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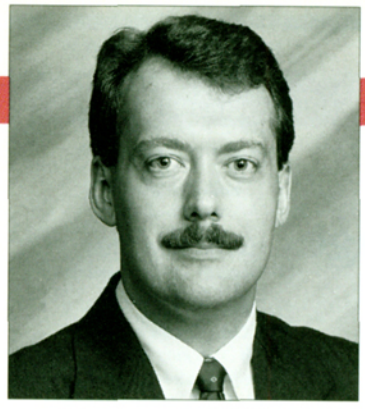

PUBLIC POLICY UPDATE

Southern State Enacts Off-Label Drug Legislation

by Jamie Young

The first four months of this year have been an exciting, busy, and successful time for the ACCC off-label drug legislation. The most noteworthy event is that Georgia has joined the growing list of states that has signed into law a version of our model legislation. On April 7 Georgia Governor Zell Miller signed into law House Bill 741,which takes effect on July 1, 1993. Many were on hand to witness Governor Miller's signing ceremony. (See photo on page 7.)

The Georgia law is similar to the law passed in Illinois last year. House Bill 741 defines "drug" as a drug or biologic used in an antineoplastic regimen. A private insurer cannot deny reimbursement for a drug for an off-label usage if it is recognized in one of the three compendia or if it is found to be safe and effective in formal clinical studies, the results of which have been published in a peer-reviewed professional medical journal published in either the United States or Great Britain.

Many groups deserve credit for our latest legislative victory, most notably the Georgia Division of the American Cancer Society, the Georgia Society of Clinical Oncology, and the Medical Association of Georgia. State Representative Butch Parrish and Senator Jack Hill, the House and Senate sponsors, provided strong leadership and guidance in getting the bill through the legislative process.

On other fronts the Indiana off-label bill was approved unanimously by the Senate Insurance Committee in late March. The hearing was emotional for those testifying and for the committee as well. In addition to ACCC and the Indiana Medical Oncology Society, other proponents who spoke included breast cancer survivors and members of the Central Indiana Chapter of Y–Me, who provided compelling testimony in favor of the bill. Although procedural problems developed unexpectedly on the Senate floor unrelated to the merits of the bill, at press time the proposal is still expected to be sent to the governor after being amended into another insurance-related bill.

The Rhode Island legislation, House Bill 6642, which had just been introduced at the time of my last writing, has since been approved by the House Health, Education, and Welfare Committee. The bill was originally written to include off-label uses of all drugs but has been narrowed to apply only to cancer drugs. ACCC provided testimony at the hearing held in late March, as did the State Division of the American Cancer Society and Louis Leone, M.D., of the Department of Medical Oncology at Rhode Island Hospital and an ACCC Delegate Representative. A special witness, former State Senator Nancy Achin Sullivan, the sponsor of the Massachusetts off-label law, also traveled to Providence to urge the committee to support the bill. Opposition testimony came from the Rhode Island Blues and a representative of the Health Insurance Association of America.

Senate Bill 1631 has been introduced in New Jersey by State Senator Jack Sinagra. The bill is written to provide coverage for off-label uses of all drugs that are recognized in the compendia and peer-reviewed literature. There is also a provision for the creation of a medical expert panel to review disputes and other possible off-label uses of FDA-approved drugs. The bill will be taken up sometime in May.

The ACCC Columbus office provided background materials and technical expertise to the H. Lee Moffitt Cancer & Research Institute in Tampa, Fla., after an interest was expressed by ACCC President Albert B. Einstein, Jr., M.D., who is also the new Associate Director, Clinical Affairs, at the Moffitt Center. ACCC worked with staff of the Moffitt Center to prepare language and information to amend Florida's Health Care Reform legislation to include an off-label drug provision. This was accomplished in the Senate but removed by the House of Representatives. We intend to work with interested parties in Florida to pursue the issue in the next session of the legislature.

Although off-label drug legislation is active in many states, ACCC has also supported the introduction of clinical trials legislation in Illinois. House Bill 2059 was introduced by State Representative Judy Erwin. It would have required insurers to provide coverage for the patient care costs of those enrolled in cancer clinical trials approved by the FDA, NIH, and its organizational components. Other trials could be reviewed for coverage by the Illinois Cancer Clinical Trial Review Board, which would have been established under the proposal. The bill was strongly opposed by the insurance and business community as a costly new mandate. Ultimately, the measure failed to advance through the House Health and Human Services Committee. The bill was placed under interim study to allow more work to be done over the summer. Clearly, the committee did not wish to alienate cancer patients and preferred to see a compromise reached between those on both sides.

The Illinois clinical trials legislation was based in part on Senate Bill 188, a Colorado clinical trials bill sponsored by Senator Jana Wells Mendez. The bill was approved by the Senate and sent to the House where it was amended by those unfavorable to the bill with the purpose of making it more likely to be rejected. In mid-April, the bill was "indefinitely postponed," a polite term for killing the bill. Not surprisingly, it was strongly opposed by the insurance industry.

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