Discussion Case: Should E-Cigarettes Be Regulated? The tobacco industry and government regulators worldwide spent decades battling over whether tobacco cigarettes should be regulated. By the mid-2010s, almost all governments had passed legislation to control the ingredients in cigarettes, how this product could be advertised, and limited their sale to individuals of a certain age, typically 18 years and older. But a new, related issue was just emerging: whether or not governments should reg- ulate e-cigarettes. Electronic cigarettes, or e-cigarettes, are products designed to deliver nicotine or other substances to a user in the form of a vapor. Typically, they are composed of a recharge- able, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor. This vapor can then be inhaled by the user. These products are often made to look like cigarettes, cigars, or pipes. They are also sometimes made to look like everyday items such as pens and USB memory sticks, for people who wish to use the product with- out others noticing. Introduced to the global marketplace in 2004, e-cigarettes have become increasingly popular around the world. By 2015, 466 brands of e-cigarettes were available globally, generating $3 billion in sales. Most e-cigarette sales initially occurred on the Internet, making the product easily accessible to both adults and teens, and at specialty vape shops. More recently, e-cigarette manufacturers have packaged their products and sold them at higher prices in convenience and grocery stores. Advocates of e-cigarettes argued that they did not have the same harmful effects as tobacco cigarettes, claiming that they did not produce harmful secondhand smoke affect- ing nonsmokers. They also touted the product as a possible smoking cessation aid. Early research on the effects of e-cigarettes showed that the nicotine in e-cigarettes was addic- tive, just as it was in tobacco cigarettes, but because e-cigarettes did not produce smoke they were less harmful to a user’s lungs than tobacco. However, much remained unknown. As one medical school professor explained, “E-cigarettes may be less harmful than ciga- rettes, but we still don’t know enough about their long-term risks or the effects of second- hand exposure.” A few countries took up the issue of e-cigarette regulation. In 2013, Singapore banned importing and selling e-cigarettes. This move surprised many, as most Asian countries have a high tolerance for smoking and Singapore did not restrict the importation or sale of tobacco cigarettes. In 2014, the European Parliament approved rules governing e-cigarettes. Begin- ning in mid-2016, e-cigarette advertising was banned in the 28 nations of the European Union, as it already was for ordinary tobacco products. E-cigarette packages were required to carry a graphic health warning and be childproof. The amount of nicotine was limited to 20 milligrams per milliliter, similar to ordinary cigarettes. But the issue of regulating e-ciga- rettes soon moved to the global stage. Despite the inconclusive evidence of harms caused by e-cigarette smoking, the World Health Organization (WHO) urged governments to restrict its use. The WHO report rec- ommended that governments “ban the use of electronic cigarettes indoors and in public places and outlaw tactics to lure young users.” It argued that the ban on indoor use was necessary “until exhaled vapor is proven to be not harmful to bystanders.” It also called for regulation to ensure the products contained a standard dose of nicotine (since the dose varied widely among manufacturers), ban sales to minors, and prohibit the manufacture of fruity, candy–type e-cigarette flavorings. Initially, most of the e-cigarette regulatory activity in the United States occurred at the state and local levels. By 2015, three states—North Dakota, New Jersey, and Utah— had banned e-cigarettes in public places such as restaurants and bars, and 18 states had passed some limitations on the use or sale of e-cigarettes. Nearly 400 cities or countries had restrictions on e-cigarettes. Yet, actions taken by the U. S. Food and Drug Adminis- tration in 2009, when it aggressively attacked the manufacturing, sale, and use of tobacco cigarettes by enforcing the Family Smoking Prevention and Tobacco Control Act, set the stage of more regulation targeting e-cigarettes. In 2014 the U.S. Food and Drug Administration took a limited regulatory approach when it announced new rules that prohibited sales of battery-powered nicotine deliv- ery devices to anyone under 18 years of age and required manufacturers to submit their products for FDA approval, in addition to disclosing ingredients and warning consumers that nicotine was addictive. But, the new FDA rules stopped short of attempting to ban advertising of e-cigarettes, Internet sales, or candy or fruit flavors, as recommended by the WHO. Makers of e-cigarettes breathed a big sigh of relief when they heard these limited restrictions. “I’m pleased the FDA has created a structure to treat these products differently than traditional combustible cigarettes,” said Miguel Martin, president of Logic Technol- ogy Development, a leading e-cigarette maker. Perhaps U.S. tobacco manufacturers had learned an important lesson from the severe regulatory controls imposed on the marketing of cigarettes, because they took initiative in effect to regulate themselves. Many placed the strongest health warnings ever on e-cigarettes, going even further than the warnings mandated on tobacco cigarette packages. Altria, the maker of Marlboro cigarettes, stated on its packages of MarkTen, its e-cigarette line, “People with heart disease, high blood pressure and diabetes should not use this product. Neither should children. Nicotine can cause dizziness, nausea and stomach pains, and may worsen asthma. Nicotine is addictive and habit forming, and is very toxic by inhalation, in contact with the skin, or if swallowed.” Similarly, Reynolds American, makers of Camel cigarettes and Vuse, an e-cigarette product, printed on their e-cigarette packages the following warning, “This product is not intended for persons who have an unstable heart condition, high blood pressure, or diabetes; or persons who are at risk for heart disease or are taking medicine for depression or asthma.” These warnings were entirely voluntary. Yet, some critics saw them as ploys to reduce potential legal liability or the threat that governments would ban this prod- uct altogether. A professor at Stanford’s School of Medicine said, “When I saw [the warning labels on e-cigarettes], I nearly fell off my chair. Is this part of a noble effort for the better- ment of public health, or a cynical business strategy? I suspect the latter.” The battle over the regulatory control on e-cigarettes will likely continue. After the FDA announced its rules in 2014, Senator Durbin of Illinois said, “Shame on the FDA. Parents across America lost their best ally in protecting their kids from this insidious prod- uct.” The director of the FDA’s Center for Tobacco Products told reporters it was continu- ing its investigation into the effects of e-smoking. “It’s sort of like, walk before you run,” indicating that more severe regulations could be forthcoming. Whether controls will come from Congress or the FDA, the issue of regulating e-cigarettes appears to be far from over. Sources: “E-Cigarettes: Questions and Answers,” Food and Drug Administration website, January 21, 2015, www.fda.gov; “E-Cigarettes: Health and Safety Issues,” WebMD, accessed June 2015, www.webmd.com; “States and Municipalities with Laws Regulating Use of Electronic Cigarettes” American Nonsmokers’ Rights Foundation, June 2015, www.no-smoke.org; “European Parliament Approves Tough Rules on Electronic Cigarettes,” The New York Times, February 26, 2014, www.nytimes.com; “World Health Organization Urges Stronger Regulation of Electronic Cigarettes,” The New York Times, August 26, 2014, www.nytimes.com; “E-Cig Makers Breathe Easier after FDA Proposes Rules,” The Wall Street Journal, April 24, 2014, online.wsj.com; and “Dire Warnings by Big Tobacco on E-Smoking,” The New York Times, September 28, 2014, [www.nytimes.com](http://www.nytimes.com).

1. Should the U.S. and other national governments ban or more severely regulate the manufacture, sale, and use of e-cigarettes? Why or why not?
2. Is the tobacco industry demonstrating a strategy of working in a collaborative partner- ship with the FDA by its voluntary warning labels on e-cigarettes?

Core Values

**Excellence**

Saint Leo University is an educational enterprise. All of us, individually and collectively, work hard to ensure that our students develop the character, learn the skills, and assimilate the knowledge essential to become morally responsible leaders. The success of our University depends upon a conscientious commitment to our mission, vision, and goals.

**Community**

Saint Leo University develops hospitable Christian learning communities everywhere we serve. We foster a spirit of belonging, unity, and interdependence based on mutual trust and respect to create socially responsible environments that challenge all of us to listen, to learn, to change, and to serve.

**Respect**

Animated in the spirit of Jesus Christ, we value all individuals’ unique talents, respect their dignity, and strive to foster their commitment to excellence in our work. Our community’s strength depends on the unity and diversity of our people, on the free exchange of ideas, and on learning, living, and working harmoniously.

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