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UNDERSTAND PREVENT & CURE CANCER

November 16, 2015

The Honorable Chris Collins
US House of Representatives
1117 Longworth House Office Building
Washington, DC 20515

Dear Congressman Collins:

I am writing to you in anticipation of the Energy & Commerce Committee hearing "Examining the Regulation of Diagnostic Tests and Laboratory Operations" scheduled for Tuesday, November 17, 2015.

As you know, Roswell Park Cancer Institute throughout its 117 year history has been an innovator. Several years ago New York State and Roswell Park made a significant investment into genomics and genetic sequencing at the cancer center creating the Center for Personalized Medicine. The investment was made ahead of the national focus on precision medicine.

The revolution in precision or personalized medicine, which can target the right treatment for a specific and genetically identified disease, is dependent on genetic sequencing. Personalized medicine is completely dependent on the rapid development and use of laboratory developed diagnostic tests (LDTs.) the proposed regulation by the FDA of these tests developed for laboratory use and not for resale could have severe and negative impact on patients and on the type of research done at Roswell Park.

The FDA's interest in regulating LDTs, as described in their draft guidance, threatens to disrupt care for millions, creating a whole new bureau in the agency for LDTs but offering no appreciable benefit in safety or efficacy.

We appreciate the interest in ensuring that LDTs are safe, effective, and transparent in their value. The Association of Molecular Pathology (AMP) has developed a proposal that in my opinion achieves the right regulatory balance by modernizing the existing federal regulatory schema—the Clinical Laboratory Improvement Amendments administered by CMS and provides a limited role for the FDA when laboratories will not share proprietary methodologies that would allow for validation of their LDTs.

The AMP proposal provides laboratories with the choice of regulatory pathways they will pursue. They can either place their tests in the "clinical commons" and be regulated under CLIA, or maintain proprietary approaches and be regulated under FDA or other authorities that require such information such as the New York State Department of Health.

For the sake of patients and ongoing innovation in cancer research, I urge you to support the AMP proposal as the basis for any bill.

You would be amazed at the work we are doing in genetics here at Roswell Park. The human genome holds the understanding of health and illness. FDA regulation will interfere with our work in achieving this understanding. As a physician, I assure you that FDA regulation of LDTs will reduce access for patients to valuable, even life-saving tests. Another unintended consequence of FDA involvement would be to undermine America's leadership in genetics, diagnostics, research and patient care.

Thank you for considering the AMP proposal as the basis for any legislation regulating LDTs.

Sincerely,

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cc:
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