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The Honorable Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Subject: Request for Inclusion of FDA Cleared Testing in Special Registration Consideration Regardless of Setting

Dear Administrator Milgram,

As outlined in our statement, offered on Day 2 of the September 2023 listening session regarding telehealth prescribing, we aim to draw attention and highlight the clinical benefits of objective data from FDA Cleared testing. Specifically, we will outline the FDA cleared medical device QbCheck within the Special Registration considerations for those who are conducting care virtually. Since our statement, data is in the process of being published which articulates, regardless of care setting, in-office or virtual, objective data is available and reliable for measuring and monitoring patients' response to treatment of Attention Deficit Hyperactivity Disorder (ADHD). This memorandum is to serve as an update with new data, to the information presented, further highlighting that safeguards are available to prescribers to facilitate treatment monitoring and dosage titration, no matter where care is accessed.

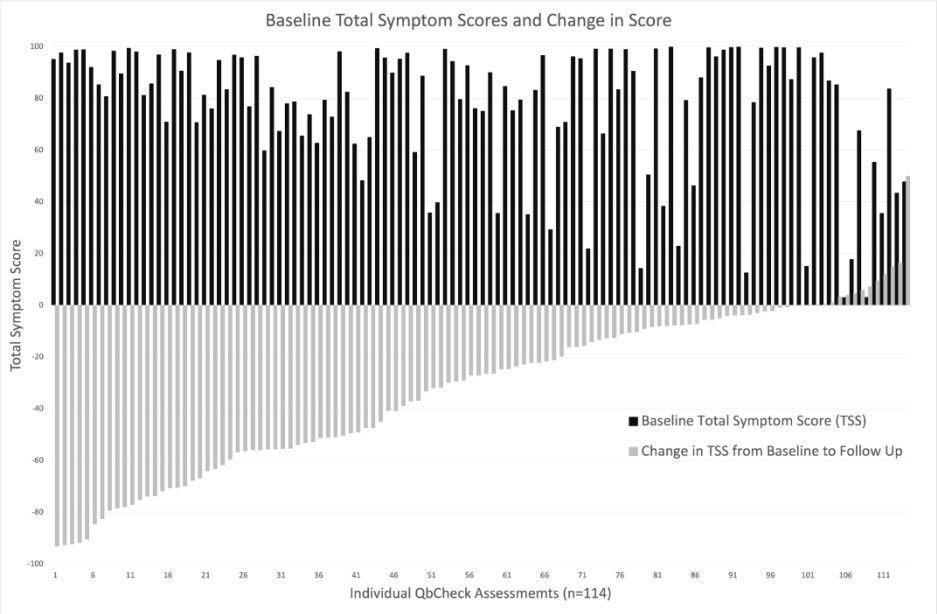
As a reminder, QbCheck is a remote medical device designed to provide licensed healthcare professionals, including those who prescribe Schedule II medications, with objective measurements of hyperactivity, impulsivity, and inattention, aiding in the clinical assessment and treatment monitoring of ADHD (Hall et al., 2017; Wehmeier et al., 2011). We should state that Qbtech is agnostic to treatment and is FDA cleared to measure any type of treatment agreed upon with clinician and patient, such as Cognitive Behavioral Therapy or pharmacologic, and trust the Administration is aware of the evidence supporting the widespread use of Schedule II medications and the impact of treated vs untreated ADHD.

Recent research on the clinical utility of QbCheck for remote monitoring of ADHD medication treatment from routine clinical assessments across various healthcare institutions in the US indicates significant improvements in symptom severity across all ADHD symptom areas, including activity, impulsivity, and attention, following initiation of treatment. These findings were submitted for publication in April 2024, and align with the already published literature conducted in both in-office and virtual settings, underscoring the reliability and validity of QbCheck as an objective measure for guiding treatment decisions and optimizing outcomes that result in responsible telehealth prescribing (Sanyal et al., submitted for review 2024).

Furthermore, research indicates that objective measures, such as the QbTest (in office) or QbCheck, are likely more sensitive to physiological changes and could be effective in early detection of treatment effects, and quicker dosage optimization. Looking at Figure 1 below from this recently

submitted manuscript, though we see an overall significant improvement in symptom severity following medication treatment, not all patients showed the same magnitude of improvement. Utilizing this data during the decision-making and medication titration process, clinicians could optimize each patient on their medication that would balance their ADHD symptoms at the lowest effective dose. This personalized approach would enhance treatment efficacy and foster a more collaborative relationship between healthcare providers, patients, and caregivers.

Figure 1: Data From Remote Adult ADHD Care
(Not all patients showed the same magnitude of improvement)

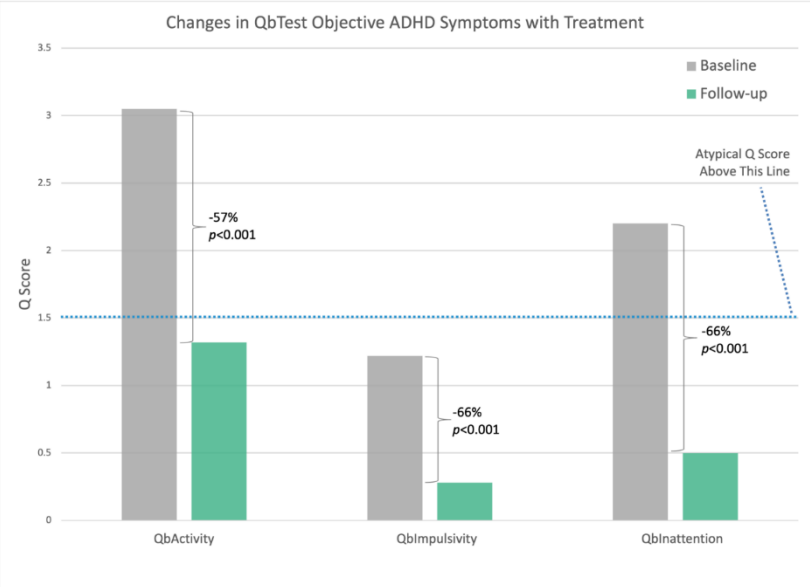


(Sanyal et al., submitted for review 2024)

There is a wealth of published literature on studies outlining the efficacy of FDA cleared objective data obtained through measuring baseline symptoms of ADHD and monitoring response to treatment in patients ranging from ages 6 to 60, including those prescribed Schedule II medications. This research spans over the last 11 years, and recently a published systematic review concluded that QbTest can distinguish pharmacological treatment effects within hours of pharmacological titration and can be used for monitoring of long-term treatment of ADHD (Gustafsson & Hansen et al., 2023).

A key study included in this review compared the effectiveness of QbTest against patients' self-reports of ADHD symptoms following stimulant medication. The findings revealed that approximately 50% of patients self-reported no symptom changes, but these patients showed an improvement in symptoms when objectively tested using our device, likely related to the numerous challenges associated with relying on self-report only (see Figure 2 below). Additionally, objective testing was shown to be more sensitive to medication effects during follow-up visits at both one-month and six-month intervals (Martin-Key et al., 2022). This emphasizes that the urgent clinical need for healthcare professionals to optimize and individually create effective treatment plans for individuals with ADHD can be supported and objectively assessed using Qbtech medical devices.

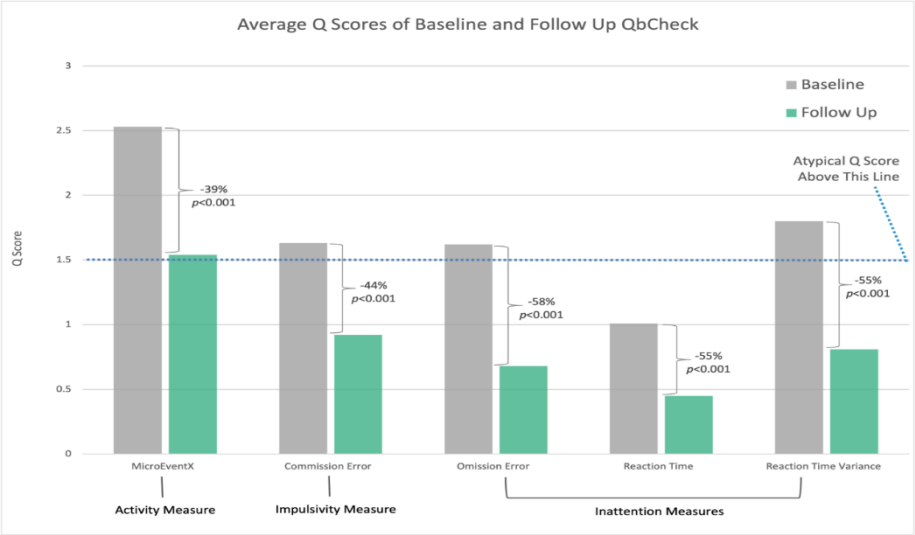
Figure 2: In Clinic Treatment Response
(Regardless of setting, group level changes are clear)



(Created based on data from Martin-Key et al., 2022)

Although the study highlighted above focused on in office testing, recent data demonstrates when evaluating the changes in ADHD symptoms following treatment in a remote setting, similarly significant improvements in symptoms were seen using the comparable QbCheck (Sanyal et al., submitted for review 2024). This suggests that regardless of setting, whether in-person or remote, objective ADHD assessments such as the QbCheck and QbTest are sensitive to treatment effects on ADHD symptoms (see Figure 3 below).

Figure 3: Remote Testing Treatment Response
(Regardless of setting group, level changes are clear)



(Sanyal et al., submitted for review 2024)

Considering these compelling findings, and more than a decade of clinical utilization of this technology, we respectfully request the DEA to consider incorporating FDA cleared testing, particularly QbCheck, within the scope of Special Registration. So, by employing objective metrics, clinicians can track changes in ADHD symptom severity more consistently, allowing for better-informed treatment decisions and improved communication among stakeholders. Stakeholders including licensed healthcare professionals such as prescribing clinicians and pharmacists would have access to a valuable and validated tool for remote decision making and monitoring of ADHD medication, tracking symptom regulation, monitoring treatment compliance, and ensuring safety with expanded access regardless of originating site.

Thank you for considering our request. We remain available to provide any additional information or clarification required.

Sincerely,

Danielle Vaeth

Danielle Vaeth
Sr. Market Manager

References:

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Gustafsson U, Hansen M. QbTest for Monitoring Medication Treatment Response in ADHD: A Systematic Review. Clin Pract Epidem Ment Health. 2023 Nov;19(1).

Martin-Key NA, Stevenson A, Roy P. Investigating the Clinical Utility of the Combined Use of Objective and Subjective Measures of ADHD During Treatment Optimization. Journal of Clinical Psychopharmacology. 2022 Apr;42(2):146–53.

Sanyal RY, Nolen R, Gustafsson U, Hansen M. Utilizing remote objective ADHD testing to monitor symptom improvement following medication treatment. (submitted for review April 2024).

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