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Federal agency rejects enhanced oversight of genetic tests

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In a decision that places cost concerns above public health, the Centers for Medicare and Medicaid Services (CMS) has rejected a petition filed by a coalition of health and consumer groups calling for the agency to strengthen standards for genetic testing laboratories. Citing cost concerns, the agency told petitioners in a recent letter that it would not pursue the safety standards.

The petition was filed jointly in September 2006 by the Genetics and Public Policy Center, Public Citizen, and the Genetic Alliance. In addition to the petition, CMS has received letters from nearly 100 organizations, including health care providers, patients, and industry, requesting that the agency create enhanced genetic testing regulations. The petition sought to increase the use of proficiency testing by requesting the creation of a "specialty" for genetic testing.

"CMS has abdicated responsibility for ensuring the quality of genetic tests and has erroneously placed cost considerations above the public's health," said Kathy Hudson, director of the Genetics and Public Policy Center. "The letter uses the word --cost -- repeatedly, but not once does it mention health and safety. That's astounding for an agency charged with protecting patients by ensuring laboratory quality."

The petition called on CMS to exercise its authority under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Congress passed this law out of concern about the quality of laboratory tests after reports of misdiagnoses and deaths following incorrectly performed Pap

smears. The law requires the secretary of the Department of Health and Human Services (HHS) to set standards for laboratories to ensure their quality, including standards for "proficiency testing." Proficiency testing provides independent confirmation that the laboratory can get the right answer reliably when performing laboratory tests. However, CMS has not mandated participation in proficiency testing for genetic testing laboratories.

Genetic tests are currently available clinically for more than 1100 diseases. "The results of these tests are being used to make life and death decisions," said Sharon Terry, president and CEO of Genetic Alliance. "A patient who is going to decide whether to have a child, or undergo surgery, or take a particular drug really needs to know that the test used to make that decision gives the right answer."

In denying the petition for rulemaking, CMS stated that few proficiency testing programs exist and that the barriers to expanding the number were "technological and financial," rather than regulatory. In fact, the College of American Pathologists now offers proficiency testing for more than two dozen genetic tests, including for widely used tests such as cystic fibrosis and Factor V Leiden, but laboratories currently are not required to enroll in them. Mandatory requirements would result in more proficiency tests being developed, the petition argued.

To support its contention that developing new proficiency testing programs is too difficult, CMS points to its experience with Pap smears -- stating that it took 17 years from the passage of CLIA to develop a nationwide proficiency testing program.

Said Peter Lurie, deputy director of Public Citizen's Health Research Group, "The agency is using its own history of bureaucratic ineptitude as the basis for not moving forward on genetic tests. That's just absurd. The excuse --it's too hard for us' is unacceptable when it comes to patient

safety."

CMS's response also dismissed reports from three federal advisory groups over the past decade recommending that the agency strengthen genetic testing oversight, and ignored data on genetic testing laboratory quality gathered by the Genetics and Public Policy Center. The Center's 2006 survey of laboratory directors of genetic testing laboratories found that laboratories do not always enroll in available proficiency testing programs. Moreover, the survey found that laboratories that reported performing less proficiency testing also reported experiencing more "deficiencies" -- or errors -- at some stage of the testing process.

Said Hudson: "At a time when the Food and Drug Administration, expert advisory groups, Congress, and the public have focused increasing attention on critical gaps in the oversight needed to ensure the quality of genetic tests, CMS has turned a blind eye to its responsibilities."

Source: Genetics & Public Policy Center, Johns Hopkins University