Legal Corner

Genetic Testing for Cancer: Legal, Ethical, and Practical Issues for the Practicing Oncologist

By Elizabeth Goss, JD

According to the nonprofit Council for Responsible Genetics, the number of genetic tests to diagnose rare diseases and to predict future health risks has increased 10-fold throughout the last decade, and the commercial impact of these products has expanded accordingly. Many of these genetic tests are becoming standard elements of the management of patients with a variety of cancers, particularly those of the breast, ovary, and colon, but increasingly others as well. Major challenges arise, however, with respect to counseling of patients undergoing such tests. In addition, there are uncertainties regarding the regulatory oversight of genetic tests, as well as the availability of reimbursement for both the tests and related services.

Counseling

ASCO recommends that genetic counseling and testing be offered when there are “personal or family history features suggestive of a genetic cancer susceptibility condition,” when “the genetic test can be adequately interpreted,” and when “the test results will aid in diagnosis or influence the medical or surgical management of the patient or family members at hereditary risk of cancer.”¹ The ASCO recommendation also posits that “genetic testing only be done in the setting of pre- and post-test counseling, which should include discussion of possible risks and benefits of cancer early detection and prevention modalities.”¹ Moreover, recognizing that genetic counseling requires specialized training and experience, the ASCO statement asserts that “oncologists should consider offering genetic testing only if they are able to provide or make available adequate genetic education and counseling as well as access to preventive and surveillance options.”¹ If the oncologist lacks this capacity, the patient should be referred to the appropriate specialist in genetic counseling.

Confidentiality and Duty to Warn

The usual physician obligation to maintain patient confidentiality is perhaps even stronger in the case of genetic information, given how readily it might be subject to misuse or misinterpretation. This obligation has been made more concrete and specific through regulations implementing the privacy protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191.²

The absolute requirement of confidentiality has been questioned in the setting of familial genetic predisposition,

where some have argued for a “duty to warn” the at-risk relatives of patients diagnosed with cancers who are known to have a genetic predisposition.

Courts are split on the issue, with one decision declaring an expansive duty to warn the biologic relatives of a patient with familial adenomatous polyposis, and another court finding that the duty to warn was satisfied when the physician advised the patient to inform blood relatives that they might be at risk for the hereditary thyroid cancer with which the patient had been diagnosed (Compare *Pate v. Threlkill*, 661 So. 2d 278 [Fla. 1995] with *Safer v. Estate of Pack*, 677 A. 2d 1188 [NJ App], appeal denied, 683 A 2d 1163 [NJ 1996]).³ These court decisions were issued before adoption of enhanced privacy protections in the HIPAA regulations, which might have affected the results.

The ASCO recommendation stresses the importance of confidentiality of genetic information, but also concludes that patients should be reminded of “the importance of communicating test results to family members, as part of pretest counseling and informed consent discussions.” Further, “ASCO believes that the cancer care provider’s obligations (if any) to at-risk relatives are best fulfilled by communication of familial risk to the person undergoing testing, emphasizing the importance of sharing this information with family members so that they may also benefit.”⁴

Direct-to-Consumer Advertising

Another controversy has derived from the recent practice of some laboratories of marketing their genetic tests (particularly tests for *BRCA1* and *BRCA2* mutations) directly to the public through various media, including the Internet. This direct-to-consumer advertising has been criticized for inefficiencies flowing from the fact that such advertising is directed to many individuals who cannot possibly benefit from the promoted tests. Physicians may be unduly burdened by the time and other demands imposed by the marketing effort:

“There is no possibility that a 15-minute office visit is adequate to address all of the issues surrounding genetic testing. There is also a paucity of genetic experts, and if the demand for genetic testing increases significantly, it will strain the resources of the entire medical community. An additional concern is that physicians might feel pressured to order genetic tests that are not indicated, as some physicians

are susceptible to patient pressure when prescribing medications.”⁵

Reimbursement and Regulatory Issues

Reimbursement for genetic testing is complicated by a number of factors, including the absence of a significant regulatory system to provide validation of the tests themselves. The laboratories in which the genetic tests are performed are regulated by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. Regulations under CLIA have been criticized as providing “minimal and insufficient oversight.”⁵ Recently, the US Food and Drug Administration (FDA) has indicated an intention for the first time to regulate many of these tests, but the standards to be applied by the FDA are a matter of conjecture.⁶ ASCO has submitted comments to the Docket criticizing the FDA initiative for insufficient transparency and regulatory detail.

Absent a more detailed and predictable regulatory pathway for these tests, there will be continued reimbursement challenges, as each test must be justified to both private and public third-party payers. Nevertheless, recognizing the value of many of these tests, a number of private insurers have extended coverage to select genetic tests, and Medicare has recently provided additional guidance as to tests covered by the program for patients already diagnosed with cancer. A remaining shortcoming of the Medicare coverage standards relates to statutory restrictions on coverage of tests for screening purposes in healthy individuals, including relatives of patients with cancer who may themselves be at risk.

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