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ANALYSIS OF MEDICAL DEVICES RECALL IN 2019

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ABSTRACT

A recall is a mechanism for the elimination or modification of items that violate the laws of the Food and Drug Administration (FDA). The FDA medical device recalls database was used to identify recalls of medical devices. Maximum devices are worldwide distribution and some are US national wide distribution at the time of recall. Recall is voluntary action. 49 medical devices recalls in 2019 compared to previous years because medical devices reliant on software or computer technology especially in July 8 recall and in September only one recall are occurred it is the highest and least number of recalls in 2019 respectively. 2 recall in January, March, October and 3 recalls in April and June. Number of medical devices recall based on their recall reason. Market numbers of medical devices are increasing that rely on computer technology it is trigger problems. If a company fails to recall any device or product associated with serious health problems or death.

Keywords: Food and Drug Administration, Medical devices, code of federal regulations, Federal Food, Drug, and Cosmetic Act

INTRODUCTION

A recall is a mechanism for the elimination or modification of items that violate the laws of the Food and Drug Administration (FDA). Recall is voluntary action because manufacturers and distributors have a duty to protect public health and well-being against products which pose or are otherwise deficient in a risk of harm or gross

disappointment. 21 CFR 7 provides recommendations for successful recall by responsible businesses. The supplier typically performs voluntary notification of medical devices in compliance with 21 CFR 7. Rarely, when the manufacturer or importing company refuses to voluntarily recall a health risk product, under 21 CFR 810 Medical Device Recall Jurisdiction, FDA can make a callback order to the manufacturer.21 CFR 810 specifies steps the Federal Food, Drug, and Cosmetic Act (FD&C ACT) (Action) must take to exercise its authority for the reclamation of medical devices in compliance with Section 518(e). Under 21 CFR 806, Correction and Removals of Medical Devices, producers and distributors are required to release to the FDA any correction or removal of any medical device(s) that was undertaken to minimize the risk to health of the patient or to address an infringement of the law caused by a product that could cause health problems. Recalls occur if a medical device is unreliable, may be a safety risk or is both unreliable and a risk to the public a medical device recall does not necessarily mean you need to avoid using the product or return the product to your company. A warning may also include reviewing, changing and repairing the medical device. If the implanted device may malfunction in an unpredictable way, companies also advise their patients to contact them and address the risk of the device being removed in relation to the risk of it being released. Examples on the types of steps which can be taken in recall the medical devices step-(i) Device inspection for issues step-(ii) Device repair step (iii) Device re-labeling step (iv) Device deletion step (v) issue notification step (vi) Health concerns patient surveillance. Often a company knows that a group of products has a problem, but it can not foresee which devices are damaged. The organization should remember a whole lot, model or product line to correctly resolve this problem. In most cases, a medical device or product is recalled on its own (volunteered) by a company (executive producer, supplier or some other responsible party.) If a company learns that a medical device or product is in violation of FDA legislation it does two things they are Initiates a recall (through correction or removal), and Notifies the FDA-The FDA could legally require an enterprise to call an item back. If a company fails to recall any device or product associated with serious health problems or death. It may happen. Through fact, however, the FDA hasn't really ordered a medical device recall **[1]**.

METHOD

The FDA medical device (MD) recalls database was used to identify recalls of medical devices in January 1, 2019, to December 2019. Approval data and recall characteristics were collected for each device, including, device class, FDA reason for recall, and total number of products affected. The FDA reason for recall included issues involving product Device Design, Under Investigation by firm, Process control, Process control, Software in the Use Environment, Component change control, Undetermined by firm, Nonconforming Material/Component, Process change control, Component design/selection, Software design, Use error, manufacturing error, software error, inaccurate INR test results. Adverse event reports unrelated to the manufacturer's reason for recall were excluded from the study. Recalls were categorized as occurring under premarket or postmarked surveillance. Premarket surveillance includes errors not initially detected during the time of product development and application review. Post market surveillance includes errors not readily detectable during the period of approval, such as production and component control. Devices marketed without undergoing FDA review were also listed as a post market surveillance recall. Institutional review board approval was not required as this study did not use human subjects and involved only publicly available data **[2]**. Recalls classified three types they are Class I-a case where there is a fair probability that the use of, or exposure to, a volatile substance could result in significant adverse health or death. Class II-a case where the use or use of a volatile drug may have transient or medically reversible adverse health effects or where the risk of severe adverse health effects is remote. Category III-a condition where the use or exposure to a volatile drug is unlikely to have negative health effects **[3]**.

RESULT

Maximum devices are worldwide distribution and some are US national wide distribution at the time of recall. In assessing the FDA-determined cause for recall, 8(16.32%) of the 49 recalls (100%) were related to device design, 8 (16.32%) are due to under investigation firm, 4(8.16%) were due to process control, 2 (4.08%) were due to soft ware error, 2 (4.08%) was due to device incorrect assembly, and 2 (4.08%) was due to non conforming material, 2 (%) are due to undetermined by firm, 2(4.08%) are due to

use error, 2(4.08%) are due to display incorrect information1(2.04%) are due to potential cyber control risk, 1(2.04%) recall due to component design, 1(2.04%) recall due to component change control, 1(2.04%) recall due to process change control, 1(2.04%) recall due to soft ware in use environment, 1(2.04%) recall due to soft ware design, 1(2.04%) recall due to manufacturing error. The details of reason for recalls listed in **Table 1**. ALL recalls are classified as Class I According to FDA data base entry.

Table 1: Number of medical devices recall based on their recall reason

Reason for recall	Number of recalls
Device design	8
Investigation firm	8
Process control	4
Soft ware error	2
Incorrect assemble	2
Non conforming materials	2
Undetermined by firm	2
Use error	2
Display of incorrect information	2
Potential cyber control risk	1
Component design	1
Component change control	1
Process change control	1
Soft ware in use environment	1
Soft ware design	1
Manufacturing error	1

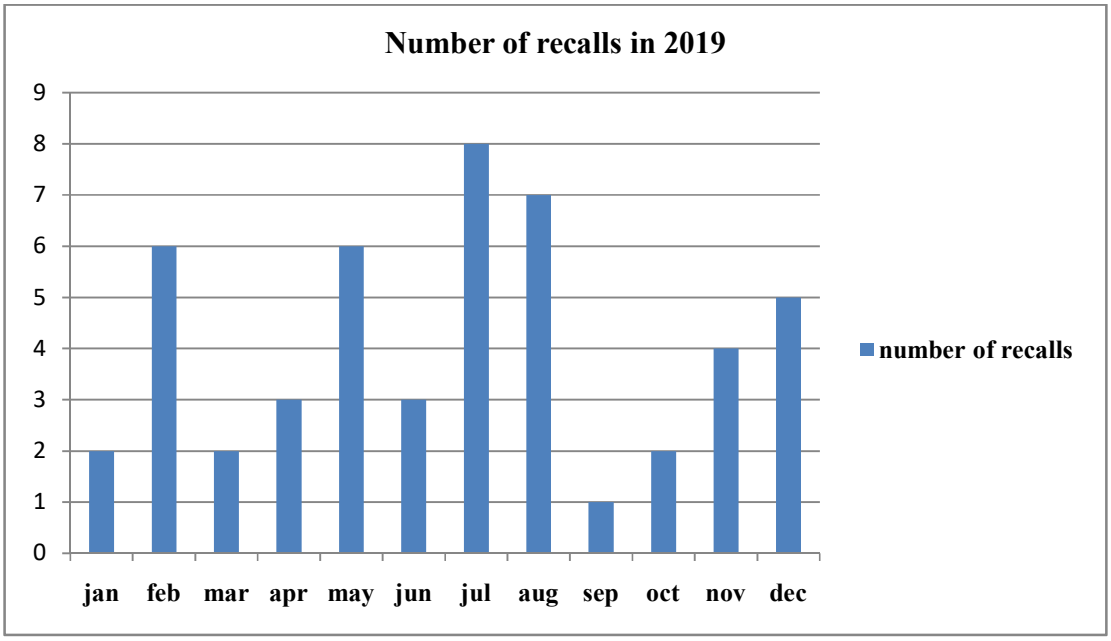

Figure 1: Number of recalls in 2019 every month

DISCUSSION

Our study showed recall of medical devices approved by FDA occur very lees in previous year but in 2019 more number of medical devices are recalled month wise recall details absorbed here there are 5 recalls that related to medical devices are seen in month December there is no death report according to FDA data base entry all are class-I device recall. Synchromed II programmable pump, they only more quantity of devices are recalled that is 10820 and Cross Cath Support Catheter- 20 devices only recalled it is least number of devices in month December. Synchromed II programmable pumps, Cross Cath Support Catheter these two are process control reason only they are recalled according to FDA determine cause **[4-8]**. And in the 11th month 4 recalls that related to medical devices are absorbed in this Rosa Brain 3.0, Centri Mag Acute Circulatory Support System Motor this recall data available 93, and 664 units recalled respectively in this no death report observed in both but Acute Circulatory Support System Motor cause 45 injuries and MiniMed Model 500 and 503 Remote Controllers and Forte Gamma Camera System these two also recalled in November all are class –I recalls **[9-12]**. ECHELON FLEX™ ENDOPATH® Staplers is recalled in October 3, 2019, 7 serious injuries and 1 death had been reported to Ethicon for affected product codes. And also SHERPA NX ACTIVE GUIDING CATHETER it also recalled in October No serious injuries or deaths were reported by this recall only 6 units of SHERPA NX ACTIVE GUIDING CATHETER are recalled both recalls in October are class –I recalls **[13-14]** and in September Natrelle Saline-Filled Breast Implant Biocell Full Height with Fill Tube UT recalled and it is distributed Worldwide and US Nationwide at the time of recalls it is Class-I recall and bio cell textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALC Total 1.4,026,287 Breast Implants and Tissue Expanders are recalled in September **[15]** and In 8th month 7 recalls that related to medical devices in this process change control and process control reason ellipse vr and Filter-Tips, 1500 up (1024 tips/kit box), are recalled and remaining are recalled undetermined cause all are class-I recalls and Sheridan Endotracheal Tube contained inside Centurion kit it was recalled by the device design reason And Edwards sapien 3 Ultra Transcatheter Heart Valve System only show seventeen (17) injuries and one (1) death were reported at the time when Edwards

initiated the Field Corrective Action in July 2019and remaining all recall in august don't shows any injuries and deaths **[16-22]**. IntraClude Intra-Aortic Occlusion Device recalled in July the firm has received 22 complaints related to balloon rupture or puncture. Three deaths have been reported and it distributed worldwide at the time of recall and Alaris Pump Infusion Set also recalled in july This device defect may cause serious adverse health consequences for patients, including death and it distributed worldwide at the time of recall and Hudson rdi neonatal ConchaSmart Breathing Circuit with Dual Heated Limb and ConchaSmart Column, Alaris Pump US national wide distribution and worldwide distribution occur respectively recalls in july month has been associated with MDR reports, several of which are associated with serious injuries Alaris Pump Component design/selection reason recalled. Giraffe Infant Radiant Warmer also recalled in July there is no death reported because of this device. But it distributed worldwide distribution and recalled reason of these devices is device design and Hamilton-G5 Ventilators devices is recalled and there is no patient injury or deaths have been reported due to recall of this device. And SmartSite Syringe Administration Sets are recalled and they not received any reports of serious injury or death **[22-30]**. In 6th month enFlow Disposable Cartridge recalled 5,782,820 units total and Advance Enforcer 35 Focal Force PTA Balloon Catheter 6mm x 4cm these undergo only 131 quantity recalls maximum recalled devices in June are worldwide distribution and US national wide distribution .in the 5th month SOLOPATH Balloon Expandable Transfemoral System, and MoniTorr 10100 10-100 CSF Drainage System w/Patient Line One Way Valve these two are recalled by same reason that is Device Design solopath Balloon Expandable Transfemoral System this firm has received a total of 14 reports of related incidents in which the device has malfunctioned in this manner, including two injuries. No deaths have been reported **[31-33]**. and recall of MoniTorr 10100 10-100 CSF Drainage System w/Patient Line One Way Valve causes Serious patient injuries associated with infection and CSF leakage (over-drainage) related to the failure mode associated with this recall were reported. There were no deaths reported.and all recalls in May are class-I recall **[34-39]**. In the 4th month Spine & Trauma 3D Navigation Software, the Miller Balloon Atrioseptostomy Catheter and Fogarty Dilation Atrioseptostomy Catheter and O-

Two Medical Technologies' e700, e600 and e500 Automatic Transport Ventilators are recalled in April. Spine & Trauma 3D Navigation Software is recalled by the reason incorrect information to display during surgery and O-Two Medical Technologies' e700, e600 and e500 Automatic Transport Ventilators recalled reason recalled because an improperly inserted screw in the ventilator screen . All recalls in April class –I recall **[40-42]**. Raindrop Near Vision Inlay, Transseptal Needle two are recalled in march Raindrop Near Vision Inlay it was recalled reason is an increased risk of corneal haze a type of cloudiness in the cornea due to inflammation) associated with the device and Transseptal Needle is recalled reason is manufacturing error both are class-I recalls **[43-44]** VIAL2BAG fluid transfer systems, the Roche Diagnostics CoaguChek XS PT Test Strips and sterile saline and sterile water products for inhalation, 131F7, 131F7J, 131F7P, 131VF7P, 151F7 Swan-Ganz Thermo dilution Catheters, dual chamber IPGs and LIFEPAK 15 Monitor/Defibrillator these are the medical devices recalled in February. dual chamber IPGs is recalled by soft ware error reason and 131F7, 131F7J, 131F7P, 131VF7P, 151F7 Swan-Ganz Thermo dilution Catheters it recalled by incorrect assembly and reversal of the catheter tubes (lumens), Roche Diagnostics CoaguChek XS PT Test Strips it was recalled by inaccurate INR test results, when compared to laboratory results . Sterile saline and sterile water products for inhalation recall is class –I recall or all are class-I recall **[45-50]**. The Synergy Cranial Software and Stealth Station S7 Cranial Software, used with the Stealth Station Surgical Navigation System and disposable VentStar and ID Breathing Circuits and Anesthesia Sets these are recalled in January both are recalled reasons are reports of incorrect information displaying during biopsy procedures and devices being incorrectly assembled respectively **[51-52]**. Number of recalls in every month in 2019 seen in **Figure 1**.

CONCLUSION

It's unclear exactly why there have been so many more medical device recalls in 2019 than in previous years, but one explanation is the fact that medical devices are increasingly reliant on software **[53]**. Or in market number of medical devices are increasing that relies on computer technology it is trigger problems. Maximum number of recall reasons is soft ware defect.

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