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Another Bumper Crop of Off-Label Laws

by Jamie Young

Already this year, twice the number of states have passed off-label drug legislation as in the previous two years combined. That number could grow by two or more states by the end of 1997.

Effective August 1, 1997, North Dakota law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer or any other condition when the off-label use is recognized by either of the two compendia or in the medical literature as safe and effective. The law was signed by Governor Edward T. Schafer on March 25. ACCC strongly supported the passage of House Bill 1428 as did the North Dakota Division of the American Cancer Society, members of the pharmaceutical industry, and the Dakotas Oncology Society.

In Mississippi the new law, which took effect July 1, 1997, requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer when the off-label use is recognized by either of the two compendia or in the medical literature as safe and effective. Coincidentally, this bill was signed by Governor Kirk Fordice on March 25, the same day the North Dakota bill was signed. ACCC strongly supported the passage of Senate Bill No. 2589. However, without the leadership of Drs. Ralph Vance and Van Lackey of the Mississippi Society of Oncology, a bill would not likely have passed this year.

Jamie Young is ACCC director for state societies and government relations.

A New Mexico Department of Insurance regulation regarding "HMO Regulation/Patient Protection" was recently adopted and took effect on March 14, 1997. Included in that package of reforms were provisions regarding coverage of off-label drugs. One provision states, "No managed health care plan that provides coverage of prescription drugs as a basic or supplemental service shall limit or exclude coverage for any drug approved by the U.S. FDA on the basis that the drug has not been approved for the treatment of a particular indication for which the drug has been prescribed, provided that the drug has been recognized as safe and effective in: a) one or more of the standard reference compendia, including the *AMA Drug Evaluations*, the *American Hospital Formulary Service Drug Information*, and *Drug Information for the Healthcare Provider*."

After two previous attempts, legislation was also enacted recently in Tennessee. House Bill 772, sponsored by Representative Doug Jackson, was signed into law on May 27, 1997, by Governor Don Sundquist. It took effect on July 1, 1997. The bill was drafted broadly and applies to off-label uses of all drugs when recommended in the compendia, the peer-reviewed medical literature, or by the Commissioner of Commerce and Insurance. The bill also includes language to establish a medical expert panel. ACCC provided letters of support to the key committee members in both chambers. The legislation was also supported by the Tennessee Oncology Practice Society and its president, Dr. Charles Penley, as well as the American Cancer

Society, Tennessee Division.

The state most likely to be next on the list is Missouri. Governor Mel Carnahan is currently considering approving House Bill 335, a managed care reform package. Governor Carnahan had until July 14 to act on the bill. Among the provisions of this legislation is a section requiring insurers to cover off-label uses of FDA-approved drugs when those uses are recognized in the compendia or peer-reviewed medical literature. Two stand-alone off-label bills were also introduced this year. Both House Bill 539 and Senate Bill 268 were approved by the committees to which they were assigned. However, they were shelved because the language in HB 335 already addressed the issue. The ACCC Columbus office provided written testimony in support of the legislation and has also been providing technical assistance on amendments and strategy.

ACCC has assisted Drs. John Rainey and Jay Brooks, president and vice president of the Louisiana Oncology Society, with the introduction and consideration of two off-label bills, House Bill 1303 and Senate Bill 722. Senate Bill 722 was amended in the Senate to narrow the definition of peer-reviewed medical literature using language provided by ACCC. The bill was approved 35-0 by the full Senate on April 24. On May 14 the bill was unanimously approved by the House Insurance Committee and similarly passed by the full House on June 3. However, an amendment was placed in the bill on the House floor exempting individually underwritten specified disease policies from the bill's provisions. The bill now goes back to the Senate for approval of House amendments. 🍷