The FDA Recommends Only Using Cleared or Approved Medical Devices to Help Assess or Diagnose a Head Injury, Including Concussion: FDA Safety Communication

Date Issued:

April 10, 2019

Audience:

- People who may be tested for a head injury
- Parents and caregivers of individuals who may be tested for a head injury
- Athletic Coaches and Athletic Administrators
- Sports medicine specialists and athletic trainers
- Health Care Providers who assess or diagnose head injury, including suspected concussion and other traumatic brain injuries

Specialties:

Primary Care Physicians, Emergency Room Physicians, Neurosurgeons, Neurologists, Nurse Practitioners, Athletic Trainers, Sports Medicine Specialists

Product:

Certain products intended to aid in the assessment, diagnosis, or management of a head injury, which includes concussion, traumatic brain injury (TBI), and mild traumatic brain injury (mild TBI or mTBI) are considered medical devices regulated by the FDA. These include products that claim to assess and diagnose any changes in brain function by having an injured person perform tests on a smartphone or tablet-based app to determine a change in mental (cognitive) status including vision, concentration, memory, balance, and speech.

Purpose:

The U.S. Food and Drug Administration (FDA) is concerned that products that do not have FDA **clearance or approval (https://www.fda.gov/medicaldevices/resourcesforyou/consumers/default.htm)** are being marketed to individuals, including parents and caregivers, athletic coaches, and health care providers for the assessment, diagnosis, or management of a head injury, including concussion. The FDA is issuing this communication to make the public and health care providers aware of the potential serious risks which may be associated with the use of unapproved or uncleared medical devices for the diagnosis, treatment or management of a concussion. The FDA reminds individuals to seek treatment by a health care provider if any head injury, including concussion, is suspected.

Summary of Problem and Scope:

The FDA has identified several manufacturers that were marketing medical devices for concussion diagnosis, treatment, or management without the FDA's approval or clearance. The use of unapproved medical devices may lead to an incorrect diagnosis. An incorrect diagnosis of "no head injury" after an injury,

for example, could lead a person with a serious head injury to return to their normal activities instead of getting medical care. Not getting needed medical care and returning to normal activities could lead to worsening of the injury.

To date, there are a limited number of medical devices that have been **approved or cleared (/MedicalDevices/ProductsandMedicalProcedures/NeurologicalDevices/ucm610799.htm)** by the FDA to aid in diagnosis, treatment, or management of head injury, including suspected concussion and other traumatic brain injuries. Additionally, the FDA has not approved or cleared any devices that can assess or diagnose a head injury, including suspected concussion and other traumatic brain injuries without an evaluation by a health care provider.

Recommendations for Individuals, Parents and Caregivers:

- Seek medical attention right away if you, your child, or a person in your care gets a head injury.
- Remember, a head injury, including concussion, should only be diagnosed by a health care provider after a thorough evaluation.
- Be aware that the FDA has not approved or cleared any devices that can assess, manage or diagnose a concussion without an evaluation by a health care provider.
- If a person in your care has been treated for a head injury, such as concussion, with a medical device and experienced a problem, the FDA encourages you to file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program. (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**

Recommendations for Athletic Coaches and Athletic Administrators:

- If you suspect an athlete or spectator may have a head injury, make sure they seek medical care right away.
- Remember, a head injury, including concussion, should only be diagnosed by a health care provider after a thorough evaluation.
- Be aware that the FDA has not approved or cleared any devices that can assess, manage, or diagnose a concussion without an evaluation by a health care provider.
- If a person in your care has been treated for a head injury, such as concussion, with a medical device and experienced a problem, the FDA encourages you to file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program. (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**

Recommendations for Health Care Providers:

- Be aware that the safety and effectiveness of devices for diagnosis, assessment, or management of head injuries, such as concussion, have been established in only a **limited number of devices (/MedicalDevices/ProductsandMedicalProcedures/NeurologicalDevices/ucm610799.htm)**, which should only be used by a health care provider.
- Be aware that there are limitations that should be considered when using cleared and approved devices to aid in diagnosing, treating, or managing concussion, and labeling should be followed closely.
- Discuss the benefits and risks of all available options for diagnosing and managing head injuries, including concussion, with your patient and their caregiver.
- If any patients experience adverse effects from procedures that involved the use of a medical device intended to diagnose, treat or manage a brain injury, the FDA encourages you to file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program. (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**

FDA Activities:

The FDA routinely monitors promotional materials and claims for medical products. Recently, the FDA became aware of firms marketing medical devices for the assessment, diagnosis, or management of a head injury, including concussion, without FDA clearance or approval. The FDA has communicated our concerns about these promotional materials to these firms.

The FDA will continue to actively monitor promotional materials, including materials on the internet and products for smartphones and tablets, and claims about uses of these and similar medical devices. Additionally, the FDA will continue to monitor complaints and adverse event reports from the public, health care providers, and industry.

We will update this communication if significant new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks of using these devices to assess, diagnose, or manage head injury, including concussion. If you experience adverse events associated with these products, we encourage you to file a voluntary report through **MedWatch (https://www.fda.gov/safety/medwatch/)**, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements (https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm)** should follow the reporting procedures established by their facilities.

If you believe a medical device is being marketed outside the scope of its FDA approval or clearance, you can report that allegation through **FDA's Allegations of Regulatory Misconduct (https://www.fda.gov/MedicalDevices/Safety/ReportingAllegationsofRegulatoryMisconduct/default.htm)** process. You can also contact your **local FDA Consumer Complaint Coordinator (/ForConsumers/ConsumerUpdates/ucm095859.htm)** for assistance with this process.

Other Resources:

- FDA Webpage on **Medical Devices for Assessing Head Injury (/MedicalDevices/ProductsandMedicalProcedures/NeurologicalDevices/ucm610799.htm)**
- **FDA Press Release: FDA warns public not to use unapproved or uncleared medical devices to help assess or diagnose a concussion (/NewsEvents/Newsroom/PressAnnouncements/ucm635720.htm)**
- **Traumatic Brain Injury: FDA Actions and Research (/ForConsumers/ConsumerUpdates/ucm519116.htm)**
- **Centers for Disease Control and Prevention Heads Up Initiative (https://www.cdc.gov/headsup/)**

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV, (mailto:DICE@FDA.HHS.GOV)**800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

2019 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm630141.htm)

2018 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)