



# Proceedings

A monthly newsletter from McGraw-Hill Education

August 2019 Volume 11, Issue 1

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## *Dear Professor,*

A new and exciting academic year is upon us! Welcome to McGraw-Hill Education's August 2019 issue of Proceedings, a newsletter designed specifically with you, the Business Law educator, in mind. Volume 11, Issue 1 of Proceedings incorporates "hot topics" in business law, video suggestions, an ethical dilemma, teaching tips, and a "chapter key" cross-referencing the August 2019 newsletter topics with the various McGraw-Hill Education business law textbooks.

You will find a wide range of topics/issues in this publication, including:

1. The United Kingdom's move toward banning bitcoin and other cryptocurrencies;
2. The Capitol One data breach;
3. The Bronx, New York District Attorney's decision not to pursue a grand jury indictment against Juan Rodriguez in the 'hot car' deaths of his twins;
4. Videos related to a) the wrongful conviction of Pennsylvanian John Miller and b) pharmaceutical giant Allergan, PLC's worldwide recall of Biocell textured breast implants and tissue expanders that have been linked to a rare form of cancer;
5. An "ethical dilemma" related to the Allergan, PLC breast implant and tissue expander product recall; and
6. "Teaching tips" related to Video 1("Man Walks Free after 21 Years in Prison When a Witness in the Murder Case Admits to the Killing"), Video 2 ("Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer") and the Ethical Dilemma ("Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders") of the newsletter.

May this academic year be your most successful one to date!

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This section of the newsletter covers three (3) topics:

- 1) The United Kingdom's move toward banning bitcoin and other cryptocurrencies;
- 2) The Capitol One data breach; and
- 3) The Bronx, New York District Attorney's decision not to pursue a grand jury indictment against Juan Rodriguez in the 'hot car' deaths of his twins.

## Hot Topics in Business Law

### Article 1: "Bitcoin Has 'No Intrinsic Value,' as U.K. 'Moves Towards' Crypto Ban"

<https://www.forbes.com/sites/billybambrough/2019/08/01/bitcoin-has-no-intrinsic-value-as-uk-moves-towards-crypto-ban/#69f9aed32d27>

According to the article, Bitcoin and cryptocurrency regulation has been pushed into the limelight over recent weeks, thanks to social media giant Facebook's high profile plans to launch its own potential rival to bitcoin sometime next year.

The bitcoin price, which had been climbing on rumors that big technology companies were taking an interest in bitcoin and cryptocurrencies, has plateaued at around \$10,000 per bitcoin after a number of countries rebuffed Facebook's plans, unveiled in June.

Now, the U.K.'s financial services watchdog has warned potential investors that bitcoin and cryptocurrencies have "no intrinsic value," with some taking the caution as a signal the country could be moving towards a bitcoin ban.

"This is a small, complex and evolving market covering a broad range of activities," said Christopher Woolard, executive director of strategy and competition at the U.K. Financial Conduct Authority (FCA), which oversees London's huge banking industry.

"Today's guidance will help clarify which crypto-asset activities fall inside our regulatory perimeter," Woolard added, with the FCA warning: "Consumers should be cautious when investing in such crypto-assets and should ensure they understand and can bear the risks involved with assets that have no intrinsic value."

The FCA branding bitcoin and cryptocurrencies as without "intrinsic value" is likely to rile many bitcoin believers who have long argued blockchain technology, which underpins bitcoin and most other cryptocurrencies, gives the digital tokens value.

"It is technically true that cryptocurrencies have no 'intrinsic value' when compared to share ownership in actual companies, however there are many examples where a marketplace bestows value on an intangible asset," Jon Ostler, of comparison site Finder.com, told the U.K.'s Telegraph newspaper. "For example, the brand of 'bitcoin' itself has value and although its future

place in society is still unclear, it is one of the most likely coins to stay the course.”

The warning from the U.K. comes shortly after U.S. president Donald Trump unleashed a scathing attack on bitcoin and cryptocurrencies, comments that were then echoed by other senior officials in his administration, including Treasury secretary Steven Mnuchin who branded bitcoin and cryptocurrencies a “national security issue.”

It's thought that Trump's attacks on bitcoin and crypto were in direct response to Facebook's libra cryptocurrency project, which, if successful, could undermine the international dominance of the U.S. dollar.

“Although not a ban, (the U.K.'s FCA warning is) a move in that direction,” said Herbert Sim, head of business development from Broctagon Fintech Group. “This lack of enthusiasm is shared by several countries; the U.S. with its scrutiny of libra, and India, who are looking to implement a similar ban on cryptocurrencies which are not state regulated. These movements could end up coming back to bite. The international competition on cryptocurrencies is heating up and there are huge risks in being left behind.”

Meanwhile, the watchdog warned investing in what it called “unregulated crypto-assets” will not be covered by the Financial Services Compensation Scheme, which pays out if the investment collapses.

“It remains possible in the future that if an unregulated token is subject to common acceptance and usage in the U.K. then either the FCA or the Bank of England will reconsider this position in order to ensure that adequate consumer protection exists,” said Tim Dolan, partner at law firm Reed Smith.

## Discussion Questions

1. What is currency. What is cryptocurrency?

*Currency is defined as a system of money in general use in a particular country. It is also defined as the fact or quality of being generally accepted or in use. Cryptocurrency is defined as a general currency in which encryption techniques are used to regulate the generation of units of currency and verify the transfer of funds, operating independently of a central bank.*

2. Are cryptocurrencies like bitcoin really currency?

*In terms of whether cryptocurrencies like bitcoin are really currency, student opinion may vary. They are not “generally” accepted or in use, and they are not issued by a central (i.e., government-associated) bank. Those who consider cryptocurrency as an acceptable medium of exchange would argue that it is a new form of currency, and that “non-traditional, non-government regulated” is actually a positive development.*

3. Do you support the U.K.'s move toward banning bitcoin and other cryptocurrencies? Why or why not?



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*This is an opinion question, so student replies may vary. Cryptocurrencies are not backed by the “full faith and credit” of an issuing government, so they are subject to “wild swings” in value (The value of cryptocurrencies is based solely on the demand for the currency relative to the supply, which determines an “equilibrium”—i.e., market—price).*

## Article 2: “Capital One Data Breach Compromises Data of Over 100 Million”

<https://www.nytimes.com/2019/07/29/business/capital-one-data-breach-hacked.html>

According to the article, A software engineer in Seattle hacked into a server holding customer information for Capital One and obtained the personal data of over 100 million people, federal prosecutors said recently, in one of the largest thefts of data from a bank.

The suspect, Paige Thompson, 33, left a trail online for investigators to follow as she boasted about the hacking, according to court documents in Seattle, where she was arrested and charged with one count of computer fraud and abuse.

Ms. Thompson, who formerly worked for Amazon Web Services, which hosted the Capital One database that was breached, was not shy about her work as a hacker. She is listed as the organizer of a group on Meetup, a social network, called Seattle Warez Kiddies, described as a gathering for “anybody with an appreciation for distributed systems, programming, hacking, cracking.”

The F.B.I. noticed her activity on Meetup and used it to trace her other online activities, eventually linking her to posts describing the data theft on Twitter and the Slack messaging service.

“I’ve basically strapped myself with a bomb vest,” Ms. Thompson wrote in a Slack post, according to prosecutors, “dropping capital ones dox and admitting it.”

Online, she used the name “erratic,” investigators said, adding that they verified her identity after she posted a photograph of an invoice she had received from a veterinarian caring for one of her pets.

According to court papers and Capital One, Ms. Thompson stole 140,000 Social Security numbers and 80,000 bank account numbers in the breach.

In addition to the tens of millions of credit card applications stolen, the company said on Monday, the breach compromised one million Canadian social insurance numbers — the equivalent of Social Security numbers for Americans.

The information came from credit card applications that consumers and small businesses had submitted as early as 2005 and as recently as 2019, according to Capital One, which is the nation’s third-largest credit card issuer, according to its website.

“Based on our analysis to date,” the bank said in a statement, “we believe it is unlikely that the information was used for fraud or disseminated by this individual.”



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The bank also said it expected that the breach would cost it up to \$150 million, including paying for credit monitoring for affected customers. Last week, the credit bureau Equifax settled claims from a 2017 data breach that exposed sensitive information on over 147 million consumers, costing it about \$650 million.

Amazon Web Services hosts the remote data servers that companies use to store their information, but large enterprises like Capital One build their own web applications on top of Amazon's cloud data so they can use the information in ways specific to their needs.

The F.B.I. agent who investigated the breach said in court papers that Ms. Thompson had gained access to the sensitive data through a "misconfiguration" of a firewall on a web application. That allowed the hacker to communicate with the server where Capital One was storing its information and, eventually, obtain customer files.

Amazon said its customers fully controlled the applications they built, and Capital One said in a news release that it had "immediately fixed the configuration vulnerability" once it discovered the problem. Amazon said it had found no evidence that its underlying cloud services were compromised.

On July 17, a tipster wrote to a Capital One security hotline, warning that some of the bank's data appeared to have been "leaked," the criminal complaint said.

Once alerted to the breach, the authorities found what they said were Ms. Thompson's online boasts that she wanted to "distribute" the materials. On June 27, she also listed "several companies, government entities and educational institutions," according to court papers, which investigators interpreted to be other hacks she "may have committed."

Other users in that channel, on Slack, expressed alarm. One said "don't go to jail plz," according to the complaint.

Recently, F.B.I. agents executed a search warrant on Ms. Thompson's house. They seized "numerous digital devices," prosecutors said, and found on them "items that referenced Capital One" and Amazon, which they referred to in the complaint only as the "cloud computing company."

"I am deeply sorry for what has happened," the bank's chief executive, Richard D. Fairbank, said in a statement. "I sincerely apologize for the understandable worry this incident must be causing those affected, and I am committed to making it right."

Capital One said the bank account numbers were linked to customers with "secured" credit cards. Secured cards require customers to put forth a sum of money — \$200 or \$250 — in exchange for a card.

"It's a way for banks to minimize the risk associated with lending to folks who don't have perfect credit or who are just getting started," said Matt Schulz, an analyst for Compare Cards. These customers are vulnerable, he said, and "often have very little financial margin for error."



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While the breach was possible because of a security lapse by Capital One, it was aided by Ms. Thompson's expertise. Information posted on social media shows she worked at one time for Amazon, as an engineer for the same server business that court papers said Capital One was using.

Capital One is a longstanding and prominent client of Amazon's. In a 2015 keynote at Amazon Web Services' main annual conference, a Capital One executive gave a presentation on the company's efforts to move critical parts of its technology to Amazon's cloud infrastructure so it could focus on building consumer applications and other needs.

Ms. Thompson will remain in federal custody until a hearing, prosecutors said. Her lawyer did not respond to an email seeking comment.

Capital One has faced security breaches before, and they are a constant, and costly, threat for the financial industry. The chief of JPMorgan Chase, Jamie Dimon, has said his bank spends almost \$600 million a year on security. Bank of America's chief has said in the past that the bank has a "blank check" for cybersecurity.

In a breach in 2017, Capital One notified customers that a former employee may have had access for nearly four months to their personal data, including account numbers, telephone numbers, transaction history and Social Security numbers. The company reported a similar breach involving an employee in 2014.

On Meetup, Ms. Thompson posted enthusiastically about hacking. "I've been meaning to put together something like a hack night or something soon," she wrote on May 13.

"It's been a crazy past two weeks, and my cat had to go to the vet everyday last week but she's finally starting to recover maybe this wednesday in capitol hill? I'll do an all day thing at starbucks until they close, I'e got nothing better to do."

## Discussion Questions

1. Define computer fraud.

*Computer fraud is the act of using a computer to take or alter electronic data, or to gain unlawful use of a computer or system. In the United States, computer fraud is specifically proscribed by the Computer Fraud and Abuse Act, which criminalizes computer-related acts under federal jurisdiction.*

2. As the article indicates, Paige Thompson was "not shy" about her work as a hacker. In your reasoned opinion, should this mitigate (i.e., lessen) the criminality of her conduct? Why or why not?

*Although student opinions may vary in response to this question, in your author's opinion the fact that Ms. Thompson was "not shy" (and even boastful) about her work as a hacker should not mitigate the criminality of her conduct; if anything, it may actually aggravate (enhance) the criminality of her conduct.*



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3. If Ms. Thompson did not use the Capital One data to her own advantage, where is the crime in this case?

*Ms. Thompson's crime is the unauthorized access of Capital One data. Had she distributed the data and/or used it for her own personal gain, that would have compounded the criminality of her conduct.*

## **Article 3: "Prosecutors Decline to Pursue Grand Jury Indictment against Father in New York Hot Car Death of Twins"**

[https://abcnews.go.com/US/prosecutors-decline-pursue-grand-jury-indictment-father-york/story?id=64706838&cid=clicksource\\_4380645\\_null\\_headlines\\_hed](https://abcnews.go.com/US/prosecutors-decline-pursue-grand-jury-indictment-father-york/story?id=64706838&cid=clicksource_4380645_null_headlines_hed)

*Note: In addition to the article, please see the related video included at the above-referenced internet address.*

According to the article, New York prosecutors said recently they will not pursue a grand jury indictment at this time against a father whose 1-year-old twins sweltered to death when he mistakenly left them for eight hours in his car on a hot day, officials said.

Juan Rodriguez, 39, a licensed clinical social worker, had already pleaded not guilty to charges of manslaughter in the deaths of his children Luna and Phoenix.

But the Bronx District Attorney's office said it is adjourning the case against Rodriguez and will not convene a grand jury at this time to pursue an indictment.

Rodriguez appeared in court at the Bronx Hall of Justice with his wife, Marissa, and their 4-year-old son.

Prosecutors said they have decided to put off presenting evidence to a grand jury, pending further investigation. Rodriguez was ordered to return to court for another hearing on August 27.

During a recent news conference, Rodriguez's attorney, Joey Jackson, issued an appeal to Bronx District Attorney Darcel D. Clark to show his client mercy, saying that Rodriguez has been truthful with investigators and "has nothing to harbor and hide other than misery and sorrow."

"We're appealing to her sense of justice to do what we believe to be the right thing, and that is to dismiss these charges," Jackson said. "We understand that they will continue to evaluate all aspects of the case and we welcome their evaluation of that. We believe that at the conclusion of them evaluating all the facts, all the evidence and everything in this case, they will come to the conclusion that this was a horrible tragedy."

Rodriguez of Rockland County, just north of New York City, dropped his 4-year-old son off at a home in Westchester, New York before driving to work at James J. Peters VA Medical Center in the Bronx, police said. He told police he forgot his infant twins were strapped into their rear-facing car seats when he arrived for work at 8 a.m.





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When he returned to his car eight hours later to drive home, he "observed Luna and Phoenix ... strapped into their car seats, not moving, not breathing and both children appeared lifeless," according to a criminal complaint.

Rodriguez pulled over and desperately screamed for help, but the children were pronounced dead on the scene at 4:10 p.m.

Temperatures reached near 90 degrees in New York City. The city medical examiner's office determined that the children's body temperatures were 108 degrees when they were found, according to the criminal complaint.

Following the tragedy, Marissa Rodriguez released a statement, calling her husband a "good person and a great father."

"I know he would've never done anything to hurt our children intentionally," Marissa Rodriguez said in her statement. "I will never get over this loss and I know he will never forgive himself for this mistake."

She added: "This was a horrific accident, and I need him by my side to go through this together. Luna and Phoenix will always live in our hearts and memories and we are working hard to come to terms with what happened. We need to grieve, be strong, and be present for our other children."

Jackson said recently that he has reached out to the speaker of the New York State Assembly on behalf of the parents, who want to work with state lawmakers on legislation requiring auto manufacturers to come up with a mechanism to alert people that children are in car seats before they exit their vehicles.

"Mr. Rodriguez and his family will certainly be dedicating their lives to the cause of assuring this does not happen to anyone else," Jackson said.

There were a record 52 hot car deaths of children in the United States last year, according to the national nonprofit group KidsAndCars.org. At least 24 children have died in hot cars across the country so far this year, the nonprofit said.

"I want to mention to everyone that this is not exclusive to New York," Jackson said. "This has happened throughout the country. My client and his family will be working with the legislature when they gain the strength to do so in ensuring that other people are protected."

## Discussion Questions

1. Define manslaughter.

*Manslaughter is the crime of killing a human being without malice aforethought, or otherwise in circumstances not amounting to murder.*





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2. In your reasoned opinion, and based on the information provided in the article, did Juan Rodriguez commit manslaughter? Why or why not?

*Although student opinions may vary in response to this question, there is a strong case to be made that Mr. Rodriguez did indeed commit manslaughter. Even if he did not intend for his twins to die, the fact that he “forgot” that they were in the back of his car and left them strapped in their car seats for eight (8) hours on a near-90 degree day might very well “shock the collective conscience” of a jury, leading the members of a jury to conclude that his inattentiveness to the needs of his children rose to the level of criminal conduct.*

3. Do you support the Bronx District Attorney's Office's decision to adjourn the case against Rodriguez and not convene a grand jury to pursue an indictment? Why or why not?

*Student responses may vary in response to this question, but ultimately, it is the prosecutor's decision as to whether to pursue a criminal indictment. The Bronx District Attorney's Office might have simply concluded that the Rodriguez family has already suffered enough.*

## Video Suggestions

### **Video 1: “Man Walks Free after 21 Years in Prison When a Witness in the Murder Case Admits to the Killing”**

<https://www.cnn.com/2019/07/31/us/pennsylvania-man-freed-after-witness-confesses-to-killing/index.html>

*Note: In addition to the video, please see the following article included at the above-referenced internet address:*

### **“Man Walks Free after 21 Years in Prison When a Witness in the Murder Case Admits to the Killing”**

According to the article, a Pennsylvania man who spent 21 years behind bars for murder was freed recently after the star witness in the case confessed to the killing.

John Miller walked out of the State Correctional institution in Frackville, about 100 miles northwest of Philadelphia, after prosecutors declined to retry him, saying there was insufficient evidence, according to court records.

"I'm very happy and excited that after 21 years I'm finally being heard and that my innocence has reached the surface," Miller said in a written statement distributed by his attorney. "I'm going home to my family. I'm overwhelmed, excited, and happy."

Miller, 44, credited his attorneys with securing his release after years of declaring his innocence.

"Without them, I don't know what would have happened or where I would have been," he said.

Miller was convicted in 1997 for the October 1996 murder of Anthony Mullen during a robbery attempt outside the 30th Street Station, Philadelphia's main railroad station, according to court records. Mullen had been shot to death. A jury convicted Miller of second-degree murder, and he was sentenced to life in prison.

David Williams was the witness who identified Miller as the killer, according to court records. Williams told police in exchange for leniency in another case that Miller had confessed to him that he killed Mullen, the court records show.

But Williams recanted his statement even before Miller's preliminary hearing, and "he has been confessing to Mullen's murder for more than a decade,"



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the Philadelphia District Attorney's Office wrote in a motion filed recently that declined to retry Miller.

Williams even sent a letter to Miller's mother in December 2002, saying in it that he committed the murder.

"I can't live with this on my conscience. Your son had no knowledge of this crime. He wasn't even there. I lied on him," he wrote, according to court records.

Miller filed 10 appeals, his attorney, Thomas Gallagher said. All were denied, he said.

Miller's legal team, which included the Pennsylvania Innocence Project, took on the case eight years ago and found evidence that had not been previously disclosed to Miller's defense team, Gallagher said in a news release. That evidence raised questions about what authorities knew about Williams initial testimony, according to court records.

A federal judge on July 1 ordered Miller be released, subject to a decision by the district attorney on whether to pursue a new trial.

In a motion filed this week, the District Attorney's Office said there was "insufficient evidence" to make a case against Miller.

"Williams' statement to the police was the crux of the case against defendant," the motion said.

Recently, a Common Pleas Court judge agreed and ordered Miller released.

The media was unable to reach Williams for comment, and it was not immediately known if he had an attorney. The District Attorney's Office has not said whether it will charge Williams in the Mullens murder.

## Discussion Questions

1. In your reasoned opinion, who (if anyone) is responsible for John Miller's wrongful conviction and twenty-one (21) years served in prison?

*David Williams falsely identified Mr. Miller as the perpetrator, so he is at least in part responsible; however, in your author's opinion, there is a strong case to be made that the court system is responsible as well. As the article indicates, Mr. Williams recanted his statement even before Miller's preliminary hearing, and he confessed to Mullen's murder for more than a decade. Further, Mr. Miller filed ten (10) appeals with the court system, and all of his appeals were denied.*

2. Should Mr. Miller receive compensation from the state of Pennsylvania for his wrongful conviction? If so, in your opinion, what amount of money would be enough to compensate Mr. Miller for his twenty-one (21) years served in prison?

*It is fairly common for a wrongfully convicted individual to receive compensation from the jurisdiction involved in the wrongful conviction. Reasonable minds might differ in terms of what amount of money would be sufficient for the wrongful conviction. Even if Mr. Miller were to receive \$21 million, representing \$1 million for each year wrongfully imprisoned, would that amount of money really be enough to compensate Mr. Miller for deprivation of his freedom during much of his youthful years (age 23 through 44)?*



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3. As the article indicates, the Philadelphia District Attorney's Office has not charged David Williams in the murder of Anthony Mullen. Should it? Why or why not?

*As the article indicates, Mr. Williams has confessed to Mullen's murder for more than a decade. Even still, confessions are not necessarily proof of guilt beyond reasonable doubt, since a defense attorney could argue that the confession was coerced, or that his or her client confessed in order to gain attention and notoriety. Ultimately, it is the prosecutor's decision as to whether to charge a defendant with the commission of a crime.*

## **Video 2: "Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer"**

<https://www.cnn.com/2019/07/24/health/breast-implant-recall-allergan-fda-bn/index.html>

*Note: In addition to the video, please see the following article included at the above-referenced internet address:*

## **"Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer"**

According to the article, Allergan issued a worldwide recall of Biocell textured breast implants and tissue expanders that have been linked to a rare cancer. The move came after the U.S. Food and Drug Administration (FDA) requested the manufacturer voluntarily recall the products.

"Allergan is taking this action as a precaution following notification of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) provided by the U.S. Food and Drug Administration," according to a press announcement by Allergan.

Textured breast implants are less commonly used in the United States compared to other countries, according to the FDA. Specifically, macro-textured implants -- the type of textured implant that Allergan manufactures -- represent less than 5% of all breast implants sold in the United States.

"It's our estimation that hundreds of thousands of women have these implants," Dr. Binita Ashar, director of the office of surgical and infection control devices at the FDA, said during a press conference recently. She added that the FDA will get more information on those numbers in the coming weeks.

The specific textured breast implant products that have been recalled include Natrelle Saline-Filled breast implants, Natrelle Silicone-Filled breast implants, Natrelle Inspira Silicone-Filled breast implants, and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants.

The recalled tissue expanders include the Natrelle 133 Plus Tissue Expander and Natrelle 133 Tissue Expander with Suture Tabs.

In 2011, the FDA first identified a possible association between breast implants and the development of a rare cancer called breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL.

The FDA does not recommend the removal of these breast implant products in women without symptoms of BIA-ALCL, according to the agency's announcement, but rather to know the symptoms and monitor the area around breast implants for any changes. If people experience any symptoms or changes, they should talk to their doctor.



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The main symptoms of BIA-ALCL are swelling or pain in the area of the implant, which may occur years after the implant was placed. As of earlier this month, a total of 573 cases globally of anaplastic large cell lymphoma related to breast implants have been reported to the FDA. There have also been 33 patient deaths, the FDA said.

"Although the overall incidence of BIA-ALCL appears to be relatively low, once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action to alert the firm to new evidence indicating a recall is warranted to protect women's health," Dr. Amy Abernethy, the FDA's principal deputy commissioner of food and drugs, said in the agency's news release recently.

"We will continue to monitor the incidence of BIA-ALCL across other textured and smooth breast implants and tissue expanders as well as other devices intended for use in the breast," she said. "If action is needed in the future, we will not hesitate to do what is necessary to protect patients."

In March, the FDA Medical Devices Advisory Committee's General and Plastic Surgery Devices Panel convened to discuss the steps it would take to maintain surveillance of breast implant safety.

"We will continually evaluate any new information and may, as a result, take action regarding other breast implants, if warranted," Dr. Jeff Shuren, director of the FDA's Center for Devices and Radiological Health said in Wednesday's news release.

"In addition, we are continuing our assessment to determine whether the risk of developing BIA-ALCL is limited to specific models of textured, or all textured breast implants," he said. "We continue to advise women and health care professionals that the use of breast implants is associated with a risk of developing BIA-ALCL and that the risk is greater with textured implants."

The FDA also announced that it is considering recommendations to change the labeling of breast implants to include a boxed warning indicating health risks, among other possible actions to help share safety information.

Breast augmentation was the most popular cosmetic surgical procedure performed last year, according to statistics from the American Society of Plastic Surgeons.

While most women have breast implants with no serious complications, as many as 20% of women who receive implants for augmentation have to have their implants removed within eight to 10 years, owing to complications, according to the FDA.

"Breast implants are not meant to be lifetime devices. They have a lifespan, and that might range from seven to 10-plus years, based on the implant and patient," Dr. Tommaso Addona, a plastic surgeon and president of the Long Island Plastic Surgical Group in New York, said in March.

He added that he often discusses benefits and risks with his own patients.

"We do discuss complications. Those range from scarring around the implant, sometimes soreness and discomfort from the implant ... to in the last seven years, probably a bit more, we've become more acutely aware of a specific type of lymphoma that is associated with breast implants," he said. "What the general public should appreciate is, as doctors and clinicians, we always want what's best and safest for our patients. We're constantly not only educating ourselves but educating our patients."



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## Discussion Questions

1. Comment on the Food and Drug Administration's (FDA's) involvement in this case. Is this an example of proper or improper government oversight and regulation?

*Student opinions may vary in response to this question. Although the FDA certainly put pressure on Allergan to engage in the "voluntary" product recall, some students might argue that proper government oversight and regulation would have identified the health risk before the product was made available to consumer-patients.*

2. Based on the information provided in the article, is this case really an example of a "voluntary" product recall? Why or why not?

*In your author's opinion, this is not really a "voluntary" product recall. The FDA certainly put pressure on Allergan to engage in the recall, and had Allergan chosen not to do so, the FDA is authorized to initiate a mandatory product recall if the public's health and well-being necessitates it.*

3. In your reasoned opinion, should medical providers be required to provide comprehensive information to patients regarding the potential risks associated with a certain medical procedure? Should medical providers be liable to patients who experience harm if they do not disclose the potential risks associated with a certain medical procedure? Explain your response.

*In your author's opinion, absolutely on both counts! Comprehensive information disclosure is essential to a reasoned consumer purchase decision, and when the consumer's health is at issue, requiring comprehensive information disclosure is even more compelling. In terms of whether medical providers should be liable to patients who experience harm if they do not disclose the potential risks associated with a certain medical procedure, the basic concept of negligence (more particularly, medical malpractice) would demand liability in such cases—the health care provider has not done what a reasonable provider would have done in the same or a similar case.*



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## Ethical Dilemma

This section of the newsletter addresses the Allergan, PLC breast implant and tissue expander product recall.

### **Ethical Dilemma (Related to Video 2— “Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer”): “Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders”**

*Note: The following is an Allergan press release related to its voluntary recall, at the behest of the United States Food and Drug Administration (FDA), of certain breast implants. Please answer the related Discussion Questions with reference to the information contained in: 1) Allergan’s press release; 2) Video 2 (“Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer”); 3) the article accompanying Video 2 (“Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer”); and 4) the information referenced in Teaching Tip 2 (the Food and Drug Administration’s news release regarding Allergan’s breast implant recall).*

**07.24.2019 | Investors**

### **Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders**

*-- Global Action Follows Notification of Updated Safety Information from the U.S. Food and Drug Administration (FDA) --*

*-- FDA Does Not Recommend Removal or Replacement of Textured Breast Implants in Asymptomatic Patients --*

*-- Smooth and MICROCELL® Breast Implants and Tissue Expanders Not Impacted --*

DUBLIN, July 24, 2019 /PRNewswire/ -- Allergan plc (NYSE: AGN) today announced a voluntary worldwide recall of BIOCELL® textured breast implants and tissue expanders. Allergan is taking this action as a precaution following notification of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) provided by the U.S. Food and Drug Administration (FDA).

BIOCELL® saline-filled and silicone-filled textured breast implants and tissue expanders will no longer be distributed or sold in any market where they are currently available. Effective immediately, healthcare providers should no longer implant new BIOCELL® textured breast implants and tissue expanders





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and unused products should be returned to Allergan. Allergan will provide additional information to customers about how to return unused products.

Patient safety is a priority for Allergan. Patients are advised to speak with their plastic surgeon about the risks and benefits of their implant type should they have any concerns. Importantly, the FDA and other health authorities have not recommended removal or replacement of textured breast implants or tissue expanders in asymptomatic patients.

This global recall does not affect Allergan's NATRELLE® smooth or MICROCELL® breast implants and tissue expanders.

The recalled products include:

Natrelle Saline breast implant styles 168, 363, 468
Natrelle and McGhan 410 breast implant styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
Natrelle and McGhan 410 <i>Soft Touch</i> breast implant styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
Natrelle 510 Dual-Gel styles LX, MX, FX
Natrelle INSPIRA breast implants, styles TRL, TRLP, TRM, TRF, TRX, TSL, TSLP, TSM, TSF, TSX, TCL, TCLP, TCM, TCF, TCX
Natrelle and McGhan Round Gel Implants, styles 110, 110 Soft Touch, 120, 120 Soft Touch
Natrelle Komuro breast implants styles KML, KMM, KLL, and KLM
Natrelle Ritz Princess breast implant styles RML, RMM, RFL, RFM
Natrelle 150 Full Height and Short Height double lumen implants
Natrelle 133 tissue expanders with and without suture tabs: styles 133FV, 133MV, 133LV, 133MX, 133SX, 133SV, T-133FV, T-133MV, T-133LV, T-133MX, T-133SX, T-133SV, 133FV-T, 133MV-T, 133LV-T, 133MX-T, 133SX-T, 133SV-T
Natrelle 133 Plus tissue expander styles 133P-FV, 133P-MV, 133P-LV, 133P-MX, 133P-SX, 133P-SV, T-133P-FV, T-133P-MV, T-133P-LV, T-133P-MX, T-133P-SX, T-133P-SV, 133P-FV-T, 133P-MV-T, 133P-LV-T, 133P-MX-T, 133P-SX-T, 133P-SV-T

U.S. healthcare providers with questions regarding this announcement can contact Medical Information at 1-800-678-1605 option #2 or IR-Medcom@allergan.com. For all other countries, please use the contact details at the following link on Allergan's website: Allergan Global Medical Information Contacts.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)



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Regular Mail or Fax: download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-FDA-1088 to request form, then complete and return address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

## About Allergan PLC

Allergan PLC (NYSE: AGN), headquartered in Dublin, Ireland, is a global pharmaceutical leader focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world. Allergan markets a portfolio of leading brands and best-in-class products primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. As part of its approach to delivering innovation for better patient care, Allergan has built one of the broadest pharmaceutical and device research and development pipelines in the industry.

With colleagues and commercial operations located in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at [www.Allergan.com](http://www.Allergan.com).

## Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective on existing trends and information as of the date of this release. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; the impact of uncertainty around timing of generic entry related to key products, including RESTASIS<sup>®</sup>, on our financial results; risks associated with divestitures, acquisitions, mergers and joint ventures; risks related to impairments; uncertainty associated with financial projections, projected cost reductions, projected debt reduction, projected synergies, restructurings, increased costs, and adverse tax consequences; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2018 and Allergan's Quarterly Report on Form 10-Q for the period ended March 31, 2019. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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## Discussion Questions

1. Note that the focus of Allergan's press release is on its investors. Considering the potential and actual harm to patients who are using Allergan's breast implants and tissue expanders, is that an appropriate focus at the present time? Why or why not?

*Student opinion may vary in response to this question. In all fairness to Allergan, its stakeholders include investors as well as consumers who purchase its products. However, if affected consumers (or the affected consumers' friends or family members) read this press release, they might conclude that Allergan is "tone deaf" in terms of understanding and appreciating the true gravity of the risk and harm associated with its products.*

2. In your reasoned opinion, to which category of stakeholders do companies own the greatest allegiance and concern: a) shareholders; or b) customers?

*This is an opinion question, so student responses may vary.*

3. Note that Allergan's press release includes the following statement: *FDA Does Not Recommend Removal or Replacement of Textured Breast Implants in Asymptomatic Patients*. Considering the potential and actual harm to patients who are using Allergan's breast implants, is the foregoing statement appropriate to include in its press release? Why or why not?

*This is an opinion question, so student responses may vary. Although some might make the case that Allergan is addressing and alleviating (at least to a certain extent) consumer fears and concerns, some could interpret this statement as an attempt by the company to "save face."*



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## Teaching Tips

This section of the newsletter will assist you in addressing Video 1 (Man Walks Free after 21 Years in Prison When a Witness in the Murder Case Admits to the Killing”), Video 2 (“Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer”), and the Ethical Dilemma (“Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders”) of the newsletter.

### **Teaching Tip 1 (Related to Video 1— “Man Walks Free after 21 Years in Prison When a Witness in the Murder Case Admits to the Killing”)**

For more information regarding the Pennsylvania Innocence Project, the organization that served as part of John Miller’s legal team, please see the following internet address:

<https://innocenceprojectpa.org/>

### **Teaching Tip 2 (Related to Video 2— “Worldwide Recall Issued for Textured Breast Implants Tied to Rare Cancer” and the Ethical Dilemma— “Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders”)**

For a Food and Drug Administration (FDA) news release regarding Allergan’s breast implant recall, please see the following internet address:

<https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan>



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## Chapter Key for McGraw-Hill Education Business Law Texts:

	<b>Hot Topics</b>	<b>Video Suggestions</b>	<b>Ethical Dilemma</b>	<b>Teaching Tips</b>
<b>Barnes et al., Law for Business</b>	Chapter 5	Chapters 5 and 46	Chapters 3 and 46	Chapters 5 and 46
<b>Bennett-Alexander &amp; Hartman, Employment Law for Business</b>	N/A	N/A	N/A	N/A
<b>Kubasek et al., Dynamic Business Law</b>	Chapters 6 and 7	Chapters 7, 10, and 45	Chapters 2, 10, and 45	Chapters 7, 10, and 45
<b>Kubasek et al., Dynamic Business Law: The Essentials</b>	Chapters 6 and 9	Chapters 6 and 25	Chapters 2 and 25	Chapters 6 and 25
<b>Liuzzo, Essentials of Business Law</b>	Chapters 3 and 36	Chapters 3 and 34	Chapters 2 and 34	Chapters 3 and 34
<b>Langvardt et al., Business Law: The Ethical, Global, and E-Commerce Environment</b>	Chapter 5	Chapters 5, 20, and 48	Chapters 4, 20, and 48	Chapters 5, 20, and 48
<b>McAdams et al., Law, Business &amp; Society</b>	Chapters 4 and 16	Chapters 4, 7, and 15	Chapters 2, 7, and 15	Chapters 4, 7, and 15
<b>Melvin, The Legal Environment of Business: A Managerial Approach</b>	Chapters 22 and 25	Chapters 9, 21, and 22	Chapters 5, 9, and 21	Chapters 9, 21, and 22
<b>Pagnattaro et al., The Legal and Regulatory Environment of Business</b>	Chapters 12 and 13	Chapters 13 and 18	Chapters 2 and 18	Chapters 13 and 18
<b>Sukys, Brown, Business Law with UCC Applications</b>	Chapters 5 and 34	Chapters 5 and 15	Chapters 1 and 15	Chapters 5 and 15



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## This Newsletter Supports the Following Business Law Texts:

- Barnes et al., Law for Business, 13<sup>th</sup> Edition ©2018 (1259722325)
- Bennett-Alexander et al., Employment Law for Business, 9<sup>th</sup> Edition ©2019 (1259722333)
- Kubasek et al., Dynamic Business Law, 5<sup>th</sup> Edition ©2020 (1260247899)
- Kubasek et al., Dynamic Business Law: The Essentials, 4<sup>th</sup> Edition ©2019 (125991710X)
- Liuzzo, Essentials of Business Law, 10<sup>th</sup> Edition ©2019 (1259917134)
- Langvardt (formerly Mallor) et al., Business Law: The Ethical, Global, and E-Commerce Environment, 17<sup>th</sup> Edition ©2019 (1259917118)
- McAdams et al., Law, Business & Society, 12<sup>th</sup> Edition ©2018 (1259721884)
- Melvin, The Legal Environment of Business: A Managerial Approach, 3<sup>rd</sup> edition ©2018 (1259686205)
- Pagnattaro et al., The Legal and Regulatory Environment of Business, 18<sup>th</sup> Edition ©2019 (1259917126)
- Sukys, Business Law with UCC Applications, 15<sup>th</sup> Edition ©2020 (1259998169)

