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FDA TO OVERHAUL MEDICAL DEVICE APPROVAL PROCESS

WASHINGTON — U.S. health officials said Monday they plan to overhaul the nation's decades-old system for approving most medical devices, which has long been criticized by experts for failing to catch problems with risky implants and medical instruments.

The Food and Drug Administration announced plans aimed at making sure new medical devices reflect up-to-date safety and effectiveness features. The system targeted by the actions generally allows manufacturers to launch new products based on similarities to decades-old products, not new clinical testing in patients.

The FDA's move came one day after the publication of a global investigationinto medical device safety by more than 50 media organizations, including The Associated Press. Led by the International Consortium of Investigative Journalists, the group found that more than 1.7 million injuries and nearly 83,000 deaths suspected of being linked to medical devices had been reported to the U.S. Food and Drug Administration over a 10-year period.

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NEWSLETTER NOTES

"We believe that newer devices should be compared to the benefits and risks of more modern technology," FDA Commissioner Scott Gottlieb said in a statement. Gottlieb said the changes under consideration would push companies to compare their devices to more up-to-date technology, rather than referencing decades-old

Some of the reforms proposed by the FDA could take years to implement, in some cases requiring new guidelines and regulations for manufacturers. And the most substantive changes could require action by Congress.

The FDA's framework for clearing more than 95 percent of devices on the U.S. market dates to 1976 and has long been criticized in reports from government watchdogs and independent medical experts. Unlike new pharmaceuticals — which are tested in patient studies — most medical devices only have to show that they are similar to devices already on the market. Only a handful of truly new devices must undergo extensive clinical testing to verify they are safe and effective.

Defective devices cleared through the streamlined system have included hip replacements that failed prematurely, surgical mesh linked to pain and bleeding and a surgical instrument that inadvertently spread uterine cancer.

As generations of devices have been cleared via the FDA's main review process, medical products have become increasingly complex and often barely resemble the decades-old "predicates" they claim to reference. Devices cleared through this system, known as the 510(k), include imaging scanners, computerized drug pumps, artificial joints and spinal implants.

In 2011, an Institute of Medicine panel recommended that the "flawed" system be replaced, because it does not actually establish safety and effectiveness. At the time the FDA said it disagreed with the group's recommendations.

The Advanced Medical Technology Association, the industry's chief lobbying group, said in a statement that some of the FDA's proposals "could prove arbitrary."

"While we believe the 510(k) pathway has proven its effectiveness over the years, we have always maintained that any process can be improved," the group said.

— Matthew Perrone

Lion Air crash: Pilots fought automatic safety system before plane plunged

The pilots of Lion Air Flight 610 were engaged in a futile tug-of-war with the plane's automatic systems in the minutes before it plunged into the ocean, killing all 189 people on board.

But investigators say they are at a loss to explain why the pilots didn't follow the same procedure performed by another flight crew the previous day when they encountered a similar issue.

A preliminary report into the crash released Wednesday by Indonesia's National Transportation Safety Committee (NTSC) reveals more details about the final moments of Flight 610, but acknowledges many questions remain.

Data retrieved from the flight recorder shows the pilots repeatedly fought to override an automatic safety system installed in the Boeing 737 MAX 8 plane, which pulled the plane's nose down more than two dozen times.

The system was responding to faulty data, which suggested that the nose was tilted at a higher angle than it was, indicating the plane was at risk of stalling.

According to the report, the pilots first manually corrected an "automatic aircraft nose down" two minutes after takeoff and performed the same procedure again and again before the plane hurtled nose-first into the Java Sea.

CNN aviation analyst David Soucie said that the circumstances created by the plane's automatic correction would have made pilot intervention "impossible."

"The fact that they fought against the MCAS (multiple) times with the trim settings was an impossible scenario to recover from," he said.

Problem previously corrected

A different flight crew had experienced the same issue on a flight from Denpasar to Jakarta the previous day, but had turned off the automatic safety feature, known as the maneuvering characteristics augmentation system (MCAS) and took manual control of the plane.

The feature is new to Boeing's MAX planes and automatically activates to lower the nose to prevent the plane from stalling, based on information sent from its external sensors. Indonesian investigators have already pointed to issues with the plane's angle-of-attack (AoA) sensors, which had proved faulty on earlier flights.

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AoA sensors send information to the plane's computers about the angle of the plane's nose relative to the oncoming air to help determine whether the plane is about to stall.

Responding to the report, Boeing said it was "deeply saddened" by the loss of the Lion Air flight -- but maintained the 737 MAX 8 "is as safe as any airplane that has ever flown the skies," and that the company is "taking every measure to fully understand all aspects of this accident."

Wednesday's preliminary report recommends that Lion Air review its safety culture while the investigation continues, and while officials search for cockpit voice recorder (CVR), which is believed to be buried under mud on the ocean floor.

It should reveal what the pilots were saying and why they didn't turn off the safety feature.

"We need to know what was the pilot discussion during the flight. What was the problem that may heard on the CVR. So why the action difference, this is the thing we need to find. At the moment I don't have the answer," said the NTSC's head of aviation, Capt. Nurcahyo Utomo.

Issue reported two minutes into flight

The preliminary report said Flight 610 reported a issues minutes after taking off from the Indonesian capital on October 29 en route to the city of Pangkal Pinang, on the island of Bangka.

Within 90 seconds of takeoff, the co-pilot asked air traffic control to confirm air speed and altitude. Thirty seconds after that he reported that they had experienced a "flight control problem," the report said.

After the aircraft's flaps retracted following takeoff, the automatic trim problem noted on the previous night's flight returned, until the flight data recorder stopped recording when the plane crashed.

The report said the pilots on the plane's penultimate flight reported that instruments were showing inaccurate readouts from the angle-of-attack (AoA) sensors.

The report said that the plane was "automatically trimming" on the previous flight -- that is, the computer was adjusting the aircraft's angle -- so the pilots switched to manual trim and, as their safety checklists didn't recommend an emergency landing, they continued to Jakarta.

Further maintenance on the AoA sensor was carried out in Jakarta prior to Flight 610's takeoff the next morning. After the flight took off, the instruments recorded a substantial discrepancy in the aircraft's angle -- as much as 20 degrees.

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Aviation expert Geoffrey Thomas called the report "very comprehensive" and said that he could not understand why Lion Air had deemed the plane suitable for service.

"Clearly the plane had serious sensor issues ... why the airplane wasn't pulled out of service beggars belief," he told CNN. "Tinkering around and replacing parts isn't enough."

As part of the continued investigation, the faulty AoA sensor will undergo further testing, the NTSC said. It plans to finish its report within 12 months.

Captain's mother: Son said sim training unnecessary

The pilot's mother Sangeeta Suneja, herself a senior commercial manager with Air India, told CNN after a family briefing Tuesday that her son was "a sunny boy. He was loved by everybody in his company."

She says her son, Capt. Bhavye Suneja told her there was no updated training simulation session when Lion Air started using the new aircraft.

"They said it was not required... When the transition happened, he said, 'Mama, I'm going to fly the MAX.' I said, 'How can you do that (when) you don't have (a) simulator session?' He said, 'We don't need to.'"

Coming from an aviation family, she said that Suneja's sister wanted to follow in his footsteps, but that the fatal accident had shaken her faith in the technology.

"Even my daughter wants to be a pilot. She was so inspired by him she also wants to be a pilot," she said. "Now I have apprehensions. I don't know. How safe it is. The trust in the machine is shaky now." She added that air safety regulation across the world needed to be re-established to reaffirm people's trust in air travel.

"Whenever they (present new aircraft) to the market, where the life of the people is at stake, the regulators must re-establish three, or five, levels of crosscheck... Someone should have questioned this."

Complaints about Boeing manual

The Allied Pilots Association (APA) and Lion Air's operational director claim Boeing's operational manual for the MAX 8 did not contain adequate information about the MCAS system.

"We don't receive any information from Boeing or from (the) regulator about that additional training for our pilots," Zwingli Silalahi, Lion Air's operational director told CNN on November 14. Both the pilot and co-pilot of Flight 610 were experienced the airline has said, with 6,000 and 5,000 flight hours respectively.

Boeing stood by the aircraft's safety record. "We are confident in the safety of the 737 MAX. Safety remains our top priority and is a core value for everyone at Boeing," a spokesperson said.Tjahjono said that due to the small size of the debris found and loss of the plane's engine blades, investigators determined that Flight 610 did not explode in the air, but was in "good shape" before it crashed 13 minutes after takeoff.

OFAC ISSUES EMBARGO FINES

SETTLEMENT AGREEMENT

This settlement agreement (the Agreement) is made by and between the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) and Societe Generale S.A. ("Respondent", or
"SG").

I. PARTIES

1. OF AC administers and enforces economic sanctions against targeted foreign countries, regimes, terrorists, international narcotics traffickers, and persons engaged in activities related to the proliferation of weapons of mass destruction, among others. OFAC acts under Presidential national emergency authorities, as well as authority granted by specific legislation, to impose controls on transactions and freeze assets under U.S. jurisdiction.

2. SG is a bank organized under the laws. of France and headquartered in Paris, France.

II. APPARENT VIOLATIONS

3. OFAC conducted an investigation of SG in connection with more than a thousand transactions processed to or through the United States or involving a U.S. financial institutions in apparent violation of the Cuban Assets Control Regulations, 31 C.F .R. Part 515 (CACR); the Sudanese Sanctions Regulations, 31 C.F.R. Part 538 (SSR); and the Iranian Transactions and Sanctions Regulations, 31 C.F.R. Part 560 (ITSR). 1

4. OF AC determined that SG did voluntarily self-disclose the Apparent Violations and that the Apparent Violations constitute an egregious case.

III. FACTUAL STATEMENT

5. For at least five years up to and including 2012, SG, through its headquarters and various branches, processed 1,077 U.S. Dollar (USD) transactions totaling $5,560,452,994.36 that appear to have violated the following sanctions programs: the Cuban Assets Control Regulations, 31 C.F.R. Part 515 (CACR); the Sudanese Sanctions Regulations, 31 C.F.R. Part 538 (SSR); and the Iranian Transactions and Sanctions Regulations, 31 C.F.R. Part 560 (ITSR). Although SG implemented a sanctions-compliance program, including several group-wide sanctions policies and trainings prior to and daring this time period, SG nonetheless processed transactions to or through the United States or U.S. financial institutions that involved countries or persons (individuals and entities) subject to the sanctions programs administered by OFAC (collectively, "OFAC-sanctioned parties").

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SG's review revealed that the bank processed certain transactions in a non-transparent manner that removed, omitted, obscured, or otherwise failed to include references to OF AC-sanctioned parties in the information sent to the U.S. financial institutions that were involved in the transactions.
1 On October 22, 2012, OFAC changed the heading of 31 C.F.R. Part 560 from the Iranian Transactions Regulations to the ITSR, amended the renamed ITSR, and reissued them in their entirety. See 77 Fed. Reg. 64,664 (Oct. 22, 2012). For the sake ofclarity, all references herein to the ITSR shall mean the regulations in 31 C.F.R. Part 560 in effect at the time of the activity, regardless of whether such activity occurred before or after the regulations were renamed.

6. On May 16, 2012, SGnotified OFAC of certain USD transactions that the Paris Rive Gauche Enterprises (PRGE) branch of SG's retail banking division in France, Banque de Detail en France ~DDF), originated on behalf of an entity ("Sudanese Entity"), a company majority owned by the Government of Sudan. On February 11, 2013, SG submitted a voluntary self-disclosure to OFAC presenting the results of its review of these Sudanese Entity transactions during the five-year review period between May 1, 2007 and May 1, 2012. The February 11, 2013 disclosure also identified other potential issues relating to Iran, Sudan, and Cuba. Following this initial review, SG expanded the review to include client relationships with sanctioned parties at six BDDF large corporate branches and sanctioned bank correspondent accounts maintained by BDDF's correspondent banking division, for the period of May l, 2007 to February 28, 2013, as well as the Iran, Sudan, and Cuba issues identified in the initial review.

7. In early 2014, following several exchanges between external counsel and OFAC (as
well as other investigating agencies), SG agreed to an expanded scope of review to cover USD transactions processed by the in-scope business lines from January 1, 2003 to December 31, 2013, as well as the bank's historical sanctions-related policies and procedures and relevant communications and documents in that period. SG agreed that the review would cover all USD transactions within: (1) BDDF's six large corporate branches and international private clients branch; (2) the Bank's correspondent banking business; and (3) the Global Finance (GLFI) division of SG's Corporate and Investment Bank (SG CIB) at the following locations: Paris, Australia, Canada, Japan, and Singapore. In addition to a global sanctions review for those business lines, the bank conducted interviews of current and former employees at key positions within each business line.

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8. Throughout its review, SG provided OFAC with multiple document productions, disclosures and related addendums, and responses to requests for information. SG also reported the results of its review to OF AC and other investigating agencies in a series of meetings and presentations between 2012 and 2017. In its submissions, SG disclosed certain transactions that raise permissibility issues, namely transactions that were both subject to U.S. jurisdiction for purposes of the relevant OFAC sanctions regulations and involved an OF AC-sanctioned party, where SG was unable to identify a contemporaneous exemption, general license, or specific license under the relevant OFAC sanctions regulations that would have exempted or authorized the payment.

9. SG's review revealed that certain business lines of SG processed non-transparent payments involving the removai omission, obscurement, or failure to include references to sanctioned parties in transactions processed to or through the United States or U.S. financial institutions. SG also had documented procedures on how to omit sanctioned parties on payment instructions destined for or transiting the United States. While some of the conduct that led to the apparent violations is specific to a particular branch and/or business line of SG (as described in detail below), several components of SG appear to have engaged in similar conduct that resulted in apparent violation of, rather than compliance with, OF AC sanctions regulations. In addition, while SG implemented sanctions compliance measures prior to and during the review period, several units of SG did not receive guidance at the time and continued to process transactions in apparent violation of OFAC sanctions.

10. At various points in 2003 and 2004, certain SG personnel circulated procedures for processing payments for parties located in embargoed countries by omitting the parties' names from the payment messages sent to U.S. financial institutions. In November 2003, a member of the Treasury Desk and Money Market Back Office (MMBO) within SG CIB received a memo entitled "Scheme for international settlement with countries under USD embargo," which described how to process different transactions for customers located in embargoed countries. .

11. Beginning in mid-2004, various units within SG began undertaking a number of effort to improve sanctions compliance at the bank, partly in response to certain U.S. government enforcement actions against non-U.S. banks for sanctions-related violations, and years before several other significant enforcement actions against non-U.S. banks. SG's compliance efforts included providing trainings, circulating compliance messages, and updating policies and procedures.

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Despite these efforts, certain SG personnel continued to process transactions in violation of the applicable OF AC sanctions, including by removing references to OF AC-sanctioned parties in the payment instructions sent to U.S. financial institutions.

12. SG's PRGE branch originated a number of payments on behalf of the Sudanese Entity. In particular, from at least May 2, 2007 through November 27, 2008, SG's PRGE branch originated SWIFT payment messages for the Sudanese Entity that used the company's French mailing address, rather than the Sudanese physical address in BDDF's client database. Because the messages did not contain references to any OF AC-sanctioned country or party, they were not flagged by BDDF's automated OF AC interdiction filter for review.

13. From December 4, 2008 through January 16, 2009, BDDF's payment message system automatically populated seven payment messages with the Sudanese Entity's Sudanese address, after someone at the PRGE branch's Middle Office had flagged in the database that mail sent to the Sudanese Entity's French address had been returned as undeliverable. BDDF's automated OFAC interdiction filter stopped all seven payments for review, and, at the direction of a senior member of the PRGE branch's Back Office, Back Office employees at the PRGE branch manually resubmitted four payments to change the Sudanese Entity's Sudanese address to the company's French address.

14. On December 4, 2008, after a first payment was automatically populated with the Sudanese Entity's Sudanese address, PRGE branch Middle Office personnel changed the Sudanese Entity's address in the client database back to the French address. On December 29, 2008, a PRGE branch Middle Office employee again changed the Sudanese Entity's physical address in the client database back to the Sudanese address. As a result, seven payments originated between December 4, 2008 and January 16, 2009 used the Sudanese address and triggered alerts in BDDF's automated OFAC interdiction filter. According to the bank, two of the messages were released "mistakenly" by the filter operators, and then rejected by a U.S. branch of a foreign financial institution, and one of which was subsequently resubmitted by a PRGE branch Back Office employee with the Sudanese Entity's French address. PRGE branch Back Office employees resubmitted three additional payments between December 4, 2008 and January 8, 2009 after removing the Sudanese Entity's Sudanese address and replacing it with the Sudanese Entity's French address. Employees gave conflicting accounts as to why this was done, although one employee on the BDDF filter monitoring team speculated it was done to avoid the OF AC interdiction filter.

EXPORT ONLY MEDICAL DEVICES

As a soldier, Wolfgang Neszpor spent a decade serving his country. But he never expected his most serious injury to come when he was safely back home in Brisbane.

Key points:

- The US-made shoulder implant has not yet been approved for use in the United States
- In Australia, there was an unusually high failure rate of the device in its early days of use
- The device is now the top performing partial shoulder replacement in Australia

These days the veteran can barely move his left arm after becoming a "guinea pig" for a prosthesis that was made in the United States but never approved there for use.

Mr Neszpor is one of the many victims of a poorly regulated global market for medical implants and devices that is the subject of The Implant Files investigation, a collaboration involving ABC News and the International Consortium of Investigative Journalists.

The product Mr Neszpor used was a partial shoulder implant that the 42-year-old needed following years serving in the infantry and playing in the Australian Defence Force rugby union team.

"Back then, being a bigger size person, you're sort of like a pack horse and they just load you up with everything," he said.

After popping his shoulder a number of times on the rugby field it was during a game in Darwin that he suffered his most catastrophic injury.

"I went to tackle somebody and the shoulder felt a bit warm," he said, recalling the incident. "[They] told me that there was absolutely no rotator cuff left. I sheared the whole thing clean off the joint."

In November 2012, after multiple operations, the father of six found his way into the surgery of one of the country's most respected shoulder surgeons, Dr Phillip Duke.

Dr Duke recommended a partial shoulder replacement using a device called a PyroTITAN.It was a new type of pyrolytic carbon implant, a durable material made from sheets of graphite.

Mr Neszpor said his surgeon described the operation as a "new fantastic procedure" and that there was a requirement to perform 300 of them to "get them passed off as mainstream".

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"When your shoulder is bad, you take anything," Mr Neszpor said, even though at the time he knew he was in a clinical trial and there was a proven steel alternative available.

'A stupid amount of pain'

The pyrolytic carbon device is favoured for its smoothness, particularly for use in younger patients because it can preserve more of their joint, for longer.

Mr Neszpor said his doctor persuaded him to take the carbon option. But what he wasn't told was that five months earlier PyroTITAN's makers, Integra LifeSciences, had issued a voluntary recall after it observed one of its devices had cracked.

"I wasn't really warned of the potential of it breaking," Mr Neszpor said. "He mentioned one of them failing; didn't mention anything else."

But that's exactly what happened to the former strongman competitor.

About two months later, sitting in the bedroom he went to move his arm and heard a loud, audible squeak.

"It was loud. You could really hear it outside my body," Mr Neszpor recalled. "I'd go to move the arm and it kept jamming."

Mr Neszpor said while he knew he was in a clinical trial he had no idea the device could crack under everyday conditions.

"I can take a fair bit of pain. But it was a stupid amount of pain."

Dr Duke said he could not comment on individual patients but said he prioritised patient safety above all else.

"I strive to ensure that the research is conducted in full compliance with all applicable regulations and medical ethics guidelines, and with the full disclosure of any known risks to trial participants.

"All the participants are fully aware of the experimental nature of the device."

Within a year of Mr Neszpor's surgery, the Therapeutic Goods Administration (TGA) had followed Integra's earlier lead, also issuing a broader hazard alert because of a high breakage rate among PyroTITAN devices.

It reported that some devices could break when faced with excessive loads on the shoulder.

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Unusually high failure rate

It wasn't until 2014 the veteran turned to Dr Des Soares, a prominent orthopaedic surgeon who has sat on expert government panels.

Dr Soares, a part-time political advisor who's been critical of the device pricing system in the past, had to perform a total shoulder replacement.

He questions how the PyroTITAN implant ever got approved for use by the TGA.

In his view, the device was "a bit thin" and was not suited for the particular joint.

"In a shoulder, I think it's probably not an appropriate implant."

The ABC News investigation has learned that instead of getting normal approvals to run a clinical trial, the makers of the PyroTITAN were granted general registration for the device in Australia, known as an ARTG number.

This allowed the device to be sold to doctors in public hospitals outside the clinical trial.

Data from the National Joint Replacement Registry suggests 13 surgeons have implanted the PyroTITAN, that's about nine more than were involved in the Australian trials.

Some orthopaedic surgeons have suggested to ABC News it was their colleagues who were less familiar with the procedure that led to the unusually high failure rate of the device in its early days, prior to the hazard alert.

Dr Soares said the situation exposed serious flaws in the system.

"That's absolutely inappropriate. To be doing experimental surgery without any evidence or data is where we lead to disasters," he said.

"And unfortunately patients are the people who suffer in those disasters."

Do you know more about this story? Email backgroundbriefing@abc.net.au or Specialist.Team@abc.net.au

System 'very broken'

Even Dr Soares was surprised to discover the PyroTITAN did not have US Food and Drug Administration (FDA) approval and said surgeons were relying on the regulator, the TGA, to get it right.

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"As a busy clinician, I don't actually physically go back and check that every implant I use has approval," he said. "I assume that a company which is supplying it to me in a hospital is not going to lie to me."

The surgeon said Australia's system of clinical assessment before a product made it to market was "very broken".

He said the TGA needed to accept responsibility for not having clinical assessment as part of its criteria.

How safe are medical devices?

At their best, they save lives. At their worst, they cut them short. More than 57,000 medical devices are approved for use in Australia, but are patients aware of the risks?
"The TGA basically does a paper assessment and looks at materials, but does not have clinicians giving them advice and that is a big failure in our system."

In a statement, the regulator said the PyroTITAN was initially approved as a Class IIb device which meant its approval was predicated on having obtained approval in Europe. It added that Australian approval was not contingent on FDA approval.

It said now, following a decision by the government, all orthopaedic implants introduced after 2012 will be given a level III classification, because of their higher level of risk. This would result in an immediate in-house review by the TGA before approval.

"The TGA draws on the expertise of a range of in-house assessors and external specialist professionals, as well as the work of overseas regulators," it said in a statement.

It said the PyroTITAN was allowed back on the market in 2014 after the regulator had overseen "corrective actions" and there was now "very strict quality control measures".

'You just feel like a guinea pig'

PyroTITAN was made by a company called Ascension Orthopedics, which was bought by Integra Life Sciences in 2011.

Ascension Orthopedics marketing material suggests the studies it used to support the PyroTITAN's use were around the use of pyrolytic carbon in wrists and knuckles.

It is believed that Ascension obtained its initial European approval by arguing that its product was "substantially equivalent" to its other steel devices and that prosthetics made from different materials would be compatible.

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But experts say that the new product should have either undergone animal, cadaver or biomechanical testing in a lab.

The Australian regulator, the doctors involved and Integra have refused to say whether this was done or release the materials they submitted to gain approval in Europe or Australia.

In a statement, the TGA said approval data submitted to the regulator was given on a commercial-in-confidence basis but could be released under certain circumstances.

Dr Duke told ABC News he was unaware the device had been supplied by its manufacturer outside the clinical trial.

"We undertook and are undertaking a research project fully approved by the appropriate ethics committees by the hospitals involved," he said.

Data from the National Orthopaedic Joint Registry suggests since the hazard alert the device is now the top performing partial shoulder replacement, it is the most used and has the lowest replacement rates. In the eight years since it was introduced in Australia, the device has been used in 390 operations. In 19 cases, the device has had to be replaced.

"It does show that the results of the use are exemplary and better than most, if not all, other alternatives for shoulder replacement," Dr Duke said.

A statement from the product's maker, Integra LifeSciences, said the device went through extensive pre-clinical performance evaluation, including "biomechanical, strength, wear and impact testing" which demonstrated it was safe and effective.

"PyroTITAN ... has enabled many patients to regain the mobility of their shoulders."

US 'export only' devices:

- About 4,600 devices are registered with the FDA as "export only"
- Devices may be sold overseas despite failing to meet standards for sale in the US
- Companies do not need to conduct post-market surveillance, analyse adverse event data, review customer complaints or other action to monitor safety mandatory for devices sold in the US
- Companies must meet the rules of the countries where the products are sold
- More than a dozen export only devices have been linked to injuries and one death, an investigation by NBC News has found

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The company said it had complied with all regulations, that it was committed to patient safety and continued to monitor the performance of the device. In a statement, the FDA said it did not have the authority to take action on export-only devices marketed in other countries. All that is little solace for Mr Neszpor who knows his full shoulder replacement, which he needed after the PyroTITAN cracked, may not last the decade.

"I'll either have a flaccid arm if this goes down or I have a fused shoulder," he said. "That's it, 42 years old. You just feel like a guinea pig."

- Explore the International Medical Devices Database, a searchable portal that gathers global recall notices, safety alerts and field safety notices

Foreign Assets Control and Cobham Holdings, Inc.

The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) today announced a $87,507 settlement with Cobham Holdings, Inc. ("Cobham") of Arlington, Virginia. Cobham has agreed to settle potential civil liability on behalf of its former subsidiary Aeroflex/Metelics, Inc. ("Metelics") for three apparent violations of the Ukraine Related Sanctions Regulations, 31 C.F.R. part 589 (URSR). The apparent violations involved the indirect export of components to be incorporated into commercial air traffic control radar to a person owned 50 percent or more, directly or indirectly, by a person identified on OFAC's List of Specially Designated Nationals and Blocked Persons in violation of URSR § 589.201. OFAC determined that Cobham voluntarily self-disclosed the apparent violations on behalf of Metelics and that the apparent violations constitute a non-egregious case.

E.U. leaders approve Brexit plan, setting up December vote in British Parliament, where it faces stiff opposition

At a carefully choreographed summit in Brussels, the leaders of the remaining 27 European Union members accepted the nearly 600-page Withdrawal Agreement, which spells out the terms for Britain's exit from the E.U. on March 29.

The Brexit package has followed a tortured path: 17 months of sometimes bitter negotiations, disagreement within May's own leadership team, ongoing concerns about how to handle the border between E.U. member Ireland and Northern Ireland, and the resignation of a string of ministers, including two Brexit secretaries. Now the challenge will be for British Prime Minister Theresa May to get the unpopular plan through her own Parliament.

Review of Controls for Certain Emerging Technologies

11/19/18
83 FR 58201

The Bureau of Industry and Security (BIS) controls the export of dual-use and less sensitive military items through the Export Administration Regulations (EAR), including the Commerce Control List (CCL). As controls on exports of technology are a key component of the effort to protect sensitive U.S. technology, many sensitive technologies are listed on the CCL, often consistent with the lists maintained by the multilateral export control regimes of which the United States is a member. Certain technologies, however, may not yet be listed on the CCL or controlled multilaterally because they are emerging technologies. As such, they have not yet been evaluated for their national security impacts. This advance notice of proposed rulemaking (ANPRM) seeks public comment on criteria for identifying emerging technologies that are essential to U.S. national security, for example because they have potential conventional weapons, intelligence collection, weapons of mass destruction, or terrorist applications or could provide the United States with a qualitative military or intelligence advantage. Comment on this ANPRM will help inform the interagency process to identify and describe such emerging technologies. This interagency process is anticipated to result in proposed rules for new Export Control Classification Numbers (ECCNs) on the CCL.

Comments on this ANPRM must be received by BIS no later than December 19, 2018.

Foundational Technology

Commerce will issue a separate ANPRM regarding identification of foundational technologies that may be important to U.S. national security. Commerce seeks public comment, however, on treating emerging and foundational technologies as separate types of technology.

Representative Technology Categories

The representative general categories of technology for which Commerce currently seeks to determine whether there are specific emerging technologies that are essential to the national security of the United States include:

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(1) Biotechnology, such as:

(i) Nanobiology;

(ii) Synthetic biology;

(iv) Genomic and genetic engineering; or

(v) Neurotech.

(2) Artificial intelligence (AI) and machine learning technology, such as: (i) Neural networks and deep learning (e.g., brain modelling, time series prediction, classification);

(ii) Evolution and genetic computation (e.g., genetic algorithms, genetic programming);

(iii) Reinforcement learning;

(iv) Computer vision (e.g., object recognition, image understanding);

(v) Expert systems (e.g., decision support systems, teaching systems);

(vi) Speech and audio processing (e.g., speech recognition and production); (vii) Natural language processing (e.g., machine translation);

(viii) Planning (e.g., scheduling, game playing);

(ix) Audio and video manipulation technologies (e.g., voice cloning, deepfakes);

(x) AI cloud technologies; or

(xi) AI chipsets.

(3) Position, Navigation, and Timing (PNT) technology.

(4) Microprocessor technology, such as:

(i) Systems-on-Chip (SoC); or

(ii) Stacked Memory on Chip.

(5) Advanced computing technology such as:

(i) Memory-centric logic.

(6) Data analytics technology, such as:

(i) Visualization;

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(ii) Automated analysis algorithms; or

(iii) Context-aware computing.

(7) Quantum information and sensing technology, such as

(i) Quantum computing;

(ii) Quantum encryption; or

(iii) Quantum sensing.

(8) Logistics technology, such as:

(i) Mobile electric power;

(ii) Modeling and simulation;

(iii) Total asset visibility; or

(iv) Distribution-based Logistics Systems (DBLS).

(9) Additive manufacturing (e.g., 3D printing)

(10) Robotics such as:

(i) Micro-drone and micro-robotic systems;

(ii) Swarming technology;

(iii) Self-assembling robots;

(iv) Molecular robotics;

(v) Robot compliers; or

(vi) Smart Dust.

(11) Brain-computer interfaces, such as

(i) Neural-controlled interfaces;

(ii) Mind-machine interfaces;

(iii) Direct neural interfaces; or

(iv) Brain-machine interfaces.

[12) Hypersonics, such as:

(i) Flight control algorithms;

(ii) Propulsion technologies;

(iii) Thermal protection systems; or (iv) Specialized materials (for structures, sensors, etc.).

*(*Continued On The Following Column)*

(i) Flight control algorithms;

(ii) Propulsion technologies;

(iii) Thermal protection systems; or (iv) Specialized materials (for structures, sensors, etc.).

(13) Advanced Materials, such as:

(i) Adaptive camouflage;

(ii) Functional textiles (e.g., advanced fiber and fabric technology); or

(iii) Biomaterials.

(14) Advanced surveillance technologies, such as: Faceprint and voiceprint technologies.

BIS welcomes comments on:

(1) How to define emerging technology to assist identification of such technology in the future;

(2) criteria to apply to determine whether there are specific technologies within these general categories that are important to U.S. national security;

(3) sources to identify such technologies;

(4) other general technology categories that warrant review to identify emerging technology that are important to U.S. national security;

(5) the status of development of these technologies in the United States and other countries;

(6) the impact specific emerging technology controls would have on U.S. technological leadership;

(7) any other approaches to the issue of identifying emerging technologies important to U.S. national security, including the stage of development or maturity level of an emerging technology that would warrant consideration for export control.

Comments should be submitted to BIS as described in the ADDRESSES section of this ANPRM by December 19, 2018.

This rule was determined to be significant by the Office of Management Budget under Executive Order 12866.

Dated: November 14, 2018
Matthew S. Borman,
Deputy Assistant Secretary for Export Administration.

Massachusetts companies feeling squeezed by tariffs

The burgeoning trade war between the United States and China poses an existential threat to some Massachusetts companies.

One CEO, answering a recent survey by Associated Industries of Massachusetts, said: "Tariffs are by far the most serious issue my company has faced in 40 years of business — much more important than health insurance costs, regulations, and finding workers."

The 4,000 employers of AIM are alarmed about the effect of tariffs — on the price and availability of raw materials, on long-established supply chains, on components, and on finished goods. These employers — from industries as varied as retail, machining, consumer goods, manufacturing, plastics, and semiconductors — also fear being caught in the crossfire of retaliatory actions by China and other trading partners, covering a broad range of raw materials and products.

Which tariffs exactly are causing all this concern? The United States imposed tariffs last spring on steel (25 percent) and aluminum (10 percent) imports. In response the European Union, Mexico, Canada, Turkey, and Russia immediately instituted retaliatory tariffs on US exports to those countries.The United States has also imposed multiple rounds of tariffs on Chinese exports coming here. The White House began the summer by announcing tariffs on $50 billion of goods from China, and then upped the ante by implementing tariffs on another $200 billion of Chinese goods in September. The 10 percent tariff rate on these China exports is scheduled to increase to 25 percent by the end of the year. China has retaliated in kind, imposing tariffs on US goods destined for China.

There's general agreement among trade experts and business leaders that China's trade practices are unfair and must be addressed. What is arguable is how to get China to the negotiating table. Imposing tariffs is not the best strategy.

"Persist until you succeed."

USTR Statement on China's Auto Tariffs

Washington, DC – U.S. Trade Representative Robert Lighthizer today released the following statement regarding China's tariffs on U.S.-produced automobiles:

"As the President has repeatedly noted, China's aggressive, State-directed industrial policies are causing severe harm to U.S. workers and manufacturers. We are continuing to raise these issues with China. As of yet, China has not come to the table with proposals for meaningful reform.

"China's policies are especially egregious with respect to automobile tariffs. Currently, China imposes a tariff of 40 percent on U.S. automobiles. This is more than double the rate of 15 percent that China imposes on its other trading partners, and approximately one and a half times higher than the 27.5 percent tariff that the United States currently applies to Chinese-produced automobiles. At the President's direction, I will examine all available tools to equalize the tariffs applied to automobiles."

Web Notice: The Directorate of Defense Trade Controls (DDTC) is currently in the process of modernizing its IT systems. During this time period, we anticipate there may be delays in response times and time to resolve IT related incidents and requests. We apologize for any inconvenience, and appreciate your patience while we work to improve DDTC services. If you need assistance, please contact the DDTC Service Desk at (202) 663-2838, or email at DtradeHelpDesk@state.gov (06.28.16)