 and the **President signed the bill into law on 11/27/13.**

Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization

Act (S. 252; P.L. 113-55)

While the primary bill language of the PREEMIE Reauthorization Act (Title I) does not include provisions specific to NIH, two other bills of interest, the Pediatric Research Network Act and the CHIMP Act Amendments of 2013, were added to the PREEMIE Reauthorization Act as amendments. The House passed the amended bill on 11/12/13, and the Senate passed the amended bill on 11/14/13. **The President signed the bill into law on 11/27/13.**

- The Pediatric Research Network Act (H.R. 225/S.424) was added to the PREEMIE Reauthorization Act as an amendment, and is included as Title II of the bill. The amended title is a modified version of the original bill, and indicates that the NIH Director may establish consortia and recognize existing NICHD pediatric research consortia, centers, and networks. Additionally, the final bill language no longer calls for a data coordinating center, and no longer mentions a specific number of centers or specific diseases (the bill mentions pediatric rare diseases and those related to birth defects, compared with previous references to spinal muscular atrophy, Duchenne muscular dystrophy, Down syndrome, and Fragile X).
- The CHIMP Act Amendments Act of 2013 (S.1561) was added to the PREEMIE Reauthorization Act as an amendment, and is included as Title III of the bill. The bill amends provisions the Public Health Service Act relating to the federal sanctuary system for surplus chimpanzees. Specifically, the bill provides the authority for the NIH to continue to fund the sanctuary system beyond the current \$30 million cap if the Secretary of HHS determines that it would enable the NIH to operate more efficiently and economically by decreasing the overall federal cost of supporting and maintaining chimpanzees from FY 2014 through FY 2023. In addition, the bill amends a provision so that the Secretary, in consultation with the federal sanctuary Board of Directors, determines if another facility meets the standards of care in the NIH regulations instead of the Board of Directors solely making that determination.

Gabriella Miller Kids First Research Act (H.R.2019)

- This bill amends the Internal Revenue Code to eliminate taxpayer financing of political party conventions and to reprogram savings to provide for a 10-year pediatric research initiative administered through the National Institutes of Health Common Fund.
 - The bill calls for funds for political conventions currently in accounts maintained by national committees of political parties to be transferred to a fund in the Treasury to be known as the “10-Year Pediatric Research Initiative Fund.” Funds would then be made available to NIH in such amounts as are provided in advance in appropriation Acts.
 - The bill authorizes appropriations to the NIH Common Fund, to be made out of the 10-Year Pediatric Research Initiative Fund, of \$12.6 million per year for each fiscal year 2014-2023.
- H.R. 2019 was introduced by Rep. Gregg Harper on 5/16/13, as the Kids First Research Act, and was renamed in honor of Gabriella Miller, a 10-year-old girl from Virginia who passed away in October 2013 due to a pediatric brain tumor, Diffuse Intrinsic Pontine Glioma. This bill is related to H.R. 1724, an earlier version of the bill, also introduced by Rep. Harper (4/25/13).
- H.R. 2019 was referred to the House Energy and Commerce Committee, Subcommittee on Health, as well as the House Committees on Administration, and Ways and Means. The bill did not proceed through mark up and was not passed out of committee. **On 12/11/13, the House passed the bill under suspension of the rules, in a vote of 295-103.**
- Current Status: The bill was placed on the Senate Legislative Calendar on 1/6/14. Reports indicate that the Senate does not plan to consider the bill.

Cancer Treatment Parity Act of 2013/Cancer Drug Coverage Parity Act of 2013 (S.1879/H.R. 1801)

- The bill aims to require health insurers to provide for coverage of oral anticancer drugs on terms no less favorable than the coverage provided for anticancer medications administered by a health care provider.
 - For the Patient-administered medication, the provider can charge annual deductibles, coinsurance, copayments, as long as they do not exceed payments for anticancer medications administered by a health care provider under the plan or coverage for the same purpose.
 - The provider cannot increase in out-of-pocket costs of anticancer medications; reclassify anticancer medications benefits; or apply more restrictive limitations on prescribed oral, intravenous or injected anticancer medications.

- S. 1879 was introduced on 12/19/13 by Sen. Al Franken (D-MN) and was referred to the Committee on Health, Education, Labor, and Pensions. H.R. 1801 was introduced on 4/26/13 by Rep. Brian Higgins (D-NY), and was referred to the House Committees on Energy and Commerce (Subcommittee on Health), Ways and Means, and Education and the Workforce (Subcommittee on Health, Education, Labor, and Pensions).
- The bills include nearly the same proposals, however the Senate bill calls for provisions to apply to health plans for plan years beginning on or after January 1, 2015, whereas the House bill would apply to health plans beginning on or after January 1, 2014.
- To date H.R. 1801 has 67 cosponsors, and S. 1879 has one cosponsor, Sen. Mark Kirk (R-IL).

Additional Information: Rep. Higgins introduced similar bills in the 112th and 111th Congresses and they did not move out of committee. S. 1879 is the first bill in the Senate to address this issue. To date, 26 states and the District of Columbia have enacted oral chemotherapy access laws, and legislative proposals have been introduced in an additional 12 states.

Breast Density and Mammography Reporting Act of 2013 (H.R. 3404):

- The bill would amend the Mammography Quality Standards Act (MSQA) of 1992 to require mammography results to include the patient's relative breast density, and for that information to be reported to patients in their mammography results summary.
- Specifically, the summary shall convey to the patient his or her risk of developing breast cancer associated with below, above, and average levels of breast density. The summary shall also include language communicating that individuals with more dense breasts may benefit from supplemental screening tests and should talk with their physicians about any questions or concerns regarding the summary.
- The proposal includes a clause specifying that if passed, the federal bill would not preempt any state requirements regarding breast density reporting.
- The Act was introduced by Rep. Rosa DeLauro (D-CT), along with Rep. Steve Israel (D-NY), on 10/30/13 and was referred to the Committee on Energy and Commerce. To date the bill has 30 cosponsors.

Additional Information: Reps. DeLauro and Israel introduced a similar bill in the 112th Congress and it did not move out of committee (DeLauro also co-sponsored a similar proposal in the 111th Congress). Rep. DeLauro's announcement notes that Sen. Dianne Feinstein (D-CA) plans to introduce a companion bill in the Senate – it has not been introduced to date. Additionally, independent of this legislative proposal, the FDA had scheduled a notice of proposed rule making for a breast density reporting amendment to the MSQA for December 2013, but has yet to release any additional information.

Selected New Bills (113th Congress)

The Protecting Children from Electronic Cigarette Advertising Act of 2014 (S. 2047)

- The Act aims to prohibit the marketing of e-cigarettes to children (under age 18), and to authorize the Federal Trade Commission (FTC) to enforce this prohibition.
- The Act permits the FTC to determine what constitutes marketing of e-cigarettes to children. The bill indicates that a violation of the prohibition would be treated as a violation of a rule defining an unfair or deceptive act or practice as described in the Federal Trade Commission Act. The FTC would also have the authority to promulgate additional rules and standards to carry out the provisions of the Act.
- The proposal would allow the FTC to work with state attorneys general to enforce the ban and to seek civil penalties. It also includes a provision indicating that the Act would not supersede any provisions of state law, except in the case of any inconsistencies between state and federal provisions.
- The bill specifies that it shall not be construed to limit or diminish the authority of the Food and Drug Administration to regulate the marketing of e-cigarettes, including to children.
- The bill was introduced by Senator Barbara Boxer (D-CA), along with colleagues Sens. Tom Harkin (D-IA), Dick Durbin (D-IL), Richard Blumenthal (D-CT), and Edward J. Markey (D-MA), on 2/26/14 and was referred to the Committee on Commerce, Science, and Transportation.

Better Care, Lower Cost Act (H.R. 3890/S. 1932)

- The bill aims to establish a Medicare “Better Care Program” to provide integrated care for Medicare beneficiaries with chronic conditions.
- Rep. Erik Paulsen (R-MN) introduced H.R. 3890, and Sen. Ron Wyden (D-OR) introduced S. 1932 on 1/15/14. The bill was referred to the House Committees on Energy and Commerce, and Ways and Means, and the Senate Committee on Finance.

Protecting Consumer Access to Generic Drugs Act of 2013 (H.R. 3709), Preserve Access to Affordable Generics Act (S. 214)

- The bills aim to prohibit the practice known as “pay-for-delay,” in which brand name drug manufacturers offer patent settlements that pay generic drug manufacturers to delay bringing lower-cost generics to market.
- Among other provisions, both bills propose to amend the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to require a brand name manufacturer and generic manufacturer to submit to the FTC any other agreements the parties enter into within 30 days of entering into an agreement related to the manufacturing, marketing, or sale of the brand name or generic drug or the exclusivity period.
- H.R. 3709 was introduced on 12/11/13 by Rep. Bobby Rush (D-IL) and was referred to the House Committees on Energy and Commerce, and the Judiciary (Subcommittees on Regulatory Reform, Commercial And Antitrust Law; and on Courts, Intellectual Property and the Internet). S. 214 was introduced by Sen. Amy Klobuchar (D-MN) on 2/4/13 and was referred to the Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. The Subcommittee held a hearing on this issue on 7/23/13, “Pay-for-Delay Deals: Limiting Competition and Costing Consumers.”

Breast Cancer Awareness Commemorative Coin Act of 2013 (H.R. 3680)

- The bill aims to establish a Breast Cancer Awareness Commemorative Coin by requiring the Secretary of the Treasury to mint not more than 500,000 \$1 silver coins.
- The coins would be sold for a total of \$11 each, the \$1 face value plus a \$10 surcharge. Once the cost of design and issuance of the coins is covered, half of the surcharge would be paid to the Breast Cancer Research Foundation, and half to Susan G. Komen for the Cure, to further research funded by the organizations.
- H.R. 3680 was introduced on 12/9/13 by Rep. Carolyn Maloney (D-NY) and was referred to the Committee on Financial Services.

Selected Recent Resolutions (113th Congress)

This section highlights resolutions introduced to raise awareness about specific diseases or issues. It is important to note that resolutions are different than bills, in that they are used to express the sentiment of one chamber (House or Senate) on an issue. As such, resolutions do not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Introduced

Rare Disease Day (H.Res. 493)

- A resolution expressing support for designating February 28, 2014 as Rare Disease Day. Childhood cancers are recognized among rare diseases listed in the resolution.
- H.Res. 493 was introduced by Rep. Andre Carson (D-IN) and colleagues (including Reps. Leonard Lance, R-NJ, and Joseph Crowley, D-NY, co-chairs of the Rare Disease Caucus) on 2/27/14 and was referred to the Committee on Energy and Commerce.

National Cancer Prevention Day (H. Res. 473)

- A resolution expressing support for designating February 4, 2014 as National Cancer Prevention Day.

- H. Res. 473 was introduced by Rep. Steve Israel (D-NY) on 2/4/14 and was referred to the Committee on Energy and Commerce.

Recognizing the 50th Anniversary of the “Smoking and Health: Report of the Advisory Committee to the Surgeon General of the United States” (S.Res. 330)

- This resolution recognizes the 50th anniversary of the “Smoking and Health: Report of the Advisory Committee to the Surgeon General of the United States” and the significant progress in reducing the public health burden of tobacco use, as well as supporting an end to tobacco-related death and disease.
- S. Res. 330 was introduced by Sen. Richard Blumenthal (D-CT) on 1/13/14 and was referred to the Committee on Health, Education, Labor, and Pensions.

Passed

Rare Disease Day (S.Res. 368)

- A resolution expressing support for designating February 28, 2014 as Rare Disease Day. Childhood cancers are recognized among rare diseases listed in the resolution.
- H.Res. 493 was introduced by Sen. Sherrod Brown (D-OH) and was passed in the Senate by unanimous consent on 2/27/14.

National Science and Technology Week (S. Res. 329)

- This resolution expresses support for the goals and ideals of the biennial USA Science and Engineering Festival in Washington, D.C. and designates April 21 – April 27, 2014 as “National Science and Technology Week”.
- S. Res. 329 was introduced by Sen. Chris Coons (D-DE) on 1/7/14 and was adopted by unanimous consent.

National Asbestos Awareness Week (S. Res. 336)

- This resolution designates the first week of April 2014 as “National Asbestos Awareness Week”.
- S. Res. 336 was introduced by Sen. Max Baucus on 1/16/14 and was adopted by unanimous consent.