2 October 2023

FDA SIGNALS INTENT TO REGULATE LAB DEVELOPED TESTS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) notes the U.S. Food and Drug Administration (FDA) has released for public comment proposed rule changes that seek to have Laboratory Developed Tests (LDTs) such as Cxbladder regulated as medical devices under the US Federal Food, Drug, and Cosmetic Act.

The proposed changes, if finalized, would require Pacific Edge and other LDT providers to present evidence to the FDA that their tests are safe and effective for their intended use in addition to the current regulatory pathway of being accredited through CLIA (Clinical Laboratory Improvement Amendments).

Pacific Edge is working through the implications on this proposed rule change to the business but notes the FDA announcement reflects an ongoing process that has been evolving for more than a decade and it has significant implications for the multi-billion dollar US clinical testing industry. In 2022, the VALID Act, which sought to establish a new framework for the FDA to regulate LDTs, did not pass Congress, and the FDA announced that it would seek to use the existing Medical Device framework to assess LDTs, something that is opposed by numerous associations, including those of which Pacific Edge is a member, the Coalition for 21st Century Medicine (C21) and the American Clinical Laboratory Association (ACLA).

The proposed rule would be phased in over a four-year period, after the changes are finalized. A 60-day comment period is expected to open on the rule changes later this week (3 October 2023), but the FDA has not provided a timeline on when it will make a final decision on the proposed changes. A coordinated response plan, including legal challenges will be handled through coalition partners, professional associations and lobby groups that have been preparing for this announcement for several months.

Pacific Edge shares many of the views of our partners in the Coalition for 21st Century Medicine (C21), the American Clinical Laboratory Association (ACLA) and many other providers of LDTs. A link to the ACLA response is below.

Chief Executive Dr Peter Meintjes said: "The current system works well for patients and therefore any changes to the regulatory system must maintain that standard outcome. We will continue to work with our partners regarding regulation of our industry that is in the best interests of all stakeholders.

"Notwithstanding this position, we have long recognised FDA's intention to extend its oversight to include LDTs. Consequently, Pacific Edge has been working to prepare the company for this potential regulatory change to minimize any disruption to our US operations, including adopting good clinical practice (GCP) guidelines, and digitalizing our clinical development program. We will continue to inform shareholders of our ability to comply with all evolving regulatory requirements."

The US FDA press release announcing the proposed regulatory change can be found here:

- FDA Proposes Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests | FDA

The proposed rule change can be found on the Federal Register here:

- FDA Proposed Rule Change

The American Clinical Laboratory Association response to the proposed regulatory change can be found here:

- ACLA Opposes Unilateral FDA Action to Regulate Laboratory Developed Tests Under Medical Device Authority - American Clinical Laboratory Association

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

For more information:

Investors:

Dr Peter Meintjes
Chief Executive
Pacific Edge
P: 022 032 1263

Media:

Richard Inder
The Project
P: +64 21 645 643

Pacific Edge: www.pacificedgedx.com

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

Cxbladder: www.cxbladder.com

Cxbladder is a urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder has been trusted by over 4,400 US urologists in the diagnosis and management of more than 100,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 75% of the population via public healthcare and all residents have the option of buying the test online.