Hospitals & Asylums

In re: Menthol Tobacco Adulteration - Alcohol, Tobacco Tax and Trade Bureau (TTB) v. Center for Tobacco Products (CTP) HA-13-8-21

By Anthony J. Sanders

TTB Science Department has been requested to conduct Attenuated total reflectance-Fourier transform infrared (ATR-FTIR) spectroscopy on Gambler menthol pipe tobacco and any other menthol tobacco that is thought to be suspect by consumers unsatisfied with the coronavirus cure. Coupled with chemometrics ATR-FTIR spectroscopy should be effective for monitoring various adulterants in essential oils such as menthol (Taylan et al '21). Forfeited, condemned, and abandoned tobacco products should be disposed of under 26USC§5753. An appropriate TTB officer shall allow payment (without interest) of an amount equal to the amount of tax paid or determined, and the Commissioner of Customs shall allow payment (without interest) of an amount equal to the amount of customs duty paid, on menthol tobacco products, which are lost, rendered unmarketable, or condemned by a duly authorized official by reason of a disaster occurring in the United States under 27CFR§46.73.

Although the public would otherwise have only to be informed: The gold standard for coronavirus treatment is hydrocortisone, eucalyptus, lavender, peppermint or salt helps water cure coronavirus allergic rhinitis. Submerging the head in saline or chlorine water instantly cures coronavirus allergic rhinitis (John 1: 26)(Luke 3: 7)(1 Peter 3: 21)(Mark 6: 24). A dab of hydrocortisone crème to the nose and chest, mentholyptus cough drops and Echinacea pills cure severe acute respiratory syndrome (SARS). The Secretary of Health and Human Services and Center for Tobacco Products (CTP) adulteration under 21USC§387b, is fined $100 million under 15USC§2, all CTP spending appropriations are forfeit for violation of internal revenues laws for 'transfer to TTB' under 27CFR§46.165 and special studies on unadulterated menthol tobacco and also eucalyptus scented humidifiers to ensure a safe return to school, are authorized to determine menthol warrants a label or sticker that states this product “cures coronavirus” pursuant to 21CFR§330.10 and 42USC§300u.

1. Monopolizing Trade a Felony
2. Unfair Competition
3. Food and Drug Administration Budget Review
4. Online Pharmacy Adulteration
5. Tobacco Control Act

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Department of Health and Human Services 20USC§3508

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FD&CA. Penalties 21USC§333

FD&CA. Prohibitions 21USC§331

FD&CA. Registration of producers of drugs and devices 21USC§360

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1. Monopolizing Trade a Felony

On May 19, 2021 Food and Drug Administration v. Center for Tobacco Products HA-19-5-21 was filed in the United States District Court for the District of Maryland. Subsequently, two witnesses have corroborated that coronavirus curing Gambler ® menthol pipe tobacco has been adulterated with mullein (an asthma treatment described online as not for habitual use, that is not effective against coronavirus). Regular Gambler tobacco may contain some manure this year, and was always so foul that it took menthol to improve its flavor and reduce emphysema, but is not particularly suspect. Gambler menthol pipe tobacco is believed to continue to be otherwise contaminated by any added poisonous or added deleterious substance (neurotoxic mullein extract) that may render the product injurious to health under 21USC§387b.

By threatening to remove coronavirus curative menthol tobacco from the market, the Secretary of Health and Human Services, abused the power of the Interagency Committee on Smoking and Health under 15USC§1341. Tobacco Product Scientific Advisory Committee Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Non-Menthol Cigarettes of March 23, 2011 already found that menthol did not pose any additional health risk to smokers pursuant to 21USC§387f(e)(1)(B)(i). Menthol is made from mint, it is widely used for its cooling effect in medicaments. The truth of the matter is that menthol, especially habitually used menthol tobacco, is a far more effective remedy for the contagious coronavirus than the COVID-19 vaccine.

Due to a publicized outbreak of COVID-19 shortly after the injunction threat against menthol tobacco, the incited menthol tobacco product adulteration is believed to have begun in Washington DC as a hate crime against the African-Americans, whose lives the Secretary of Health and Human Services was ostensibly saving from lung cancer, by threatening to rob their beloved menthol tobacco, and unbeknownst to the masses, coronavirus cure. The adulteration is believed to have been widespread, across many states, nations, brands, Taylor made and pipe tobacco, however many brands were passed over, while others suffered only small batches of contamination, for which most vendors do not offer any sort of return policy. The removal of first and second hand menthol tobacco smoke that cured coronavirus in about 10% of the population is believed to have caused the global coronavirus breakthrough infection of summer 2021, that was noted to have gone as far as Japan, where they were hosting the Olympics. Menthol smokers, and those treated by their second hand smoke, who took their immunity for granted and were not aware of the many curative over-the-counter remedies for coronavirus, were thought to have finally succumbed to the highly contagious coronavirus and they reinfected the population, including, especially the similarly sheepish people who put their faith in the defective COVID-19 vaccine propaganda, that in fact takes two weeks to cure their contagious allergic rhinitis for an instant, without any pseudo-ephedrine brain shrink of the sort public health officials sustaining the pseudo-science are exposed to. Many people died.

There is no denying that the Secretary of Health and Human Services conspired with the Center for Tobacco Products to adulterate a large market share of the menthol tobacco harvest under 21USC§387b and this is a penal offense under 21USC§331 and §333. He was suppressing information that menthol tobacco cures coronavirus and that a dab of hydrocortisone crème to the nose and/or chest cures both coronavirus and hard lung nodules from carcinogenic invasive pulmonary aspergillosis, eg *Aspergillus niger*. The FDA recalled the aflatoxin contaminated dog food, but the contaminated menthol tobacco, injunction threat against all menthol tobacco and bio-terrorist Secretary of Health and Human Services politician require injunction pursuant to §332.

To make it very clear that adulteration of tobacco products is not acceptable, the Center for Tobacco Products (CTP), is liable for paying the maximum $100 million fine for felony monopolization under 15USC§2. It is preliminarily estimated that this $100 million be distributed - $10 million to TTB, to both pay the tax refund and increase tax revenues under 27CFR§46.73. This $10 million is a preliminary settlement for TTB, that can be increased to afford the tax refund, to appropriate all CTP revenues for the General Fund, whereas CTP grants are not authorized by law and their adulteration research and teen rebellion propaganda has malevolently contaminated the tobacco harvests in 2013 (green tomatoes) and 2021 (anti-depressants, mullein etc.). However, the FDA requires some time for inflation to get their total spending from $6 to remain over $7 billion within 42 months (Revelation 13:10) for which same reason CTP itself must be authorized to tardily increase their revenues by $100 million by taxing e-cigarettes. It is held, TTB must immediately seize all CTP revenues in behalf of the General Fund tobacco tax revenues, through forfeiture, whereas for the time being the FDA budget needs to account for CTP revenue spending as 'transfer to TTP' under 27CFR§46.165.

The remainder of the $100 million fine is to redress felony monopolization issues in the Food and Drug Administration (FDA), Health and Human Services (HHS) and World Health Organization (WHO). $20 million for the US Postal Service (USPS) to redress online pharmacy theft from the International Mail Facilities (IMF) and counterfeiting by FDA Office of Regulatory Affairs (ORA) trained customs infringement in violation of the postal policy of speedy delivery of online pharmaceuticals under 39USC§101. $80 million to compensate online home remedy vendors of coronavirus cures for wrongful injunctions against their advertising that their products cure coronavirus and secure clinical trials of OTC coronavirus cures due under 21CFR§330.10 to redress anticompetitive vaccine propaganda monopolization under 15USC§13a with remedial and preventive suits for personal injury $5,000 - $15,000 per clinical trial of OTC coronavirus cures under 15USC§15 (Mark 6: 24).

2. Unfair Competition

It is the policy of Congress to deal with cigarette labeling and advertising with respect to any relationship between smoking and health under 15USC§1331. Informed consumers are essential to the fair and efficient functioning of a free market economy under 15USC§1451. In the course of preventing “secret” information lawfully within the control of governments and governmental agencies from being disclosed pursuant to the protection of undisclosed information under Sec. 7, Art. 39 of the TRIPS agreement and Arts. 2(1), 12, 58, 93(1) and 100(1) of the UN Charter the malicious censure of the mass media is certain to be sued for effective protection against unfair competition and control of anti-competitive practices in contractual licenses as provided in Art. 10bis of the Paris Convention for the Protection of Industrial Property (1967), Art. 40 of the TRIPS Agreement, Sherman Anti-Trust Act 15USC§1 and §2, and Clayton Ant-Trust Act under 15USC§13 and §13a especially in regards to “precision medicine” uncodified by the identity robbing biological experimentation and information

blocking of the 21st Century Cures Act.

Whereas WTO cases languish for years, it is very important that the Secretary of Health and Human Services and Center for Tobacco Products are prosecuted to take appropriate measures to prevent the abuse of intellectual property rights, resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology necessary to protect the public health and nutrition under Art. 8 of the TRIPS agreement. To end the COVID-19 pandemic the countries of the Union are bound to assure effective protection against unfair competition by COVID-19 vaccines and other even more elusive newly developed prescription drugs under Art. 10bis of the Paris Convention for the Protection of Industrial Property (1967). The adulteration of menthol tobacco products is an excellent example of the crimes COVID-19 vaccine monopolists are willing to perpetrate to sell their patently defective, third rate product, and menthol consumers world-wide requires protection against the disastrous adulteration of the menthol tobacco products under 26USC§5753 and 27CFR§46.73. Art. 10bis provides, any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition. The following acts of scientific misinformation in particular shall be prohibited.

(1) Acts of such a nature as to create confusion. Confusion regarding COVID-19 is primarily attributed to the fact that the World Health Organization (WHO) germaphobically does not "nose" how to treat coronavirus allergic rhinitis, although allergic rhinitis immediate indicates the presence of contagion and that there are a cornucopia of safe and effective over-the-counter remedies. To ineffectively defend health care professionals against persecution for their contagious "Pinocchio nose", that is life-threateningly dangerous to SARS patients, they surrendered to random testing and invented the myth of the asymptomatic patients regarding the asymptomatic, rather than immediate onset of highly contagious allergic rhinitis symptoms from COVID-19 before it causes flu-like symptoms in three days or so, and possible death from fluid filled lungs of severe acute respiratory syndrome (SARS). Informing the public that there is "no treatment" for coronavirus, although corticosteroids had been proven to be effective in severely ill hospitalized patients, and library and market research with human test subjects has swiftly proven that nearly all treatments for allergic rhinitis cure coronavirus, in particular "Hydrocortisone, eucalyptus, lavender, peppermint or salt helps water cure coronavirus allergic rhinitis. Eucalyptus or lavender, usually mentholyptus cough drops and Echinacea, also cure the wet cough of influenza and severe acute respiratory syndrome (SARS).

(2) False allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities. Injunction threats by the FDA resulted in the withdrawal of several online herbal remedy competitors with vaccines, regarding the advertisement that they cure coronavirus, without giving them fair human trials, for which the FDA is fined up to $5,000 to pay the human trials of each of these drugs by the demoralized victim under 21CFR§330.10 and 15USC§13a. The racially charged proposal by the Secretary of Health and Human Services (HHS) to ban menthol flavored tobacco, and omit the fact that hydrocortisone crème cures carcinogenic *Aspergillus niger*, in one metaphorical blow of his Pinocchio nose, to retaliate against the discovery that chain smoking menthol cigarettes is a particularly effective cure for coronavirus, may be entitled to equal treatment. In light of the subsequent doubling of African-American COVID-19 infection rates in Washington DC an up to $100 million fine for felony monopolization under 15USC§2. It is very important for the United States to effectively prosecute their pharmaceutical product adulterating health department to stop being a global leader in coronavirus fatalities, redress the contamination of the global menthol tobacco market and set an example for the World Trade Organization to redress global misinformation due to

patently defective COVID-19 vaccine propaganda monopolization of the government and news media.

(3) Indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of public goods. COVID-19 vaccine propaganda is misleading, because it is third rate medicine, that cures coronavirus in two weeks for an instant, and it is not conceivable that such a medicine is capable of ending the contagious global pandemic, saving all lives from SARS, and it is definitely not competitive with the many gold and silver standard OTC remedies. The public is misled because the COVID-19 vaccine does not immediately cure, not confer any long-lasting immunity to the consumer, who is as snot nosed, contagious and ignorant as the day snot nosed COVID-19 vaccine babies were born, with possible developmental defects, that are chronically unreported by physicians for vaccine injury compensation. COVID-19 vaccines do not confer any lasting immunity upon the chronic coronavirus patient, who is cured with one or two shots, greatly improving their ability to heal, for a while, but not being capable of ending the pandemic because it does not truly prevent the contagious allergic rhinitis, severe illness and death, everyone must know how to treat with the readily available, cheap, safe, and effective over-the-counter remedies, soaps, cleansers and eucalyptus scented humidifiers to sterilize public indoor airspaces, such as classrooms to ensure the return to school is coronavirus and influenza free.

3. Food and Drug Administration Budget Review

Beginning as the Division of Chemistry and then (after July 1901) the Bureau of Chemistry, the modern era of the FDA dates to 1906 with the passage of the Federal Food and Drugs Act; this added regulatory functions to the agency's scientific mission. The Bureau of Chemistry's name changed to the Food, Drug, and Insecticide Administration in July 1927, when the non-regulatory research functions of the bureau were transferred elsewhere in the department. In July 1930 the name was shortened to the present version. FDA remained under the Department of Agriculture until June 1940, when the agency was moved to the new Federal Security Agency. In April 1953 the agency again was transferred, to the Department of Health, Education, and Welfare (HEW). Fifteen years later FDA became part of the Public Health Service within HEW, and in May 1980 the education function was removed from HEW to create the Department of Health and Human Services, FDA's current home. The agency grew from a single chemist in the U.S. Department of Agriculture in 1862 to a staff of more than 18,100 employees and a budget of $6 billion in 2021. The Food and Drug Administration (FDA) advances public health by protecting the nation’s food supply and ensuring safe and effective drugs are available in the United States. FDA is responsible for oversight of more than $2.6 trillion in food, medicines, devices, and other consumer products accounting for 20 percent of every dollar spent by U.S. consumers.

The FDA has dedicated $500 million from Congress towards, the felonious monopolization of public information regarding novel COVID-19 vaccines and new therapeutics to enable development to unjustifiably usurp the 21st Century Cures Act precision medicine research discovery that hydrocortisone, eucalyptus, lavender, peppermint or salt help water cure coronavirus and eucalyptus or lavender cure influenza. The Coronavirus Treatment Acceleration Program is designed to help bring new COVID-19 therapies to market as soon as possible. The program uses every available method to move new treatments to patients as quickly as possible, while at the same time evaluating whether they are helpful or harmful. Currently, there are more than 600 COVID-19 drug development programs in the planning stages, with more than 400 trials that have been reviewed by the FDA, and 10 treatments

authorized for use during the COVID-19 pandemic through Emergency Use Authorizations. The FDA must be sued to release their list of approved COVID-19 treatments under the Freedom of Information Act, informed that they will be publicly fined up to $100 million under 15USC§2 if they fail to authorize the COVID-19 polygraph under 21CFR§330.10 for the edification of the Secretary under 42USC§300u: Hydrocortisone, eucalyptus, lavender or peppermint help water cure allergic rhinitis from coronavirus. Eucalyptus or lavender also cure the wet cough of influenza. Mentholyptus cough drops are the front line treatment for both influenza and coronavirus, with a little nose washing. To end the COVID-19 pandemic the most effective strategy is probably to place eucalyptus, lavender or peppermint soap in public restrooms, with instruction to "wash your face and nose". Lysol is approved for environmental cleaning. Intensive care units (ICUs), waiting rooms and public airspaces of all sorts may be sterilized of both influenza and coronavirus with eucalyptus scented humidifiers (diffusers).

The Fiscal Year (FY) 2022 President's Budget requests $6.5 billion program level for FDA, an increase of $477 million above FY 2021 enacted. This total includes $3.6 billion in budget authority and $2.9 billion in user fees. The plan is to increase Center for Tobacco Products and National Center for Toxicological Research program levels after 48 months more than 42 months $600-$700 and $60-$70 million allowed respectively (Revelation 13:10). At regular 3% growth the total FDA program level will take 48 months to achieve $7 billion FY 25, this is too long. The FDA is too vulnerable to poison, to fail to capitalize on the doomsday prophecy to express their faith in an extra $121 million FY 24 spending. According to this most economically depressing and poisonous of all health theologies the FDA must immediately redress the product adulteration of the Center for Tobacco Products (CTP) with $18 million and National Center for Toxicology Research $3 million additional program level FY 21. CTP may budget for $18 million FY 21 for compensation for personal suits for injury by consumers and vendors whose tobacco products were adulterated. Quitting tobacco spending is put on hold. The National Center for Toxicology Research is encouraged to investigate brain damage caused by pseudo-ephedrine and statin drugs and stroke risk posed by the lucid dreaming drug Galantamine indicated to cause "sleep paralysis" in young recreational consumers. The investigation on statin drug induced brain damage must take into consideration the high risk of antibiotic resistant pneumococcal meningitis infection from taking statin drugs without Pneumovax because the brain doesn't heal fast enough and require unwise statin consumers receive Pneumovax. A meaningful drug abuse warning must be put out, especially on pseudo-ephedrine, and also statin drugs and Galantamine for the Secretary to help the Court regain their capacity to publish under 42USC§242.

Food and Drug Administration FY 17 - FY 24
(millions)

Budget Authority	FY 17	FY 18	FY 19	FY 20	FY 21	FY 22	FY 23	FY 24
Foods	1,041	1,033	1,078	1,098	1,110	1,194	1,230	1,267
Human Drugs	1,330	1,611	1,882	1,973	1,997	2,121	2,185	2,250
Biologics	339	358	402	419	437	458	472	486

Animal Drugs and Food	195	187	225	239	245	286	295	303
Medical Devices and Radiological Health	448	505	577	600	628	677	700	718
National Center for Toxicological Research	63	63	67	67	67	77	79	82
Tobacco Products	596	600	667	680	682	781	804	829
FDA Headquarters	281	314	310	302	318	344	354	365
FDA White Oak Operations	47	46	51	54	53	56	57	59
GSA Rental Payments	232	238	239	241	236	236	236	237
Other Rent Related	117	123	124	133	136	155	155	155
Subtotal Salaries and Expense	4,689	5,078	5,622	5,806	5,909	6,385	6,567	6,751
Export Certification Fund	5	5	5	5	5	9	9	9

Color Certification Fund	10	10	10	10	11	11	11	11
Rare Pediatric Priority Review Vouchers	8	8	8	13	13	13	13	13
Building and Facilities	12	12	12	32	13	31	14	14
21st Century Cures Act	20	20	70	75	70	50	50	50
Emerging Health Threats	10	10	0	0	0	0	0	0
Over-the Counter monograph	0	0	0	0	28	29	30	31
Seafood Safety Studies	0	0	0	0	1	0	0	0
Total Program Level	4,754	5,143	5,727	5,941	6,050	6,528	6,694	6,879
Additional Opioids Allocation	0	0	10	10	0	0	0	0
Revised Total Program Level	4,754	5,143	5,737	5,941	6,050	6,528	6,694	6,879

Total User Fees								
Prescription Drug	755	911	1,010	1,075	1,107	1,142	1,176	1,212
Medical Device	126	193	205	220	236	241	246	251
Generic Drug	323	494	502	513	520	528	536	544
Biosimilars	22	40	39	42	43	43	44	45
Animal Drug	24	18	30	31	33	34	35	36
Animal Generic Drugs	0	0	18	20	23	23	24	24
Family Smoking Prevention and Tobacco Control Act	635	754	625	712	712	712	812	812
Food Re-inspection	6	6	6	7	7	7	8	8
Food Recall	1	1	1	1	1	1	1	1
Mammography Quality Standards Act	21	21	21	18	19	19	20	20
Export Certification Fund	5	5	5	5	5	5	5	5
Color	10	10	10	10	11	11	11	11

Certification Fund								
Rare Pediatric Priority Review Vouchers	8	8	8	13	13	13	14	14
Voluntary Qualified Import Program	5	5	5	5	6	6	6	7
Third Party Auditor Program	1	1	1	1	1	1	1	1
Outsourcing Facility	1	1	2	2	2	2	2	2
Subtotal, Current Law User Fees	-1,943	-2,468	-2,488	-2,675	-2,739	-2,789	-2,841	-2,893
Proposed Law User Fees								
Export Certification	0	0	0	0	0	4	4	4
Increase to the Tobacco User Fee	0	0	0	0	0	100	100	100
Subtotal,	0	0	0	0	0	-104	-104	-104

Proposed Law User Fees								
Less Total, User Fees	-1,943	-2,468	-2,488	-2,675	-2,739	-2,893	-2,945	-3,101
Revised Total Program Level	4,754	5,143	5,737	5,941	6,050	6,528	6,292	6,464
Total Federal Outlays	2,811	2,675	3,249	3,266	3,311	3,635	3,749	3,778
FTEs			17,603	17,677	18,187	18,662	18,849	19,037

Source: Ostroph, Stephen M.; Hahn, Stephen. FY 2021 Justification of Estimates for Appropriations Committees. Department of Health and Human Services. FY 17 & FY 21. HHS Budget-in-Brief FY 19, 21 & 22.

FDA strategically manages infrastructure and facilities, including 56 laboratories located across the continental United States and Puerto Rico. Each year, about 48 million people in the United States get sick, 128,000 are hospitalized, and 3,000 die from food-borne diseases. FDA is transforming the nation's food safety system by shifting the focus from response to prevention. The FY 2022 budget includes $1.6 billion, an 8% increase of $134 million above FY 2021 enacted, to ensure the safety of human and animal food supply. Of the total, $1.6 billion is budget authority and $17 million is user fees, a 40% decrease from $28 million FY 2021. FDA is committed to protecting the public health and improving regulatory pathways for the lawful marketing of cannabis and cannabis-derived products within the agency's jurisdiction. The Budget provides $5 million to support FDA regulatory activities for cannabis and cannabis derivatives. Since the enactment of the Food Safety Modernization Act, FDA has made great strides in transforming the nation's food safety system by focusing on preventing foodborne illness. There is an initiative to reduce per- and polyfluoroalkyl substances (PFAS) in foods. In 2020, FDA released the New Era of Smarter Food Safety Blueprint, which outlines steps FDA will take over the next decade. The blueprint is centered around four core elements: (1) Tech-enabled Traceability; (2) Smarter Tools and Approaches for Prevention and Outbreak Response; (3) New Business Models and Retail Modernization; and (4) Food Safety Culture.

In April 2021, FDA announced a comprehensive plan to continue the agency's work and further reduce levels of toxic elements, such as lead, cadmium, mercury, and arsenic in foods for babies and young children. The "Closer to Zero: Action Plan for Baby Foods" identifies actions the agency will take to reduce exposure to toxic elements in foods eaten by babies and young children and provide action levels for industry to decrease these elements over time. To not misunderstand their sale of defective baby food products, FDA needs to advocate for 6 months exclusive breastfeeding pursuant to *Essential Nutrition Actions: Mainstreaming Nutrition Through the Life-Course* (2019) that accidentally excludes

calcium supplementation to prevent osteoporosis, especially for older women, but is quite good for pregnancy and other age groups. Exclusive breastfeeding - defined as the practice of only giving an infant breast milk for the first 6 months of life – has the single largest potential impact on child mortality of any preventive intervention. Together with appropriate complementary feeding, breastfeeding has the potential to reduce mortality among children under 5 years of age by 19%. Exclusive breastfeeding reduces the risk of gastrointestinal infection and of all-cause mortality, and protects infants from respiratory infections. Exclusive breastfeeding also has a protective effect against obesity later in life. Key recommendations are to improve maternity protection through the workplace (e.g. 6 months of mandatory paid maternity leave and polices to encourage women to breastfeed in the workplace), to empower women to exclusively breastfeed.

More than 130 people a day die from opioid-related drug overdoses across the country. In FY 2014, FDA approved a new form of naloxone – a drug that rapidly reverses the effects of an opioid overdose – with an auto-injector to enable a caregiver to administer the drug. Using expedited approval processes, FDA approved both an auto-injector in FY 2014 and an intranasal formulation in November 2015, both designed for use by lay bystanders, as well as first responders. Naltrexone is a generic oral opiate agonist. On April 1, 2015, FDA issued final guidance, "Abuse-Deterrent Opioids – Evaluation and Labeling," to assist industry in developing opioid drug products with potentially abuse-deterrent properties. Prescription opioid products are an important component of modern pain management, but abuse and misuse of these products have created a serious and growing public health problem. One potentially important step towards creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse. FDA has recently approved additional treatment options for patients who overdose on opioids. The FDA continues to address all facets of the epidemic to: (1) decrease exposure and prevent new addiction; (2) support the treatment of those with opioid use disorder; (3) foster the development of non-opiate pain treatment therapies; and (4) improve enforcement and assessing benefit-risk. Of over 50,000 products (stolen and counterfeited) from the International Mail Facilities, 215 opioids were discovered. After a brief period of statistical success at reducing opioid use and overdoses in the second half of 2018. Preliminary data from 2020 suggests that overdose deaths, which were already increasing, accelerated during the pandemic. A record 90,000 drug overdose deaths occurred in the United States in the 12 months ending in September 2020. To reduce the burgeoning popularity of opiate prescriptions, because the 21st Century Cures Act mentions only opiates by name, funding for opiate research needs to be limited to the Substance Abuse Mental Health Services Administration (SAMHSA). Buprenorphine and subloxone (buprenorphine with naloxone) have been approved for the treatment of opiate addiction in pregnant women. Non-opiate alternatives to addictive epidurals given to women during childbirth, especially young ones who are most prone to addiction, are needed, such as without pain killers, or cannabis derived CBD analgesic.

FDA oversees the safety, effectiveness, availability, and quality of an extensive range of regulated products available to Americans, including over-the-counter and prescription drugs, animal drugs, medical devices, and biologics including vaccines, blood products, and gene therapies. FDA's Human Drugs Program is responsible for ensuring the safety and efficacy of new, generic, and over-the-counter drug products quality to prevent and detect substandard or counterfeit drugs in the U.S. market. The budget requests $4 billion for medical product safety investments—an increase of $223 million above FY 2021 enacted. The request includes $2 billion in budget authority and $2.1 billion in user fees. Drug user fees are the bread and butter of the FDA and this money is distributed to finance most of their operations. Together with federal partners through the Public Health Emergency Medical Countermeasures Enterprise, FDA works to build and sustain medical countermeasure programs

necessary to protect against chemical, biological, radiological, nuclear, and emerging infectious disease threats. In FY 2019, FDA approved 33 medical countermeasures, including the first vaccine for the prevention of monkey pox disease. During the pandemic, FDA authorized COVID-19 vaccines in an expedited timeframe while adhering to FDA's rigorous standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization and transparently enhance public and medical community trust and confidence in vaccines (especially felony monopolization by influenza and coronavirus vaccine propaganda).

Currently, there are more than 600 COVID-19 drug development programs in the planning stages, with more than 400 trials that have been reviewed by the FDA, and 10 treatments authorized for use during the COVID-19 pandemic through Emergency Use Authorizations. The public needs to be informed of all approved treatments on an equal basis with vaccines, provided they are not all felony monopolizations by unethical researchers. The standard treatment is: Hydrocortisone, eucalyptus, lavender or peppermint help water cure coronavirus allergic rhinitis and eucalyptus, or lavender also cure the wet cough of influenza. Mentholyptus cough drops are the front line treatment for both influenza and coronavirus, with a little nose washing. To end the pandemic the most effective strategy is probably to place eucalyptus or lavender soap in and institutional showers, baths and public restrooms, with instruction to "wash your nose/lava su nariz". Intensive care units and public airspaces may be sterilized with eucalyptus scented humidifiers (diffusers) not used since the 1950s.

American Patients First, is the FDAs blueprint to lower drug-pricing costs. The FDA does not set drug prices, but can help lower prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs. FDA-approved generic drugs now account for 90 percent of the prescriptions dispensed in the United States, and in 2018 competition from generic drugs saved the healthcare system an estimated $293 billion. In FY 2019, the agency approved an all-time record 1,171 generic drugs, following previous records of 971 approvals in FY 2018 and 937 approvals in FY 2017. First generics approved in FY 2019 included drugs to treat emergency opioid overdose, pulmonary arterial hypertension, breast cancer, seizures, depression, and various infections. FDA is also increasing approvals of complex generic drugs, which are harder to copy and traditionally lack competition. The Budget provides $49 million, a $5 million increase above FY 2020, for FDA influenza preparedness activities. First enacted in the Prescription Drug User Fee Act in 1992, industry fees support FDA capacity to carry out its food and medical product safety responsibilities. The Budget reflects increases to all currently authorized medical product user fees by an additional $198 million. In addition, the Budget continues to include a legislative proposal to modernize the over-the-counter drug monograph system and establish a user fee for an estimated $28 million in FY 2021. Medical devices regulated by FDA–everything from personal protective equipment to ventilators to remote patient monitors–were critical components of the U.S. response to the COVID-19 pandemic. The FDA is cited for corrupt approval of combination test that tests positive for coronavirus whether it is influenza or coronavirus, and has a duty to inform the public that mentholyptus cough drops are the frontline treatment for both influenza and coronavirus, with a little nose washing. The FDA needs to approve eucalyptus scented humidifiers (diffusers) to sterilize intensive care units (ICUs), waiting rooms and other public airspaces.

4. Online Pharmaceutical Adulteration

To regulate the online pharmaceutical industry after extensive felony monopolization, theft from International Mail Facilities (IMF) and counterfeiting since the passage of An Act to amend the Federal

Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes P.L. 113-54 of Nov. 27, 2013. Repeal Section 801(u) to the FD&C Act under 21USC§381(u). Insert online pharmacy consumer before pharmacist in 21USC§384(a)(1). Delete 'from Canada' from §384(b). Replace 'to submit to the Secretary' with 'record' at §384(d)(1). Insert 'foreign' before establishment and delete 'within Canada' under §384(f). Repeal paragraphs i to end §384(i-m).

An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes P.L. 113-54 of Nov. 27, 2013 created a situation whereby domestic wholesalers and compounders were facilitated to adulterate superior generic pharmaceuticals manufactured in India and purchased online and thereby discredit the competition violation of felony monopolization under 15USC§2 and adulteration, mislabelling and counterfeiting under 21USC§331. The Trump Administration extensively blocked international bank transaction so that an online pharmacy consumer would have to call their bank and pay a reasonable fee to pre-authorize an international transaction, or their card would be blocked, the transaction would not go through and they would need to call to reactivate their card so that it could be used at all. This has been somewhat mitigated by conscientious international vendors. The FDA FY 21 Justification of Estimates for Appropriations Committees reports an alarming increased in ORA international drug interceptions from International Mail Facilities (IMF) and Ports of Entry and destruction attributed to the, now contested, SUPPORT Act Public Law No: 115-271 of Oct. 24, 2018. FY 19 the FDA increased the number of special agents and import investigators responsive to illicit activity involving FDA-regulated products arriving through International Mail Facilities (IMF) and Ports of Entry. FY 19 more than 17,000 violative drug products were destroyed across all nine IMF (an increase of 15,522 over FY 18) with a reported value of more than $1.5 million (an increase of more than $1 million over FY 18).

The FY 21 Budget provided $45 million for opioid activities at international mail facilities to increase enforcement. This investment will enable FDA to inspect 100,000 packages per year, many containing multiple products. As provided in sections 303(f) and 401(h) of the Controlled Substances Act (21USC§823(f) and §841(h)), it is unlawful for any person who falls within the definition of "online pharmacy" as set forth in section 102(52) of the Act under 21USC§802(52)) and 21CFR§1300.04(h)) to deliver, distribute, or dispense a controlled substance by means of the Internet under 21CFR§1301.11(b). It is inappropriate to target online pharmacies because they do not sell controlled substances. Shipments from legitimate online pharmacies registered under 21USC§360(i) should not be searched or delayed. Section 3022 of the SUPPORT Act Public Law No: 115-271 of Oct. 24, 2018 added Section 801(u) to the FD&C Act under 21USC§381(u) that needs to be repealed because it is unconstitutionally vague to abuse the term "drug" so that its effect is that any import may be deemed to be illicit, seized and counterfeited by aforementioned drug compounders, regardless of whether or not it is or was at time of entry into an International Mail Facility (IMF) counterfeit under (u)(2). The Budget provides an additional $4.5 million, $78 million total, to ostensibly strengthen the compounding scientific framework, develop a list of bulk drug substances approved for compounding by industry, bolster regulatory compliance, and expand policy development. The Budget will enable FDA to evaluate the over 300 unique bulk drug substances nominated for inclusion on the list of substances approved for compounding by industry. This ORA compounding program is highly suspected of being an organized high-tech counterfeit operation capable of repackaging adulterated and substandard drugs in fancy foil packages that look just like the quality generic Indian pharmaceutical, that were imported and destroyed.

For the past several years banks have infringed on international transactions so that they would need to be pre-authorized by the bank to prevent the account from being frozen since 2020 in conspiracy with India. The National Commission on Electronic Fund Transfers should hold a hearing to redress restraint of trade pursuant to 12USC§2404(a) and 15USC§1. For the most part this has affected +/-$10 billion annual online pharmaceutical imports to individuals residing in the United States. The delay in international mail deliveries due to the COVID-19 pandemic is adulterously long, up to 5-8 weeks for an express delivery that should not take longer than 5-8 days. These shipments of lifesaving must not be delayed or subjected to unlawful search and adulteration. The Postal Service shall provide prompt, reliable, and efficient services to patrons in all areas and shall render postal services to all communities under 39USC§101(a). States must remove any impediments arising to the free exportation of goods required for humanitarian needs, such as (i) medicines and medical devices; 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.

The rule of law is that the prescriptions pharmaceutical drugs may be purchased without prescription. Pharmaceutical drugs manufactured in India's several full service generic pharmaceutical drug manufacturers tend to be of equal or higher quality than American pharmacy drugs. In general the foil packages sold by the online pharmacy are far safer from adulteration than the American child-proof cap under 16CFR§1700.14. There is a credible fear that there is an organized conspiracy to counterfeit the sealed packages and replace their contents with toxic substances. There is believed to be at least one high tech online pharmacy counterfeit operation in business since at least 2014 that has opportunistically resurfaced to predate upon the delay in the international delivery of the mail. Pfizer forensic service to the US District Attorney is highly encouraged to pursue the up to $15,000 fine for each and any prohibited online pharmacy counterfeiting devices, up to $1 million, discovered by the Postal Service pursuant to the Food Drug and Cosmetic Act (FD&CA) under 21USC§333(f). To avoid the looming cost of devaluation it would be really nice to buy American foil wrapped antibiotics online without prescription by converting the online pharmaceutical counterfeiting machines to legitimate use pursuant to 24USC§225h.

5. US Attorneys prosecute pharmaceutical drug counterfeiting. On January 27, 2021 Antonio Walthour (28) was sentenced to three and a half years for conspiring to sell counterfeit drugs. These drugs were made with fentanyl to make pills and pressing them to look like legitimate pharmaceutical controlled substances with markings such as “Xanax,” “Lortab,” “Percocet,” or “Watson.” Eric and Holly Falkowski were sentenced in 2017 for their roles in the conspiracy to 188 months and 36 months, respectively. In 2020 U.S. Immigration and Customs Enforcement’s (ICE) Homeland Security Investigations (HSI) New Orleans seized 51,000 counterfeit items valued at more than $16.7 million during a holiday-related intellectual property rights surge operation. David Beckford was sentenced to more than 10 years in prison for his role in a conspiracy to manufacture counterfeit Xanax pills with a pill press. The problem seems to be that the FDA is not certifying online pharmacies who deliver from the high quality generic pharmaceutical manufacturers in India. US Attorneys and law enforcement infringe on this weakness to seize everything they can get their hands on. In cases where there are real manufacturing devices, these devices get into the hands of law enforcement and their health professional informants and are used to counterfeit drugs with the monopolistic intent to adulterate the non-DEA licensed competition, and thereby justify payments for their refusal to treat, improper ineffective and/or experimental prescriptions, and poisonous enforcement, but only generate more mistrust, chronic illness and death. The drug and product mislabelling and counterfeiting device operation is believed to be located in California using equipment seized by the federal police. The FDA

has a responsibility to ensure online pharmacies get their products from Indian generic pharmaceutical manufacturers and their shipments are not intercepted and counterfeited pursuant to felony monopolization under 15USC§2.

5. Tobacco Control Act

To perfect the Tobacco Control Act it is necessary 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. Even before the adulteration of menthol tobacco in the summer of 2021, 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
Revenues	686,991	686,991	661,739	762,612	762,612	763,000
Total Tobacco Expenditures	666,832	686,991	661,739	762,612	662,612	763,000
Center	652,065	676,457	647,055	747,765	647,765	74,782

Field Tobacco Control Act	14,767	10,534	14,684	14,847	14,847	15,218
FTE	942	942	1,016	1,068	1,068	1,079

Source: Hahn, Stephen. 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. There were a total of $253 billion in alcohol sales in the United States and $818 billion in global tobacco sales. 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).

Art. 55 of the Constitution of Hospitals & Asylums Non-Government Economy (CHANGE) of 11 August 2021 provides: Marijuana must be repealed from Schedule I(c)(17) of the CSA under 21USC§812(c) to facilitate the Treasury Department to change the name of Alcohol and Tobacco Tax and Trade Bureau (ATTTB) to Bureau of Alcohol, Tobacco and Marijuana (ATM) to remind consumers to pay in cash. Justice Department will change the name of Bureau of Alcohol, Tobacco and Firearms (ATF) to Bureau of Firearms and Explosives (FE). (To prevent further adulteration, it is not advised to engage the Attorney General in any of this "drug" litigation, whereas the disclosure requirement is facially invalid because it burdens *Americans for Prosperity Foundation v. Bonta, Attorney General of California* No. 19-215 July 1, 2021).

Art. 53 of CHANGE provides: The Department of Health, Education and Welfare (HEW) was created in Reorganization Plan No. 1 of April 1, 1953 42USC§3501. Sec. 509 of the Department of Education Re-organization Act of May 4, 1980 provided that any reference to HEW would be deemed to refer to Health and Human Services (HHS) 20USC§3508 (b). More than 600,000 Americans have died from COVID-19 untreated with hydrocortisone, eucalyptus (echinacea), lavender, peppermint or salt helps water cure contagious coronavirus allergic rhinitis. It is proposed to change the name to Public Health Department. To negotiate reasonable prices it is necessary repeal 'Medical records and payments' from Fair Credit Reporting Act 15USC§1681a(x)(1).

Spectrometry and chemometrics are needed to put an end to frequent adulteration of online pharmaceuticals and tobacco products, especially the 2021 adulteration of menthol tobacco, a more practical cure for coronavirus than vaccines, for 10% of the population. Repeal extraneous tobacco definitions in 21USC§321(rr) para. 2-4. Repeal international mail theft (IMF) and counterfeit justification in 21USC§381(u). Insert online pharmacy consumer before pharmacist in 21USC§384(a)(1). Delete 'from Canada' in §384(b). Replace 'to submit to the Secretary' with 'record' at §384(d)(1). Insert 'foreign' before establishment and delete 'within Canada' in §384(f). Repeal paragraphs i to m §384(i-m).

Certificate of Service

Alcohol, Tobacco, Tax and Trade Bureau Science Department and Tobacco Expert; Federal Trade Commission Anti-Trust; World Trade Organization. Department of Health and Human Services unserved due to Prohibition against Retaliation and Coercion under Sec. 503 of the Americans with Disabilities Act under 42USC§12203