OIF E-Newsletter
Special Edition: Federal Advocacy Update

OI community member Kyle Mulroy, Founder of Washington Strategic Consulting (WSC), and his colleague, Ross Airington, Director of Health Policy at WSC, put together this special edition issue of the OIF E-Newsletter.

Thank you, Kyle and Ross, for assisting the OI Foundation in sharing up-to-date information on advocacy issues concerning the OI community.

The OI Foundation's federal advocacy team is preparing for another eventful year on Capitol Hill. Despite the ongoing political tumult in Washington, the OIF continues working with Members of Congress from both parties, and federal agency officials, to promote bipartisan policies that will improve the lives of those touched by OI now and in future generations.

Working together with the OI community, we have made great strides in advancing OI awareness among key decision makers in recent years and we look forward to pushing forward our funding and legislative priorities in the year ahead. As we embark on this year's OI advocacy agenda, we are pleased to provide this special edition of E-News summarizing the key issues from 2017 and a preview of 2018.

Federal Advocacy Update: Looking Back at 2017

Healthcare Reform

Perhaps no issue elicited as much emotion – or controversy – in 2017 than the efforts in Congress to repeal the Affordable Care Act (ACA). For its part, the OI Foundation urged policymakers to take into account the ways in which legislative and regulatory proposals to reform the health care industry, including ACA repeal, would impact people with OI and other rare, chronic disorders and disabilities.

The debate consumed most of the year but ended in a stalemate, with Congress unable to agree on policies to replace the ACA. The president and congressional leaders intend to revisit the ACA repeal debate in the future. The OI Foundation will continue to advocate for health reforms that promote access to consistent and comprehensive insurance coverage.

Tax Reform

Congress's most significant legislative accomplishment in 2017 was passage of the Tax Cuts and Jobs Act of 2017, a bill that represents the most sweeping U.S. tax reform changes in more than three decades. The legislation reduces tax rates and modifies other policies, credits, and deductions for individuals and businesses.

The law has a number of provisions that could impact health research and access to care for individuals with OI:

Medical Expense Deduction
Prior to the tax bill, federal law allowed families to take a deduction for medical expenses that amount to more than 10 percent of their income. The Tax Cuts and Jobs Act reduced that to 7.5 percent of family income in tax years 2018 and 2019, allowing more people to take advantage of the deduction.

Orphan Drug Tax Credit
The Orphan Drug Tax Credit (ODTC) provides a crucial incentive for rare disease drug development when 95 percent of rare diseases remain without one single treatment. Prior to the passage of the tax bill, federal law allowed drug companies to take a credit for 50 percent of their costs related to clinical trials for developing rare disease treatments.

The Tax Cut and Jobs Act reduced the 50 percent tax credit to 25 percent. While the cut is not ideal, it is undoubtedly preferable to Congress's initial proposal that would have eliminated the credit.

Individual Mandate

The individual mandate clause of the Affordable Care Act requires individuals to buy insurance or pay a penalty at tax time, unless they qualify for a limited number of exemptions. The Tax Cuts and Jobs Act repeals the individual mandate beginning in 2019. The Congressional Budget Office (CBO) estimates that this change will result in as many as 13 million people forgoing health insurance by 2027.

The individual mandate was designed to incentivize healthy individuals to purchase health insurance, resulting in lower premiums for individuals with complex conditions or rare diseases like OI. The CBO also estimates that, due to fewer healthy people in the risk pool, individual health insurance premiums could increase by as much as 10 percent in next few years, potentially pricing even more people out of the market.

Food and Drug Administration Approval of Rare Disease Drugs

Last summer, Congress passed legislation extending funding for five years for the Food and Drug Administration's (FDA) authority to approve new prescription drugs and medical devices.

The legislation included new provisions intended to encourage the development, and accelerate approval of, drugs that treat rare diseases. Specifically, the FDA will grant "exclusivity" to a new rare disease drug if that drug is superior to a similar, already approved drug. The new drug must have significant therapeutic advantages and provide a major contribution to patient care.

The legislation also extends funding for grants that support clinical trials of drugs intended to treat rare diseases.

Federal Advocacy Update: Looking Ahead to 2018

Children's Health Insurance Program

In January, Congress ended a four-month political stalemate over extending funding for the Children's Health Insurance Program (CHIP). CHIP provides health insurance to 8.9 million children in working families who earn too much to qualify for Medicaid but cannot afford or access private coverage. With approximately 50 percent of individuals with rare diseases being children, CHIP is especially important to the rare disease community.

Unlike Medicare and Medicaid, CHIP is not considered a "mandatory" program, so funding must be reauthorized every few years to ensure that funding continues. The program was last reauthorized in late 2015 with the passage of the Medicare Access and CHIP Reauthorization Act. That funding, however, expired on September 30, 2017.

President Trump recently signed into law a bill that includes a six-year extension of funding for CHIP. The program will now be fully-funded through federal fiscal year (FY) 2023.

Funding for the National Institutes of Health

Strong annual funding levels provided by Congress for the National Institutes of Health (NIH) are extremely important to OI research and activities, including the Brittle Bone Disorders Rare Disease Clinical Research Consortium, the OIF's annual scientific meeting and the OI Research Center and Clinic.

For 2017, Congress appropriated an additional $2 billion for the NIH, the largest increase in a decade. In May of last year, President Trump submitted a budget proposal to Congress that called for cutting the NIH's budget by 25 percent in 2018, or $6 billion. Congress and the president have been unable to reach an overall budget agreement for 2018 and have therefore temporarily continued 2017 funding levels for all federal programs and agencies, including the NIH, while

negotiations continue.

As Congress works to finalize the 2018 budget and begins negotiations for 2019, the OIF's advocacy team and our partners will continue its presence on Capitol Hill to lobby in favor of NIH funding that directly and indirectly supports programs and projects of importance to the OI community.

Medicaid Reform

Similar to the effort to repeal and replace the ACA, legislative proposals in Congress to restructure the Medicaid program ended in stalemate last year. As a result, the Trump Administration has begun using its executive authority to work on a state-by-state basis to limit Medicaid benefits, impose new eligibility restrictions and increase beneficiary out of pocket cost sharing.

Some state-level lawmakers are launching fresh efforts to expand Medicaid as many who had previously blocked the expansion say they're now open to it because of Trump administration's decision earlier this month to allow states to limit the program by imposing work requirements for able-bodied beneficiaries. Ten states have already filed requests for such waivers, and the Trump administration has approved work requirements for Kentucky. Legislators in the 17 remaining non-expansion states are hoping to win over their colleagues by packaging the expansion with work requirements or other limits.

21st Century Cures

The 21st Century Cures Act, signed into law on December 13, 2016, authorized resources and new authorities for the National Institutes of Health (NIH) and Food and Drug Administration (FDA) to support biomedical research and medical product development.

The law included an extension of the Rare Pediatric Disease Priority Review Voucher Program, which incentivizes the development of new therapies for children with rare diseases. It also streamlined the U.S. FDA review of genetically targeted and protein variant therapies for rare diseases and provided nearly $5 billion in funding through the NIH Innovation Fund for a number of highly innovative scientific research initiatives.

The long-term sustainability of the medical research workforce was another top priority for the Cures Act. As a direct result of the law, in June, NIH launched the Next Generation Researchers Initiative aimed at strengthening the biomedical workforce with a focus on early career investigators or investigators who are at an early stage in their career.

OIF Advocacy in Action

In addition to the OIF's regular presence on Capitol Hill, we will continue to raise awareness about OI among lawmakers by harnessing the power of our community. Stay on the lookout for notices from the OIF about ways in which you can help promote our agenda in Washington, particularly during the next OI

Awareness Week from May 5-12, 2018.

Osteogenesis Imperfecta Foundation

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