In the United States District Court for Maryland

Food and Drug Administration v. Center for Tobacco Products HA-19-5-21

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To repeal extraneous tobacco definitions in 21USC§321(rr) at paragraphs 2-4, increase tobacco revenues by $100 million FY 21, reduce tobacco spending by 50% FY 22 and pay up to $100 million compensation for the pandemic of felony monopolization under 15USC§2 and §15.

The Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act (Tobacco Control Act) P.L. 111-31 was signed by President Barack Obama, an African-America smoker, on June 22, 2009. It created the Center for Tobacco Products (CTP) under 21USC§387a(e) to provide technical and "non-financial" assistance to small tobacco manufacturers to comply with the provision of this law (f). FDA's Center for Tobacco Products advances the mission to protect Americans from tobacco-related death and disease by regulating the manufacturing, distribution, and marketing of tobacco products and has corruptly and without statutory authority laid claim that all tobacco user-fee revenues be spent on propaganda to educate the public (especially young people) about tobacco products and their harmful health effects. After years of delay, the outrageous tobacco excise tax increase from the Children's Health Insurance Program Reauthorization Act (CHIPRA) of February 2009 has been redressed by the Alcohol, Tobacco, Tax and Trade Bureau (TTB).

Subsequently, numerous instances of widespread tobacco product adulteration and counterfeiting under the influence of corrupt police and health professionals, have occurred in violation of 21USC§387b and §387c(a)(6). In 2015 Fresh Empire teen anti-smoking propaganda seems to have incited the contamination of all or nearly all the entire pipe tobacco harvest with throat toxic green tomatoes best treated with slippery elm based Throat Coat. Hard lung nodules from carcinogenic *Aspergillus niger* cured with a dab of hydrocortisone to the chest and slimy sphincter and black stool from carcinogenic rat poison induced intestinal bleeding were noted locally in sealed packages of tobacco and water bottles around 2017 along with two deaths from colon cancer. In the beginning of 2021 nearly all pipe tobacco sold in California and Oregon gas stations and convenience was contaminated with either a noxious substance or psychiatric drug induced temporomandibular join (TMJ) discomfort. CTP must prioritize the safety of tobacco products against terrorist, involuntary research using tobacco consumers as human test subjects, and cease to finance the corrupt research and youth anti-smoking propaganda that motivates corrupt police officers and health professionals.

After the Child Nicotine Poisoning Prevention Act of 2015 (CNPPA) required the safe packaging of liquid nicotine products, known as flow restrictors, in 2018 it became obvious that CTP only intended to enroll e-cigarette manufacturers in a collegiate pre-market approval process, while the FDA became exceedingly corrupted by the SUPPORT Act. The Hippocratic Oath provides that the lot of the perjurer is the opposite, a major reason children of health professionals get addicted to tobacco products, including the new, purportedly low risk, e-cigarettes. Reported e-cigarette use among high school students, was 16.0 percent in 2015, had decreased to 11.3 percent in 2016 and held steady in 2017, however in 2018 use skyrocketed and 27.5 percent of high school students and 10.5 percent of middle school students were current e- cigarette users in 2019. On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise the federal minimum age of

sale of tobacco products from 18 to 21 years. It is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21. The National Youth Anti-Drug Media Campaign under 21 U.S. Code § 1801 to 1804 was repealed by Pub. L. 109–469, title V, § 501(b), Dec. 29, 2006, 120 Stat. 3533. It is held that the Center for Tobacco Products must stop spending their tobacco revenues on tobacco propaganda so tobacco user-fees will generate a net profit for the FDA.

The FDA Budget includes $812 million in tobacco user fees that should not be used exclusively to support the FDA tobacco program, but to reduce federal outlays for the FDA and immediately pay compensation for personal suits for injury under 15USC§15 caused by the pandemic of felony monopolization in the health propaganda sector that weighs heavily on the negligence of the FDA to approve the right, safe, effective and low cost treatments needed to respond to pandemics and other outbreaks of disease and organized crime under 15USC§2. The Budget includes a legislative proposal to increase user fee collections in support of the tobacco program by $100 million, and make e-cigarette manufacturers and importers subject to the user fees. This is a good idea, especially taxing e-cigarettes, but it is much more valuable and medically necessary to desist in financing youth anti-tobacco propaganda, for the exact same reason tobacco manufacturers have been enjoined to stop targeting their marketing to young adults. Because the lot of a perjurer is the opposite, when the FDA or public health sector, is perceived as being corrupt, virtually always, anti-smoking propaganda targeting youth will have the aforementioned statistically significant reverse effect, older, less rebellious individuals, not specifically targeted by this propaganda, would not tend to think about in binary.

The HHS FY 21 Budget proposes to reform tobacco regulation by moving the Center for Tobacco Products out of FDA and create a new agency within HHS to strengthen accountability and more effectively respond to tobacco related public health concerns. This is not corroborated in the FDA Justification of Estimates for Appropriations Committees. Transferring CTP to HHS would only result in HHS adopting the expense for the corrupt propaganda. HHS employs legions of corrupt anti-smoker health professionals who already get paid to counsel people to quit smoking. The FDA would lose the long-standing regulatory victory of gaining jurisdiction over tobacco, that should maybe be extended to alcohol, at some time in the extremely distant future when public health is not so absolutely corrupted by coronavirus vaccine propaganda suppressing the safety and effectiveness of hydrocortisone, eucalyptus, lavender or peppermint or some other felony monopolization. Once, again it is held that the Center for Tobacco Products must stop spending their tobacco revenues on tobacco propaganda and be a net profit for the agency, but with prejudice against any malicious health regulation of alcohol and tobacco products, to prevent product adulteration and terrorism against products taxed by the Alcohol and Tobacco Tax and Trade Bureau (TTB), and consider repealing the Tobacco Control Act in its entirety, although it is well written, because it corrupts the FDA and would corrupt HHS, even worse, like all health legislation since 2009, for that matter.

The only obvious error in the Tobacco Control Act is that paragraphs 2-4 of the introductory definition of tobacco products needs to be repealed under 21USC§321(rr) 2-4. Congress should not have invoked long standing semantic “drug” abuse and neglect regarding tobacco not being a “drug” or “device” or “combination product” to justify tobacco not be marketed in combination with any food, drug, medical device, cosmetic or dietary supplement. In *Action on Smoking and Health (ASH) v. Harris* 655 F. 2d. 236 No. 79-1397 (1980) the Food and Drug Administration (FDA) refused to assert jurisdiction over cigarettes containing nicotine as a "drug" under section 201(g)(1)(C) of the Federal Food, Drug, and

Cosmetic Act under 21USC§321(g)(1)(C). ASH was attempting to abuse the term "drug" to limit tobacco sales to pharmacies and falsely cited Dr. Charles C. Edwards, FDA Commissioner's 1972 testimony before a Senate subcommittee whereby *Federal Trade Commission v. Liggett and Myers Tobacco Company* (108 F.Supp. 573, 1952) held that cigarettes are not drugs within the meaning of the act unless a therapeutic purpose is claimed. Indeed, if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended us [sic]. Sic is used in brackets after a copied or quoted word that appears odd or erroneous.

The immediate grievance is that the FDA and HHS Secretary recently conspired to ban menthol flavored tobacco on April 29, 2021, although menthol cigarettes comprise a quarter of all cigarettes and are particularly popular amongst African-Americans and women. The truth of the matter is that CTP is liable to be sued for up to $100 million for retaliating against and blocking information regarding two recently surfaced, critical pieces of health information, in one blow of their contagious although vaccinated Pinocchio nose under 42USC§300jj-52 and 15USC§2. One, menthol and menthol flavored cigarettes, in particular, are highly effective cure for coronavirus in chain smokers. Two, hydrocortisone crème cures hard lung nodules of *Aspergillus niger* that produces carcinogenic aflatoxin. In this they are a million times more reprehensible than the stage II lung cancer patient who preferred to smoke fentanyl than try a dab hydrocortisone crème to cure the underlying pulmonary aspergillosis and abate the pain and cause of carcinogenesis, for our amusement.

The Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Non-Menthol Cigarettes by the Tobacco Product Scientific Advisory Committee of March 23, 2011 held, the weight of evidence supports the conclusion that menthol in cigarettes is not associated with an increase in disease risk to the user. 11 studies found there was no difference in rates of disease between menthol and non-menthol smokers. Two studies held there was a slight improvement in health outcomes of menthol smokers. Menthol is widely used in drug products, foods, cosmetic products, and cigarettes, and generates a minty taste and a cooling sensation. Menthol is made from mint and retains all the medicinal properties of mint, particularly as a cure for coronavirus and allergic rhinitis noted in the Advisory Opinion that Hydrocortisone, Eucalyptus, Lavender or Peppermint help (Water) and Vaccines Cure Coronavirus HA-23-3-21. There is no denying that it is a crime of genocide to not merely deprive smokers of information that menthol cigarettes cure coronavirus, without so much a s human trial of menthol to cure coronavirus pursuant to usual procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs 21CFR§330.10 but to attempt to ban menthol cigarettes altogether in flagrant violation of the Application of the Convention on the Prevention and Punishment of the Crime of Genocide (*The Gambia v. Myanmar*) Summary 2020/1 23 January 2020 that is open to civil action for deprivation of rights under 42USC§1983 and paragraph 98 of Alleged violations of the 1955 Treaty of Amity, Economic Relations, and Consular Rights (*Islamic Republic of Iran v. United States of America*) No. 175 3 October 2018.

United States v. 46 Cartons Etc., 113 F. Supp. 336 (D.N.J. 1953) held, the libellant contends that the leaflet accompanying the article suggests and represents that the article is effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis (parrot fever). Libellant further contends that claimant represents that the smoking of these cigarettes is innocuous for persons suffering from circulatory diseases, high blood

pressure and various heart conditions. Claimant, understandably, does not believe it is selling drugs. It admits that the product has none of the curative or preventive powers implied in the leaflet. But throughout the leaflet claimant has tried to capture a share of the cigarette market by a subtle appeal to a natural and powerful desire on the part of us all to avoid the infectious diseases or ailments therein mentioned. In this case claimant does believe regularly smoking menthol cigarettes greatly reduces, even eliminates daily mentholyptus cough drop consumption to treat frequent contagious allergic rhinitis from venturing into public places during the COVID-19 pandemic, whether or not vaccinated pursuant to 21CFR§330.10. The eucalyptus in the mentholyptus cough drop also cures the occasional influenza, whose wet cough and fatigue, symptoms are mistakenly described as coronavirus, that begins with a Pinocchio nose and ends in death from fluid filled lungs.

In general, tobacco use is attributed with being the leading cause of preventable death and disease in the United States. More than 400,000 deaths per year in the United States, are said to be caused by tobacco use, about the same percentage of people who are active smokers, but cause of death is often due to untreated misdiagnosis, of which smoking bears a fair share. Research on lung cancer is an effective way to get up the gumption to try to quit smoking, but many non-smokers develop lung cancer, and one must no forget to treat aspergillosis with hydrocortisone, that can be transmitted by contaminated tobacco products. Whereas heavy smoking populations in Japan and Israel have longer live-expectancies than the United States, it is probably not true that smoking is the leading cause of preventable death and disease, except that smoking is obviously an unhealthy addiction, and that "smokers" are prescribed highly effective pneumococcal infection preventing Pneumovax 23 vaccine, other non-health professional working age people, even those with heart, lung and brain damage whose lives would be most improved, are categorically denied, although tobacco smoking has some sub-therapeutic lung sterilizing qualities contraindicated in cases of infection, when smoking becomes unpleasant, painful and this is excruciating to the addict. The addiction is decidedly unpleasant to non-smokers and smokers, who pay the expense, alike.

Nearly 9 out of 10 adult daily smokers began smoking by age 18. The reason given by pediatricians is that juvenile brains are more susceptible to addiction and become addicted more quickly and with fewer exposures. The focus of tobacco addiction prevention is therefore to prevent teenagers from smoking. However, it is very important that the method of instruction is scientific and fact based and that propaganda and false information, such as almost any health and economic statistic ever produced on the topic, is not financed, or else teenage rebellion against common public health corruption, will result in increased addiction, much like attempts by patently corrupt drug enforcement to infiltrate elementary schools with their sample case of UN controlled substances. For instance, the "The Real Cost" campaign claims more than 587,000 youth aged 11 to 19 were prevented from initiating cigarette smoking – half of whom might have gone on to become established smokers – saving more than $53 billion by reducing smoking- related costs. Investment in tobacco prevention can have huge returns: the campaign has a cost savings of $180 for every dollar of the nearly $250 million invested in the first two years of the campaign. Self-serving lies.

On May 10, 2016, FDA finalized a rule – Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act) – which extended FDA's tobacco authorities to all tobacco products, including electronic nicotine delivery systems (ENDS) - such as e-cigarettes, cigars, hookah (waterpipe) tobacco, pipe tobacco and nicotine gels. Then, according to findings from the 2018 National Youth Tobacco Survey (NYTS), there was a dramatic increase in youth use of e-cigarettes: From 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school

students and a 48 percent increase among middle school students. On January 2, 2020, FDA issued a final guidance for industry entitled "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization." Under this policy, companies that do not cease manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) within 30 days risk FDA enforcement actions. Manufacturers that wish to market any ENDS product – including flavored e-cigarettes or e-liquids – are required by law to submit an application to FDA that demonstrates that the product meets the applicable standard in the law, such as whether the product is appropriate for the protection of the public health. Before marketing a tobacco product to reduce harm or the risk of tobacco-related disease, manufacturers must submit a Modified Risk Tobacco Product Application (MRTPA) and receive an FDA order authorizing that the product reduces harm or the risk of tobacco-related disease. On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise the federal minimum age of sale of tobacco products from 18 to 21 years.

In FY 2019, FDA invested more than $226 million in scientific research with a focus on reducing youth initiation of tobacco use, reducing tobacco product harms, and encouraging those who already use tobacco products to quit. In FY 2019, FDA funded 112 research projects via NIH. In FY 2019, FDA funded 41 new grants to support regulatory science research on tobacco products in the fields of biomedical, behavioral, and social sciences. Since the beginning of FY 2019, as part of the Youth Tobacco Prevention Plan, FDA has taken the following actions to stop youth use of, and access to, JUUL and other e-cigarette products: conducted well over 150,000 retail inspections to crack down on the sale of tobacco products, including e-cigarettes, to minors at both brick-and-mortar and online retailers issued thousands of warning letters and civil money penalties to retailers for illegally selling e-cigarette products to minors. FDA has also been working tirelessly alongside CDC and other federal, state, and local partners to investigate the distressing incidents of severe lung injuries and deaths associated with the use of vaping products. As of October 31, 2019, FDA had contracts for tobacco retailer compliance check inspections in 54 states and territories, and one tribal jurisdiction. FDA conducts compliance check inspections and issues advisory and enforcement actions such as Warning Letters, Civil Money Penalties, and No-Tobacco-Sale-Orders when violations are found. FY 19 there 146,905 inspections, 14,673 warning letters, 4,707 civil money penalties (18% in Ohio) and 13 no-tobacco-sale-orders. FDA has four active youth campaigns (ages 12-17) in market - "The Real Cost" Cigarettes campaign, "The Real Cost" Smokeless campaign, "The Real Cost" E-Cigarette Prevention campaign, and the "Fresh Empire" campaign.

Center for Tobacco Products FY 19 - FY22
(thousands)

	FY 19 Final	FY 19 Actual	FY 20 Enacted	FY 21 President's Budget	FY 21 Law	FY 22 Addicted	FY 22 Law
Revenues	686,991	686,991	661,739	762,612	762,612	763,000	763,000
Total Tobacco Expenditures	666,832	686,991	661,739	762,612	662,612	763,000	381,500
Center	652,065	676,457	647,055	747,765	647,765	74,782	366,282
Field Tobacco Control	14,767	10,534	14,684	14,847	14,847	15,218	15,218

Act							
FTE	942	942	1,016	1,068	1,068	1,079	1,079

Source: FDA FY 21 Justification of Estimates for Appropriations Committees. Pgs. 247 & 268

The FY 2021 Budget Request is $762,612,000 all from user fees. This amount is $100 million above the FY 2021 level authorized in the Tobacco Control Act less the amounts for GSA Rent, FDA Headquarters, FDA White Oak Consolidation, and Other Rent and Rent Related, which are shown in their own sections of the budget request. This amount is $100,873,000 above the FY 2020 Enacted Budget. The Center for Tobacco Products amount in this request is $747,765,000. Currently, the Tobacco Control Act does not provide a means for FDA calculation of user fees for ENDS products and certain other deemed products. These products represent an increasing share of the tobacco marketplace as well as FDA's tobacco regulatory activities. The FY 21 proposal includes a request to enable FDA to include all deemed products in the tobacco user fee assessments. To escape the number of the beast the FDA requests an additional $100 million and requests authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. Although the FY 21 data is inconclusive the CTP does not appear to have fled the persecution of the number of the beast in less than 42 months (Revelation 13:10). The increase in teen e-cigarette 2016 to 2017 probably marks the time when 42 months between $600 and $700 million elapsed. There is no denying the proposal to increase user-fee on e-cigarette manufacturers and importers by $100 million to increase revenues from $662 million to $763 million FY 21. However, with per FTE spending of $714,000, demand for tobacco revenues to reduce federal outlays, need to eliminate spending on youth anti-smoking propaganda, no accountability for anything but $15 million in field inspection work that produces nearly all the statistics, $226 million in scientific research of irregular quality, and liability for up to $100 million to settle all felony monopolization cases involving HHS, including tobacco product adulteration, attempt to prohibit coronavirus curing menthol, it is proposed to reduce CTP spending by 50%.

It has been advised that the Center of Tobacco Product be abolished, because FDA inspectors should not spend their tobacco and other revenues on "tobacco". Alcohol, Tobacco, Tax and Trade Bureau (TTB) was formed in January 2003, under the Homeland Security Act of 2002, but its history began more than 200 years ago as one of the earliest federal tax collection agencies. The history of taxation and regulatory control on the alcohol and tobacco industries the first Federal taxes levied on distilled spirits in 1791 by Alexander Hamilton that paid off the Revolutionary War debts at the cost of a Whiskey Rebellion. The Alcohol and Tobacco Tax and Trade Bureau (TTB) was created in January of 2003, when the Bureau of Alcohol, Tobacco and Firearms (ATF), was extensively reorganized under the provisions of the Homeland Security Act of 2002. TTB is the third largest tax collection agency in the U.S. government, behind the Internal Revenue Service (IRS) and U.S. Customs and Border Protection (CBP). Annual revenues from the alcohol, tobacco, firearms, and ammunition industries are approximately $22 billion. TTB excise tax collections reached an historic high of nearly $24 billion in FY 2010, principally due to an unfair increase in the price of pre-rolled and roll-your-own tobacco that has driven dwindling consumers to smoke pipe tobacco and causing steadily dwindling tobacco revenues. TTB collected nearly $22 billion in excise taxes and other revenues from more than 14,000 taxpayers in the alcohol, tobacco, firearms, and ammunitions industries FY 17.

Historical Table 2.4 regarding Excise Taxes OMB lists alcohol and tobacco as separate spending categories, ignores other less significant sources of revenues and produces a total that is $2.7 billion higher than total revenues reported by TTB. This could be explained by $3 billion in excise taxes on alcohol and tobacco imports by Customs, that should be left with Customs. To normalize agency reporting OMB Table 2.4 is advised to be simplified by consolidating alcohol and tobacco excise taxes into a figure that exactly matches net collections reported by TTB. Due to the unfairness of the 2010 tobacco both total TTB excise tax revenues and smoking rates are in decline. TTB has no recourse but to propose a federal excise tax on recreational marijuana to Congress. TTB is highly advised to change the name of their agency to Alcohol, Tobacco and Marijuana (ATM), to support the taxation of recreational marijuana by Congress and release of nonviolent drug prisoners from federal prison, with the clever acronym for a Treasury agency that needs to remind consumers to pay in cash for alcohol, tobacco and marijuana. Congress and the Attorney General must only repeal marijuana from Schedule I(c)(17) of the CSA under 21USC§812(c).