FDA's Battle to Regulate Electronic Cigarettes

Perspective
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Perspective

This is the tale of how a court decision transformed a device created by Hon Lik for smoking cessation into a recreational tobacco product.

In 1938 FDR signed into law the Food, Drug and Cosmetic Act (FDCA) which expanded the role of government to regulate consumer products. Drugs now had to be proven safe to use before they could be sold to the public, their labels had to tell the consumer how to safely use the drug, and making false therapeutic health claims was prohibited. Later additions to the FDCA included requiring drug manufacturers to prove the efficacy of a new drug, and allowed the regulation of medical devices [1].

The FDA is now a division of the Department of Health and Human Services with five sections: 1. Office of the Commissioner, 2. Office of Foods and Veterinary Medicine, 3. Office of Global Regulatory Operations and Policy, 4. Office of Policy, Planning, Legislation and Analyses, 5. Office of Medical Products and Tobacco.

The Office Medical Products and Tobacco consists of: 1. Center for Biologics Evaluation and Research, 2. Center for Devices and Radiological Health, 3. Center for Drug Evaluation and Research (CDER), 4. Center for Tobacco Products (CTP).

The Center for Tobacco Products was added to the FDA when the Family Smoking Prevention and Tobacco Control Act was signed into law in 2009. This amended the FDCA to grant the FDA authority to regulate tobacco products, including cigarettes, which until this time were largely unregulated Figure 1.

So as you can see the FDA is not a single entity but a large organization with many offices and divisions [2].

In 2007 NJOY and a distributor, Smoking Everywhere, started importing and selling electronic cigarettes in the United States. Marketing and promotional materials claimed:

I. "less health risk, and I can smoke anywhere and everywhere"

II. "cheaper and healthier than real cigarettes"

III. "smokers still get their nicotine, but don't get any harmful side effects of smoking traditional cigarettes"

In March 2009 the FDA directed the US Customs and Border Protection to deny entry of e-cigarettes into the United States and the shipments be either exported or destroyed. The FDA claimed that under the FDCA electronic cigarettes were an unapproved combination drug and medical device which required pre-approval, registration and listing with the FDA under the office of CDER; which regulates other nicotine products used to treat nicotine addiction.

A combination medical product has two different components which includes a drug and a device that are packaged together as a single item and is "intended to affect the structure or any function of the body" or "is intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease".

The FDA made the claim that electronic cigarettes fell under the definition of a combination drug/medical device because in their marketing and promotional materials they claimed to be a way to quit smoking which is recognized as treating and/or mitigating the symptoms of nicotine addiction.

The next month a Federal complaint seeking an injunction was filed by Smoking Everywhere (NJOY later joined the lawsuit) against the FDA claiming that the FDA's interference with the importation of electronic cigarettes was illegal because the FDA had overstepped its boundaries because electronic cigarettes were not a drug, a drug delivery system nor a drug device combination but a tobacco product.

The justification used was the 2000 court case of the "FDA v. Brown and Williamson", where the courts ruled that the FDA did not have the authority to regulate tobacco products and that electronic cigarettes are the "functional equivalent of traditional cigarettes". It was from this 2000 court decision that Congress worked on legislation to regulate tobacco products which eventually became the Family Smoking Prevention and Tobacco Control Act [3].

The timing of the embargo of electronic cigarettes, the resulting lawsuit, and the passage of the Family Smoking Prevention and Tobacco Control Act (TCA) are intertwined. The original FDA order to stop the importation happened prior to the passage of the TCA which was passed during the time period of the lawsuit.

In June 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (TCA) which did give the FDA the authority to regulate tobacco products. While the only tobacco products specifically listed in the TCA were cigarettes, smokeless tobacco, and roll-your-own loose leaf tobacco the TCA gave the FDA the right to regulate any product that was made or derived from the tobacco plant.

The act established a new FDA office: The Center for Tobacco Products (CTP) which opened in 2010 with two employees. It also

require that any tobacco product introduced after February 15, 2007 would need to file a premarket application with the FDA. As soon as the CTP opened, the agency was inundated with over 3,500 applications for product review. The application process for a new tobacco product was supposed to take 90 days, but often took more than a year because not only was the CTP a new agency unused to regulating tobacco but the tobacco companies were also new to regulation [4,5].

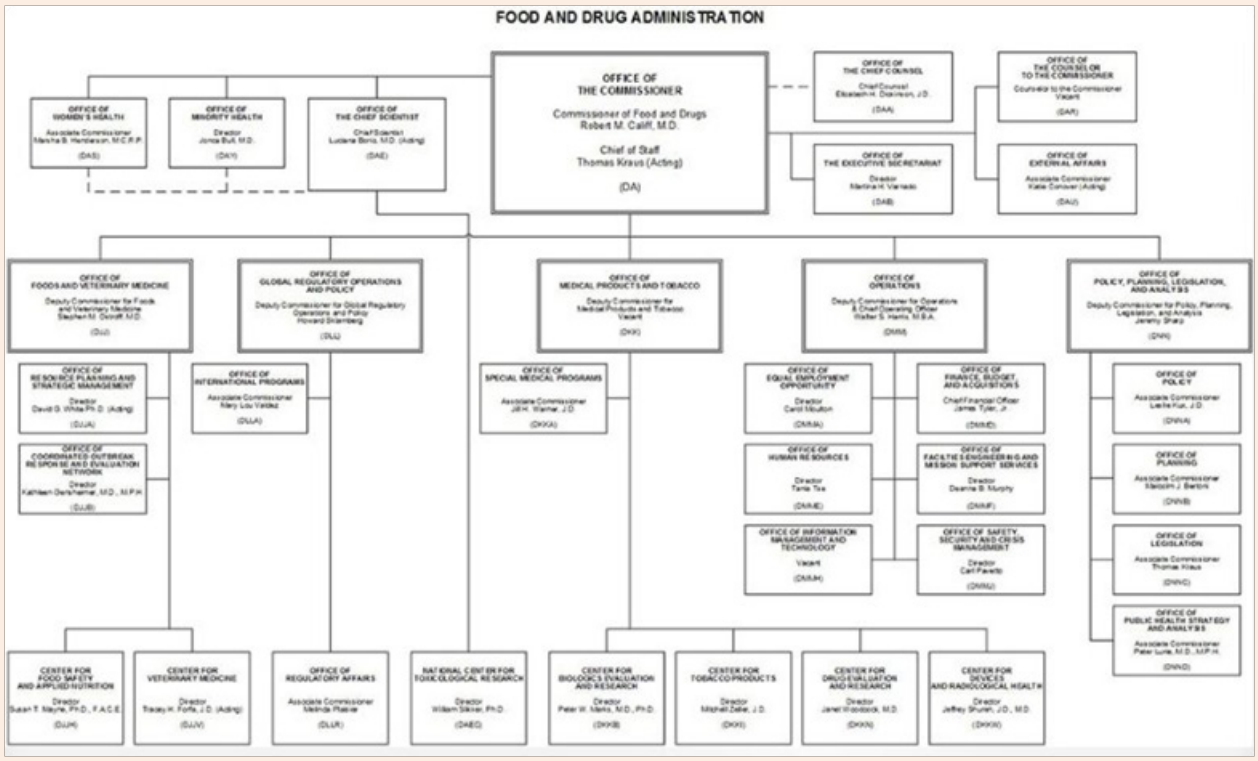

Figure 1: Food and Drug Adminis Tration.

The court case wound its way through the justice system with an initial injunction stopping the FDA from seizing electronic cigarettes. An appellate court put a hold on the injunction pending an appeal, and finally the US appeals court ruled that the FDA can only regulate electronic cigarettes as combination drug/medical device if the manufacturer makes a therapeutic health claim such as an intention to treat a disease, illness such as nicotine addiction. However, the court ruled that since the TCA had passed giving the FDA authority to regulate tobacco products, the FDA could regulate electronic cigarettes as a tobacco product since they did contain nicotine derived from the tobacco plant.

So if a company makes a "therapeutic claim" such as electronic cigarettes can help a smoker quit smoking, then the FDA can regulate them as a combination drug/medical device under CDER. However, if no therapeutic claim is made, then electronic cigarettes cannot be considered a combination drug/medical device and cannot be regulated as such.

In April 2014, the CTP announced its intention to regulate "electronic cigarettes not marketed for therapeutic purposes" under the TCA. This final deeming regulation goes into effect on August 8, 2016 [6].

Since electronic cigarettes were introduced into the U.S. market after February 15, 2007, every device and liquid will be required to register with the FDA and submit a premarket review. The premarket review process will allow the CTP to:

I. "evaluate ingredients, product design and health risks, as well as the appeal to youth and non-users"

II. "protect adult users by making sure products are appropriately manufactured and used and address such things as exploding batteries".

Companies have 24 months to submit their application to the CTP and up to an additional year for review. Should any electronic cigarette manufacturer want to make the claim their product can be used for smoking cessation, an application would instead be made to CDER under its own guidelines. Since the CDER guidelines for a drug require more extensive research showing not only that the drug/medical device is safe but also effective, it is expected that electronic cigarette manufacturers will not make any therapeutic claims [7].

Many people have wondered why it has taken the FDA so long to regulate electronic cigarettes and I have to give them credit - they have been trying for many years but due to lawsuits, confusing

regulation, and a new agency it has not been a fast process and it will probably take several more years before any real changes are made to the electronic cigarette market.

Another twist in this saga is the Cole Bill (H.R. 2058) that making it's way through Congress. It basically says that a tobacco product is not deemed a tobacco product until it is called a tobacco product. This is just a roundabout way to change the grandfather date of February 15, 2007 to August 8, 2016 when the FDA regulations take effect. Should this pass, then all electronic cigarettes on the market prior to August 8, 2016 would not be required to file a premarket review.

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