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InMode: Company Only Recently Began Submitting Required Malfunction and Injury Reports to FDA

Prior to last month, InMode (INMD), a manufacturer and vendor of aesthetic medical devices, had not been submitting mandatory reports to the Food and Drug Administration regarding injuries and malfunctions stemming from the use of its devices, according to a *Capitol Forum* analysis of an FDA database. The omission may violate the Food, Drug, and Cosmetic Act and could result in civil monetary penalties and revocation of device clearances.

Under federal regulations, manufacturers are required to submit medical device reports (MDRs) to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database when they become aware that a device has malfunctioned or caused a serious injury or death.

The interactive MAUDE website is updated monthly and, while the FDA seeks to include all reports received prior to the update, it notes that some reports may be delayed. A recent search of the MAUDE database finds that, prior to February 2023, no MDRs had ever been submitted by InMode; instead, reports in the database about InMode products had been submitted by doctors and patients harmed by the devices.

After *The Capitol Forum* began investigating this issue, however, InMode submitted seven MDRs to the FDA between February 15 and February 20, 2023, according to a recent search.

The timing of InMode's submissions is curious, given that some of the events it reported occurred in 2021.

Moreover, a search of personal injury lawsuits filed against InMode over the last several years indicates that the company has been aware of dozens more alleged serious injuries that it never reported to the FDA. At least one lawsuit even accuses InMode of unlawfully suppressing reports to MAUDE.

Before the February 2023 MDRs had been made available on the MAUDE website, *The Capitol Forum* asked the company about the lack of any reports submitted by InMode. Legal counsel responded that InMode has submitted at least seven reports to MAUDE.

After the February 2023 update to the MAUDE site, *The Capitol Forum* followed up with questions regarding the company's apparent decision to begin reporting adverse events to MAUDE, the timing of that decision, and why there weren't any reports submitted by InMode on the MAUDE website prior to February. The company did not respond to these questions.

InMode's devices generally use high levels of radiofrequency energy to damage skin in a controlled manner in order to melt fat and promote new skin cell growth; as a result, a lot of injuries alleged in lawsuits and complaints relate to burn marks and permanent scarring from the energy produced by the devices. Some of the alleged injuries that relate to the company's facial devices also detail permanent nerve damage.

Madris Kinard, the former adverse event subject matter expert at the FDA and founder of Device Events, which provides analysis of the MAUDE database, tells *The Capitol Forum* that the types of injuries described by patients and plaintiffs "would absolutely be MDR-reportable."

"There is not a single report from the manufacturer which almost always signals to me that they don't report complaints to the FDA as MDRs," Kinard opined in an interview before the recent update of the MAUDE database.

Company required to submit adverse events to MAUDE. According to the Code of Federal Regulations, manufacturers are required to report adverse events within 30 days of becoming aware that a marketed device "may have caused or contributed to a death or serious injury, or has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

Importantly, the regulations define a serious injury as one that is either "life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage."

InMode's own SEC filings note this requirement, saying that "the timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event."

"We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product," the filing continues, "If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products."

This, however, is not the first time that InMode has been scrutinized for not reporting adverse events to MAUDE. In 2015, a local news station found that InMode was not submitting MDRs to the FDA in a report about two women severely burned by the company's Fractora device.

According to that article, "the FDA would not comment specifically on the [InMode] case but told CBS11 through email if a manufacturer does not comply with these and other medical device reporting requirements, the FDA may take enforcement action against the manufacturer."

The Capitol Forum reached out to the FDA about any follow up it had conducted regarding InMode's reporting requirements since 2015; the FDA did not respond.

Injuries identified in MAUDE data would trigger reporting requirements. While there is no indication that an InMode device has ever contributed to a death, numerous adverse events identified by *The Capitol Forum* likely meet the FDA's definition of serious injuries given that they result in permanent damage and impairment to the body. Some MDRs also mention the need for corrective surgery, another detail that would likely meet the definition for a serious injury.

Examples of permanent injuries requiring surgical repair can be found within the MAUDE database itself in the MDRs submitted by doctors and patients.

For example, an MDR submitted about a Morpheus8 treatment in January of 2023 notes that the procedure resulted in "unwanted permanent fat loss, changes in my face structure, and indentations in my face which will require surgical repair."

Other MAUDE reports indicate nerve damage resulting from InMode treatments, such as a 2021 FaceTite procedure which resulted in the patient's "right side of mouth sagging post FaceTite treatment."

Some of the MDRs submitted by doctors and patients also indicate that the company was notified of these issues. According to one, a patient who was burned by a BodyTite procedure "emailed MFR [manufacturer] from PT [Patient] inquiry form on company's website stating she has burns on legs from BodyTite treatment and to contact her," but InMode did not appear to report this injury to the FDA.

Voluntary reports submitted by a doctor or patient do not satisfy the reporting obligations of the manufacturer, Kinard explained.

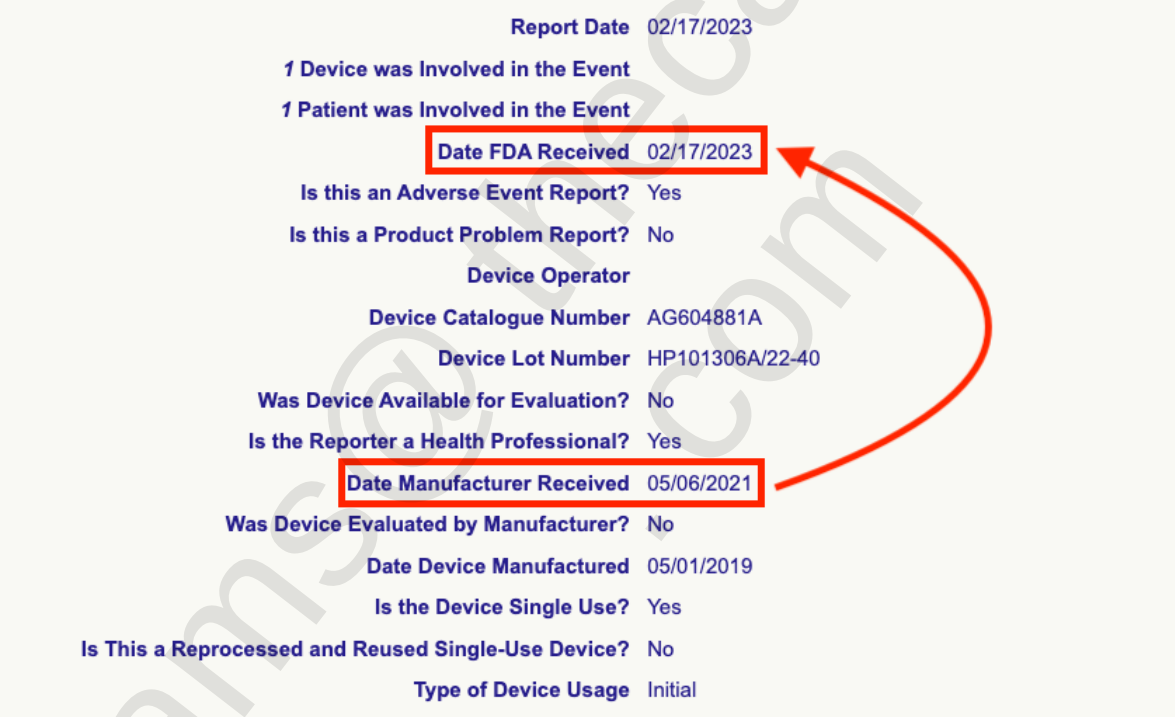
"Physician reports directly to the FDA are deemed to be voluntary reports because physicians are not mandated to report. With that being said, the manufacturer should be submitting a manufacturer

narrative in an MDR to the FDA anytime there is a report to the FDA," Kinard said, "This is required if a User Facility reports, but certainly the FDA would welcome the additional information a manufacturer can provide even when the report is deemed voluntary."

By comparison, Cutera (CUTR), a company which makes devices that offer similar sculpting and skin care procedures, has submitted over 40 MDRs to the FDA, constituting roughly two-thirds of all reports concerning its products. Prior to February 2023, there were 27 reports in the MAUDE database for InMode products, none of which were submitted by the company.

Company submits seven reports in February, company knew of three in 2021, and five blame user error. As previously mentioned, after *The Capitol Forum* began investigating this issue, InMode submitted seven MDRs to the MAUDE database.

While those reports were submitted to the FDA in mid-February, several of the reports indicate that the company knew of the injury for over a year before notifying the FDA; three of the seven reports indicate that InMode was informed of the event in 2021.



Report Date	02/17/2023
1 Device was Involved in the Event	
1 Patient was Involved in the Event	
Date FDA Received	02/17/2023
Is this an Adverse Event Report?	Yes
Is this a Product Problem Report?	No
Device Operator	
Device Catalogue Number	AG604881A
Device Lot Number	HP101306A/22-40
Was Device Available for Evaluation?	No
Is the Reporter a Health Professional?	Yes
Date Manufacturer Received	05/06/2021
Was Device Evaluated by Manufacturer?	No
Date Device Manufactured	05/01/2019
Is the Device Single Use?	Yes
Is This a Reprocessed and Reused Single-Use Device?	No
Type of Device Usage	Initial

Source: FDA MDR Report 3010511300-2023-00036

It is unclear why InMode waited so long to report the adverse events to the FDA. All of the MDRs relate to injuries, which the company is required to report to the FDA within 30 days of becoming aware; InMode did not respond to questions regarding this delay.

Five of the seven MDRs submitted by InMode also appear to blame user error, rather than the devices itself, for the injuries. For example, one relating to a 2021 injury from a FaceTite procedure that left a patient with facial nerve damage blames "mechanical user error related to an incorrect maneuver of the cannula in the area of the path of the marginal mandibular nerve, in contrary to the instructions given in our user manual."

Two of the narratives submitted by the company also appear to be written in a way to not discourage use of the device, citing other instances that did not result in injuries.

For example, one narrative regarding nerve damage from a 2022 Morpheus8 treatment states "the actual ability of frf [radiofrequency] to damage the mandibular nerve are negligible considering the mode of penetration of the needles, the depth of action and the fact that we have never had a similar case, having a history of hundreds of thousands of treatments with m8 [Morpheus8]."

InMode's contention that it has never had a similar case is interesting, given that the company was sued in 2018 after its Fractora device (the predecessor to the Morpheus8) caused similar nerve damage in a patient, as discussed below.

Personal Injury lawsuits indicate company is likely aware of more injuries. Despite InMode's recent submissions to the MAUDE database, the company has likely been made aware of other serious injuries given that it has been sued by several of its patients.

The Capitol Forum found 16 lawsuits against InMode from patients that detail several serious injuries; some lawsuits involve multiple injuries stemming from multiple InMode treatments.

Many of the claims for relief in the lawsuits also seek or sought payment for corrective surgeries for the damage caused by InMode's products, which would further meet the FDA's definition of a serious injury.

One lawsuit, for example, was brought by Janice Newman, a weather anchor at Fox News. According to the complaint, InMode's Fractora procedure "left Janice with severe—and, to date, permanent— nerve damage, causing continuing facial paralysis, drooping and an uneven smile. For months, Janice suffered symptoms so severe, she could not speak clearly and had difficulty eating and drinking."

Newman's lawsuit, filed with two other women harmed by the Fractora procedure, also claims that InMode has purposefully withheld reports to the FDA regarding injuries.

"[InMode] has unlawfully suppressed reporting of adverse events that may have prevented injury

to Plaintiffs. Plaintiffs are aware of at least eleven victims of the Fractora procedure—all of whom [InMode] is aware—that fall within the mandatory reporting guidelines," the complaint alleges, "In some cases, the President of [InMode] has himself referred to the incidents as 'adverse events. Yet, [InMode] has yet to report a single adverse event related to the Fractora procedure."

The Capitol Forum spoke with Amy Davis, a lawyer in Dallas who has represented several plaintiffs, including Newman, in personal injury cases against InMode.

Davis told *The Capitol Forum* that she estimated that there should be at least twice as many reports to MAUDE, based just off of the cases of which she is aware.

The number of cases filed against InMode directly, however, likely belies the total number of legal cases involving the company's products, according to Louiza Tarrassova, another plaintiff's attorney specializing in cosmetics and cosmetic procedures.

Tarrassova currently has three cases involving burns and scarring resulting from use of InMode's Diolaze hair-removal system. However, those cases have been brought against the physicians that performed the procedures, rather than InMode itself.

"It's actually pretty hard to bring a case against the manufacturer themselves, because there is a learned intermediary issue," Tarrassova explained, "The responsibility largely falls on the provider, even though manufacturer is in the best position to know these issues about their device."

"Unfortunately, I have taken depositions where the doctors were under the impression, based on the representations from the sales reps, that these devices can be used by unexperienced or unlicensed technicians on their patients," Tarassova continued, "But these devices are very powerful and can hurt people even in the most experienced hands. The doctors are completely blindsided when an injury occurs."

Davis echoed this sentiment, telling *The Capitol Forum* that "in cases I've had, I feel for these doctors. They feel they have been duped just as bad by InMode as the patients. For a long time, InMode was selling these powerful lasers to gynecologists, family care practitioners, providers that have no business using the devices. InMode would promise to help them with marketing and training, and then wouldn't support them, and these doctors would injure people because the instructions are way too aggressive."

The Capitol Forum has reported that InMode sales representatives have previously misrepresented the licensing requirements for operation of the company's machines as well as the earnings potential of the devices to doctors.

User error triggers mandatory reporting. According to Kinard, some manufacturers like to stick to relatively limited interpretations of the reporting requirements. However, Kinard notes that the definitions in the regulations are very specific, such as the definition of "caused or contributed," which includes issues resulting from malfunctions or use errors.

While InMode may fault the provider themselves, Kinard says that even those should trigger mandatory reporting on the part of InMode.

"Even if the manufacturer is putting the onus on the care provider, they are still required to report it," Kinard explained, "It's concerning that physicians don't report more, but they feel they are self-reporting and will get in trouble. The FDA's function isn't to go after doctors, though. When they don't report the device, it makes it appear to the FDA that the device is safer than it is."

Davis also noted that it is unreasonable for the company to blame users given that the doctors she has dealt with are mostly using InMode's devices the way the company has trained them to.

"InMode recommends using the devices at the most aggressive settings because in plastic surgery, results are king," Davis explained, "No one wants to not be able to tell the before and after photos from each other. It's ridiculous for InMode to blame issues on user error because they are using them how the company has told them to."

"Even so, manufacturers are supposed to give instruction based on the intended use and the foreseeable misuse of the device," she added.

While InMode may feel that some damage caused by its products or their use by doctors does not warrant reporting, Tarassova tells *The Capitol Forum* that InMode patients represent a vulnerable population that should be given all necessary information when deciding to undergo treatment.

"You've got to look at what the patient went there for," Tarassova said, "These people are very vulnerable because they go in with an insecurity about something in their appearance and now they are walking away with this adverse effect that's made their problem worse and more visible."

"There is a lot of shame involved," Tarassova opined, "They blame themselves for the vanity of it. And that's the sad thing, because companies like InMode make millions of dollars off the insecurities of people and can damage them with little responsibility."