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The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

Smaller Medical Providers Get Burned by Ransomware

Cyberattacks are pummeling doctors, dentists and community hospitals around the U.S., causing some to turn away patients and others to shut down

Campbell County Health, which operates a 90-bed community hospital in Wyoming, was hit by a cyberattack.

Oct. 6, 2019 9:00 am ET Andy Fitzgerald, chief executive of a community health system in Wyoming, was visiting his son in Georgia last month when he received a distressing text message from his chief operating officer: Their company had been hit by a cyberattack.

Hackers had locked up sensitive patient information and medical devices at Campbell County Health and de-manded a ransom.

"My initial thought was, 'Oh crap,'" said Mr. Fitzgerald, who declined to say whether he paid the demand.

In the days after the attack, the health system, which operates a 90-bed community hospital and other facilities, was forced to cancel services including radiology, endocrinology and respiratory therapy. The organization transferred patients to hospitals as far away as South Dakota and Denver. Cash registers, email and fax were unavailable. Doctors had to resort to pen and paper to document medical conditions, and with prescription records inaccessible, patients were asked to bring medication bottles to visits.

Employees have worked around the clock in the past few weeks to restore services, which are mostly back to normal, he said.

A warning is displayed at the top of Campbell County Health's website. Photo: Campbell County Health Cyberattacks like this are pummeling doctors, dentists and community hospitals around the country, causing some to turn away patients and others to close their doors permanently.

Health organizations are an attractive target for cybercrime thanks to their valuable medical and billing information, said Jennifer Barr, a health-care analyst at Moody's Corp. The data can be sold for insurance-fraud purposes or it can be locked up and used to extort money from the affected health organization, she said.

Smaller health-care organizations are at greater risk because they generally don't have the resources for robust security tools and might not have a dedicated cybersecurity specialist to monitor and patch their systems, Ms. Barr said. Last year, about 57% of medical practices in the U.S. had 10 or fewer physicians and about 15% were run by solo practitioners, according to the American Medical Association.

Adding Up Average cost of a data breach per customer record, including customer notification, credit monitoring, fines, legal fees and other items Source: IBM; Ponemon Institute Note: Study of 507 companies with recent data breaches; excludes mega-breaches such as Equifax' 2017 Healthcare Financial services Energy Education Entertainment Transportation Hospitality Retail $200$400$600

Three Alabama hospitals have been operating under emergency procedures since a cyberattack on Oct. 1, spokes-man Bradley Fisher said Friday. The hospitals—DCH Regional, Northport and Fayette—are part of the same system and share IT resources.

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"Everybody is familiar with [the emergency procedures] but you obviously don't want to do it for days," Mr. Fisher said. There is no forecast for when the hospitals will be functioning normally, he said.

Like at the Wyoming health system, email is down, and doctors are keeping written notes after patient visits. IT staff is working around the clock on eight-hour rotations, Mr. Fisher said, and about 60 nurse managers, department directors and other top administrators gather with the chief operating officer four times a day to go over technology and operational updates.
The hospital system is encouraging nonemergency patients to seek assistance from other providers.

In August, the American Dental Association said that hundreds of dental practices were affected by a ransomware attack that month against two dental-focused technology providers. The incident locked dentists out of their data but patient information is believed to be uncompromised, Brenna Sadler, director of membership and communications for the Wisconsin Dental Association, said in an email.

A Wisconsin dentist who asked not to be named said she has been "overwhelmed dealing with the incident [and] there are more repercussions than one might assume." She declined to give details. After a ransomware attack, companies typically conduct digital forensic investigations to make sure systems and data are no longer vulnerable. Some equipment might have to be replaced and if backup data is outdated or encrypted, rebuilding files can be expensive and lengthy.

Some small health-care organizations don't have the money to bounce back from a cyberattack, said Linn Freed-man, head of the privacy and cybersecurity practice at law firm Robinson & Cole LLP.

A ransomware incident in August is forcing Wood Ranch Medical in Simi Valley, Calif., to close its doors Dec. 17, according to a note posted on its website.
"Unfortunately, the damage to our computer system was such that we are unable to recover the data stored there and, with our backup system encrypted as well, we cannot rebuild our medical records," the note reads. "As much as I have enjoyed providing medical care to you, I will not be able to attend to you professionally after that date."

The statement is unsigned; the practice is run by Shayla Kasel, a family medicine doctor, who didn't respond to requests for comment.
Brookside ENT and Hearing Center in Battle Creek, Mich., permanently closed its doors in April after a ransomware attack, according to a receptionist reached by phone shortly after the incident. All of the company's electronic data was made inaccessible after it decided not to pay a ransom, and the practice stayed open for a short time to refer patients to other health providers, she said.

FDA warns of medical device shortages

Plastics News Staff
Food & Drug Administration

With recent and potential closures of certain ethylene oxide sterilization facilities, the U.S. Food & Drug Administration is concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care.

The U.S. Food and Drug Administration is asking manufacturers of medical devices that need to be sterilized with ethylene oxide to assess their inventories following the closure of some large-scale facilities that use the gas to remove potentially harmful germs.
The permanent closure of a Sterigenics ethylene oxide sterilization facility in Illinois on Sept. 30, contract sterilizer Viant's closure in Grand Rapids, Mich., and the temporary closures of another Sterigenics facility in Georgia and a large Becton, Dickinson and Co. sterilization facility, also in Georgia, could affect the availability of some medical devices used by health care professionals and patients.

The sterilization facilities are being temporarily and permanently closed by Environmental Protection Agency officials for emitting unsafe levels of ethylene oxide into the air around their sites. The National Institutes of Health says exposure to dangerous levels of ethylene oxide can cause cancer.

However, another health concern is rising. More than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide and there's currently no viable alternative to this process, according to Norman Sharpless, the acting FDA commissioner. Sharpless is sounding the alarm about potential disruptions in the supply chain for medical devices, such as emergency surgical kits for cesarean sections, feeding tubes for neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts and other implantable devices.

"Because the number of ethylene oxide

contract sterilization facilities in the U.S. is limited, we are very concerned that additional facility closures could severely impact the supply of sterile medical devices to health care delivery organizations that depend on those devices to take care of patients," Sharpless said in an Oct. 25 statement. "The impact resulting from closure of these and perhaps more facilities will be difficult to reverse and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care."

FDA said the facilities cover sterilization for hundreds of products:

Willowbrook handled 46 different devices in Michigan. Sterigenics' Willowbrook, Ill., site handled 594 devices while another 402 are handled in Atlanta. Becton Dickinson sterilized 464 different devices in Covington, Ga. FDA began monitoring and raising concerns about the situation earlier this year. In February, the Illinois EPA ordered Sterigenics to stop sterilizing medical products at its Willowbrook, Ill., facility. The order caused a temporary shortage in April of silicone pediatric breathing tubes manufactured by Smiths Medical Inc.

Sharpless said FDA helped the Minneapolis-based manufacturer change sterilization sites and minimize the supply interruption, but that's no solution going forward. About 50 percent of all medical devices require ethylene oxide sterilization before getting to patients, and there aren't enough facilities to do the work.

Sterigenics announced Sept. 30 that its Willowbrook facility would not reopen. Meanwhile, the company's contract sterilization facility in Atlanta has been closed since August while it undergoes construction to reduce ethylene oxide emissions.

Then, on Oct. 28, Becton, Dickinson and Co. agreed to temporarily shut down its medical sterilization facility in Covington, Ga., until Nov. 7. The company also agreed to take steps to reduce ethylene oxide emissions after it resumes operations.

"Although medical devices can be sterilized by several methods, ethylene oxide is the most common method of sterilization of medical devices in the U.S. and is a well-established and scientifically proven method of preventing harmful microorganisms from reproducing and causing infections," Sharpless said.

Still, FDA is seeking alternatives. In July, the agency asked academic institutions, the medical device industry and other stakeholders to submit ideas for sterilization methods that don't use ethylene oxide as well as develop new strategies to reduce ethylene oxide emissions. Submissions were due Oct. 15.

In the meantime, if the sterilization facility closures lead to any shortage for a critical medical device, the FDA may look for a firm outside the U.S. that is willing and able to redirect safe and effective product into the country, Sharpless said.

FDA has set up a special email account — deviceshortages@fda.hhs.gov — for patients, manufacturers and health care organizations to report distribution delays of new products and anticipated shortages. "It's never too early to contact us — the sooner we are aware of a potential shortage, the better we can assist in proactively developing a plan to mitigate its effects on patient care," Sharpless said.

FDA also is asking hospitals and other health care organizations to work together and not hoard any products or attempt to buy larger quantities of devices beyond their normal purchase volumes.

An FDA advisory committee is meeting Nov. 6 and 7 in Gaithersburg, Md., to discuss how best to encourage innovation in medical device sterilization.

Here's the case for single-source medical device manufacturing

October 31, 2019 By Nancy Crotti Leave a Comment

Companies that outsource medical device manufacturing can either parse the production work among several providers or unify the effort from a single source. Both tactics have advantages, but the use of multiple suppliers can have expensive downsides.

Medical device manufacturers have a wealth of resources available to handle outsourcing production needs. Experts-for-hire can address everything from design and engineering to assembly and legal/regulatory reviews. There are advantages to adopting this business model, including partnerships with service providers who are adept at their manufacturing specialty.

However, more often than not, the decision to use multiple suppliers on a medical device can have a variety of unintended consequences. These drawbacks can delay a project timeline, increase costs, lower finished quality and create undue workload and stress for the internal project team.

A vertically integrated, single-source contract manufacturer has many benefits. Reduce supplier audits and validation Consolidating design and engineering functions with manufacturing provides significant synergies.

The design team will lean heavily toward materials and components from suppliers who have already been audited and are part of the company's existing supply chain. Similarly, engineers will generally design devices with pre-validated components and materials from these suppliers, eliminating the time and expense required with the validation process.

Minimize variability

Engineers intimately familiar with their manufacturing processes understand how to design to make the most of their equipment and processes while minimizing manufacturing variability. Smart design can imbue a product with a standard of quality from the outset.

Planning in this way can accommodate requirements for functionality (the ability to sterilize a valve or tube, for example), clarity in documentation and quality-control metrics.

Reduce management time

Working with an integrated contract manufacturer eliminates the need to manage multiple vendors and the time associated with that management. One project manager is responsible for the entire timeline from the earliest design stages through assembly and sterilization.

A single-stream supply chain also alleviates managerial concern for accountability. With an integrated manufacturer, there's no question about who is responsible for resolving an issue. As one client has expressed, he likes having "…one throat to choke."

Prepare for a long product lifecycle

An integrated contract manufacturer can deliver benefits over a longer product lifecycle. For example, a contract manufacturer that also provides sustaining engineering capabilities will be better able to address improvements, enhancements and changes to the product as feedback returns from the field.

Likewise, the longer an integrated team works on a medical device from design through production and sterilization, the more institutional knowledge they can provide. A vertically integrated contract manufacturer acts as a full extension of the customer's team to provide critical insight and history about everything from material selection to engineering.

Which model works best?

Of course, there is no one model that works best for every company. Some might opt for an approach akin to selecting a group of "All-Stars" to play together on the same field or court. However, judging from the lackluster level of teamwork evidenced in such sporting events, that direction might not be ideal for something as critical as a medical device.

As the design, production and distribution of medical devices become increasingly complicated and regulated, there is tremendous value in consolidating resources with a single contract manufacturer that can provide an integrated team to steward a product from conception through many years of production. The long-term benefits in terms of time-to-market, overall quality, thoroughness of documentation and accountability will typically outweigh any perceived short-term benefits of a multiple-source approach.

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The opinions expressed in this blog post are the author's only and do not necessarily reflect those of Medical Design and Outsourcing or its employees.

Trump to Nominate Stephen Hahn, Cancer Researcher, to Head F.D.A.Trump to Nominate Stephen Hahn, Cancer Researcher, to Head F.D.A.

In choosing him, President Trump is passing over the acting F.D.A. commissioner, Norman E. Sharpless, who has been running the agency since Scott Gottlieb resigned last spring.

The F.D.A. has been run by an acting director since Dr. Scott Gottlieb stepped down as commissioner in April.Credit...Jacquelyn Martin/Associated Press

By Katie Thomas NYT

Nov. 1, 2019

President Trump said Friday that he intended to nominate Dr. Stephen M. Hahn, a top executive at The University of Texas M.D. Anderson Cancer Center, to be the next commissioner of the Food and Drug Administration.

If he is confirmed by the Senate, Dr. Hahn would fill the vacancy left by Dr. Scott Gottlieb, who stepped down as commissioner in April. In doing so, he passed over the acting commissioner, Dr. Norman E. Sharpless, who had the support of previous commissioners and an array of patient groups.

The Department of Health and Human Services said Friday that Dr. Sharpless would be returning to his role as director of the National Cancer Institute, which he previously held before taking over as acting commissioner. Dr. Brett Giroir, the assistant secretary for health, will fulfill the duties of acting commissioner while Dr. Hahn goes through the confirmation process.

Dr. Hahn, 59, is credited with returning M.D. Anderson— considered one of the nation's best cancer centers — to stable footing after a series of financial and ethical controversies involving its previous president, Dr. Ronald DePinho, who resigned in 2017. Dr. Hahn is also a noted radiation oncologist and cancer researcher.

A Washington outsider without significant policy experience, Dr. Hahn would step into a high-intensity job that requires deft political skills and oversight of a sprawling federal agency that regulates everything from lifesaving cancer therapies to dog food.

He would take over as the agency is grappling with a number of urgent issues, including the opioid epidemic, contaminants in common drugs and an outbreak of mysterious lung illnesses caused by vaping.

Image

"The F.D.A. is, as always, at front and center," said Dr. David A. Kessler, who served as the agency's commissioner during the administrations of George H.W. Bush and Bill Clinton. He described the challenge of navigating competing interests as "white heat."

Dr. Hahn would have time working against him, Dr. Kessler and others said, taking over just as Mr. Trump's re-election campaign gets underway, with the possibility he would only have about a year to stay in the job. "It's somewhat of a gamble," Dr. Kessler said.

Dr. Robert Califf, who was F.D.A. commissioner during the Obama administration and has supported Dr. Sharpless, said the learning curve at the agency is steep. "It takes six months to figure out where the bathrooms are," he said. "The loss of continuity seems like a big negative."

Some health interest groups said they were looking forward to working with Dr. Hahn

The FDA's New Guidance On Natural History Studies In Rare Diseases: What You Need To Know

Source: Premier Research

In March 2019, the FDA released draft guidance on the design and implementation of natural history studies to support the development of safe and effective treatments for rare diseases. The document, *Rare Diseases: Natural History Studies for Drug Development*,[1] addresses one of the major challenges sponsors encounter when developing therapies for rare disease: the lack of natural history data to guide the design of successful clinical trials.

Value of natural history studies

The natural history of a disease is the course it takes in the absence of investigational intervention. To gain insight into this, investigators conduct observational studies designed to follow the course of the disease. The objective of these studies is to identify demographic, genetic, environmental, and other factors that correlate with the development and outcomes of the disease.

Natural history studies can play an important role in drug development from discovery to clinical trial design. They can be used for:

- **Identifying the patient population.** This is useful in rare diseases which typically exhibit substantial genotypic and/or phenotypic heterogeneity.
- **Identifying or developing clinical outcome assessments.** Natural history studies can be an appropriate setting for the validation of disease-specific scales and functional assessments. Such validation is critical given the focus on therapeutic value as it relates to marketing approval and reimbursement.
- **Identifying or developing biomarkers.** If robustly validated, these biomarkers can serve as primary or surrogate endpoints in clinical trials.
- **Serving as non-concurrent comparator arms in externally controlled studies.** Natural history models can, in some cases, serve as non-concurrent comparator arms for studies where it may be infeasible to randomize patients to placebo. This use must be approved by the appropriate regulatory agencies, and this permission is granted only rarely — such as in the case of very small patient populations.

The benefits of natural history studies may go beyond drug development to include establishing communication pathways with patients, care partners, and advocacy organizations; identifying disease-specific centers of excellence; facilitating the understanding of current standard of care; and identifying opportunities to improve patient care.

[1] Source: U.S. Food and Drug Administration. Rare Diseases: Natural History Studies for Drug Development—Draft Guidance, Published March 2019. Available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM634062.pdf.

A Little off track for the Oracle

Have some anxieties amid the rising economic talk of a downturn? You may be on to something. For over the past 150 years one of the precursors of an economic downturn in the US and world has been a significant decline in the sale of men's underwear, or so the pundits say. For the past six months the sale of men's underwear is off by 35 to 40%. Now you know, but not sure what.