Tobacco Products Regulation (Food and Drug Law Book 11)

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The purpose of this volume is to detail tobacco products regulation by the United Stated Food and Drug Administration (FDA). Smoking has plagued America for generations; however, the issue had never received more serious scrutiny than the past decade. According to he American Cancer Society, estimates for lung cancer in the United States include a diagnosis of approximately 228,190 new cases of lung cancer (118,080 men and 110,110 women) as well as an estimated 159,480 deaths from lung cancer (87,260 men and 72,220 women). According to the World Health Organization, the use of tobacco use is the most significant risk factor for cancer. Worldwide this accounts for 71% of global lung cancer deaths.
The Centers for Disease Control and Prevention, over 443,000 deaths every year are attributed to tobacco use in the United States. Over 8.6 million Americans have chronic illnesses linked to smoking. Approximately 4,000 youth start smoking and 1,000 youth become daily smokers. The rise of teen smoking and the long-term effects of nicotine addiction prompted a change. To that end, on June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA). This historic legislation conferred authority to FDA to regulate tobacco products. This law amended the FDCA and other federal laws by permitting FDA regulatory authority over the manufacture, marketing, and distribution of all tobacco products. This includes all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. For example, large graphic warnings are required on cigarette cartons that describe the health consequences of smoking.
The impetus for the FSPTCA was due to the United States Supreme Court decision of FDA v. Brown and Williamson Tobacco Corp. The Supreme Court in Brown held that FDA lacked the authority to regulate tobacco. FDA asserted jurisdiction over tobacco products based on the FDCA definitions of “drug” and “device.” Nearly ten years after this United States Supreme Court decision, Congress provided FDA with explicit legal authority or jurisdiction to regulate tobacco products. This volume includes the Brown decision, First Amendment challenges, enforcement and e-cigarettes. Critical analysis issues are included.

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