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E-Cigarette Regulation in China: The Road Ahead

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E-CIGARETTE REGULATION IN CHINA: THE ROAD AHEAD

Eric A. Feldman,* Chai Yue†

The global electronic cigarette industry has exploded in the past decade—from \$20 million in sales in 2008 to an estimated \$7 billion in 2014—and China has been an essential part of that growth.¹ As the world's largest consumer of combustible tobacco products, accounting for about one-third of the global market. China is also a prime contender to become the largest consumer of electronic cigarettes. These simple facts raise a critical question—what should the Chinese government do about regulating electronic cigarettes?

So far, the regulation of electronic cigarettes in China has attracted scant attention.² This paper begins to fill that gap by identifying the key issues confronting regulators in China and suggesting a way forward. It first describes the origin and development of e-cigarettes in China and then discusses the current regulatory status of e-cigarettes. Because two of the key regulatory options Chinese regulators are likely to consider—treating electronic cigarettes as tobacco products or as pharmaceutical products—represent the approaches of the United States and Japan respectively, the paper discusses e-cigarette regulation in those countries and analyzes its relevance to China. The paper concludes by suggesting that regardless of whether Chinese regulators decide to treat e-cigarettes as tobacco products or pharmaceuticals, there are a number of areas that invite immediate regulatory action. They include the dubious health claims made by many e-cigarette companies, such as suggesting that e-cigarettes are good for one's

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¹ *Electronic Cigarette Statistics*, STAT. BRAIN RES. INST. (Mar. 2, 2016), <http://www.statisticbrain.com/electronic-cigarette-statistics/>; Martinne Geller, *Special Report: When It Comes to E-cigs, Big Tobacco Is Concerned for Your Health*, REUTERS (Mar. 23, 2015), <http://www.reuters.com/article/2015/03/23/us-ecigarettes-regulations-specialreport-idUSKBN0MJ0GN20150323>.

² Yan Dingfei (严定非), *Dianzi Yan: Silue Zai Wuzhu Zhi Di* (电子烟:肆虐在无主之地) [*E-cigarettes Are Raging in No Man's Land*], SOUTHERN WEEKEND (Mar. 24, 2015), <http://www.infzm.com/content/102764>.

health, and the lack of quality control provisions governing the electronic cigarette manufacturing process. More generally, tobacco control measures targeted at combustible cigarettes should be strengthened to better control combustible tobacco consumption and address the increased use of e-cigarettes. Priority should be placed on regulating sales to youth.

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The global electronic cigarette industry has exploded in the past decade—from \$20 million in sales in 2008 to an estimated \$7 billion in 2014—and China has been an essential part of that growth.³ A Chinese chemist in 2003 developed the first e-cigarette, and China quickly emerged as the world's largest manufacturer of e-cigarettes, currently responsible for over 90% of global e-cigarette production.⁴ As the world's largest consumer of combustible tobacco products, accounting for about one-third of the global market, China is also a prime contender to become the largest consumer of electronic

³ *Electronic Cigarette Statistics*, STAT. BRAIN RES. INST. (Mar. 2, 2016), <http://www.statisticbrain.com/electronic-cigarette-statistics/>; Martinne Geller, *Special Report: When It Comes to E-cigs, Big Tobacco Is Concerned for Your Health*, REUTERS (Mar. 23, 2015), <http://www.reuters.com/article/2015/03/23/us-ecigarettes-regulations-special-report-idUSKBN0MJ0GN20150323>.

⁴ Most e-cigarettes are manufactured in Shenzhen Province. The Chinese electronic cigarette market is expected to reach 9.6 billion Yuan in three years, according to the Engineering Institute of the lithium battery industry, a private think tank with a focus on strategic emerging industries in China. *Dianzi Yan Shichang San Niannei Guimo Jiang Da 96 Yi Yuan* (电子烟市场三年内规模将达 96 亿元) [*The Electronic Cigarette Market Is Expected to Reach 9.6 Billion Yuan in Three Years*], GAOGONGLI DIAN (高工锂电) [ENGINEERING INSTITUTE OF THE LITHIUM BATTERY INDUSTRY] (Dec. 3, 2013), <http://www.gg-lb.com/asdisp2-65b095fb-11448-.html>.

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So far, the regulation of electronic cigarettes in China has attracted scant attention.⁵ This paper begins to fill that gap by identifying the key issues confronting regulators in China and suggesting a way forward. It first describes the origin and development of e-cigarettes in China and then discusses the current regulatory status of e-cigarettes. Because two of the key regulatory options Chinese regulators are likely to consider—treating electronic cigarettes as tobacco products or as pharmaceutical products—represent the approaches of the United States and Japan respectively, the paper discusses e-cigarette regulation in those countries and analyzes its (relevance to China. The paper concludes by suggesting that regardless of whether Chinese regulators decide to treat e-cigarettes as tobacco products or pharmaceuticals, there are a number of areas that invite immediate regulatory action. They include the dubious health claims made by many e-cigarette companies, such as suggesting that e-cigarettes are good for one's health, and the lack of quality control provisions governing the electronic cigarette manufacturing process. More generally, tobacco control measures targeted at combustible cigarettes should be strengthened to better control combustible tobacco consumption and address the increased use of e-cigarettes. Priority should be placed on regulating sales to youth.

We are attentive to the fact that e-cigarette regulation in China will be shaped to some degree by the nation's high rate of combustible tobacco consumption, the economic importance of tobacco as a source of tax revenue, and the public health consequences of its high smoking rate. Public health policy always involves both predictions and tradeoffs, and government regulators will have to assess the potential costs and benefits of more or less aggressive e-cigarette regulation. Nonetheless, we argue in this paper that continued regulatory inaction is not viable. It is time for China—like the United States, Japan, the EU, and many other jurisdictions—to engage e-cigarettes and craft a regulatory strategy, even one that is likely to be imperfect.

⁵ Yan Dingfei (严定非), *Dianzi Yan: Silue Zai Wuzhu Zhi Di* (电子烟:肆虐在无主之地) [*E-cigarettes Are Raging in No Man's Land*], SOUTHERN WEEKEND (Mar. 24, 2015), <http://www.infzm.com/content/102764>.

I. THE ORIGIN AND DEVELOPMENT OF E-CIGARETTES IN CHINA

In 2003, Han Li (韩力), a pharmacist from the Liaoning Chinese Medicine Research Institute, obtained a patent for “A Flameless Electronic Atomizing Cigarette.”⁶ Later named “RuYan” (如烟), which in Chinese is evocative of a romantic ephemerality,⁷ the first e-cigarettes hit the market in China in 2004, with exports by the Golden Dragon Group of Hong Kong starting the following year. RuYan was quickly copied by new companies that entered the e-cigarette market. Although the products were eventually differentiated by shape, color, and size, all of them used the same basic technology, consisting of a prefilled or refillable cartridge containing liquid nicotine and other ingredients (e-liquid), an atomizer, a heating element, and a battery.⁸ Inhaling on an e-cigarette heats the e-liquid and creates vapor, which mimics the effect of smoking traditional tobacco products.

In recent years, e-cigarette consumption in China has increased rapidly.⁹ According to the China Domestic E-cigarette Market Analysis, an industry report published in November 2014, the average rate of e-cigarette use was 3.4% among smokers in five representative cities including Beijing, Shanghai, Xi’an, Guangzhou

⁶ *Yi Zhong Fei Keranxing Dianzi Wu Hua Xiangyan* (一种非可燃性电子雾化香烟) [A Flameless Electronic Atomizing Cigarette], China Patent No. 031111734 (filed Mar. 14, 2003), http://cpquery.sipo.gov.cn/txnQueryBibliographicData.do?select-key:shenqingh=031111734&select-key:backPage=http%3A%2F%2Fcpquery.sipo.gov.cn%2FtxnQueryOrdinaryPatents.do%3Fselect-key%3Ashenqingh%3D031111734%26select-key%3Azhuanlimc%3D%26select-key%3Ashenqingrxm%3D%26select-key%3Azhuanlilx%3D%26select-key%3Ashenqingr_from%3D%26select-key%3Ashenqingr_to%3D%26inner-flag%3Aopen-type%3Dwindow%26inner-flag%3Aflowno%3D1442572578938&inner-flag:open-type=window&inner-flag:flowno=1442572597279.

⁷ The name “RuYan,” meaning “just like tobacco/smoke,” was carefully chosen. Characters named RuYan appear in various romantic novels, songs, and movies thick with nostalgia for the “good old days,” and there is an elegant fictional female character called Miss RuYan who appears in various media.

⁸ They are also now differentiated by name, with some called e-cigarettes, others vaporizers, and still others vaping pens or e-hookahs.

⁹ China Central Television, for example, reported in 2015 that the consumption of e-cigarettes was booming and sales were increasing annually. *Dianzi Yan Qinru Xiaoyuan Shou Xuesheng Zhuipeng, Yizhi Nigu Ding Shangying* (电子烟“侵入”校园, 易致尼古丁上瘾) [E-cigarettes “Invade” the Campus and Are Popular Among Students], CCTV NEWS (May 7, 2015), <http://m.news.cntv.cn/2015/05/07/ARTI1430961909196900.shtml>.

and Harbin.¹⁰ E-cigarettes use among minors has also taken hold. A May 2014 survey by the Chinese CDC indicated that of 155,117 junior high school students (age 13–15) across 31 provinces, 45% had heard of e-cigarettes, and 1.2% had used them in the past thirty days.¹¹ The use of e-cigarettes among youth has been noted by the mass media, with one news report focusing on the sale of e-cigarettes as toys at the entrance of a primary school and others describing the preference for fruit flavors among youth and the concerns of parents about their children who use e-cigarettes.¹²

Market data also tell a story of increased e-cigarette consumption. In 2013, with a growth rate of 150%, China's domestic e-cigarette market reached ¥ 3.5 billion.¹³ In 2014, the market also witnessed a growth spurt, with both sales and the number of users increasing by 263% and 259% respectively over the previous year.¹⁴ Over the next five to ten years, according to industry researcher Xia

¹⁰ However, the sample size was quite small (500 people in each city). Clearly, more data are needed. *Dianzi Yan Guonei Shichang Fenxi* (电子烟国内市场分析) [*China Domestic E-cigarette Market Analysis*], CECMOL (Nov. 14, 2014), <http://www.cecmol.com/news/show-3344.html>.

¹¹ *2014 Zhongguo Qingshaonian Yancao Diaocha Baogao* (2014 中国青少年烟草报告) [China Youth Tobacco Survey], CHINESE CTR. FOR DISEASE CONTROL AND PREVENTION (May 2015), <http://www.tcrc.org.cn/UploadFiles/2015-07/251/2015070910174559651.pdf>.

¹² *Hefei Yi Xiaoxue Menkou Dianziyan Dang Wanju Mai, Laoban Cheng Mei Weihai* (合肥一小学门口“电子烟”当玩具，老板称没危害) [*E-cigarettes Are Sold as Toys at the Entrance of a Primary School, but the E-cigarette Owner Asserts No Harm*], ZHONG'AN ZAIXIAN (Feb. 9, 2015), http://news.ifeng.com/a/20150209/43131134_0.shtml; *Yizhong Daiyou Guowei De Dianziyan Zai Xuesheng Zhong Liuxing Dan Weifa* (一种带有果味的“电子烟”在学生中流行但违法) [*Fruit-Flavored E-cigarettes Popular Among Students*], NANTONG DAILY (Jan. 13, 2015), http://www.js.xinhuanet.com/2015-01/13/c_1113978067.htm; *Haizi Chou Dianziyan Ling Jiazhang Youxin, Zhuanjia: Cilei Shangpin Hui Wudao Weichengnianren* (孩子抽“电子烟”令家长忧心专家：此类商品会误导未成年人) [*Parents Are Concerned About Children Using E-cigarettes. Expert Said This Kind of Product Will Misguide Minors*], TAIZHOU EVENING NEWS (Jan. 28, 2015), <http://www.tznews.cn/2013/news/shehui/2015/01/2015-01-28220752.html>.

¹³ *Dianzi Yan Shichang San Niannei Guimo Jiang Da 96 Yi Yuan* (电子烟市场三年内规模将达96亿元) [*The Electronic Cigarette Market Is Expected to Reach 9.6 Billion Yuan in Three Years*], GAOGONGLI DIAN (高工锂电) [ENGINEERING INSTITUTE OF THE LITHIUM BATTERY INDUSTRY] (Dec. 3, 2013), <http://www.gg-lb.com/asdisp2-65b095fb-11448-.html>.

¹⁴ An interview by the China Medicine Economic Newspaper, sponsored by the China Food and Drug Administration Southern Medicine Economic Institute, provides these figures. *Guonei Dianziyan Shichang Xushi Daifa* (国内电子烟市场蓄势待发) [*Domestic Electronic Cigarette Market Is Ready*], MED. ECON. NEWS (Jan. 19, 2015), http://www.yjjb.com/html/2015-01/19/content_219407.htm.

Long, “the market compound growth rate will exceed 30%.”¹⁵ Taobao, the largest online Business-to-Customer platform and an important venue for the sale of e-cigarettes,¹⁶ was the site of \$22 million USD in sales of the top ten brands of e-cigarettes in 2014.¹⁷ Although the overall number of e-cigarette consumers in China and gross sales are still relatively modest, analysts speculate that in the upcoming decades, they will overtake the popularity of conventional combustible cigarettes.¹⁸

Indeed, the potential market for such products in China is vast. For every 1% rate of substitution of e-cigarettes for combustible cigarettes, the Chinese e-cigarette market will increase by almost \$5 billion USD.¹⁹ Moreover, China Tobacco (also known as the State Tobacco Monopoly Administration) began to research and develop its own e-cigarette product in 2013. In 2014, China Tobacco of Hubei, a provincial subsidiary of the national tobacco monopoly China Tobacco, launched its first series of e-cigarette products in Wuhan, which marked China Tobacco’s formal entry into the e-cigarette business.²⁰

The involvement of China Tobacco in the e-cigarette business is a significant event. As the government’s key tobacco-related agency, it is responsible for almost all aspects of the tobacco industry, including tobacco growth, production, sales, human resources, finance, marketing, and trade. It includes thirty-three provincial Tobacco Monopoly Administrations (provincial tobacco monopoly subsidiary corporations), sixteen industrial companies, fifty-seven cigarette industrial enterprises, more than 1,000 commercial

¹⁵ *Dianziyan Zaoyu Binghuo Liangchongtian* (电子烟遭遇冰火两重天) [*E-cigarettes Encounter Ice and Fire*], TECH. DAILY (Sep. 2, 2014), <http://scitech.people.com.cn/n/2014/0902/c1007-25585378.html>.

¹⁶ *Woguo Dianzi Yan Hangye Shichang Zhuangkuang Fenxi* (我国电子烟行业市场状况分析) [*Analysis of the E-cigarette Market in China*], TIANYA.CN (May 20, 2014), <http://bbs.tianya.cn/post-141-628048-1.shtml>.

¹⁷ *Dianziyan Zaoyu Binghuo Liangchongtian*, *supra* note 15.

¹⁸ *See Zhongguo Ban Jinyanling Dianziyan You Shangji* (中国颁禁烟令, 电子烟有商机) [*China Bans on Combustible Cigarette, E-cigarette Will Have Business Opportunities*], SHENZHEN ECON. DAILY (Jan. 17, 2014), http://szsb.sznews.com/html/2014-01/17/content_2756998.htm (stating that e-cigarettes are not very common in the Chinese market, but in the next ten years, the sales of e-cigarettes will exceed the sales of ordinary cigarettes).

¹⁹ *Dianziyan Zaoyu Binghuo Liangchongtian*, *supra* note 15.

²⁰ Mark O’Neill, *How China is Lighting up the E-cigarette Market*, EJINSIGHT (Aug. 11, 2014), <http://www.ejinsight.com/20140811-china-e-cigartte/>.

enterprises, and over 510,000 employees.²¹ Additionally, more than 20 million people in China are directly linked to the tobacco industry, including 1.3 million farming households and 5 million retailers, who are all under the supervision of the Monopoly Administration.²² With China's massive government tobacco monopoly setting its sights on the e-cigarette market, and the rapid growth of private sector manufacturers (the number of e-cigarette enterprises more than doubled in 2013), the use of e-cigarettes in China could become staggering.²³

The advertising and promotion of e-cigarettes in China, not always truthful, has both contributed to their increased popularity and illustrated the need for regulation. RuYan, for example, was promoted as a lower-risk alternative to conventional cigarettes. The manufacturer claimed that RuYan contained neither tar nor carcinogens²⁴ and that it qualified as a nicotine replacement therapy that would enable smokers of combustible cigarettes to kick their tobacco addiction.²⁵ Other e-cigarette manufacturers, attentive to the increasing social awareness about the health harm of combustible tobacco products, have ignored the lack of data on the health impact of e-cigarettes and marketed their products as "healthy," "low harm," and "helpful to quit smoking."²⁶

Because e-cigarettes are so new, scientists are still evaluating their impact on public health. Studies are underway, but at this point

²¹ *Zhongguo Yancao Hangye Gaikuang* (中国烟草行业概况) [*Chinese Tobacco Industry Overview*], CHINA TOBACCO, <http://www.tobacco.gov.cn/html/10/1004.html> (last visited Oct. 12, 2016).

²² *Zhongguo Yancao Kongzhi Guihua [2012-2015]* (中国烟草控制规划 [2012-2015年]) [*China Tobacco Control Plan (2012-2015)*], CHINA TOBACCO, http://www.tobacco.gov.cn/history_filesystem/2013yckz/ghqw2.htm (last visited Oct. 12, 2016).

²³ According to the Engineering Institute of the lithium battery industry, a private think tank with a focus on strategic emerging industries in China, the electronic cigarette market is expected to reach 9.6 billion Yuan by 2018. GAOGONGLI DIAN, *supra* note 4.

²⁴ The claim regarding the absence of tar is correct, but the absence of carcinogens is more complicated. Most experts agree that e-cigarettes are significantly less carcinogenic than combustible tobacco, but they also agree that e-cigarettes contain certain ingredients that are carcinogenic.

²⁵ *Ruyan – Jiuqing Shi Shenme Yan?* (“如烟”——究竟是什么“烟”?) [*RuYan—What Is RuYan After All?*], PEOPLE'S DAILY (Dec. 18, 2006), http://news.xinhuanet.com/life/2006-12/18/content_5503100.htm.

²⁶ Li Baojiang (李保江), *Zhongguo Yancao Zhongshui Zhengce dui Zengjia Zhengfu Shouru he Jianxiao Yancao Xiaofei de Yingxiang* (中国烟草重税政策对增加政府收入和减少烟草消费的影响) [*Effects of Increasing Tobacco Taxes on Government Revenue and Consumption in China*], 16 ACTA TABACARIA SINICA, no. 5, 2010, at 82.

the only conclusion justified by the evidence is that no one knows whether e-cigarettes are harmful to users or to bystanders. Nor is it clear whether they will serve as a useful smoking cessation tool or will be a gateway to the use of combustible cigarettes. As the World Health Organization succinctly stated in a recent bulletin, “there are only a few studies on the health risks and we don’t know the long-term effects; for now the evidence is inconclusive about whether ENDS [electronic nicotine delivery systems, i.e., e-cigarettes] can be an effective smoking cessation aid.”²⁷ A recent panel of experts convened by the U.S. National Institute of Health similarly concluded that the short-term and long-term effects of e-cigarettes on human physiology and behavior are uncertain, and that there is very limited data directly addressing whether e-cigarettes reduce combustible tobacco consumption.²⁸ In short, although e-cigarettes are a multi-billion-dollar global industry, the scientific evidence regarding their impact on individual and public health remains limited.

II. REGULATORY INACTION OVER E-CIGARETTES IN CHINA

Despite the rapid growth of China’s e-cigarette industry and the interest Chinese consumers have shown in e-cigarettes, the manufacture, sale, and use of e-cigarettes in China remains largely unregulated. Indeed, each of the agencies that might plausibly exercise some regulatory control over e-cigarettes appears to be studiously avoiding a leadership role. Their reluctance to engage the regulation of e-cigarettes has been evident since RuYan appeared on the market in 2006.

During a press conference held by the Ministry of Health (now the National Health and Family Planning Commission) in May 2006, for example, a journalist from the China Daily asked whether the Ministry would regulate RuYan as a smoking cessation product.²⁹

²⁷ *Countries Vindicate Cautious Stance on E-cigarettes*, 92 BULL. WORLD HEALTH ORG. 856, 856-857, WORLD HEALTH ORGANIZATION [WHO] (2014), <http://www.who.int/bulletin/volumes/92/12/14-031214/en/>.

²⁸ Kevin Walton et al., *NIH Electronic Cigarette Workshop: Developing a Research Agenda*, 17 NICOTINE & TOBACCO RES. 259, 260 (2014).

²⁹ *Weishengbu “2006 Nian Zhongguo Xiyun Yu Jiankang Baogao” Fabuhui Neirong Shilu – Kongyan Yu Fang’ai Fangzhi* (卫生部《2006年中国“吸烟与健康”报告》发布会内容实录——控烟与防癌防治) [Press Conference Record of “Smoking and Health” Report in 2006 by Ministry of Health—Tobacco Control and Prevention of Lung Cancer],

The deputy director of the Maternal Child and Community Health Division responded by saying that the main ingredient of RuYan was nicotine, a product defined as a “dangerous chemical” that should be regulated by the State Council under its Dangerous Chemicals Regulations.³⁰ Moreover, the official continued, the regulation of RuYan implicated a number of other ministries: the State Administration of Work Safety was responsible for manufacturing safety, the State Administration for Industry and Commerce was responsible for advertising, and the Ministry of Health was responsible for safety and toxicological tests. Together, in the official’s view, these authorities were responsible for regulating e-cigarettes.

That same year, China Tobacco echoed the view that RuYan should be regulated under the State Council’s Dangerous Chemicals Regulations, which distanced it from e-cigarette regulation.³¹ Officials from other ministries were similarly evasive. In a series of assertions reminiscent of *Rashomon*, those from the State Administration of Work Safety stated: “It’s true that the production and transportation of dangerous chemicals should be under our supervision, however, a product which uses a dangerous chemical and may cause harm to people should be regulated by other relevant government authorities who are responsible for products. We’re asking for instructions from our superior officials.” According to officials from the Advertising Department in the State Administration for Industry and Commerce, “Since the advertisement of RuYan is not in the category of tobacco product, there is no requirement for pre-approval by the agency. State Administration for Industry and Commerce has noted related health concerns. So we’ve asked the Ministry of Health, State Food and Drug Administration, and the State Administration of Work Safety, to carry out identification

CHINA NAT’L HEALTH AND FAMILY PLANNING COMMISSION (May 29, 2006), <http://www.moh.gov.cn/usb/pxwfb/200804/28081.shtml>.

³⁰ The Regulation has a number of general requirements applicable to the production, storage, use, operation, and transportation of dangerous chemicals.

³¹ For the Three Ministries’ response to the RuYan issue, see *San Bumen Jiu Ruyan Wenti Zuochu Huiying, Ruyan Rengzai Miwu Zhong* (三部门就“如烟”问题作出回应, 如烟仍在迷雾中) [*Three Ministries Responded to “RuYan” Issue, and Ruyan Is Still in the Mist*], PEOPLE’S DAILY ONLINE (Dec. 1, 2006), <http://politics.people.com.cn/GB/1027/5116023.html> (reporting that the manufacture and sales of RuYan shall be regulated under dangerous chemicals regulations because RuYan contains nicotine, which is listed in the dangerous chemicals checklist).

testing.”³² Officials from the State Food and Drug Administration stated that they had never approved any e-cigarette as either a pharmaceutical product or a medical device. In June 2006, the agency issued a document explicitly stating that nicotine electronic vaporizers were used for eliminating smokers’ physiological needs for nicotine and easing withdrawal symptoms, and that such devices did not fit under the regulatory framework developed for medical devices in China.³³ RuYan had become the proverbial hot potato, and no regulatory agency was willing to risk getting burned.

Almost ten years have passed since RuYan was brought to market, and little regulatory progress has been made. As of May 2016, no government agency in China has taken responsibility for regulating e-cigarettes. Instead, as e-cigarettes grow in popularity within and beyond China, and Chinese manufacturers continue to produce most of the world’s e-cigarette devices, the relevant government agencies seem anxious to make the regulation of e-cigarettes someone else’s affair.

In the absence of regulations in China that treat e-cigarettes as medical devices, pharmaceutical products, or tobacco products, they are considered ordinary consumer products, subject to litigation under the Product Quality Law³⁴ and the Tort Liability Law.³⁵ The Product Quality Law,³⁶ enacted in 1993, includes general provisions that govern the manufacturing process, including product labeling requirements, product adulteration, and counterfeit products. The 2010 Tort Liability Law³⁷ includes specific product liability

³² *Id.* (stating that if RuYan is identified as a tobacco product or tested toxic, the agency will definitely ban advertising; if the company continues to advertise, the agency will investigate and deal with it according to relevant laws).

³³ For the applicable government notice that is administratively binding, see *Guanyu Baixibao Huisheng Xitong Deng Chanpin Fenlei Jieding De Tongzhi* (关于白细胞回升系统等产品分类界定的通知) [A Notice About the Product Classification of Recovery System of Leukocytes] (promulgated by China Food and Drug Administration, June 18, 2006), art. 41, <http://www.sfda.gov.cn/WS01/CL0845/10571.html>.

³⁴ *Zhonghua Renmin Gongheguo Zhipin Pinzhi Fa* (中华人民共和国制品品质法) [Product Quality Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 22, 1993, effective Sept. 1, 1993, amended by the Standing Comm. Nat'l People's Cong. on July 8, 2000), http://www.npc.gov.cn/wxzl/wxzl/2000-12/05/content_4578.htm (China).

³⁵ *Zhonghua Renmin Gongheguo Qinquan Zeren Fa* (中华人民共和国侵权责任法) [Tort Liability Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 26, 2009, effective July 1, 2010), http://www.gov.cn/flfg/2009-12/26/content_1497435.htm.

³⁶ Product Quality Law, *supra* note 34.

³⁷ Tort Liability Law, *supra* note 35.

provisions, as well as other provisions that enable consumers to sue for personal injuries. Although it may be sensible to treat e-cigarettes as ordinary consumer products in a tort law context, that approach cannot substitute for public health regulation. If e-cigarettes pose health risks that can endanger users and bystanders, ex post tort remedies are likely to fail to achieve the appropriate level of public health protection. Moreover, tort litigation imposes a significant cost on plaintiffs, both in terms of time and money, and could result in limited or no compensation due to the large number of small and possibly undercapitalized e-cigarette manufacturers.

The rising popularity of e-cigarettes in China and the country's dominance as a global e-cigarettes producer make China's regulatory paralysis particularly troubling as a matter of global public health. Chinese children can purchase e-cigarettes with ease, e-liquids are widely available in different flavors and with varying quantities of nicotine, the public use of e-cigarettes is unrestricted, and manufacturing standards are extremely weak. These concerns have not been entirely lost on the media. Indeed, in 2011 the *People's Daily Online* noted, "there are large numbers of counterfeit e-cigarette products on the market with little safety guarantee, the industry in China is in chaos."³⁸ Recent articles in the *Southern Weekend* and *The New York Times* have also highlighted the absence of e-cigarette regulations in China, the lack of quality control standards, the existence of heavy metals in e-cigarettes, and the risk of exploding products.³⁹

What, then, should be done? Should e-cigarettes be regulated aggressively and kept out of the hands of consumers? Or, given the well-known and profoundly negative impact of combustible tobacco products on public health, should e-cigarettes be regulated more modestly, with the hope that they will reduce the use of conventional cigarettes and thus improve public health? In short, should Chinese

³⁸ See Dianziyan HangyeLuanxiang Dai Bian (电子烟行业乱象待“变”) [*The E-cigarette Industry's Chaos Are Waiting for Changes*], PEOPLE'S DAILY ONLINE (Dec. 14, 2011), <http://finance.people.com.cn/stock/GB/222942/16603305.html>

³⁹ David Barboza, *China's E-Cigarette Boom Lacks Oversight for Safety*, N.Y. TIMES (Dec. 13, 2014), <http://www.nytimes.com/2014/12/14/business/international/chinas-e-cigarette-boom-lacks-oversight-for-safety-.html>; *Xinxingyan Dingxing Buming, Baiwan Shichang Wu Jianguan* (新型烟定性不明, 百亿市场无监管) [*Unknown Classification of the New E-cigarettes Left Ten Billion Yuan Market Unregulated*], SOUTHERN WEEKEND (Aug. 1, 2014), <http://www.infzm.com/content/102764>.

regulators embrace the precautionary principle, or is harm reduction the better approach?

To make that determination, it is instructive to look at how other nations are regulating e-cigarettes. Indeed, Chinese regulators have recognized both the practical and rhetorical power of invoking foreign models, pointing to how other nations are regulating e-cigarettes in order to support their domestic policy preferences.⁴⁰ Two examples are particularly illuminating; the United States, which issued regulations in May 2016 that treat e-cigarettes as tobacco products, and Japan, which is regulating them as pharmaceutical products. As the old Chinese proverb goes, “there are other hills whose stones are good for working jade.” In addressing the question of e-cigarette regulation, Chinese policy makers should be aware of what regulators elsewhere are doing as they move toward developing their own regulations.

III. E-CIGARETTE REGULATION IN THE U.S. AND JAPAN

A. *United States*

The U.S. e-cigarette saga began in October 2008, when the FDA detained an inbound shipment of electronic cigarettes at the Los Angeles International Airport.⁴¹ Two companies, NJOY and Smoking Everywhere, were importing the e-cigarettes from China with the intention of selling them in the United States, but the FDA thwarted their plans by claiming that nicotine-containing e-cigarettes could not enter the United States without FDA approval. In the FDA’s view, nicotine was a drug as defined in the Food, Drug, and Cosmetic Act (FDCA), and e-cigarettes therefore had to be evaluated by the FDA for safety and efficacy, like all drugs marketed in the

⁴⁰ Li Baojiang (李保江), *Quanqiu Dianziyan Shichang Fazhan, Zhuyao Zhengyi ji Shichang Guanzhi* (全球电子烟市场发展, 主要争议及政府管制) [A *Global Perspective on the Future Development of Electronic Cigarettes and Related Controversial and Regulatory Issues*], 20 ACTA TABACARIA SINICA, no. 4, 2014, at 101, 101.

⁴¹ See *FDA Fighting for Authority to Regulate Electronic Cigarettes*, AM. ACAD. FAMILY PHYSICIANS (Mar. 2, 2010), <http://www.aafp.org/news/health-of-the-public/20100302e-cig-fda.html> (detailing the FDA’s appeal to regulate e-cigarettes as drug delivery devices, rather than as tobacco products and providing background on the FDA’s detainment of e-cigarette shipments at the Los Angeles Airport); *Electronic Cigarettes and the FDA*, ELECTRONIC CIGARETTE SPOT, <http://electroniccigarettespot.com/book/export/html/9> (last visited Feb. 20, 2015).

United States.⁴² According to FDA Commissioner Margaret Hamburg, “[t]he FDA is concerned about the safety of these products and how they are marketed to the public.”⁴³

Not surprisingly, e-cigarette importers aggressively fought back. In their view, e-cigarettes could not be regulated under the FDCA unless therapeutic claims were made on their behalf, such as their utility as smoking cessation aids. Since importers had not made such claims, they argued that their products did not fall within the FDA’s jurisdiction over pharmaceutical products. Instead, they insisted that the FDA could only regulate e-cigarettes under its authority to regulate tobacco products, an authority that Congress had only recently granted to the agency.⁴⁴ Importers demanded that the FDA put a halt to the detention of their products, and sued the FDA in the D.C. Circuit Court.⁴⁵

U.S. District Court Judge Richard Leon’s ruling in the case, later affirmed on appeal, offered a sharp rebuke to the FDA’s position and provided the plaintiff e-cigarette companies, and the e-cigarette industry more generally, an open door to the cultivation of a U.S.-based e-cigarette market.⁴⁶ In Judge Leon’s view, the FDA could only regulate e-cigarettes as drugs or drug delivery devices if they were marketed with claims about their therapeutic effects.⁴⁷ In all other cases, he ruled, the FDA could only regulate e-cigarettes by invoking its jurisdiction over tobacco products.⁴⁸

The District Court’s opinion, affirmed on appeal, left the FDA in a difficult position. The U.S. Tobacco Control Act defines “tobacco product” as any product “made or derived from tobacco” that is not a “drug,” “device,” or combination product under the Act.

⁴² 21 U.S.C. § 360d (1938).

⁴³ *Food and Drug Administration, FDA and Public Health Experts Warn About Electronic Cigarettes*, U.S. FOOD AND DRUG ADMIN. (July 22, 2009), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm173222.htm>.

⁴⁴ *See Tobacco Control Act*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm298595.htm> (last visited Feb. 23, 2015) (describing how the Tobacco Control Act of 2009 gives the FDA broad authority to regulate the manufacture, distribution, and marketing of tobacco products). *See also* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

⁴⁵ *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 72 (D.D.C. 2010), *aff’d sub nom; Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (2010).

⁴⁶ *Id.*

⁴⁷ *Id.* at 72–75.

⁴⁸ *Id.* at 77.

It permits the FDA to regulate conventional tobacco products as well as other tobacco products that the Agency “by regulation deems to be subject to the law.” The language is convoluted, but the direction is clear: the FDA must first bring e-cigarettes into its regulatory orbit by “deeming” them to be “tobacco products;” it can then regulate them as it sees fit, so long as its specific regulations do not run afoul of the Act.

In April 2014, more than four years after the District Court’s decision, the FDA announced that it would extend its regulatory authority over tobacco to e-cigarettes and other “tobacco products,” such as cigars and hookah.⁴⁹ Under the FDA’s proposed regulations, e-cigarette manufacturers will be required to provide the FDA with a list of product ingredients, submit all “new” products for FDA review, refrain from claims about the reduced risk posed by their products, and not distribute free samples.⁵⁰ The FDA will also apply three key tobacco control regulations to e-cigarettes: age restrictions on sales, health warnings on packs, and limitations on vending machine sales.⁵¹

As with all proposed agency regulations in the United States, the FDA was required to publish its proposed regulations in the *Federal Register* and seek public comment. In a clear sign of the extraordinarily high degree of public and corporate interest in the FDA’s approach to e-cigarettes, the publication of the FDA’s deeming regulations garnered over 135,000 comments. The FDA spent two years reviewing those comments, and in May 2016 announced a Final Rule that fundamentally reaffirms the provisions contained in the proposed regulations.⁵²

Three important points emerge from the U.S. experience. First, the government had a clear preference for regulating e-

⁴⁹ Heidi Ledford, *FDA Proposes Regulation of Electronic Cigarettes*, NATURE (Apr. 24, 2014), <http://www.nature.com/news/fda-proposes-regulation-of-electronic-cigarettes-1.15105>.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,973 (May 10, 2016). During the FDA’s long period of inaction, many states and municipalities stepped into the breach and enacted a wide variety of local e-cigarette controls, such as purchasing age limits, and public and/or work place bans.

cigarettes as pharmaceutical products; treating them as tobacco products came at the insistence of the court, and was not the FDA's regulatory strategy. Second, having been forced by the court to regulate e-cigarettes as tobacco products, the FDA has crafted a precautionary policy that imposes a number of restrictions on e-cigarettes and could (depending upon subsequent regulatory interpretation and implementation) significantly limit the availability of e-cigarettes.⁵³ Third, in the absence of sufficient data about the health risks of e-cigarettes and about whether e-cigarettes are more likely to be a gateway to the use of combustible tobacco products or an effective NRT, the FDA's approach has been criticized as both too restrictive and too lax.

B. Japan

The Ministry of Finance has long held the legal authority to regulate tobacco products in Japan, and it continues to be the controlling shareholder of Japan's only tobacco corporation, Japan Tobacco.⁵⁴ Article 1 of the Tobacco Business Law, which governs Japan's tobacco industry and articulates its tobacco policy, highlights the importance of "promoting the sound development of the Japanese tobacco industry, thereby securing national revenues."⁵⁵ Political support by the agricultural sector (within which tobacco farmers have been influential) for Japan's long-dominant political party, the Liberal Democratic Party, has muted political support for regulations that might decrease domestic tobacco consumption and sharpen the regulatory strategy toward tobacco products.⁵⁶ Perhaps not surprisingly, the Ministry of Health, Labor and Welfare (MHLW) has limited power when it comes to tobacco control, which further helps

⁵³ Among the important issues that will be clarified over the next two years is the number of e-cigarette products that the FDA will determine to be "substantially equivalent" to products marketed in the United States prior to February 15, 2007, which enables such products to avoid the potentially costly and time-consuming process of pre-market authorization.

⁵⁴ Eric A. Feldman, *The Landscape of Japanese Tobacco Policy: Law, Smoking and Social Change*, 49 AM. J. COMP. L. 679, 681–682 (2001).

⁵⁵ Tabako Jigyō Hō (たばこ事業法) [Tobacco Business Act], Law No. 68 of 1984 (Japan).

⁵⁶ See Eric A. Feldman, *The Culture of Legal Change: A Case Study of Tobacco Control in 21st Century Japan*, 27 MICH. J. INT'L L. 743, 746–747 (2006) (analyzing how the political economy of tobacco in Japan explained the absence of laws involving tobacco consumption).

to explain Japan's weak of tobacco control policies. Given this institutional history, the question raised by e-cigarettes in Japan is whether the Ministry of Finance will regulate them as tobacco products or the Ministry of Health, Labor, and Welfare will treat them as pharmaceutical products.

In early December 2010, the MHLW announced that the Pharmaceutical Affairs Law would be applied to e-cigarettes. According to the Ministry, Article 2 of the 1984 Tobacco Business Act defines a "tobacco product" (製造たばこ) as a product that is constituted in whole or in part of tobacco leaves and is capable of being smoked, chewed or sniffed.⁵⁷ In turn, "tobacco leaf" (葉たばこ) is defined as the leaf of a tobacco plant, and a "tobacco plant" (たばこ) is a plant of the nicotiana genus (タバコ属). That definition, according to the MHLW, makes clear that e-cigarettes vaporizing a nicotine-containing liquid are not tobacco products and cannot be regulated as such. Instead, according to the MHLW, e-cigarettes, like other products that contain nicotine, should be regulated under the Pharmaceutical Affairs Law. On December 27, 2010, the MHLW ordered local governments (prefectures and municipalities) to monitor the sale of e-cigarettes containing nicotine, to prohibit pharmacies from selling them, and to recall all nicotine-containing e-cigarettes.⁵⁸ The result is a de facto ban on e-cigarettes, at least until an e-cigarette company seeks regulatory approval from the MHLW on the basis that its product is safe and effective.

There is, however, a wrinkle on the regulatory fabric. The MHLW's approach was aimed at e-cigarettes that vaporize nicotine-containing liquid. Some electronic cigarettes, however, vaporize tobacco leaf, not liquid. Instead of being regulated as pharmaceutical products by the MHLW, such vaporizers qualify as tobacco products (since they contain tobacco leaf) and are regulated by the Ministry of Finance.⁵⁹ From a public health perspective, there is little justification for such a regulatory divide. There is no evidence that leaf vaporizers pose fewer health concerns than liquid vaporizers, and

⁵⁷ Tobacco Business Act, *supra* note 55.

⁵⁸ *Nikochin wo Ganyusuru Denshi Tabako ni Kansuru Kigai Boshi Sochi ni Tsuite* (ニコチンを含む電子タバコに関する危害防止措置について) [*Harm Prevention Measures Related to Electronic Cigarettes Containing Nicotine*], JAPAN MINISTRY OF HEALTH, LABOR AND WELFARE (Dec. 27, 2010), <http://www.mhlw.go.jp/stf/houdou/2r985200000zlvf.html>.

⁵⁹ Interviews with officials at the Japanese Ministry of Finance and the Ministry of Health, Labor and Welfare (Dec. 2014) (on file with author).

one can speculate that because tobacco leaf contains over seventy known carcinogens and leaf vaporizers operate at higher heat than liquid vaporizers, they may pose greater health risks. But data are not the primary concern when it comes to tobacco control in Japan. Perhaps it is only a coincidence that Japan Tobacco did not have a liquid-vaporizing e-cigarette in its product line but had made a significant investment in a leaf vaporizer that it was ready to bring to the Japanese market. Nonetheless, a regulatory strategy that imposes a de facto ban on liquid vaporizers and enables the sale of leaf vaporizers appears to satisfy the economic, political, and institutional interests that have long animated tobacco policy in Japan and maintained a powerful alliance between the Ministry of Finance, Japan Tobacco, and other key players.

C. The US and Japanese Approaches to E-Cigarette Regulation: Implications for China

What lessons, if any, do the U.S. and Japanese experiences hold for China? At least three general points emerge from the preceding analysis. First, e-cigarette regulation is likely to reflect prior institutional arrangements. These include the legal definition of pharmaceutical and tobacco products, regulatory policy and politics, patterns of tobacco consumption and control, and the weighing of economic, political and health considerations in the crafting of public health policy. Second, as the U.S. courts have made clear, the claims manufacturers make about e-cigarettes—that they are safe, for example—may be a critical factor in how they are regulated. Third, uncertainty about the nature of e-cigarettes—what they should be called, how they work—has led regulators to treat them like their most obvious analog, combustible cigarettes, even though they are different in a variety of notable ways. Policymakers in the U.S. and Japan have adopted different regulatory strategies, yet their differences are more a reflection of domestic power relations and politics than of reasoned policy analysis. Chinese policymakers can benefit from understanding those differences, but they are left with the difficult task of having to identify a workable regulatory approach that is more attentive to public health than private and state profit.

IV. CHINA'S REGULATORY OPTIONS

A. *Legal Definitions*

In considering China's primary regulatory options—regulating e-cigarettes as pharmaceutical or tobacco products—one must first examine the relevant Chinese laws governing those approaches.

Article 2 of the 1991 China Tobacco Monopoly Law, modified in 2009, 2013, and 2015, defines “tobacco monopoly products” as including cigarettes, cigars, pipe tobacco, re-dried tobacco leaf, tobacco leaf, cigarette paper, cigarette filter rods, tow for cigarette, and cigarette manufacturing equipment. It defines “tobacco products” as cigarettes, cigars, pipe tobacco, and re-dried tobacco leaf.⁶⁰ E-cigarettes do not naturally fit any of these categories. For e-cigarettes to be folded into the Tobacco Monopoly Law, the nicotine extracted from tobacco leaf (all tobacco leaf in China is controlled by the Tobacco Monopoly Bureau) would itself have to be legally defined as a “tobacco product.” In the absence of such a redefinition or interpretation, e-cigarettes will remain beyond the reach of China's Tobacco Monopoly Law.

China's Drug Administration Law, enacted in 1984 and modified in 2001 and 2015, defines pharmaceutical products as “articles which are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications, usage and dosage are established, including Chinese crude drugs, prepared slices of Chinese crude drugs, traditional Chinese medicine preparations, chemical drugs substances and their preparations, antibiotics, biochemical drugs, radioactive pharmaceuticals, serum, vaccines, blood products and diagnostic agents.”⁶¹ This definition establishes three criteria for a product to be considered a drug: it must be “used in the prevention, treatment and diagnosis of human diseases,” be “intended for the regulation of the physiological functions of human

⁶⁰ Yancoo Zhuanmai Fa (烟草专卖法) [China Tobacco Monopoly Law] (promulgated by the Standing Comm. Nat'l People's Cong., June 29, 1991, effective Jan. 1, 1992, amended Apr. 24, 2015), art. 2, http://www.tobacco.gov.cn/html/27/2701/270101/4830381_n.html.

⁶¹ Yaopin Guangli Fa (药品管理法) [China Drug Administration Law] (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 28, 2001, effective Dec. 1, 2001, amended Apr. 24, 2015), art. 102, http://www.npc.gov.cn/npc/cwhhy/12jcw/2015-04/25/content_1934604.htm.

beings,” and have “established indications, usage and dosage.” Do e-cigarettes fall under this definition? As in the United States, that will at least in part depend upon the interpretation of the meaning of intent, as well as on how e-cigarettes are advertised and promoted. To the degree that Chinese e-cigarette corporations continue to market their products as smoking cessation aids or as healthy alternatives to smoking, they invite regulation under the Drug Administration Law. But so far, regulators in that agency show no sign of action.

Additionally, in the recently modified *Regulations for the Supervision and Administration of Medical Devices* enacted by the State Council, the definition of medical device emphasizes that a “medical device’s principal action in or on the human body is not achieved by means of pharmacology, immunology or metabolism.”⁶² This definition may preclude e-cigarettes, the utility of which generally relies on the pharmacological efficacy of nicotine on human metabolism.

In short, current legal provisions in China indicate that e-cigarettes do not clearly fall under the definition of tobacco products, pharmaceuticals, or medical devices. Regulating e-cigarettes in China will thus inevitably involve amending existing legislation, most likely by the Standing Committee of the National People’s Congress or through a binding judicial interpretation from the Supreme People’s Court and the Supreme People’s Procuratorate. If such amendments are necessary, which types of amendments would be most desirable?

B. Regulating E-Cigarettes as Pharmaceutical Products

There are both theoretical and practical reasons to regulate e-cigarettes as pharmaceuticals. Theoretically, the precautionary principle invites the government, in the absence of sufficient scientific evidence that establishes the safety of a product, to adopt a relatively strict regulatory approach for the sake of public health. Given the scientific uncertainty about e-cigarettes, keeping them off

⁶² The regulations make clear that a pharmacological, immunological or metabolic impact must be a secondary, not primary, function.

the market or strictly limiting their availability would seem a prudent precautionary approach.⁶³

Pragmatically, the fact that many manufactures in China promote their products by asserting that e-cigarettes are less harmful than combustible cigarettes and are helpful in smoking cessation also calls for preemptive regulation. According to a content analysis of e-cigarette manufacturers' websites in China, health-related benefits were claimed most frequently (89%), followed by claims of no secondhand smoke exposure (78%) and utility for smoking cessation (67%).⁶⁴ A search of Taobao.com using "e-cigarette" (电子烟) as the key word reveals that all twenty of the top e-cigarette products as of May 2015 are promoted with claims about "smoking cessation" or "harmlessness." (See the promotional pictures from the top three best-selling e-cigarettes on Taobao.com below.)⁶⁵



Illustration 1. Title: XX E-cigarettes are popular everywhere. The six small signs refer to hotels, hospitals, schools, offices, airports and restaurants. The caption states: "XX e-cigarettes not only assist in smoking cessation, but also solve the problem of smoking bans in public places like offices, schools, hospitals and restaurants, since they do not produce second hand smoke."⁶⁶

⁶³ The precautionary approach in China is often discussed and has been adopted in environmental law and marine environmental protection in recent years. See, e.g., Zhang Luoping (张珞平), et al., *Yujing Yuanze Zai Huanjing Guihua Yu Guanli Zhong de Yingyong* (预警原则在环境规划与管理中的应用) [*Application of Precautionary Principle in Environmental Planning and Management*], 43J. XIAMEN UNIV. (NATURAL SCIENCE) 221, 221 (2004) (discussing the precautionary principle and its application in environmental planning and management).

⁶⁴ Tingting Yao et al., *A Content Analysis of Electronic Cigarette Manufacturer Websites in China*, 25 TOBACCO CONTROL 188, 188 (2016).

⁶⁵ Even Judge Richard Leon, whose opinion in the e-cigarette litigation made clear his distaste for government regulation, would have little trouble accepting the need for government regulations in the face of such unsubstantiated health claims.

⁶⁶ Downloaded from <https://www.taobao.com> (May 30, 2015).

购买电子烟的八大理由

健康自己，关爱家人，自由享受烟趣乐趣，家人远离二手烟危害

MIYOSHI

干选助您戒烟

有效替烟 轻松减烟 辅助戒烟

无二手烟传播，无烟焦油危害，无致癌物质，无燃烧无明火，无一氧化碳

购买干选电子烟都已成功戒烟

Illustration 2. Eight significant reasons to buy e-cigarettes. The eight reasons as shown in the small pictures include no tobacco ash, no tar, various flavors, trendy and fashionable, assist in smoking cessation, effective smoking cessation, no second hand smoke, and portable.⁶⁷

⁶⁷ *Id.*



Illustration 3. Certificate of guarantee. Many sellers assert that their products have been examined and/or approved by domestic and international institutions, like the CDC in China and the FDA in the U.S. The picture displays certificates one seller claims to have received for its e-cigarettes.⁶⁸

For Chinese policymakers to treat e-cigarettes as pharmaceuticals, the current legal definition of drugs will have to be modified. Such modification may be on the way. The Chinese Drug Administration Law, part of the National People’s Congress legislative reform program, is now being revised by the Chinese Food and Drug Administration and is expected to be completed before March 2018. Some scholars have proposed that the CFDA should have the discretion to decide which substances should be deemed pharmaceutical products, in order to establish “the most stringent drug regulatory system” required by the Premier. Indeed, the public online database of the CFDA includes twenty-four nicotine-based drugs for nicotine replacement therapy (twenty-two imported and two domestic) divided into five categories, including chewing gum, patches, transdermal agents, active pharmaceutical ingredients, and

⁶⁸ *Id.*

sublingual tablets.⁶⁹ Clearly, some nicotine products in China have already been placed under the CFDA's domain.

If the CFDA is granted regulatory control of e-cigarettes, companies will be required to submit product applications with information on clinical trial data, product ingredients, dosage, and more. An expert panel within CFDA will evaluate product safety, efficacy and other relevant indicators and make a decision about product approval. Manufacturers, suppliers, and users will then be subject to a variety of supervision and inspection rules, such as the Good Manufacturing Practices in accordance with the Chinese Drug Administration Law.⁷⁰ Ultimately, the CFDA could issue detailed standards for e-cigarettes. Although high product quality is not produced merely by strict government regulation, a relatively strict review, approval, and supervision system can benefit consumers by providing at least better quality products. In addition, existing pharmaceutical laws and regulations, such as drug labeling requirements, will apply to e-cigarettes and will help keep consumers informed.

There are, however, some potential costs to regulating e-cigarettes as pharmaceuticals. First, for those e-cigarette corporations not making health claims about their products, it may be difficult to justify the imposition of pharmaceutical regulations. If the presence of such claims invites regulation as a drug, surely the absence counters such regulation. Second, there is a possibility that e-cigarettes will turn out to be an effective nicotine replacement therapy. However, accumulating data that show safety and efficiency will take years, and during that time, many people's health would be harmed by combustible tobacco products. Finally, the Japanese approach to regulating e-cigarettes as pharmaceuticals provides a cautionary tale. Even more so than Japan, the Chinese government retains a monopoly over the tobacco industry, and tobacco taxes and profits constitute a considerable proportion of both central and local

⁶⁹ The definition from China Drug Administration Law now decides what counts as a drug. The CFDA has not been given the deeming power, i.e., defining a product as a drug merely out of CFDA's own discretion.

⁷⁰ See, e.g., *Zhonghua Renmin Gongheguo Yaopin Guanli Fa* (中华人民共和国药品管理法) [Drug Administration Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Sept. 20, 1984, amended Feb. 28, 2001), art. 9, <http://www.sda.gov.cn/WS01/CL0064/23396.html> (China).

government revenue.⁷¹ Even if e-cigarettes that contain nicotine are brought under the control of the CFDA, products that vaporize tobacco leaf could, as in Japan, be regulated by those responsible for the lax regulation of combustible tobacco products—namely China Tobacco, under the China Tobacco Monopoly Law. Such an approach is unlikely to prioritize public health and could well lead to similar problems as those experienced under China’s “double-track” regulatory system in the food and drug area.⁷²

C. *Regulating E-Cigarettes as Tobacco Products*

Regulating e-cigarettes as tobacco products would sidestep some of the potential problems inherent in the pharmaceutical approach. Rather than justifying regulation by pointing to the representations made by e-cigarette manufactures, a tobacco control approach focuses on the public health consequences of e-cigarettes. Such a focus would regulate liquid and leaf vaporizers similarly, unless data on their public health impact counsel a different approach. The most significant benefit of regulating e-cigarettes as tobacco products will be realized if studies ultimately support the view that the use of e-cigarettes reduces morbidity and mortality caused by the use of combustible cigarettes. Chinese smokers currently consume about one-third of all tobacco products smoked per annum globally, and as a result, over 1 million Chinese die annually from tobacco-

⁷¹ In 2014, tobacco tax combined with profit reached 1 trillion Yuan, which constituted over 6% of government revenue. *2015 Nian Quanguo Yanco Gongzuo Huiyi Xianchang Shishi Baodao* (2015 年全国烟草工作会议现场实时报道) [*Live Report of the 2015 National Tobacco Conference*], E. TOBACCO J. (Jan. 15, 2015), http://www.eastobacco.com/zxbk/wzzt/2015nqgycgzhuztbd/2015zbbd/201501/t20150114_354690.html; *2014 Nian Caizheng Shouzhi Qingkuang* (2014 年财政收支情况) [*2014 Fiscal Balance*], CHINESE GOV. NETWORK (Jan. 30, 2015), http://www.gov.cn/xinwen/2015-01/30/content_2812441.htm. See also Li, *supra* note 26 (emphasizing the importance of tobacco tax and profit to government revenue in China).

⁷² Previously, governance over food and drugs in China was divided between several ministries, leading to an unclear division of responsibility among agencies. Problems with food safety were generally attributed to such multiple governances. In March 2013, at the beginning of the central government’s new term, it tried to create a unified and centralized food and drug regulatory system. *Guojia Shipin Yaopin Jianguan Zhongju Guapai Shipin Jianguan Buzai “Jiulong Zhishui”* (国家食品药品监管总局挂牌食品监管不再“九龙治水”) [*State Food and Drug Administration Established; Food Supervision Is No Longer Responsibility-Diverse*], XINHUA NEWS (Mar. 22, 2013), http://news.xinhuanet.com/2013-03/22/c_115125786.htm.

related diseases.⁷³ Because regulating e-cigarettes as tobacco products generally results in control rather than prohibition, it could lead to the growing popularity of e-cigarettes, a drop in combustible tobacco use, and an overall improvement in public health.

In order to regulate e-cigarettes as tobacco products, the definition of tobacco products under the China Tobacco Monopoly Law (the “CTML”) must be revised. Because the CTML is a national code ratified by the Standing Committee of the National People’s Congress, the State Tobacco Monopoly Administration (the agency that manages the tobacco monopoly) is responsible for justifying the need for a legal change and drafting revisions. Alternatively, drafting a new law could be avoided if the Supreme People’s Court and Supreme People’s Procuratorate issued a new judicial interpretation of the law. Indeed, in 2013, the media reported that a new judicial interpretation of the China Tobacco Monopoly Law would soon place e-cigarettes under the tobacco monopoly system.⁷⁴ However, no such judicial interpretation has yet been presented.

In addition to the possibility that regulating e-cigarettes as tobacco products could help reduce tobacco-related morbidity and mortality in China, it also has significant financial implications for the government. Tobacco monopoly income is a major source of government revenue; tobacco taxes combined with profit constitute over 6% of total government income.⁷⁵ At the regional level, a tobacco leaf tax (tax rate is 20%) flows directly to local government, together with 25% of the value-added tax (tax rate is 17%).⁷⁶ In provinces like Yunnan and Guizhou, where tobacco is a pillar

⁷³ See *Zhongguo Yancao Kongzhi Guihua (2012-2015 Nian)* (中国烟草控制规划 (2012-2015 年)) [*China Tobacco Control Plan (2012-2015)*], CHINA TOBACCO, http://www.tobacco.gov.cn/history_filesystem/2013yckz/ghqw-more.htm (last visited May 10, 2016) (discussing a control plan for tobacco in China from the year 2012 to 2015).

⁷⁴ See *Niandi Guojia Youwang Chutai Yancao Zhuanmai Sifa Jieshi Han Dianzi Yan* (年底国家有望出台烟草专卖司法解释含电子烟) [*Tobacco Monopoly Law Judicial Interpretation Hopefully Could Be Issued by the End of the Year, Which Would Include Electronic Cigarettes*], PEOPLE.COM.CN (Dec. 4, 2013), <http://js.people.com.cn/html/2013/12/04/272979.html> (discussing the possibility of issuance of a judicial interpretation of the Tobacco Monopoly Law in China).

⁷⁵ Li, *supra* note 26. The central government collects a tobacco excise tax, a value-added tax, and a certain amount of net profit from the China National Tobacco Corporation.

⁷⁶ Value-added tax is a kind of shared tax by central and local government in China. The tax rate is 17%. Central government gets 75% of it, while local government gets 25%. See Bu Wei, *Zhongguo Difang Caizheng Dui Yancao Shuishou de Yilai* (中国地方财政对烟草税收的依赖) [*The Dependence of Local Finance on Tobacco Tax in China*], CNKI (2014), <http://cdmd.cnki.com.cn/Article/CDMD-80201-1014046237.htm>.

industry, the tobacco leaf tax is particularly important.⁷⁷ Regulating e-cigarettes as tobacco products would enable the Chinese government to potentially collect a large sum of tax and profit. Regardless of whether e-cigarettes turn out to be a gateway to or exit from the use of combustible tobacco products, they would become a significant generator of revenue for both the central and local government.

Folding e-cigarettes into the government's tobacco monopoly also presents a number of challenges. By defining e-cigarettes as tobacco products and asserting government control, the legal status of hundreds of private e-cigarette factories and thousands of online and brick and mortar retailers will be called into question. How, and how quickly, could China Tobacco absorb those companies or issue monopoly licenses? Moreover, China Tobacco faces a steep learning curve in regulating e-cigarettes. So far, it has little experience in regulating manufactures of vaporizers or e-liquids that contain various amounts of nicotine. Doing so effectively requires research and planning in terms of equipment, personnel, and more. In addition, particularly given the large number of Internet-based sellers, effective enforcement will be a challenge.

Finally, regulating e-cigarettes as tobacco products begs the question of whether China has effectively regulated other tobacco products. Unfortunately, the answer is no. Formally, China signed the WHO's Framework Convention on Tobacco Control in November 2003, and ratified it in August 2005. In April 2007, the State Council approved the establishment of the "FCTC Implementation Inter-Ministerial Coordination Leading Group," with members from the National Health and Family Planning Commission, State Tobacco Monopoly Administration, and other relevant ministries.⁷⁸ Under the leadership of that group, efforts have been made to prohibit tobacco advertising in the mass media, ban tobacco

⁷⁷ *Id.*

⁷⁸ See *Guowuyuan Guanyu Tongyi Chengli Yanco Kongzhi Kuangjia Gongyue Lvye Gongzuo Buji Xietiao Lingdao Xiaozu de Pifu* (国务院关于同意成立烟草控制框架公约履约工作部际协调领导小组的批复) [*The State Council Agreed to Set up the FCTC Implementation Inter-Ministerial Coordination Leading Group*], CHINALAW.GOV.CN (Mar. 30, 2010), <http://www.chinalaw.gov.cn/article/fgkd/xfj/fgxwj/201003/20100300251040.shtml> (discussing the setting up of the FCTC Implementation Inter-Ministerial Coordination Leading Group and specifying the composition and functions of the group).

use in indoor public places, and forbid sales to minors.⁷⁹ Moreover, under the China Tobacco Control Plan (2012-2015), more rigorous measures such as prohibiting smoking in public places, strengthening warnings on cigarette packets, and banning tobacco promotion and sponsorship are on the way.

Nonetheless, tobacco control policy in China has long been criticized as weak and poorly enforced.⁸⁰ Per capita smoking rates are high, second-hand smoke exposure is ubiquitous, youth access is widespread, and public education is poor. Extending this weak tobacco control regime to e-cigarettes is a troubling prospect. Further, China Tobacco's goal is to improve sales and make a profit, and it has little interest in a more robust tobacco control policy. Indeed, with an eye toward maximizing profit, one can easily imagine that China Tobacco will be inclined to promote the still-unclear benefits of e-cigarettes and minimize their potential risks.

V. CONCLUSION

The explosion in the growth of the e-cigarette industry, the popularity of e-cigarettes among consumers and their unclear impact on public health make e-cigarette regulation in China a necessity. While regulatory choices in the United States and Japan may be instructive for Chinese regulators, in neither country has e-cigarette regulation been free of controversy, and neither presents a ready-made approach that can be applied to China. The Chinese government can learn about e-cigarette regulation elsewhere and

⁷⁹ The Smoking Control Ordinance of Shenzhen Special Economic Zone focused on strengthening the enforcement of smoking-bans in public places. It created six municipal agencies – Public Security Bureau, Urban Management Bureau, Transportation Commission, Health Supervision Bureau, Sports and Tourism Bureau, and Market Supervision Bureau – responsible for enforcing the Ordinance in their own domains. From March 1 to December 31, 2014, 100,253 public places were inspected and 8,675 people were administratively fined a total of ¥ 420,100. Shenzhen, where the most aggressive smoking regulations were implemented in 2014, is seen as a model tobacco control city in China.

⁸⁰ See Hong Yu (洪宇), *Zhongguo Kongyan Zhengce Bianqian: Jiyu Zhichi Lianmeng Kuangjia de Fenxi* (中国控烟政策变迁: 基于支持联盟框架的分析) [*The Change of China Tobacco Control Policy: An Advocacy Coalition Framework-Based Analysis*], 7.3 CHINESE J. HEALTH POL'Y 20, 20 (2014) (analyzing the historical changes in Chinese tobacco control policy). See also Jun Lv, et al., *Implementation of the WHO Framework Convention on Tobacco Control in Mainland China*, 20 TOBACCO CONTROL 309, 309 (2011) (discussing how China has implemented the WHO FCTC on tobacco).

hopefully learn from those experiences. But it must craft its own set of policies.

As Chinese policy makers ponder their approach to e-cigarette regulation, they should consider taking immediate action in several arenas. First, the dubious health claims made by many (most) e-cigarette companies can and should be regulated under the China Advertising Law. Promotional materials claiming that e-cigarettes will help people stop smoking and touting their safety can mislead consumers and harm public health. The Advertising Law, revised in September 2015, includes several articles relevant to e-cigarette regulation.⁸¹ Article 4 requires that “advertisements must not contain false or misleading content and must not deceive or mislead consumers.”⁸² Article 17 states that “except for medical, pharmaceutical, and medical device advertising, any other advertising related to the treatment of disease is prohibited; medical terms or other terms that may suggest that the product confused with pharmaceutical or medical device are prohibited.”⁸³ In addition, Article 28 defines false advertising as “false or misleading advertising content to deceive or mislead consumers.”⁸⁴ The State Administration for Industry and Commerce is responsible for enforcing the Advertising Law, which applies to all consumer products. In doing so, it can inspect, survey, inquire, require relevant certificates and documents, and demand the suspension of advertising. Failure to adequately police advertising exposes the State Administration for Industry and Commerce to potential legal liability.

Second, China is the world’s e-cigarette factory, but it lacks adequate quality control standards. Such standards should cover (but not be limited to) the raw materials used to manufacture e-cigarettes, the microchips that are placed into e-cigarettes, the types of batteries they use, the presence of heavy metals, and many other factors that can lead to manufacturing defects, design defects, and consumer harm. In addition, China produces a significant amount of e-liquid, and that too is in need of quality controls that address the quality of

⁸¹ Zhonghua Renmin Gongheguo Guanggao Fa (中华人民共和国广告法) [Advertising Law of the People's Republic of China] (promulgated by Standing Committee of the Nat'l People's Cong., Apr. 24, 2015, effective Sept. 1, 2015), http://www.gov.cn/zhengce/2015-04/25/content_2853642.htm (China).

⁸² *Id.*

⁸³ *Id.*

⁸⁴ If e-cigarettes were legally defined as tobacco products or drugs, advertising would require governmental review and approval. However, in the absence of a clear definition, the State Administration for Industry and Commerce has justified regulatory inaction. *Id.*

the concentration of nicotine, the use of additives, and types of flavorings. Quality control provisions can come from a number of sectors: industrial organizations can draft manufacturing codes of practice; individual companies may seek quality certificates from reliable third-party institutions; and government agencies such as the General Administration of Quality Supervision, Inspection, and Quarantine or the China Food and Drug Administration could together issue standards.

Third, the regulation and use of e-cigarettes is inevitably tied to the regulation of combustible tobacco. Pragmatism and public health both counsel that tobacco control measures in China should be strengthened as a precursor/companion to e-cigarette regulation. One priority should be the regulation of underage sales. The Law on Protection of Minors and the Law on Prevention of Juvenile Delinquency both state that “no business places may sell cigarettes or alcoholic drinks to minors.”⁸⁵ The China Advertising Law prohibits tobacco advertising to minors, and the China Tobacco Monopoly Law discourages young people from smoking and forbids primary and middle school students to smoke.⁸⁶ However, according to China National Radio, nearly half of all cigarette retailers do not post signs, as required under the law, stating that they do not sell tobacco products to minors, and middle school students can easily purchase tobacco products in shops near their schools.⁸⁷ A more robust ban, with enforced legal penalties, would help limit tobacco consumption in China and set a useful baseline for e-cigarette regulation. Other tobacco control measures, such as packet warnings, taxation, and bans on smoking in public places should also be pursued. Enforcement must also be a key component of a more vigorous tobacco control agenda.

⁸⁵ Article 2 of the Law on Protection of Minors states that minors refers to citizens under eighteen years old. *Zhonghua Renmin Gongheguo Weichengnianren Baohu Fa* (中华人民共和国未成年人保护法) [Law on Protection of Minors of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Sept. 4, 1991, effective Jan. 1, 1992), art. 2 (China).

⁸⁶ A more explicit ban on sales of cigarettes to juveniles would help to limit tobacco consumed in China, and would set a useful baseline for e-cigarettes.

⁸⁷ See *Diaocha Cheng Woguo Jinban Yandian Dui Weichengnian Bu Shefang* (调查称我国近半烟店对未成年不设防) [Survey Shows Nearly Half of Tobacco Retailer Shops in China Take No Measures to Prevent Sales to Minors], CHINA.CNR.CN (June 25, 2015), http://china.cnr.cn/qqhygbw/20150625/t20150625_518955879.shtml (discussing the facts and reasons why many tobacco shops are undefended to minors).

Finally, future e-cigarette regulation in China should pay special attention to the impact and implication of China's current smoking epidemic. Tobacco consumption in China is extremely high, tobacco control policies are weak, and there is no sign that smoking rates in China are decreasing at a significant pace. This environment, quite different than in the United States and Japan, may have meaningful implications for future e-cigarette regulation. One possibility is that e-cigarettes should be regulated less aggressively in China than elsewhere because of the urgent need to lower tobacco consumption rates. Harm reduction, in other words, may have greater urgency in China, and that urgency may persuade policymakers to err on the side of relatively permissive e-cigarette regulation. The opposite approach may be equally persuasive; perhaps e-cigarettes should be regulated aggressively because they could further complicate or worsen China's combustible tobacco consumption problem. Whichever direction Chinese policymakers turn, they are likely to discover what is already apparent to their counterparts in the United States and Japan. No approach to e-cigarette regulation is wholly satisfactory, but the worst approach is no approach at all.