Requesting PACCARB Support of Novel Reimbursement Programs for Innovative Diagnostic Tests That Can Help Mitigate Antimicrobial Resistance

Inflammatix is a Silicon Valley-based molecular diagnostics company developing tests that measure patterns of the human immune response (host mRNA) to reliably identify the presence, type, and severity (sepsis) of an acute infection. Unlike traditional pathogen-detection approaches like blood culture or molecular detection tests, host response testing can be highly sensitive. Studies to date show that our tests perform well enough so that physicians are likely able to confidently rule-out bacterial infection and, potentially, reducing antibiotic prescribing for unwarranted cases. **Widespread use of our tests could contribute to less antibiotic resistance.**

Our test systems will consist of a small point-of-care instrument (toaster sized) and single use diagnostic test cartridges that are intended to be simple to use and deliver timely results (under 30 minutes). The key innovations associated with our tests include the measurement multiple markers (host mRNAs) from a simple blood draw and their combination using advanced machine learning algorithms into actionable results.

Unfortunately, current reimbursement rules impose barriers to patient access of novel tests like ours. CMS classifies them as Multianalyte Assay with Algorithmic Analysis (MAAA) tests. Novel MAAA used in the outpatient setting, in the best of circumstances, take **at least a year and half** from the time such a test is cleared for use (by the FDA and/or CLIA) to having it routinely paid (not considering MAC delays).

When such tests are used in the inpatient setting, hospitals pay for such innovative tests without any reimbursement modification to their Diagnosis Resource Group (DRG) payment associated with the patient's hospital stay. Partial relief to the providers may come from the New Technology Add On Payment (NTAP) program, but it can takes years to become eligible and the relief is only partial subsidy (65% of the cost).

Thus, instead of patients and providers flocking to adopt these potentially game changing tests, they hesitate to order them given their reimbursement challenges. Additionally, investors shy away from funding potential high impact diagnostic companies, given the incremental delays (and often-times uncertainty) in achieving a reasonable return on capital. As a result, patient access to game changing diagnostic tests is limited.

Paths do exist for novel technologies to be adopted while providing assurance that their impact is positive and enduring. As a result, we encourage PACCARB to support "coverage with evidence in development" programs: These include **ensuring that the newly proposed Medical Coverage of Innovative Technology (MCIT) program includes novel diagnostic tests**, a more timely and generous NTAP program, and by adding diagnostics coverage to the DISCARM Act under consideration by congress.

These and potentially other ideas should be implemented as temporary measures (e.g. 4 years), allowing the new tests to clearly demonstrate clinical utility and patient safety when used in routine care. The tests that meet this high bar can then transition to permanent coverage status. In the interim, support for these programs allow patients to access clinically valuable tests that can also make strides to limiting antimicrobial resistance.

Jonathan Romanowsky
COO, Inflammatix, Inc.