Advances in genetic testing have brought several policy issues to the forefront of state and federal government activities. Discrimination, quality of testing, informed consent, and storage of DNA samples have become leading concerns when discussing genetic testing.

**Discrimination by Insurance Providers**

Several members of the House and Senate have drafted legislation that aims to protect a patient’s medical privacy to help avoid potential discrimination by employers and health insurance providers. For example, Sen Olympia Snowe (R, Me) and Rep Louis Slaughter (D, NY) have introduced Senate Bill (SB) 89 and House Resolution (HR) 306, respectively, to protect individuals from discrimination by health insurance providers based on results of genetic testing. The bill states, “A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not request or require a participant or beneficiary...to disclose to the plan or issuer genetic information about the participant, beneficiary, or applicant.”

In legislation of some states, discrimination language focuses on which providers may receive genetic test results and how they might use such information. For example, Oregon SB 1107 prohibits insurance providers from using the results of genetic testing to discriminate against an enrollee. The bill defines an insurance provider as “an insurance company, health care service contractor, fraternal benefit organization, insurance agent, third party administrator, insurance support organization, or any other person subject to regulation by the Insurance Code.” Other bills have proposed broader definitions of who should not receive genetic information, such as Tennessee House Bill 413, which defines insurance provider as “an insurer or other entity providing health insurance coverage.”

**Quality of Genetic Testing**

In September 1997, the Task Force on Genetic Testing, created by the National Institutes of Health—Department of Energy Working Group on Ethical, Legal, and Social Implications of Human Genome Research, announced its recommendations to ensure the development of safe and effective genetic tests. The Task Force recommended ways to ensure the quality of laboratories performing genetic tests.

One recommendation supported the creation of a genetics subcommittee of the Clinical Laboratory Improvement Advisory Committee. The proposed subcommittee would “consider the creation of a [laboratory] specialty of genetics that would encompass all predictive genetic tests that satisfy criteria for stringent scrutiny.” Also, the Task Force recommended formal training in human and medical genetics for laboratory directors or technical supervisors who perform high-complexity molecular genetic, biochemical genetic, and cytogenetic testing.

**Informed Consent for Releasing Genetic Test Results**

Disclosure of genetic information is at the core of legislation introduced at the federal level. To confront the problem of improper disclosure and to protect an individual’s right to privacy, several bills have been introduced in Congress. One proposal, common to several bills, would require written authorization before genetic information...
could be disclosed. The specific requirements for authorization vary from bill to bill. Rep Cliff Stearns (R, Fla) proposed in HR 2189, the Genetic Privacy and Nondiscrimination Act of 1997, that a group health plan could not disclose genetic information about a person unless that person or that person’s legal representative gave written authorization. The written authorization would need to include a description of the information to be disclosed, the name of the person, group, or institution who would receive the information, and the purpose of giving the information.

Many states have passed laws requiring informed consent. Louisiana House Bill 1590 reads “no insurer shall obtain genetic information from an insured or enrollee, or from their DNA sample, without first obtaining written informed consent from the insured, enrollee, or their representative.” A Tennessee law requires that “an insurance provider may not disclose genetic information about an individual without prior written authorization of the individual or legal representative of the individual. Such authorization is required for each disclosure and shall include an identification of the person to whom the disclosure would be made.”

Storage and Ownership of DNA Samples
Sen Pete Domenici (R, NM) drafted legislation, the Genetic Confidentiality and Nondiscrimination Act of 1997, to include specific language on storage and genetic analysis of DNA samples. The bill states that a DNA sample may be stored only if written authorization has been obtained. The bill also states “that the individual has the right to order destruction of an identifiable DNA sample at any time.” Sen Domenici’s bill specifically addresses the circumstances surrounding how DNA samples and genetic information may be collected, stored, and analyzed.

The Arkansas Human Research Subject Protection Act of 1999, known as Interim Study Proposal 97-10, states that “all tissues and fluids obtained in an investigational activity that are no longer useful for the diagnosis or treatment of the patient shall be transferred to the institution conducting the research, and no human subject shall retain a continuing property interest in the tissues and fluids or in drugs, medical devices, or other inventions or discoveries that may result therefrom. Such institutions may transfer such tissues and fluids to other institutions or agencies for further analysis and storage.” In other words, tissue and fluid samples that can no longer aid in the diagnosis and treatment of a patient’s condition become the property of the institution using those samples for research.

Another example, Oregon SB 1107, contains specific language on the storage of genetic samples. This law says that DNA samples used for research, unless they are from anonymous donors, will be destroyed when the research study is completed or the person withdraws from the study, unless the person or the person’s legal representative gives permission for the researcher to continue using the sample.

Conclusion
ASCP believes adequate safeguards must be implemented to protect against the misuse of genetic information. The ASCP Washington office continues to monitor legislative proposals for genetic testing at the state and federal levels to ensure an appropriate balance between patient confidentiality and the needs for medical research.