Put It on the Board

written by CAP TODAY
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Safeguarding cancer surveillance and lab services

September 2025—CAP president Donald Karcher, MD, in a July 25 letter urged the chairs and ranking members of the Senate and House appropriations subcommittee on labor, health and human services, education, and related agencies to apply pressure to obligate and award already approved funding for the CDC Division of Cancer Prevention and Control.

“Even though Congress approved FY 2025 funding in March, the CDC has not issued notice of awards to provide funding to state and local health departments for the remaining FY 2025 funds,” he said. “State and local health departments are challenged to continue their work without knowing if they will be reimbursed. State health departments and grantees are on the verge of shutting down programs and furloughing staff.”

Further delays or terminations of these grants, he wrote, will have disastrous effects on cancer surveillance, screening, and prevention.

The letter seeking support for ongoing funding of vital cancer surveillance programs for the remainder of the current fiscal year and for FY 2026 was sent to Shelley Moore Capito (R-W.Va.) and Tammy Baldwin (D-Wis.), chair and ranking member in the Senate, respectively, and Robert Aderholt (R-Ala.) and Rosa DeLauro (D-Conn.), chair and ranking member, respectively, in the House.

The FY 2026 budget request eliminates critical work by the nation’s cancer registries, the letter says.

“We cannot maintain progress in cancer diagnosis and treatment without support for surveillance and public health programs that allow us to understand the causes of cancer and develop effective tools for prevention, screening, treatment, and survivorship,” Dr. Karcher tells the lawmakers.

In another letter, sent Aug. 22 to U.S. Department of Commerce secretary Howard Lutnick, Dr. Karcher said the CAP urges the administration to exempt medical device products from the imposed tariffs, particularly those products needed to develop and provide critical diagnostic services. He said the CAP also urges the administration to pursue an exemption for these products, in its negotiations, from retaliatory tariffs other countries might impose.

“Without an exemption for medical device products,” he said, “the CAP is concerned that cost increases for these products will negatively impact clinical laboratory testing, particularly in rural and other medically underserved areas.

“These additional costs, on top of federal and private payer reimbursement cuts,” he continued, “could delay and/or limit necessary testing, decrease innovation in laboratory medicine, and compound the difficulties pathologists currently face in managing declining and shifting resources as they continue to care for the communities they serve.”

AMP publishes HRD testing recommendations

A dozen recommendations for clinical homologous recombination deficiency assay validation, testing, and reporting were published last month in the *Journal of Molecular Diagnostics* (Hsiao SJ, et al. *J Mol Diagn*. 2025;27[8]:685–704).

The recommendations are listed in a joint consensus statement of the AMP, the CAP, and the Association of Cancer Care Centers.

HRD is a genomic feature present in some malignant neoplasms and attributed to the failure of the homologous recombination repair pathway. “Tumors with an HRD-positive status may have a distinct prognosis and/or response to therapies,” the authors write, “including poly (ADP-ribose) polymerase inhibitors.”

Among the recommendations are the following:

- Laboratories developing assays to assess HRD phenotypes (genomic scars and/or mutational signatures) should include samples in their validation that are negative for *BRCA1* and *BRCA2* mutations but positive for an HRD phenotype.
- Laboratories that perform germline *BRCA1* and *BRCA2* mutation testing should include deletion/duplication analysis. If not included, the limitations of testing should be described clearly in the reported results.

For the full list of recommendations, see the consensus statement at doi.org/10.1016/j.jmoldx.2025.05.003.

FDA clears Cobas Respiratory 4-flex

The Food and Drug Administration granted 510(k) clearance for the Roche Cobas Respiratory 4-flex, which is the first FDA-cleared assay using Roche’s TAGS (temperature-activated generation of signal) technology.

The new test provides PCR results for SARS-CoV-2, influenza A and B, and RSV, and it includes a digital reflex option, which allows for additional testing from the same sample.

TAGS technology uses multiplex PCR testing, combined with color, temperature, and data processing, to enable the detection and differentiation of multiple targets within a single optical channel.

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