

Oncology Issues



ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

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To cite this article: Jamie Young (1994) Off-Label Drug Bills from Coast to Coast, Oncology Issues, 9:2, 10-13, DOI: <u>10.1080/10463356.1994.11904457</u>

To link to this article: https://doi.org/10.1080/10463356.1994.11904457

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Off-Label Drug Bills from Coast to Coast

by Jamie Young

he passage of off-label drug legislation in New Jersey just prior to the end of last year capped 1993 with another victory for access to quality cancer care for cancer patients. In all, 11 states have now passed some version of an off-label drug bill into law. The New Jersey legislation, Senate Bill 1631, is a strong piece of legislation that, like the California law, applies to offlabel uses of all drugs and not just anti-cancer drugs. ACCC worked very closely with Dr. Mark Pascal, Chairman of the Clinical Issues Committee of the Oncology Society of New Jersey, the New Jersey Division of the American Cancer Society, and members of the pharmaceutical and biotech industry. In addition, State Senator Jack Sinagra worked tirelessly to promote the bill among his colleagues. Governor James Florio signed the bill into law on December 23. It takes effect after 180 days.



MONTGOMERY

The result of our success on the state and federal level has resulted in even greater interest among the states in introducing legislation in 1994. Staff participated in a meeting in early February with representatives of the Alabama Society of Clinical Oncology and a member of the Alabama Legislature. The Oncology Providers Network of Alabama, an ACCC state chapter member, is also heavily involved in this effort. A bill is expected to be filed as a result of these discussions.

Jamie Young is ACCC Director of Government Relations.



PHOENIX

The Arizona Clinical Oncology Society (TACOS), an ACCC state chapter, has been successful on its second attempt to have the model off-label drug bill introduced in its state. State Senator Ann Day, chairperson of the Senate Health, Welfare and Aging committee, has introduced Senate Bill 1329. A hearing was held on February 8, and despite opposition from the insurance industry, the bill was approved. Because the legislative session is expected to be short this year, the bill's outlook is not clear at this time.



HARTFORD

In Connecticut, LCO 703 was introduced on January 7 by State Senator Ken Przybsz. The introduction of this bill is the result of many discussions that have taken place over the previous six months between the ACCC and the Connecticut Division of the American Cancer Society. In its original form, the bill inadvertently left out any mention of the peerreviewed literature but has been amended to now include this important provision. The Connecticut Oncology Association is also an active proponent of this legislation.



Last year, off-label language was briefly considered as part of a larger health care reform effort in Florida. However, this year separate legislation, Senate Bill 456, has been filed by State Senator John Grant. The ACCC is supplying technical information to representatives of the H. Lee Moffitt Cancer Center in Tampa and other proponents of the legislation. A companion bill in the House is also expected to be introduced.



ANNAPOLIS

Delegate Salima Siler Marriott has agreed to sponsor legislation that will be considered by the Maryland House of Delegates. The ACCC Columbus office is working with the recently formed Maryland Oncology Society, headed by Dr. Joan Edwards. The session in this state should run until mid-April.



MINNEAPOLIS

The Minnesota Society of Clinical Oncology is hoping the third time will be the charm for off-label legislation. Previous attempts have met with stiff opposition from Minnesota Blue Cross/Blue Shield. The Minnesota Legislature did not convene until February 22 and is expected to adjourn by the end of April.



RICHMOND

Hearings have begun in Virginia on off-label drug legislation

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(continued from page 10) sponsored by State Senator Clancy Holland, who is also a physician. Senate Bill 403 was approved on February 7 by the Senate Commerce and Labor Committee. The bill had been introduced at the request of ACCC and the Virginia Association of Hematologists and Oncologists and their president, Dr. Robert Burger. The bill is one of 3800 introduced in what is considered the "long" session, lasting only 60 days.



COLUMBUS

In Ohio, the House Insurance Committee unanimously approved Senate Bill 157 on January 19. The bill is currently awaiting a vote by the full House. A technical amendment is necessary on the House floor, which will require that the bill then go back to the Senate for concurrence. Once this procedural hurdle is cleared, the bill will go to Governor George Voinovich for his signature. The ACCC Columbus office will continue to work with our Ohio membership and with Dr. Dale Cowan, President of the Ohio/West Virginia Medical Oncology Society, to assure the governor's support.



PROVIDENCE

While the hopes for an agreed-to bill have dimmed in Rhode Island, State Representative Nancy Benoit is still determined to re-introduce last year's bill with some modifications aimed at eliminating the opposition of the Rhode Island Blues.

STATE ONCOLOGY SOCIETIES GEAR UP FOR LEGISLATIVE ACTION

As state legislatures discuss plans for their own versions of health care reform, state oncology societies—including those in Minnesota, Washington State, Oregon, Iowa, and Illinois—are gearing up to testify at committee hearings and to educate state legislators.

"Oncologists need to network and to become involved early on in the legislative process," said Burton Schwartz, M.D., President of the Minnesota Society of Clinical Oncology, who spoke at the recent ACCC-sponsored Presidents' Retreat. "And they need to form a strong political base in which they will influence state legislation."

Members of the Minnesota Society of Clinical Oncology, now in its second year, are working to form relationships with primary care physician groups and new emerging health care cooperatives. Eleven oncologists have already joined Minnesota Specialty Physicians (MSP), which is made up of 12 different specialties. Through the development of practice guidelines, integrated systems, and effective working relationships with primary care physicians and hospitals, MSP will manage specialty medical costs to achieve optimum values for patients, buyers, and the larger community.

Concerned about state health care reform, the Washington State Oncology Society, a new ACCC state chapter, is preparing to work with its state legislature.

"All health care under the state plan will be run through a gatekeeper," said Robert E. Burdick, M.D., Society President, who also spoke at the Presidents' Retreat. "Our fears are that this function will be used to suppress referrals from providers to oncologists, and the patients will not get the optimal care they are getting now."

"And we are worried about how, in a state-run system, we can get clinical trials paid for," he said.

In Olympia, the Washington State Health Care Commission started its charge to develop a comprehensive, state health care reform proposal on January 1, 1994. The Commission will have to report findings on this complicated plan by summer or fall 1994 in order to have it implemented in July 1995 by companies of 500 employees or more. Thereafter, the plan will be phased in gradually for all companies with fewer than 500 employees.

State societies are also working to curb the growing power of Blue Cross/Blue Shield, HMOs, and private insurers. For example, the Illinois Medical Oncology Society (IMOS) spent a tumultuous seven weeks responding to restrictive oncology guidelines issued by the Illinois Blue Cross/Blue Shield.

With the help of the American Society of Clinical Oncology and under the leadership of President James L. Wade, III, M.D., IMOS established a committee to analyze the guidelines and develop a formal rebuttal. The committee found that the development of the Blues' guidelines did not follow established scientific patterns. Thanks to these efforts, the Blues have reconsidered their intervention in the management of oncology patients.

"We recognized that our state was the trial balloon," said Wade. "If we hadn't tried to carry things off calmly and successfully, other states would have had the pleasure of facing these guidelines as well."