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Proceedings

A monthly newsletter from McGraw-Hill Education

August 2017 Volume 9, Issue 1

Contents

Dear Professor,

The 2017-2018 academic year is upon us! Welcome to McGraw-Hill Education's August 2017 issue of Proceedings, a newsletter designed specifically with you, the Business Law educator, in mind. Volume 9, 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 2017 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. Allegations of sexual harassment against American Apparel founder Dov Charney;

2. The First Amendment to the United States Constitution's "free speech" clause as it relates to hate speech;

3. A serious injury sustained by a three-year-old boy at a Florida trampoline park;

4. Videos related to a) a new rule established by the Consumer Product Safety Commission that bans financial firms from requiring consumers to settle group disputes through arbitration and b) the Federal Communication Commission's recent decision to start changing "net neutrality" rules;

5. An "ethical dilemma" related to drug pricing; and

6. "Teaching tips" related to Video 1 ("With 'Rip-Off Clause' Quashed, Consumers Can Now Sue Banks in Class-Action") and Video 2 ("Tech Companies Rally for Net Neutrality Day of Action as FCC Aims to Roll Back Rules") of the newsletter.

I hope all of you had a safe, restful, and enjoyable summer, and I wish you a prosperous 2017-2018 academic year!

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Of Special Interest

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

1) Allegations of sexual harassment against American Apparel founder Dov Charney;

2) The First Amendment to the United States Constitution's "free speech" clause as it relates to hate speech; and

3) A serious injury sustained by a three-year-old boy at a Florida trampoline park.

Hot Topics in Business Law

Article 1: "American Apparel Founder Dov Charney Gives Odd Answer to Question about Having Sex with Employees"

http://fortune.com/2017/07/12/american-apparel-dov-charney-los-angeles-apparel/

According to the article, American Apparel founder Dov Charney, who left after a string of sexual harassment allegations from his own employees, had a strange response when asked if he was having sex with workers at his new clothing company, Los Angeles Apparel.

"That question is private, and it should be private," Charney said recently in an interview with Bloomberg when asked if he was "going down the same path at Los Angeles Apparel and hooking up with employees."

The interviewer then asked if Charney was being "more careful" at his new company. "You always have to be cautious in the lawsuit society that we're in, you know. ... I love the company, and I love the people I work with," he responded.

"We're very close and we're holding hands and walking through the fire. We intend to be successful," Charney added.

Charney was never charged or convicted for the sexual harassment claims brought against him, which included allegations from American Apparel board members that he kept kept graphic photographs of him having sex with staff members on company computers.

The company did end up settling cases with four models who claimed that Charney had either harassed or sexually assaulted them. Two models settled for $3.4 million dollars — the others' were confidential.

Shortly after Charney left, American Apparel accused him of violating policies on harassment and retaliation against former employees.

"The company discovered voluminous evidence of Mr. Charney's sexual liaisons with employees and models," American Apparel said in court papers.

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Discussion Questions

1. Define sexual harassment.

   According to the Equal Employment Opportunity Commission (EEOC), sexual harassment consists of:

   Unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when:

   a) Submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment, or

   b) Submission to or rejection of such conduct by an individual is used as a basis for employment decisions affecting such individual, or

   c) Such conduct has the purpose or effect of unreasonably interfering with an individual's work performance or creating an intimidating, hostile, or offensive working environment.

2. As the article indicates, American Apparel, Mr. Charney's former company, settled sexual harassment cases with four models who claimed that Charney had either harassed or sexually assaulted them. Two models settled for $3.4 million dollars — the others' were confidential. Is this an admission of liability on the part of Mr. Charney and/or his former company? Why or why not?

   Under most circumstances, litigation settlement does not constitute an admission of liability. In fact, most settlement agreements include language indicating that settlement is not an admission of liability. Sometimes, the terms of settlement agreements are disclosed (as was the situation in the subject case when two models settled with Mr. Charney and American Apparel for $3.4 million), and sometimes they are not (as was the situation for the other two models).

3. Assess Mr. Charney's statement that we (in the United States) live in a "lawsuit society."

   Student responses may vary in response to this statement. Perhaps the inference here is that in the United States, individuals are "sue-happy" and are quick to litigate in order to "make a buck." Such a generalized statement, however, dismisses the fact that many individuals have meritorious claims, and deserve their day in court before a trial jury, as guaranteed by the Bill of Rights to the United States Constitution.

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Article 2: "How to Defend the Constitution When the KKK Comes to Town"

http://www.cnn.com/2017/07/12/opinions/free-speech-isnt-free-kendrick-opinion/index.html

Note: This is an opinion piece written by Leslie Kendrick, Vice Dean and Albert Clark Tate Jr. Professor of Law at the University of Virginia. She has published widely on issues of free expression, particularly the scope and structure of free speech rights.

As a law professor, I usually explain free speech to my students by talking about when the Nazis tried to march in Skokie, Illinois in the late 1970s.

As many Americans are aware, a great deal of what most would call hate speech is protected by the First Amendment. The Nazis in Skokie are the classic case. In 1977, the National Socialist Party of America proposed to march in this predominantly Jewish community, home to many Holocaust survivors. The ACLU defended their right to wear Nazi uniforms and display swastikas, and courts upheld that right. The Nazis won (though they ultimately decided to march elsewhere).

Until now, I would have said there is no better illustration that the United States has the strongest speech protections in the world. But my new go-to illustration is Charlottesville, summer of 2017. I teach at the University Of Virginia School Of Law in Charlottesville, Virginia. Since the spring, when our city council voted to remove a prominent monument to Robert E. Lee and to rename parks containing the Lee statue and a monument to his fellow Confederate general Stonewall Jackson, Charlottesville has been the site of targeted demonstrations by neo-Nazis, white nationalists and, recently, the Ku Klux Klan.

I used to talk about freedom and its costs in terms of Skokie. This fall, when the students return, I will be talking about home.

As in Skokie, the demonstrations in Charlottesville have proved the strength of the First Amendment but also shown its steep cost. The Nazis chose Skokie precisely because its residents would find their message deeply offensive. Hate groups have targeted Charlottesville precisely because it voted to take down the monument, and because it is a community actively grappling with a thorny Confederate and Jim Crow past.

Not only that, but the Ku Klux Klan, neo-Nazis and white nationalists all reject a basic tenet of the American system: that all people are created equal. So why does our Constitution protect them?

Not because they deserve respect. In popular culture, people sometimes act as though "exercising my First Amendment rights" should earn them a pat on the back and, if not

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agreement, at least grudging respect. Nothing about the First Amendment requires that. We permit hate speech, but we need not respect it.

We also need not worry that we're wrong in our lack of respect. Judge Learned Hand, quoting Oliver Cromwell, said that every courthouse and public building should have inscribed above its entrance, "Consider that ye may be wrong." But there are certain facts that do not require hedging, and the fundamental equality of all people is one of them.

Free speech is also not, as some judges have argued, a safety valve that prevents bad actions. Racist and anti-Semitic speech is not the hallmark of an otherwise enlightened society. And anyone who thinks speech is a harmless safety valve has not pictured the combination of armed Klansmen, hundreds of angry counter-protestors, and a police force tasked with keeping order.

Whatever this is about, it isn't safety.

The law offers two reasons to protect free speech, even in the face of social disgust or unrest. First, democracy may require it. After much wrestling, the courts concluded, in cases about socialists and communists, that a person does not have to agree with American values in order to get the protection of the First Amendment. The Constitution protects even those who would try to destroy it, up to the point of a clear and present danger. Otherwise, what we have are not legitimate democratic outcomes but manufactured consensus. On this view, democracy does not prevail if the Klan is censored. Democracy prevails if the Klan speaks and loses on the merits.

Second, the alternative is letting the government choose who can speak and who cannot. Given the government's track record -- not just the McCarthy era and the Red Scare but censorship of abolitionist pamphlets before the Civil War and Southern states' attempts to shut down press coverage of the civil rights movement -- maybe it is not outlandish to think it is better to let the Klan speak than to let the government decide who should.

But these reasons have their costs, and those costs are not borne equally. They fall disproportionately on African-American, Jewish, Muslim, and other minority members of the community. They are the ones who absorb these very public, very ugly assertions that they are worth less than other Americans.

They are the ones who get the message that these monuments were erected to be -- and still are -- symbols of white supremacy. When the KKK and neo-Nazis show up to defend "history" in a place with a legacy, like Charlottesville's, for displacing its black residents, that message could not be clearer.

They are the ones who have to live with not only the message of these demonstrations but also the unpredictability of where all this is going. In the short term, the city is preparing for

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another rally of white nationalists on August 12. In the long term, the fact is that free speech is not free, and we do not split the check evenly.

One thing we must all do is be conscious of these costs. Another is to recognize that, in permitting all viewpoints, the First Amendment puts the responsibility on us to choose what to espouse and what to reject. All views are not equally good. It may be vital to the legitimacy of our system that we have the freedom to choose. It is vital to its survival that we choose wisely.

Discussion Questions

1. Describe the First Amendment to the United States Constitution's "free speech" clause.

   As stated in the First Amendment to the United States Constitution, "Congress shall make no law…abridging the freedom of speech." This is known as the free speech clause, and establishes the standard for freedom of expression in the United States.

2. Assess Ms. Kendrick's statement that we (in the United States) "permit hate speech, but we need not respect it." Do you agree or disagree with her assessment? Why or why not?

   This is an opinion question, so student responses may vary. As defined by the American Bar Association, hate speech is speech that offends, threatens, or insults groups, based on race, color, religion, national origin, sexual orientation, disability, or other traits.

   Hate speech is offensive to a reasonable person, yet the United States Supreme Court recognizes it as a form of speech protected by the First Amendment to the United States Constitution. With that being said, nowhere is it written that it must otherwise be respected.

3. According to the article, what are the two reasons the law protects free speech? In your reasoned opinion, which one of the two is a more compelling reason? Explain your response.

   According to the article, the law offers two reasons to protect free speech, even in the face of social disgust or unrest. First, democracy may require it. As Ms. Kendrick indicates in her article, the United States Constitution "protects even those who would try to destroy it, up to the point of a clear and present danger. Otherwise, what we have are not legitimate democratic outcomes but manufactured consensus." Second, the alternative is letting the government choose who can speak and who cannot. In a free society, the government should not be able to pick "winners and losers" with respect to freedom of speech.

   Both reasons cited are interrelated and compelling reasons for the law to protect free speech, even speech that is offensive.

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Article 3: "3-Year-Old in Body Cast after Visiting Trampoline Park"

http://www.cbsnews.com/news/3-year-old-in-body-cast-after-visiting-trampoline-park/

According to the article, a 3-year-old Florida boy is in a cast from the waist down for an injury suffered while jumping at a trampoline park.

The case has circulated nationally on social media and raised questions about age restrictions for trampolines.

Kaitlin Hill said recently her son Colton broke his thigh bone late last month while bouncing on a trampoline at an indoor park in Tampa that promoted toddler use. She says the orthopedic surgeon told them the repetitive pressure from jumping may have caused the fracture.

Hill's Facebook post warning other families not to allow their toddlers on trampolines has been shared more than 235,000 times.

"Our lives have been turned upside down since Colton's accident and every day is a struggle for his sweet 3 year old self as he adjusts to life in a hip spica cast for the next 6 weeks," she writes. "... We hope by sharing his story it will prevent a child and their family from experiencing the trauma and heartbreak associated with trampoline injuries in young children."

The American Academy of Orthopedic Surgeons says children younger than 6 years old should not be allowed on trampolines.

A study published last year in Pediatrics found that emergency room visits in the U.S. for trampoline park-related injuries jumped more than ten-fold in recent years. An analysis showed that there were nearly 7,000 trampoline park-related injuries in 2014, compared to about 580 in 2010.

Most of the injuries were leg injuries, including strains and fractures, but some of the more serious injuries included two spinal cord injuries, a skull fracture, and open fractures.

The American Academy of Pediatrics recommends against recreational trampoline use by children altogether. But for those who do jump, the group advises a number of safety precautions, including constant adult supervision, protective padding on and around the trampoline, avoiding flips and somersaults, and allowing just one jumper on the trampoline at a time.

Discussion Questions

1. Define negligence.

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Negligence is the failure to do what a reasonable person would do under the same or similar circumstances. In order to prove a negligence case, the plaintiff must establish, by a preponderance of the evidence, the following:

a) The defendant owed the plaintiff a duty of reasonable care;

b) The defendant breached the recognized duty of care;

c) Such breach proximately caused the plaintiff's harm; and

d) The plaintiff experienced damages (economic and/or physical) as a result of the defendant's failure to exercise reasonable care.

Negligence is a civil cause of action, with the plaintiff having the legal right to sue the defendant in civil court to recover monetary damages.

2. Assess the negligence liability of the Tampa trampoline park for Colton Hill's injuries.

Without further evidence (i.e., additional evidence beyond the information included in the article), it is difficult to assess the negligence liability of the trampoline park. Ultimately, negligence is a determination for the jury to make, with the plaintiff having the burden of proof.

As noted in the article, the American Academy of Orthopedic Surgeons says children younger than 6 years old should not be allowed on trampolines. Further, the American Academy of Pediatrics recommends against recreational trampoline use by children altogether. However, unless it becomes an industry standard for trampoline parks to ban young children from access to their facilities, it would be difficult to conclude that the individual trampoline park in Tampa was negligent simply by allowing the 3-year-old to be there.

Certain questions (and their answers) are obviously relevant to this case, including:

a. Does the Tampa trampoline park monitor those who use its facility, and if so, what is the extent of the monitoring?

b. Was Kaitlin Hill monitoring her son when the accident and injury occurred?

c. Did Kaitlin Hill sign a waiver of liability form on behalf of her child?

d. Did a defect in the equipment or otherwise on-site cause the accident and injury?

e. How many other individuals, particularly children, have been injured at the Tampa facility?

3. Define assumption of the risk. In terms of the negligence liability of the Tampa trampoline park for Colton Hill's injuries, is assumption of the risk a strong defense in this case? Why or why not? Would evidence of the mother's lack of due care for her child assist the trampoline park in the defense of this case? Explain your response.

   Assumption of the risk is a defense to negligence liability. If a trial jury accepts the assumption of the risk defense, it is a complete defense to liability, meaning that the plaintiff recovers nothing from the defendant, even if the defendant was negligent.

   Assumption of the risk is voluntarily and willing proceeding in the face of danger, knowing or having reason to know that injury could occur. Foreseeability is a key element of the assumption of the risk defense.

   In the subject case, assumption of the risk is not a strong defense, since courts are reluctant to conclude that children can assume the risk. This is based on the premise that children do not have the mental capacity to appreciate the risk involved in a certain activity.

   Evidence of the mother's lack of due care for her child would not really be relevant in this case. Instead, if the case is tried, the trial court judge will instruct the jury to focus on whether the trampoline park owed a duty of care to the child, and if so, whether that duty of care was breached (based on the unique facts and circumstances of the case as revealed by the evidence introduced at trial).

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Video Suggestions

Video 1: "With 'Rip-Off Clause' Quashed, Consumers Can Now Sue Banks in Class-Action"

https://www.usatoday.com/story/money/2017/07/11/banks-gear-up-fight-rule-banning-mandatory-arbitration/468504001/

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

"With 'Rip-Off Clause' Quashed, Consumers Can Now Sue Banks in Class-Action"

According to the article, the lucrative and costly business of class-action lawsuits has been turned upside down by a new federal rule. And the fight to save or kill it has just begun.

After years of review on the subject, the Consumer Financial Protection Bureau, an independent federal watchdog agency, declared a new rule recently that bans banks, credit card companies, payday lenders and other financial firms from requiring consumers to settle group disputes through arbitration. These mandatory arbitration clauses, found in many credit card and bank account contracts, have effectively killed class-action lawsuits.

With the rule in place, consumers can now freely band together to fight back what they consider to be illegal or fraudulent products or practices and more class-action lawsuits are inevitable. It will also force financial firms to proactively monitor their own practices, its advocates say.

"The biggest step has been taken. This is a huge victory for consumers" said Amanda Werner, campaign manager at Americans for Financial Reform and Public Citizen. "We expect a lot of misconduct is going to be rooted out sooner."

Wells Fargo's much-maligned fake-account scandal, revealed in 2013 by a *Los Angeles Times* report, would have been more widely known sooner if the arbitration clause hadn't been in its contracts, she says. Consumers have repeatedly sought to sue the bank for years for the bank's practice of creating unauthorized checking and credit card accounts. "But their case has been kicked out over and over again" because of the arbitration requirement, Werner said.

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Wells eventually agreed to pay $185 million in penalties and $5 million in customer reimbursement for opening as many as 2 million accounts without customers' authorization.

Odds are stacked against consumers when it comes to arbitration. They lack the institutional knowledge of banks whose legal teams are familiar with arbitrators. And that's partly why there are so few arbitration cases. Only about 400 consumers file arbitration per year against financial companies.

The likelihood of consumers winning in arbitration is also low. Only 9% of consumers win in arbitration against financial companies, the consumer bureau said in a report.

Compared to lawsuit outcomes, arbitration also leads to smaller payouts for consumers. In studying the five-year period from 2008 to 2012, the bureau said over 34 million harmed consumers received payments of about $1 billion that were ordered by judges or juries in lawsuits. But in about 1,000 cases in the two years that the bureau studied, arbitrators awarded about $360,000 to 78 consumers.

Bankers counter that the average per-individual payout is higher in arbitration. "The CFPB's own study shows the average consumer receives $5,400 in cash relief when using arbitration and just $32 through a class action suit," said Richard Hunt, CEO of Consumer Bankers Association.

For banks, the possibility of facing more class-action lawsuits will likely drive them to store more funds in their reserves and possibly pass-on costs to consumers in fees, Hunt said.

But there's no evidence to the assumption that banks will raise fees, Werner said. Bank of America and Capital One have already dropped the arbitration clause for group disputes. And they haven't raised their fees as a result, she said.

Still, banks aren't whimpering away. Hunt said he'd "leave no stone unturned" in his fight to quash the rule. And industry-friendly lawmakers also promised carry on the fight to retain banks' right to mandate arbitration. Financial firms will lobby to kill the rule in Congress. And if that fails, there will likely be lawsuits.

Sen. Tom Cotton, R-Ark., heeded the industry's call, announcing recently he has started a process to kill the rule using a law called the Congressional Review Act. The law allows Congress to kill an agency rule with 60 legislative days with simple majority votes in both chambers.

Rep. Jeb Hensarling, R-Texas, who is chairman of the House Financial Services Committee, also called for the rule to be killed.

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Both sides expressed confidence that they will prevail. The rule has wide populist appeal and despite their majority, Republican lawmakers could find it difficult amass enough votes, Werner said. Last year, a poll by Pew Charitable Trusts found that 95% of Americans support financial consumers' right to be heard in court. "This is big-guy vs. little-guy."

If there's no legislative fix on their favor, financial firms will sue and they will likely seek an injunction to block the rule from going into effect while litigation is pending, said Quyen Truong, an attorney at Stroock & Stroock & Lavan and former deputy general counsel for litigation, enforcement, and oversight at the bureau.

Leadership changes at the consumer bureau could also play a role in how the rule is enforced. Richard Cordray, the Obama administration appointee who runs the agency as its director, is scheduled to step down next year and be replaced by a Trump appointee. "There may be new leadership at the CFPB that wouldn't defend the rule as aggressively as the current leadership," Truong said.

Discussion Questions

1. What is a mandatory arbitration clause?

   Arbitration is an alternative method of dispute resolution (i.e., an alternative to civil litigation). In arbitration, a neutral third party known as the arbitrator serves as the fact-finder and applies the law to the facts of the case in order to reach a decision. Arbitration can be either binding or non-binding. If it is binding, the arbitrator's decision is final, and cannot be appealed. If it is non-binding, one or both parties can pursue the case further in civil court.

   Usually, arbitration is decided by agreement. In other words, the parties stipulate in a contract that in the event of a dispute, they will have their case addressed via arbitration.

   A mandatory arbitration clauses simply means that in the event of a dispute, the parties must submit their case to arbitration.

2. What is a class action lawsuit?

   A class action lawsuit is a collective lawsuit brought by a number of plaintiffs who believe they have been harmed as a result of the defendant's wrongful actions. The number of plaintiffs in a class action lawsuit can be in the thousands, depending on the number of aggrieved individuals who choose to participate in the class action.

3. As the article indicates, in a poll conducted by Pew Charitable Trusts last year, 95% of Americans support financial consumers' right to be heard in court. If that is the case, why would Senator Cotton and Representative Hensarling favor "killing" the new rule that bans

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banks, credit card companies, payday lenders and other financial firms from requiring consumers to settle group disputes through arbitration?

Perhaps the best way to answer this question would be to present it to Senator Cotton and Representative Hensarling! Arguably, the strongest argument in favor of their initiative is that both parties (financial firm and consumer) have agreed to arbitration by way of consent to the arbitration clause. However, are arbitration clauses really negotiable if they are included as standard language in virtually every credit card and bank account contract? Another argument in favor of arbitration is that it reduces the caseload in our judicial system. However, the Seventh Amendment to the United States Constitution does guarantee the right to a jury trial in a civil case.

Video 2: "Tech Companies Rally for Net Neutrality Day of Action as FCC Aims to Roll Back Rules"

http://www.cbsnews.com/news/net-neutrality-day-of-action-protest-fcc-plan-to-roll-back-rules/

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

"Tech Companies Rally for Net Neutrality Day of Action as FCC Aims to Roll Back Rules"

According to the article, some of the biggest tech companies, like Facebook and Google, are participating in the Net Neutrality Day of Action, a protest of the Federal Communications Commission's plan to roll back Obama-era rules that increased government oversight and required online service providers to treat all internet traffic the same.

But in May, the Republican-led FCC voted to start changing net neutrality rules. Information online flows over pipes to your computer, Wired editor-in-chief Nicholas Thompson explained. Net neutrality prevents internet service providers including Comcast, Time Warner Cable or Verizon from treating websites using those pipes differently.

"So the companies that own the pipes can't say, 'you know what? We don't want that website to be fast. We want that one to be slow. And we don't like what that one is saying, so we're going to stop it all together. And maybe you'd like a tiered plan so you can get Wikipedia, right?' So net neutrality is a very important principal for the people on the internet," Thompson said.

The core of net neutrality is that "the internet has been a place of openness," Thompson said. "It's a place where you can start a company, where you can do what you want, and you can be reasonably certain that if you put a website on the internet, people will be able to get to it. But if we don't have net neutrality, and you start a company that is opposed to something that Comcast is running and is a competitor to something that Time Warner Cable has, they can

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shut you down. So it's not just competition," Thompson said. "It's the entire principle of the internet. That's why people are so riled up about this."

Thompson said the internet providers' posture is "if we make more money, we'll invest more heavily in (the pipes), and you'll get faster speeds." For the FCC, Thompson said one reason the agency wants to roll back the net neutrality rules is because "they're very close to the telecom companies."

"They want to do what's right for the telecom companies. They will argue that if you give the telecom companies more freedom to control their pipes, they'll innovate more," Thompson said. "What everybody else is saying is, no, every time you relax and let telecom companies do what they want, they stifle innovation. It's not good for everyone."

Discussion Questions

1. Define “net neutrality.”

   As indicated in the article, net neutrality prevents internet service providers including Comcast, Time Warner Cable or Verizon from treating websites using the internet differently. Net neutrality prevents internet service providers from picking “winners and losers” with respect to internet access.

2. What is the argument in favor of net neutrality? What is the argument against it?

   The argument in favor of net neutrality is that it does not favor “winners and losers” regarding internet access in terms of the ability to pay more for faster internet speeds. The argument against it is that internet service providers are businesses operating in the free enterprise system, and that they should be able to charge whatever the market will bear for internet access. As referenced in the article, another argument against net neutrality is that if internet service providers are able to make more money by charging differential rates, providers will invest more in internet infrastructure, resulting in faster internet access speed in general. This, of course, depends on whether the companies would voluntarily choose to reinvest such revenue.

3. Do you favor or oppose net neutrality? Explain your response.

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

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Of Special Interest

This section of the newsletter addresses the ethics of drug pricing.

Ethical Dilemma

"The Price Dilemma over a $16,000 Drug"

http://www.foxbusiness.com/features/2017/07/12/price-dilemma-over-16000-drug.html

According to the article, Novartis AG recently discovered that a drug it sells for a group of very rare diseases could be used to treat a much more common ailment. There is just one problem: its $16,000-per-dose price tag.

The drug, called ACZ885, is already sold under the brand name Ilaris for certain rare inflammatory disorders affecting a very small number of people. But a recent clinical trial suggests it could also reduce the risk of serious complications like strokes in people who have suffered a heart attack.

If the drug does pan out with regulators, Novartis would have to drastically cut its price to make it competitive with other cardiovascular drugs. That would mean jettisoning a small, but reliable, revenue stream on an uncertain bet that the drug could become a top seller as a cardiovascular medicine.

"They've got a bit of a puzzle on their hands," said Bernard Munos, a senior fellow at nonprofit Faster Cures who previously worked at Eli Lilly & Co.

A Novartis spokesman said it is too early to discuss its pricing strategy. "We will continue to fully analyze the data, plan to discuss these with regulatory agencies and determine how it would fit into clinical practice," he said.

Rare-disease, or orphan, drugs can command sky-high prices because they are typically the only treatment option available. The small number of patients also limits the overall bill to the health-care system.

That is not the case for drugs for common ailments. If approved for use in patients recovering from a heart attack, ACZ885's potential market would skyrocket: around 615,000 people in the United States survive a heart attack every year, according to the American Heart Association. Novartis estimates that the drug, which helps patients who also suffer from inflammation in the arteries, could be suitable in around 40% of those cases.

Novartis's revenue from ACZ885, at $283 million last year, is modest.

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Adding heart-attack patients, even at a vastly reduced price, could bring that figure to as much as $3.6 billion, according to Jefferies analysts. Credit Suisse analysts put the peak sales estimate at closer to $1.5 billion.

On paper, that seems an obvious gamble to take. But because of the way drugs are priced in the United States, Novartis would have to drop the price it charges rare-disease patients as well, giving up most of that revenue stream. Once the price of a drug is cut, it is difficult to raise it again.

And there is no guarantee that the drug will be widely used if the price comes down. Cardiologists can be reluctant to put their patients -- especially those already on several medications -- onto new drugs. That problem that has dogged several recently launched heart drugs, including Novartis's own Entresto.

Another potential problem: ACZ885 is already late in its patent cycle, making it uncertain whether Novartis could really get all that additional business if it dropped the price now. Credit Suisse analysts say they expect ACZ885 to lose patent protection around 2024, at which point lower-cost versions can enter the market and sharply erode sales.

To keep a lid on cost, insurers also tend to impose higher copays or complex approval processes for patients to get access to new, pricey drugs for common conditions. One example: insurance plans are curbing access to a new class of cholesterol-lowering drugs that cost around $14,500 a year before rebates or discounts, in a bid to keep all but the most serious cases patients on pennies-per-day statins, which work well for the majority of people. ACZ885 -- dosed every three months at its current pricing before rebates and discounts -- would cost around $64,000 a year for heart-attack patients. Novartis may need to drop the price by more than 90% "to get close to palatable," according to Craig Granowitz, chief medical officer at Amarin Corp., a small pharmaceutical company that focuses on cardiovascular medicine.

Ilaris came on the market in 2009 to treat a group of rare inherited conditions called cryopyrin-associated periodic syndromes, whose sufferers have a genetic mutation that causes the body to overproduce an inflammatory protein. Novartis has since won further approvals for a few other rare diseases, but hasn't altered the price as a result.

In 2011, Novartis hoped that a positive result in a gout trial would sharply broaden the market for Ilaris, but the drug was denied approval by the U.S. Food and Drug Administration over safety concerns in these patients. At the time, the company's then-head of drug development Trevor Mundel acknowledged that if the drug had won approval in gout, it would have had to lower the price to win coverage from insurers.

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Setting a single price that holds for every use of the drug discourages companies from exploring new disease areas for their medicines, said Ed Schoonveld, a pricing and market access expert at consultancy ZS Associates.

Novartis's spokesman said the trial that tested ACZ885 in heart-attack patients "wasn't designed with any commercial implications in mind at the time" and that its main purpose was to discover whether inflammation played a role in cardiovascular disease.

A big hurdle is how U.S. drugs are priced for federal programs. Drug makers must sell drugs to Medicaid at the lowest price they have offered to any private insurer. And they must sell their medicines to Medicare at the average selling price, plus 4%.

Under current legislation, there is no room to vary the price of a drug based on its application. The lowest price would have to apply to all uses, according to Mr. Schoonveld. Such dynamics could discourage companies from investigating whether an approved, rare-disease drug could have a much broader application, he said.

"Should you keep [a rare-disease drug] off the market because it treats common disease?" said Marlene Haffner, a consultant and former director of orphan drug development at the Food and Drug Administration. "Everybody would say no."

Discussion Questions

1. As the article indicates, ACZ885 is already “late in its patent cycle.” What does that mean, and how (if at all) should that affect Novartis AG’s pricing strategy for the drug?

   A patent is the exclusive right of an inventor or creator to control his intellectual property for a certain, limited period of time. By referencing that ACZ885 is “late in its patent cycle,” the article means that Novartis AG will soon lose its right of exclusivity regarding production and sale of the drug. After the patent expires, other pharmaceutical firms will be able to offer competing versions of the drug.

   Student responses may vary regarding how (if at all) the fact that ACZ885 is “late in its patent cycle” should affect Novartis AG’s pricing strategy regarding the drug. One reality is obvious, however—After Novarits AG loses its right of exclusivity, the market will no longer allow it to charge $16,000 per ACZ885 dose. Competitive forces will substantially drive the price down.

2. Describe the strategic dilemma Novartis AG faces in terms of ACZ885. In your reasoned opinion, what choice should Novartis AG make regarding this dilemma?

   As the article indicates, Novartis has a choice: It can either continue to focus on the small market of individuals with rare inflammatory disorders, or it can expand its focus to the larger

group of individuals who face health complications (like the possibility of a stroke) after a heart attack.

Student opinions may vary in terms of the choice Novartis AG should make regarding this strategic dilemma. In your author's opinion, Novartis should focus on expanding its market to cover the 615,000 people in the United States (and countless others across the world) who survive a heart attack every year. Even if such a focus will serve to drive the price for ACZ885 down, the "clock is ticking" in terms of the company's right to exclusivity regardless, the company does have the prospect of generating revenue based on the sheer volume of sales to heart attack survivors, and serving others is the "right thing" to do in terms of the social responsibility of business.

3. In your reasoned opinion, is it ethical for a drug company to charge $16,000 per dose?

Student opinions may vary in terms of the answer to this question. The ultimate issue here is whether the rules of the "free market" should apply to health care, and whether it is right to capitalize on another person's illness.

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Of Special Interest

This section of the newsletter will assist you in addressing Video 1 ("With 'Rip-Off Clause' Quashed, Consumers Can Now Sue Banks in Class-Action") and Video 2 ("Tech Companies Rally for Net Neutrality Day of Action as FCC Aims to Roll Back Rules") of the newsletter.

Teaching Tips

Teaching Tip 1 (Related to Video 1: "With 'Rip-Off Clause' Quashed, Consumers Can Now Sue Banks in Class-Action")—The Consumer Financial Protection Bureau (CFPB)

Please see the following internet address for more information regarding the Consumer Financial Protection Bureau (CFPB), the federal administrative agency referenced in Video 1:

https://www.consumerfinance.gov/

For a short video describing the CFPB, please specifically refer to the following:

https://www.consumerfinance.gov/about-us/the-bureau/

Teaching Tip 2 (Related to Video 2: "Tech Companies Rally for Net Neutrality Day of Action as FCC Aims to Roll Back Rules")—The Federal Communications Commission (FCC)

Please see the following internet address for more information regarding the Federal Communications Commission (FCC), the federal administrative agency referenced in Video 2:

https://www.fcc.gov/

For more information regarding the organizational structure and specific functions of the FCC, please specifically refer to the following:

https://www.fcc.gov/about-fcc/what-we-do

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Chapter Key for McGraw-Hill/Irwin Business Law Texts:

	Hot Topics	Video Suggestions	Ethical Dilemma	Teaching Tips
Barnes et al., Law for Business	Chapters 4, 7 and 25	Chapter 46	Chapter 3	Chapter 46
Bennett-Alexander & Hartman, Employment Law for Business	Chapters 2, 3, 8 and 9	N/A	N/A	N/A
Kubasek et al., Dynamic Business Law	Chapters 5, 9 and 43	Chapters 44 and 45	Chapter 2	Chapters 44 and 45
Kubasek et al., Dynamic Business Law: Summarized Cases	Chapters 5, 9, and 43	Chapters 44 and 45	Chapter 2	Chapters 44 and 45
Kubasek et al., Dynamic Business Law: The Essentials	Chapters 5, 7 and 24	Chapters 4 and 25	Chapter 2	Chapters 4 and 25
Liuzzo, Essentials of Business Law	Chapters 4, 5 and 32	Chapter 6	Chapter 2	Chapter 6
Mallor et al., Business Law: The Ethical, Global, and E-Commerce Environment	Chapters 3, 7 and 51	Chapters 47 and 48	Chapter 4	Chapters 47 and 48
McAdams et al., Law, Business & Society	Chapters 5, 7 and 13	Chapters 8 and 15	Chapter 2	Chapters 8 and 15
Melvin, The Legal Environment of Business: A Managerial Approach	Chapters 2, 9 and 12	Chapter 17 and 21	Chapter 5	Chapters 17 and 21
Pagnattaro et al., The Legal and Regulatory Environment of Business	Chapters 6, 10 and 20	Chapters 15 and 18	Chapter 2	Chapters 15 and 18
Sukys, Brown, Business Law with UCC Applications	Chapters 2, 6 and 23	Chapter 15 and 28	Chapter 1	Chapters 15 and 28

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This Newsletter Supports the Following Business Law Texts:

Barnes et al., Law for Business, 13th Edition ©2018 (1259722325)
Bennett-Alexander et al., Employment Law for Business, 8th Edition ©2015 (0078023793)
Kubasek et al., Dynamic Business Law, 4th Edition ©2017 (1259723585)
Kubasek et al., Dynamic Business Law: Summarized Cases, 1st Edition ©2013 (0078023777)
Kubasek et al., Dynamic Business Law: The Essentials, 3rd Edition ©2016 (007802384X)
Liuzzo, Essentials of Business Law, 9th Edition ©2016 (07802319X)
Mallor et al., Business Law: The Ethical, Global, and E-Commerce Environment, 16th Edition ©2016 (0077733711)
McAdams et al., Law, Business & Society, 11th Edition ©2015 (0078023866)
Melvin, The Legal Environment of Business: A Managerial Approach, 3rd edition ©2018 (1259686205)
Pagnattaro et al., The Legal and Regulatory Environment of Business, 17th Edition ©2016 (0078023858)
Sukys, Brown, Business Law with UCC Applications 14th Edition ©2017 (0077733738)