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by Jamie Young

The bitter cold and snow of January and February may have turned many parts of the country into a frozen tundra, but it has not kept numerous state legislatures from heating up the legislative agenda. This has been particularly true pertaining to off-label drug legislation and to a lesser extent clinical trials coverage.

In North Dakota, Rep. Dale Heneger introduced his version of the ACCC off-label drug legislation, House Bill 1428, during the week of January 20. The bill was heard in the House Industry, Business, and Labor Committee on January 27 and February 5 and was approved 14-1. The North Dakota House of Representatives quickly passed the bill 91-2 (with five members absent). Next up will be Senate hearings scheduled to begin the last week of February.

Equally as impressive has been the progress of off-label drug legislation in Mississippi. Two off-label bills, SB 2859 and HB 1199, were passed unanimously by their respective committees by the end of January. On January 31, the house bill was approved by the full House of Representatives. ACCC provided assistance in preparing an impact statement that was required before the bills could be considered. The bills have also benefitted from the very active support of the Mississippi Society of Oncology, particularly Dr. Ralph Vance and Dr. Van Lackey.

In nearby Louisiana, Dr. John Rainey, president of the Louisiana Oncology Society, has provided a draft of off-label legislation to a potential sponsor in Baton Rouge.

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The regular session of the legislature will convene in March, following the completion of a special session in February. A bill will likely be introduced at that time.

ACCC government relations staff has been meeting with interested parties from the pharmaceutical industry, the Minnesota Division of the American Cancer Society, the Minnesota Society of Clinical Oncology, and the Oncology Nursing Society to coordinate introduction of an off-label bill in Minnesota. The legislation was expected to be introduced by the end of February.

In Missouri, an amendment for off-label drug coverage was recently added to an omnibus managed care reform bill. ACCC government relations staff reviewed the amendment and requested revised language. In addition, Senate Bill 268 has been introduced by Sen. Sam Graves with the identical language from the amendment. A House version of the off-label bill, again with identical language, will also be introduced.

Nebraska's unicameral legislature has also been the site of an off-label bill introduction. Freshman Senator Deborah Suttle introduced LB 849 the week of January 20th. The bill is limited to off-label uses of drugs used in the treatment of cancer and HIV/AIDS. It is expected to be referred to the Banking, Commerce, and Insurance Committee for hearings.

In the West, Oregon State Senator Jeanette Hamby has introduced an off-label drug bill. The bill was filed on January 24 and has until mid-March to pass the Senate to meet the deadline set for passage of bills from the house of origin. Sen. Hamby is chair of the Senate Health and Human Resources Committee, which is expected

to hold hearings on the bill.

On January 27, I met in Harrisburg with Rep. Dennis O'Brien, the new chair of the House Health and Human Services Committee. As a result, we hope that an off-label bill will be introduced in Pennsylvania by March.

In regard to clinical trials, Illinois House Bill 3168 did not receive consideration by the Senate before the end of the session as was hoped. The legislation was reintroduced in early February in both the House and Senate. A press conference took place in Chicago on February 10 to announce the bill's reintroduction. A legislative reception was planned for February 26 in Springfield to be hosted by the Illinois Medical Oncology Society, ACCC, and the Illinois Division of the American Cancer Society.

In addition, Pennsylvania State Senator Roy C. Afflerbach is expected to reintroduce his bill, which requires third-party reimbursement of patient care costs associated with cancer clinical trials. The Pennsylvania Health Care Cost Containment Council, which sought independently certified documentation defining the social and financial impact and medical efficacy of the proposal, released its report last fall and decided there was insufficient information to make a recommendation one way or the other to the legislature. ACCC had assisted in the development of a coordinated response to the council's request for comments.

Additional activity is expected on the off-label issue in Nevada, Virginia (to expand the current law), Delaware, and Tennessee. There is also interest in New York for the reintroduction of clinical trials legislation that was hotly contested last year as well as a new bill in Georgia. ☐