UNITED STATES DISTRICT COURT

for the

District of New Jersey

United States of America
v.
Pentax of America, Inc., dba Pentax Medical Company

Case No. 20-2054

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of 7/2013-9/2013, 4/2014-9/2015 in the county of _____ in the _____ District of New Jersey, the defendant(s) violated:

Code Section	*Offense Description*
21 U.S.C. 331(a), 333(a), 333(a)(1)	Introduction of misbranded medical devices into interstate commerce

This criminal complaint is based on these facts:

See Attachment A

☑ Continued on the attached sheet.

Joseph E. Niedzwecki -S

Digitally signed by Joseph E. Niedzwecki -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=20006 66827, cn=Joseph E. Niedzwecki -S
Date: 2020.04.02 12:15:16 -04'00'

Complainant's signature

Joseph Niedzwecki, Special Agent, FDA-OCI

Printed name and title

Sworn to before me and signed in my presence.

Date: 04/07/2020

Judge's signature

City and state: Camden, New Jersey

Joel Schneider, United States Magistrate Judge

Printed name and title

ATTACHMENT A

STATEMENT OF FACTS

Summary

1. PENTAX OF AMERICA, INC., doing business as PENTAX MEDICAL COMPANY ("PENTAX"), which has its principal place of business in Montvale, New Jersey, is a United States subsidiary of HOYA, a medical technology corporation based in Tokyo, Japan.

2. PENTAX manufactures and distributes medical devices, including endoscopes. An endoscope is a thin, flexible tube with a powerful light and a tiny camera that is inserted into the body to give a physician a view of the internal parts of a patient's body. Endoscopes may have instruments at the end of the tube that physicians use to perform surgical procedures. Among the endoscopes that PENTAX manufactures and distributes are duodenoscopes, colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes.

3. From 2013 to 2015, within the District of New Jersey, and elsewhere, acting through its employees, including senior managers, PENTAX introduced and delivered for introduction into interstate commerce medical devices that were misbranded, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(1).

   a. From on or about July 25, 2013, until on or about September 20, 2013, and from on or about July 27, 2014, until on or about December 15, 2014, PENTAX failed to file required Medical Device Reports ("MDRs") with the U.S. Food and Drug Administration ("FDA") about adverse events involving PENTAX's duodenoscope. The shipment of duodenoscopes for which information required by the FDCA had not been furnished rendered the medical devices misbranded, pursuant to 21 U.S.C. § 352(t)(2).

   b. From on or about April 9, 2014, until on or about September 30, 2015, PENTAX distributed four types of endoscopes in the United States with unapproved instructions for use ("IFUs"). The shipment of endoscopes with inadequate instructions for use rendered the medical devices misbranded, pursuant to 21 U.S.C. § 352(f).

Failure to Timely File Medical Device Reports

The FDA and the FDCA

4. The FDA is responsible for protecting the health and safety of the American public by assuring, among other things, that medical devices intended for use in the treatment of human beings are safe and effective for their intended uses. Pursuant to its statutory mandate, the FDA regulates the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

5. The FDCA, among other things, governs the manufacture and interstate distribution of medical devices for human use, as codified at 21 U.S.C. §§ 301-399f.

6. The FDCA and its implementing regulations provide a mechanism that allows FDA, and others, to identify and monitor adverse events (deaths and serious injuries) and certain malfunctions involving medical devices. Pursuant to 21 U.S.C. § 360i(a) and 21 CFR Part 803, medical device manufacturers must (1) develop, maintain, and implement written procedures for the identification and evaluation of all malfunctions, serious injuries, and deaths to determine whether an MDR is required for an event; (2) submit MDR reportable events involving their medical devices to the FDA; and (3) establish and maintain complete files for all MDR events.

7. Manufacturers must file an MDR with the FDA within thirty (30) days of receiving or becoming aware of information that reasonably suggests that a device the manufacturer markets (a) may have caused or contributed to a death or serious injury or (b) has malfunctioned, and the device or a similar device the manufacturer markets would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

8. MDRs are one of the post-market surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of devices.

9. A device is deemed to be "misbranded" under 21 U.S.C. § 352(t)(2) if a manufacturer fails or refuses to furnish any material information required by or under 21 U.S.C. § 360i respecting the device, including MDRs and supplemental MDRs. The FDCA prohibits the introduction of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

Advocate Lutheran General Hospital

10. On or about June 25, 2013, PENTAX learned that four patients at Advocate Lutheran General Hospital in Chicago, Illinois, were infected with carbapenem-resistant Enterobacteriaceae after being treated with the same PENTAX duodenoscope. PENTAX later learned that more than 30 patients at that hospital were infected, including two patients who died, although the duodenoscope was not necessarily the cause of the infections and the infections were not necessarily the cause of death.

11. PENTAX was required to file MDRs about the infections of the four patients by July 25, 2013, but did not do so because the employees involved misunderstood the company's MDR-reporting responsibilities.

12. PENTAX filed an MDR about the infections at Advocate Lutheran General Hospital on or about September 20, 2013.

Massachusetts General Hospital

13. On about June 27, 2014, PENTAX learned that four patients at Massachusetts General Hospital in Boston, Massachusetts, were infected after being treated with the same PENTAX duodenoscope. PENTAX later learned that approximately 12 patients at that hospital were infected with Escherichia coli bacteria, none of whom died.

14. PENTAX was required to file MDRs about the infections of the four patients by July 27, 2014, but did not do so because the employees involved misunderstood the company's MDR-reporting responsibilities.

15. PENTAX filed an MDR about the infections at Massachusetts General Hospital on or about December 15, 2014.

16. PENTAX's gross profits from sales of the duodenoscope sales during the two months in 2013 and the four months in 2014 when the scope was misbranded were about $350,000.

Distribution of Endoscopes with Unapproved Instructions for Use

17. Because endoscopes are reusable devices, endoscopes must be cleaned – or "reprocessed" – after each use. If an endoscope is not cleaned properly, infectious material may remain on or in the endoscope, and subsequent patients treated with the endoscope may become infected, which may lead to serious illness or death.

18. The FDCA requires medical devices to bear adequate instructions for use. An endoscope's instructions for use include the reprocessing procedures established by the manufacturer.

19. A device is deemed to be "misbranded" under 21 U.S.C. § 352(f) if it bears inadequate instructions for use. As noted above, the FDCA prohibits the introduction of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

20. In or around 2011, the FDA issued new guidance that called for manufacturers to make instructions for cleaning scopes more specific and more stringent.

21. In or around 2013, PENTAX submitted to the FDA revised IFUs for cleaning four of its endoscopes that were already being lawfully distributed in the United States. The four types of endoscopes included PENTAX's colonoscopes, gastroscopes, bronchoscopes, and ultrasound bronchoscopes, and will hereinafter be referred to as the "four scopes."

22. The FDA rejected the revised IFUs for the four scopes and said PENTAX either needed to (a) conduct additional testing to "validate" – *i.e.*, prove to the FDA – that the IFUs PENTAX had submitted would be effective in cleaning the scopes or (b) add additional steps to the instructions to meet worst-case scenarios.

23. PENTAX advised the FDA that it would meet the FDA's requirements by initially implementing the latter (adding steps to the cleaning instructions) while working to satisfy the FDA as to the former (conducting studies to try to validate the shorter set of cleaning instructions).

24. On or about April 9, 2014, the FDA approved revised PENTAX IFUs for the four scopes that contained additional cleaning steps. At that point, PENTAX was required to distribute these four scopes with the newly FDA-approved IFUs.

25. Instead, for the next 18 months, through September 2015, PENTAX shipped the four scopes with the old IFUs, not the new, more stringent, FDA-approved, now-required IFUs. PENTAX made a deliberate business decision to continue to use the older IFUs because it feared the additional cleaning steps required by the new IFUs would result in the loss of business. "Taking a manual cleaning process from 5 to 25 minutes is going to be catastrophic," one PENTAX employee wrote to another employee on April 4, 2014. Another internal email, on July 28, 2014, predicted the result of the new IFUs would be that customers "will be very upset and could switch away from PENTAX because of the extra time, labor, manpower, and cost to perform the new protocol."

26. In or around the end of September 2015, PENTAX began distributing two of the four types of scopes with the IFUs that the FDA had approved on or about April 9, 2014, and began distributing the other two types of scopes with new, shorter, validated cleaning instructions.

27. PENTAX's gross profits from sales of the four types of scopes from April 2014 to September 2015, when the scopes were misbranded, were about $18 million.