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Captaining a Crisis: Signs, Symptoms and Defensive Actions to Right the Ship

Bryant Godfrey, Areta Kupchyk, Lynn Neils, Veronica Renzi & Peter Sullivan

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**Bryant Godfrey**

Partner

Washington, DC

202.261.7393

bgodfrey@foleyhoag.com

**Areta Kupchyk**

*Partner, Co-Chair, Administrative Law
Department and FDA Practice*

Washington, DC

202.261.7324

akupchyk@foleyhoag.com

**Lynn Neils**

Partner

New York

212.812.0420

lnails@foleyhoag.com

**Veronica Renzi**

Partner

Washington, DC

202.261.7316

vrenzi@foleyhoag.com

**Peter Sullivan**

Partner

New York

212.812.0310

psullivan@foleyhoag.com

- Wannabea Device Co., Inc (“Wannabea”) recalled its top-selling Oh-So Good™ Ventilators in December 2021 due to a defect in the sound abatement foam, which is used to reduce sound and vibration while the devices are running. The foam, which is made of a polyester-based polyurethane (PE-PUR), reportedly could break down and debris could enter the device’s air pathway and, thus, could be inhaled by a patient using the device.
- Exposure to PE-PUR debris could cause serious adverse events in patients such as irritation (skin, eye, and respiratory tract), asthma, inflammation, nausea/vomiting, adverse effects to other organs (e.g., kidneys and liver), and carcinogenic effects

- FBI conducts a search of Wannabea's manufacturing site on February 7, 2022, arriving at 7:00am, and agents proceed to interview employees at the site as part of its investigation
- DOJ also issues a CID to Wannabea for documents related to its recall of its Oh-So Good™ Ventilators, including drafts of all reports and notes of all meetings with FDA, on the same day
- The Press gets wind of the search of Wannabea's manufacturing site and shows up on site, while the FBI is conducting its search; reporters asking company and site management for comment

- The first complaint of debris in the air pathway was reported in January 2021
- 75 complaints were reported in the next two months (January-February)
- At the end of February, Wannabea opened an investigation and worked with the device contract manufacturer but was not able to identify a root cause of the debris seen in the air pathway
- 75 complaints were reported during the following 2 months (April-May)
- 25 complaints were reported in June
- Less than 10 complaints were reported in July
- No complaints were received after July

- Wannabea continued its investigation and narrowed the probable root cause to the foam
- Turns out the manufacturer had changed foam suppliers the previous December 2020 because of supply chain problems
- In May 2021, the manufacturer again changed suppliers - back to its original foam supplier - when the supply chain problem was resolved. Complaints then decreased dramatically
- No adverse events were reported
- The device has a safety feature that shuts down the ventilator if any debris is detected
- Because of this critical safety feature and the complete lack of adverse events, Wannabea decided not to prepare a formal Health Hazard Evaluation because it concluded there was no risk to patients
- Users returned the devices that had turned off because of the presence of debris and received new devices from Wannabea

Quality Unit and Management Decision

- In an internal company meeting, the Wannabea Quality Unit recommended initiating a recall in March
- Because the investigation was ongoing in March, Management decided to wait until the investigation was completed before deciding whether to initiate a recall
- Because the number of complaints and returns had significantly declined, and because of the safety feature that shuts down the device when debris is present was working properly, Wannabea management decided not to conduct a recall

- FDA conducted an inspection of Wannabea in November 2021 after receiving a tip from a former employee
- FDA asked Wannabea to provide the HHE in response to the complaints
- Wannabe explained why they had not done an HHE
- FDA asked for minutes of the Quality Unit meeting where they had decided not to conduct the HHE or a recall
- Wannabea's SOP stated that minutes would be kept of all Quality Unit meetings
- Wannabea never finalized its minutes of the meetings, therefore, had nothing to provide to FDA

- Based on comments by the FDA investigator during the inspection, Wannabea decided to do the following during the inspection:
 - Finalize its minutes and provide them to FDA
 - Finalize its draft HHE and provide it to FDA
 - Initiate a recall of the Oh-So Good™ Ventilators made with the suspected foam component.
- After finalizing the minutes and the HHE, a manager at Wannabea instructed employees to delete all drafts of meeting minutes discussing the HHE and drafts of the HHE, including the underlying notes, saying that they were no longer needed
 - The initial Whistleblower tells the FDA that important evidence is being destroyed

Investigation into Complaints

Interaction between Quality Unit and Management at the Meeting

Meeting Minutes (Recall and HHE Decision)

Preservation of documents/evidence

Response to regulatory and enforcement actions and press inquiries

Investigation into Complaints

Interaction between Quality Unit
and Management at the Meeting

Meeting Minutes
(Recall and HHE Decision)

Preservation of documents /
evidence

Response to regulatory &
enforcement actions and press
inquiries

- What went wrong?
 - Investigation could not turn up the root cause (quickly or w/specificity)
 - Unaware of a change in a component that could affect quality/safety

- Best Practices
 - Robust change control provisions in manufacturing agreements
 - Site Audits
 - SOPs governing company investigations
 - Solicit outside expert assistance when needed
 - Don't delay investigating
 - Works to stymie the "snowball" effect

Investigation into Complaints

**Interaction between Quality Unit
and Management at the Meeting**

Meeting Minutes
(Recall and HHE Decision)

Preservation of documents /
evidence

Response to regulatory and
enforcement actions and press
inquiries

- What went wrong?
 - Disagreement over when and whether to initiate a recall
- Best Practices
 - SOPs on handling safety issues (including decision trees)
 - Help curb emotion & split decision-making
 - SOPs on handling of disagreements in meetings
 - Ensure that commercial objectives do not trump safety and regulatory obligations

Investigation into Complaints

Interaction between Quality Unit
and Management at the Meeting

**Meeting Minutes
(Recall and HHE Decision)**

Preservation of documents /
evidence

Response to regulatory and
enforcement actions and press
inquiries

Meeting Minutes

- What went wrong?
 - Minutes not finalized
- Best Practices
 - Neutral person should capture minutes
 - Stick to big picture topics
 - Capture all sides
 - Document conclusions and/or next steps, not the deliberation.
 - Select appropriate personnel to review & finalize

Investigation into Complaints

Interaction between Quality Unit
and Management at the Meeting

**Meeting Minutes
(Recall and HHE Decision)**

Preservation of documents /
evidence

Response to regulatory and
enforcement actions and press
inquiries

Recall Decision

- What went wrong?
 - Decided not to conduct a recall
- Best Practices
 - SOPS that discuss when and how to conduct recalls
 - Appropriate personnel should be included in the decision (e.g., Regulatory, Quality, Safety, legal)
 - Follow FDA's Recall Policy
 - Consider shortages and notify FDA

Investigation into Complaints

Interaction between Quality Unit
and Management at the Meeting

**Meeting Minutes
(Recall and HHE Decision)**

Preservation of documents /
evidence

Response to regulatory and
enforcement actions and press
inquiries

Risk Analysis: HHE

- What went wrong?
 - Did not conduct an HHE
- Best Practices
 - HHE not only reserved in the case of recalls
 - SOPs that discuss when and how to conduct HHE
 - Takes guesswork out of the equation
 - Appropriate personnel involved (scientific, product engineers, quality, etc.)
 - Involve outside experts when needed
 - Document all steps taken

Investigation into Complaints

Interaction between Quality Unit
and Management at the Meeting

Meeting Minutes
(Recall and HHE Decision)

**Preservation of documents /
evidence**

Response to regulatory and
enforcement actions and press
inquiries

■ What went wrong?

- Order by company manager to get rid of drafts of documents and notes of meetings led government to assume that the company, or its employees, might be trying to destroy evidence
- Led to DOJ obtaining a search warrant, which is disruptive to the business, provides an opportunity for agents to interview employees, and leads to press inquiries and speculation; gives ammunition to prosecutors and other litigants in subsequent legal proceedings

■ Best Practices

- Think ahead: when FDA commences an investigation or makes inquiries, consider hold-notice, or instructions to personnel to safeguard all documentation, including drafts, even if no formal action taken yet
- Establish clear policies about what types of documents should be kept regarding meetings with regulators/regulatory decisions.
- Appropriate personnel should be included in all decisions (e.g., Regulatory, Quality, Safety, Legal)
- Document company's efforts, including to preserve all relevant evidence

Investigation into Complaints

Interaction between Quality Unit
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Meeting Minutes
(Recall and HHE Decision)

Preservation of documents /
evidence

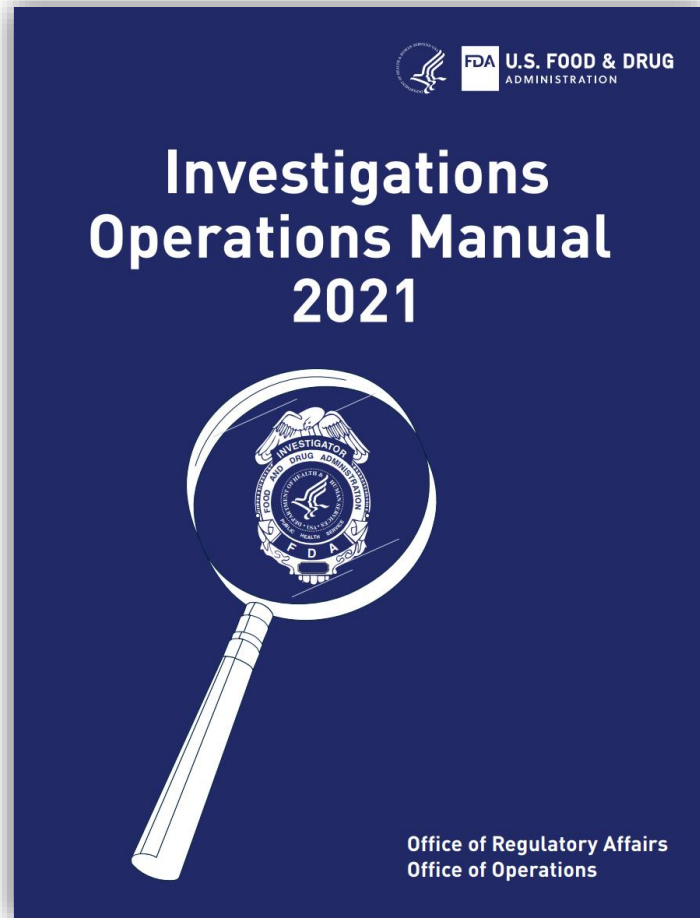
**Response to regulatory and
enforcement actions and press
inquiries**

■ What went wrong?

- Claim regarding destruction of documents leads to implication that company and personnel are hiding something, even if no intent
- Led to DOJ conducting a search of the manufacturing site/issuing a CID
- Search warrant results in agents on site and undocumented interviews of employees and disruption to the business
- Search warrant of site leads to press inquiries and requests for explanations/statements

■ Best Practices

- As indicated before, clear policies about what types of documents should be kept regarding meetings with regulators/regulatory decisions
- SOPs on what to do if government outreach, with examples of the types of government outreach and what to do, including whom to contact
- SOPs or other policies on press inquiries – who, how, when to notify
 - Press inquiries and government actions lead to other issues that will be discussed in future programs, including crisis response, regulatory disclosure (if public company) and board notice and involvement



- The IOM is the primary operational reference for FDA employees who perform field investigational activities.
- It directs the conduct of all fundamental field investigational activities.

CHAPTER 8 - INVESTIGATIONS

8.1 - INVESTIGATIONS AND INSPECTIONS	8-4
8.1.1 - BACKGROUND – WHAT IS AN INVESTIGATION?	8-4
8.1.2 - INVESTIGATIONS, INSPECTIONS, AND FORM 482? – WHEN DO YOU ISSUE AN FDA 482?	8-4
8.1.3 - EXTERNAL REQUESTS FOR INVESTIGATIVE INFORMATION – WHAT IF SOMEONE ASKS YOU ABOUT AN INVESTIGATION?	8-4
8.1.4 - OFFICE OF CRIMINAL INVESTIGATIONS – WHO IS OCI?	8-4
8.1.4.1 - OCI RESPONSIBILITIES	8-4
8.1.4.2 - REPORTS OF CRIMINAL ACTIVITY	8-4
8.1.4.3 - LIAISON WITH LAW ENFORCEMENT / INTELLIGENCE COMMUNITY	8-5
8.1.5 - TYPES OF INVESTIGATIONS – WHAT SITUATIONS LEAD TO INVESTIGATIONS?	8-5
8.1.5.1 - DEFECTIVE PRODUCTS	8-5
8.1.5.2 - INJURY, ILLNESS, DEATH	8-6
8.1.5.3 - CRIMINAL INVESTIGATIONS	8-6
8.1.5.4 - SURVEILLANCE	8-6
8.1.5.5 - WASHOUTS	8-7
8.1.5.6 - FOR CAUSE/FACT-FINDING/INFORMATION GATHERING	8-7
8.1.5.7 - COMPLAINTS	8-7
8.1.5.8 - DISASTER/EMERGENCY RESPONSE – HOW DO WE PROTECT THE CONSUMER DURING A DISASTER OR EMERGENCY?	8-10
8.1.5.9 - COUNTERFEITING AND TAMPERING	8-18
8.1.6 - GENERAL INVESTIGATIVE TECHNIQUES – WHAT DO I DO DURING AN INVESTIGATION?	8-22
8.1.6.1 - INTERVIEWS	8-22
8.1.6.2 - MEDICAL RECORDS	8-24
8.1.6.3 - SAMPLE COLLECTION	8-26
8.1.6.4 - INTERNET INVESTIGATIONS	8-26
8.1.7 - LOCATIONS FOR INVESTIGATIONS – WHERE COULD YOU CONDUCT AN INVESTIGATION?	8-27
8.1.8 - INTERNAL AND EXTERNAL ORGANIZATIONS INVOLVED - WHO ELSE WILL I ENCOUNTER DURING AN INVESTIGATION? WHY ARE THEY INVOLVED?	8-27
8.1.8.1 - INTERAGENCY REFERRAL	8-27
8.1.8.2 - INTRA-AGENCY/CROSS-PROGRAM	8-27
8.1.9 - GENERAL INVESTIGATION REPORTING - HOW DO I REPORT MY INVESTIGATION? HOW DO I GET CREDIT FOR THE TIME I SPENT ON IT?	8-28
8.1.9.1 - ENTERING INVESTIGATION OPERATIONS IN ENSPECT	8-28
8.1.9.2 - INVESTIGATION MEMO: FORMAT, CONTENT, ENDORSEMENT, AND ROUTING	8-29
8.1.9.3 - REPORTING COMPLAINTS/FOLLOW-UPS	8-29
8.1.9.4 - REPORTING INFORMATION OBTAINED FROM A CONFIDENTIAL INFORMANT	8-30
8.1.9.5 - REPORTING INVESTIGATIONS CONDUCTED DURING DISASTER RESPONSE	8-30
8.2 - HUMAN AND ANIMAL FOOD INVESTIGATIONS	8-32
8.2.1 - COORDINATION	8-32
8.2.2 - FOODBORNE ILLNESS OUTBREAK INVESTIGATIONS	8-32
8.2.2.1 - COOPERATION WITH OTHER AGENCIES	8-32
8.2.2.2 - OUTBREAKS ON FOREIGN FLAG VESSELS	8-33

8.1.5 - Types of Investigations – What situations lead to investigations?

You may conduct a variety of investigations in your career. Some types of investigations include, but are not limited to complaint investigations, disaster investigations, health fraud investigations, and product tampering investigations. When conducting any investigation, keep an open mind. Each investigation will be unique.

8.1.5.1 - Defective Products

A defective product is one that fails to do what it is expected to do. For example, a diabetes medication that fails to adequately control blood sugar levels that is prescribed for that reason. A defective product will typically result in a recall where the product may be destroyed or reconditioned.

Investigations into defective products could be initiated as a result of consumer or industry complaints that may indicate the need for follow up with the consumer or industry representative, which would be conducted as an investigation. Investigations are initiated in order to determine facts surrounding a claim related to the status or disposition of a subject FDA-regulated product. Subsequent findings would determine necessary follow-up and/or FDA action (e.g. inspection, sampling, product recall).