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1996 Off-Label Drug Scorecard

by Jamie Young

With another year coming to a close and hotly contested legislative elections over, preparations for our 1997 legislative agenda are heating up. Off-label drug legislation is expected to be considered next year in several states, including Delaware, Louisiana, Minnesota, Mississippi, Missouri, Louisiana, Nebraska, Nevada, Pennsylvania, and Tennessee. Five years ago when ACCC was advocating passage of our model legislation, we could point to only two states having enacted such legislation. Next year when bills are considered in the aforementioned states, we can talk about the twenty states where cancer survivors with private insurance can be assured access to medically appropriate off-label therapies. This is an astounding record of success, and ACCC continues to receive requests for information on a weekly basis on these success stories.

Below is a summary of states that have off-label drug laws in place. Special information regarding clinical trials legislation is indicated where legislative action has occurred or is under consideration. Copies of each of these laws are available through the ACCC Columbus office.

MONTGOMERY
On May 6, 1994, Governor James E. Folsom, Jr., signed Senate Bill 103 into law. The bill took effect immediately upon the governor's signature. The law applies to off-label uses of drugs recognized for the treatment of life-threatening illnesses, such as cancer, AIDS, and heart disease when those uses are indicated in the drug compendia, (the American Medical Association's *Drug Evaluations*, the United States Pharmacopeia's *Drug Information*, and the American Society of Hospital Pharmacists' *AHFS Drug Information*), the medical literature, or by the Commissioner of Insurance.

SACRAMENTO
Governor Pete Wilson signed Assembly Bill 1985 into law in September 1992. This law, which took effect on January 1, 1993, applies to drugs used in the treatment of life-threatening illnesses, not just cancer drugs.

In 1994, clinical trials legislation was vetoed by Governor Pete Wilson. A veto of the bill was urged by the insurance industry. The bill would have required insurers to pay for the patient care costs of clinical trials.

This year legislation was enacted, Assembly Bill 1663, which enables terminally ill patients who are denied health plan coverage for experimental treatments to seek review of their cases from independent expert panels.

HARTFORD
On May 27, 1994, Connecticut Governor Lowell P. Weicker, Jr., signed into law a bill assuring access to off-label uses of anticancer drugs for the citizens of this state. File #88 (Senate Bill 249), which took effect on October 1, 1994, requires the use of the compendia to guide reimbursement decisions but does not have provisions for a medical expert panel or use of the peer-reviewed medical literature.

TALLAHASSEE
Effective July 1, 1995, Florida law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer when the off-label use is recognized by one of the compendia or peer-reviewed medical literature as safe and effective. Specific amendments were also adopted to the bill, Senate Bill 486, which state that the law is not to affect the determination as to whether particular levels, dosages, or usage of a medication associated with bone marrow transplant procedures are covered. The amendments also include language providing that the law does not apply to specified disease or supplemental policies.

ATLANTA
House Bill 741 was signed into law by Governor Zell Miller on April 7, 1993. It took effect on July 1, 1993. The bill applies only to cancer drugs.

SPRINGFIELD
Senate Bill 1533 was signed by Governor Jim Edgar on September 1, 1992. The Illinois off-label law took effect January 1, 1993.

This year ACCC has worked with the Illinois Medical Oncology Society, an ACCC state chapter, and the Illinois Division of the American Cancer Society to advocate passage of House Bill 3168, legislation that would provide coverage of patient care costs of clinical trials.

INDIANAPOLIS
On June 30, 1993, the Indiana legislature voted in special session to override Gov. Evan Bayh's veto of HB 1001, the state budget bill. Included in the bill was a provision

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for coverage of off-label drugs used to treat cancer. The law took effect immediately.

ANNAPOLIS
Maryland Governor William Donald Schaefer signed House Bill 1222 into law on May 26, 1994. The law, which took effect on October 1, 1994, is broadly written. It applies to off-label uses supported in the compendia or the medical literature for any FDA-approved drug for any disease. It also creates a medical expert panel to assist with disputes that may arise between providers and insurers. Corrective legislation was passed in 1995 to amend the law to include health maintenance organizations, which were inadvertently excluded from the original law. In addition, legislation was considered this year that would have required insurance companies to disclose the process they use in determining whether to cover experimental treatments and to consult with local medical specialists in making those decisions. However, this legislation did not pass. In its place a task force has been appointed to examine the issues surrounding coverage of these treatments.

BOSTON
On July 10, 1994, Governor William Weld chose not to veto a portion of the state budget which extended the off-label provisions of the existing state law for cancer patients to those being treated with drugs for HIV/AIDS related conditions. As with the original law, signed in early 1993, it applies when the off-label use is recognized as appropriate by one of the three compendia or medical literature.

LANSING
Michigan was the first state to enact off-label drug legislation, although it does not use the compendia provisions. House Bill 4078, which applies to cancer drugs only, became effective on July 1, 1989.

TRENTON
On December 23, 1993, Governor James Florio signed Senate Bill 1631 into law. It took effect in June of the following year. The law is broadly written and applies to all diseases.

ALBANY
New York became the second state with off-label drug legislation when Chapter 853 became effective on January 1, 1991. The law applies to cancer drugs only.

In 1996 clinical trials legislation was considered in the New York General Assembly. Senate Bill 5232 contained provisions regarding several cancer related issues, including coverage of clinical trials, expansion of the off-label drug law to all drugs, and coverage of diagnostic screening of prostate and ovarian cancer. The bill received passage in the Assembly but was blocked in the Senate.

RALEIGH
The legislature ratified Senate Bill 622 in July 1993. The bill took effect in October and applies to contracts entered into on or after January 1, 1994. It does not contain language requiring the use of the peer-reviewed medical literature.

COLUMBUS
On May 11, 1994, Ohio Governor George Voinovich signed Senate Bill 157 into law. Effective August 10, 1994, the law dictates that no private insurer providing coverage for prescription drugs shall exclude coverage of any such cancer drug on the grounds that the off-label use of the drug has not been approved by the FDA for that indication, provided, however, that the drug is recognized for the treatment of such indication in one of the three compendia or in the medical literature.

In February of this year, Governor Voinovich signed Senate Bill 107 into law. The legislation expands the off-label provisions of the original law to drugs used for all illnesses. The ACCC Columbus office closely monitored this bill to assure that the existing law was not weakened. Language suggested by ACCC was adopted into the bill to make certain that scientific literature used in conjunction with the Medicare law would be acceptable for purposes of the state law.

OKLAHOMA CITY
On May 26, 1993, Governor David Walters signed into law Senate Bill 106, which included off-label drug language. It took effect on September 1, 1993.

PROVIDENCE
Effective July 12, 1994, Rhode Island law requires coverage of off-label indications of FDA-approved cancer drugs when the off-label use is recognized by one of the compendia or peer-reviewed medical literature as safe and effective.

In addition, Governor Bruce Sundlun formally signed S. 2623 into law on October 13, 1994. The law requires health insurers to provide coverage of new cancer therapies still under investigation. The law is limited to Phase III or IV

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clinical trials that have been approved by NIH in cooperation with NCI (CCOPs); the Food and Drug Administration in the form of an IND exemption; the Department of Veterans' Affairs; or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants. The proposed therapy must also have been reviewed and approved by a qualified institutional review board. The new law took effect on January 1, 1995, and was due to sunset on December 31, 1996. However, legislation was enacted in 1996 to remove the sunset provisions from the law.

COLUMBIA

On May 29, 1996, South Carolina became the twentieth state to pass off-label drug legislation when Governor David Beasley signed House Bill 4585 into law. It incorporated the language negotiated by ACCC, the pharmaceutical industry, and the South Carolina Alliance for Managed Care. While the law applies only to cancer drugs, it does follow the ACCC model legislation in that it relies on the three compendia and the medical literature to substantiate off-label uses that must be covered by insurers. The new law took effect 120 days following the governor's signature.

RICHMOND

Effective July 1, 1994, Virginia law requires coverage of off-label indications of FDA-approved cancer drugs when the off-label use is recognized by one of the three compendia as safe and effective. The law was signed by Governor George Allen on April 6, 1994.

OLYMPIA

The Washington State Commissioner of Insurance, Deborah Senn, adopted administrative rules requiring Washington insurers to provide coverage of off-label uses of FDA-approved drugs when the use is recognized in one of the three compendia or in the peer-reviewed medical literature. The language of the rule, which has the force of law, has its roots in the ACCC model legislation. It became effective January 1, 1995.