

Before the Food and Drug Administration (FDA)
Department of Health and Human Services
5600 Fishers Lane, Rockville, MD 20857

In the Matter of "E-
Cigarette,") a Nicotine Delivery Device,) _____
_____ and the FDAs Jurisdiction Over It)

Initial Citizen Petition by Action on Smoking and Health (ASH) Requesting That the FDA Assert Jurisdiction Over This New Nicotine Delivery Device AND Take Whatever Regulatory Action is Appropriate Under its Jurisdiction According to Existing Law

SUMMARY OF ARGUMENT

I. The FDA has long asserted jurisdiction over nicotine as a drug, and over devices which deliver nicotine as nicotine delivery devices e.g., gum, patches, and so-called smokeless cigarettes.

II. Indeed, it successfully asserted jurisdiction over a remarkably similar device known as Favor, which was also a white tube containing nicotine which looked very much like a cigarette.

III. The only challenge to the FDAs jurisdiction over nicotine was the Brown case, but that holding was very clearly limited to tobacco products, and especially to normal cigarettes defined by federal law as containing tobacco which Congress has often regulated; thus the Brown decision does not apply in any way to tubes containing nicotine.

IV. Because both health and quitting claims have been made both directly and by implication about the new product, it is clear that it is intended to "affect the structure or any function of the body and is therefore a drug subject to FDA jurisdiction under the statutory definition.

V. Having been put on notice by the wide-spread publicity about the product, a failure to even formally assert jurisdiction could stymie the FDAs power in the future by legal arguments in the nature of estoppel, laches, lack of clean hands, and unfairness especially if the agencies failure to act were challenged in court.

VI. Any failure by the FDA to react decisively would also seriously undermine its credibility, and do so at a time when it has been widely criticized for failing to take decisive action regarding many other different products also clearly within its jurisdiction.

VII. Since nicotine is both a deadly and addictive drug, there is at least a reasonable probability that it could be causing harm both to the users and to others in the vicinity who inhale the vapor, and therefore the product should be appropriately regulated without further delay.

VIII. Even if the FDA later holds that e-cigarettes harmful effects are outweighed by their benefits as it has with nicotine gum and patches the FDA may nevertheless find it appropriate to require health-related warnings, and/or limit its sales (e.g., to adults upon presentation of proof of age, etc.)

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RELIEF REQUESTED

The undersigned submits this petition under 21 C.F.R. §§ 10.25, 10.30, and other relevant authority to request the Commissioner of Food and Drugs (FDA) to take the following administrative action in light of numerous reports in responsible media outlets of which the agency is now even more clearly put on official notice that this product is being

sold in various locations in the United States. It is clear that the product is being shipped in interstate commerce and across state lines, especially since it is reportedly made outside the U.S. in China,

A. To avoid any possible argument of or in the nature of estoppel, laches, lack of clean hands, and unfairness, and in view of its earlier decisions to assume regulatory jurisdiction over other so-called smokeless cigarettes (such as Favor) as well as chewing gum and patches containing nicotine, the FDA should immediately issue a public statement and provide notice to the manufacturer, distributors, and others directly affected that the device falls within the FDA's jurisdiction as a "drug" or, more likely, as a "drug delivery device" ("medical device").

B. To initiate, at his earliest possible convenience, any and all appropriate regulatory proceedings under existing federal law, agency regulations, relevant judicial decisions, and its own customs and practices regarding this new device which falls under its jurisdiction.

RELATIONSHIP TO OTHER REQUESTS REGARDING THIS PRODUCT

ASH is aware of requests, from U.S. Senator Frank Lautenberg[<http://lautenberg.senate.gov/newsroom/record.cfm?id=310318>] and major health organizations[<http://www.lungusa.org/site/apps/nlnet/content2.aspx?c=dvLUK900E&b=34893&ct=6858815>], that the FDA immediately take these products off the market until they are proven safe.

ASH is also aware of equally adamant requests, from the American Association of Public Health Physicians and others in opposition to such a step. See, e.g., <http://www.ecigarettdirect.co.uk/campaign/lautenberg-letter.html>

ASH respectfully suggests a middle ground. While it make take time for additional study and research to determine the best regulatory approach for this new product, it is very important that the FDA at very least make it clear that the product does come within its jurisdiction, and is therefore subject to whatever regulations may be found to be appropriate.

Failure to take this simple step of asserting its jurisdiction could lead to later arguments in the nature of estoppel, laches, lack of clean hands, and unfairness from this particular manufacturer, encourage other companies to produce similar products which may be even more dangerous, and seriously undermine the FDAs credibility and perhaps even the credibility of President Barack Obama at a time when the agency has been widely criticized for failing to take decisive action regarding many other different products.

In short, ASH urges the FDA to immediately assert its jurisdiction which is abundantly and overwhelmingly clear and to begin appropriate formal regulatory proceedings.

INTERESTS OF ACTION ON SMOKING AND HEALTH (ASH)

Petitioner Action on Smoking and Health (ASH) is a national non-profit scientific and educational organization which focuses on the problems of smoking, and protects the right of non-smokers not to have to breathe in other persons' tobacco smoke. ASH and its Executive Director, John F. Banzhaf III, have brought and participated in many legal actions related to smoking, including, but not limited to:

Banzhaf v. FCC, 405 F. 2d 1082 (D.C. Cir. 1968) (upholding FCC ruling that television and radio stations must provide substantial free time for anti-smoking messages); Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582 (3-judge, DC 1971), aff'd 405 U.S. 1000 (1972) (upholding the constitutionality of the statute banning cigarette commercials); ASH v. CAB, 699 F.2d 1209 (D.C. Cir. 1983) (requiring former Civil Aeronautics Board to adopt reasonable regulations for non-smoking sections on airplanes, since expanded to a ban on smoking on all domestic flights);

ASH v. Lujan, Civ. Act. 91-0357 JGP (U.S. Dis. Ct. DC) (forcing U.S. Park Service to discontinue permitting cigarette promotions in U.S. park); Shimp v. New Jersey Bell Telephone Company, 368 A.2d 408 (1976) (first injunction ever obtained against smoking in a workplace);

Pletten v Department of the Army, U.S. Merit Systems Protection Board Nos. CH07528010099, CH01520 2901 (1981) (establishing principle that persons sensitive to tobacco smoke are protected as "handicapped persons").

ASH originally filed a petition with the FDA to regulate cigarettes containing nicotine on May 26, 1977, and appealed the FDA's denial of the petition. *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). That holding that in determining the intent of the manufacturer, the FDA was not restricted to using only health claims made by the vendors or manufacturers, but rather could use any relevant source including inferences from consumer intent provided a basis for the FDA's subsequent decision to regulate nicotine in cigarettes.

Moreover, in the complaint in their law suit seeking to stop the FDA from asserting jurisdiction over tobacco products containing nicotine [Beahm v. U.S.FDA], the major tobacco companies acknowledge the major role ASH played regarding this matter. As they assert:

61. On June 15, 1995, the Action on Smoking and Health ("ASH"), an anti-tobacco group, threatened to file a lawsuit against FDA if FDA did not regulate cigarettes by August 15, 1995. ASH announced that the basis of the suit would be FDA's failure to act on ASH's pending petition before FDA. That petition was filed by ASH on March 4, 1994 and seeks the initiation of a rulemaking to regulate cigarettes.

62. Soon after ASH's threat to sue, rumors surfaced that FDA had made the decision to regulate cigarettes. See, e.g., FDA Seeks to Mount Attack on Smoking by Minors That Could Mean Regulation, Wall St. J. (July 13, 1995), at A3.

63. Over the last few weeks, anti-smoking groups continued a carefully orchestrated public relations campaign designed to put pressure on the White House and FDA to issue Commissioner Kessler's proposed regulations.

Finally, on August 10, 1995 without any further direction from Congress and apparently bowing to the anti-tobacco groups Commissioner Kessler announced that FDA had concluded that it has jurisdiction over cigarettes.

ASH files this petition on behalf of itself, and on behalf of its tens of thousands of members who are adversely affected by cigarettes, cigarette smoke, nicotine released by e-cigarettes, cigarette advertising, and children becoming addicted to smoking.

I. The FDA has long asserted jurisdiction over nicotine as a drug, and over devices which deliver nicotine as nicotine delivery devices e.g., gum, patches, and smokeless cigarettes.

As this agency knows all too well, it has with the exception of actual cigarettes consisting of any roll of tobacco wrapped in paper or in any substance not containing tobacco [15 U.S.C. 1331] always maintained that it has jurisdiction to regulate nicotine as a drug, and devices containing nicotine as drug delivery devices.

Under that principle, the FDA initially regulated nicotine contained in chewing gum not only as a drug, but as a drug requiring a prescription. Subsequently, when in accordance with its own rules and procedures it evaluated the relative dangers and benefits of such gums, it relaxed its regulations to permit the gum to be sold over the counter as a non-prescription drug. Nevertheless, it has always remained a drug clearly subject to FDA jurisdiction.

Similarly, when patches containing nicotine were first introduced, the FDA regulated the nicotine not only as a drug, but also as a drug requiring a prescription. Subsequently, when in accordance with its own rules and procedures it evaluated the relative dangers and benefits of such patches, it relaxed its regulations to permit the patches to be sold over the counter as a non-prescription drug. Nevertheless, it has always remained a drug clearly subject to FDA jurisdiction.

Moreover, as described immediately hereinafter, the FDA classified the nicotine contained in the so-called smokeless cigarette Favor as a drug, and reportedly forced the manufacturer to withdraw it from the market when it was unable to show that it met the FDA's requirements with regard to such a drug and such a drug delivery device.

II. Indeed, it successfully asserted jurisdiction over a very similar device known as Favor, which was also a white tube containing nicotine which looked very much like a cigarette.

In a letter dated February 9, 1987 and addressed to J. Philip Ray, Director, Advanced Tobacco Products, Inc., the FDA ruled that Favor Smokeless or Smoke-Free cigarettes (in regular, menthol, and lights) were nothing more than a "nicotine delivery system intended to satisfy a nicotine dependence" and therefore subject to the FDA's jurisdiction. See, e.g.: <http://tobaccodocuments.org/rjr/506125414-5416.html>

The product, as described by the FDA in its letter, was quite similar to e-cigarettes:

a plug impregnated with a nicotine solution inserted within a small tube corresponding in appearance to a conventional cigarette" with each pack having "a nicotine delivery capacity intended to satisfy the average smoker of conventional cigarettes for an entire day. [emphasis added]

In short, a product manufactured to look and feel like a cigarette, marketed in cigarette-like packs, and designed to permit a user to inhale it like a cigarette and to obtain an inhalation mixture containing a significant amount of nicotine was held to contain a "drug." This description and therefore this determination also clearly applies to e-cigarettes.

III. The only challenge to the FDA's jurisdiction over nicotine was the Brown case, but that holding was very clearly limited to tobacco products, and especially to normal cigarettes defined by federal law as containing tobacco which Congress has often regulated; thus the Brown decision does not apply in any way to tubes containing nicotine.

In *FDA v. Brown & Williamson Tobacco Corp*, 529 U.S. 120 (2000), the United States Supreme Court overturned the FDA's attempt to assert jurisdiction over tobacco products. But it is abundantly clear that this holding has nothing whatsoever to do with e-cigarettes specifically or, even more broadly, so-called smokeless cigarettes or other alternative nicotine delivery devices. This is obvious even from a brief glance at the official Synopsis of the case.

1. The holding is set forth as follows in the Court's Synopsis: Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority to regulate tobacco products as customarily marketed. [emphasis added] Thus, the holding is expressly stated to be limited to tobacco products. It further states that it is limited to tobacco products customarily marketed. So even if one ignores the express limitation in the holding to tobacco products, an e-cigarette was not a product customarily marketed at the time of the Brown decision. Further, the holding was in the context of Congress' subsequent tobacco-specific legislation, and although Congress did pass a number of laws related to tobacco products, it has never passed any legislation related specifically to e-cigarettes, not even more generally to so-called smokeless cigarettes or other non-tobacco nicotine delivery devices.

2. Section (b) of the Synopsis explains that Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. [emphasis added] Indeed, both the Synopsis and the full text of the decision itself repeatedly use the words tobacco products. No tortured logic can make e-cigarettes a tobacco product since it reportedly contains no tobacco whatsoever.

3. The very next section of the Court's Synopsis further explains that The history of tobacco-specific legislation also demonstrates that Congress has spoken directly to the FDA's authority to regulate tobacco products. [emphasis added] Once again, there is no legislation tobacco-specific or otherwise which in any way directly or indirectly relates to e-cigarettes and/or other non-tobacco nicotine delivery devices.

4. Finally, in Section (d) of the Synopsis, the Court argues that Congress did not want the FDA to have regulatory authority over an industry constituting a significant portion of the American economy.

So by no stretch of the imagination could that holding be applied to a new product with only a tiny share of any relevant market, and one which is reportedly made in a foreign country.

IV. Because both health and quitting claims have been made both directly and by implication about the new product, it is clear that it is intended to "affect the structure or any function of the body and is therefore a drug subject to FDA jurisdiction under the statute.

EXPRESS CLAIMS RELATED TO REDUCED HEALTH RISK

As National Public Radio reported, specific and express health claims are being made for e-cigarettes: In an advertisement, the maker of one e-cigarette, Smoking Everywhere, claims, "Fact: Smoking everywhere electronic cigarette is the healthier way to smoke. [emphasis added]

The masthead of the ECigarette website claims: A healthier way to smoke . . . without all the harmful effects [emphasis in original] A major Internet web site promoting the product proclaims: Smoke a cigarette with many of its more harmful substances removed . . . Benefits: fewer carcinogens [emphasis added]
See: <http://www.ecigarettdirect.co.uk/campaign/lautenberg-letter.html>

A press release issued by the e-cigarette company assures potential customers that: With no tobacco, no tar, no real smoke and no other chemicals like traditional cigarettes that can cause lung cancer, smokers can enjoy the same feel and taste of a real cigarette for half the cost and health damage of a real cigarette. [emphasis added] See: <http://www.prurgent.com/2009-04-13/pressrelease35790.htm>

The above are only a few examples of health claims which are clear and express. Telling prospective customers that they can enjoy a product with: half the . . . health damage of a real cigarette because it contains no other chemicals . . . that can cause lung cancer [like traditional cigarettes] benefits include fewer carcinogens many of the harmful substances removed a healthier way to smoke are about as clear health claims as one could possibly imagine.

EXPRESS CLAIMS RELATED TO SMOKING CESSATION

The new product, on its Internet web site (and perhaps elsewhere), also makes a variety of claims that the product is very useful in helping smokers to quit smoking tobacco.

This is especially important because it was this exact claim which required the FDA to regulate nicotine gum and nicotine patches.

For example, the masthead of the ECigarette website claims: Take the ECigarette Challenge! If you quit smoking in three weeks or less by using ECigarettes and give us your testimonial, we'll refund \$50 of the purchase price. [<http://www.ecigarettesusa.com/>]

The clear implication is that the product will help smokers quit, and readers are encouraged to try using the product to help them quit and thereby become entitled to a reward.

The same web site contains the following on its Comments & Testimonials page:

"Finally a product that really helps people quit a bad habit. I'm glad ECigarettes USA, Inc. has brought this great product to America." J.M., FL

"I quit smoking in just three weeks! I still use the ECigarette when I get the craving, but at least I'm not getting the chemicals and poisons I got from real cigarettes." D.H., FL

"I haven't fully quit smoking yet, but using the ECigarette, is helping! It costs LESS than real cigarettes." G.S., FL

"I'm cutting back on my real cigarette usage with the help of the ECigarette. In these hard economic times, I'm spending less on cigarette smoking." T.P., FL [emphasis added throughout]

Indeed the page also includes numerous videos making the same smoking cessation claims, including comparing the effectiveness of e-cigarettes with other cessation techniques such as hypnosis, explaining the medical benefits in a hospital setting, etc. These types of cessation claims are very important for several reasons.

First, with regard to products which claimed they helped smokers to quit smoking like nicotine gum and patches, the FDA required manufacturers to prove with clear evidence that the product was safe for its intended use or at least safer than nicotine administration by smoking tobacco cigarettes. E-cigarettes make exactly the same claim, but there is apparently no proof.

Second, gum and patch manufacturers were required to provide persuasive clinical evidence that the product was effective in actually helping smokers quit. This typically consisted of supervised clinical trials pairing those using the product with a control group which did not use the product, and comparing the quit rates of both groups. Here there is no such evidence.

Moreover, it must be remembered that, even if these claims were proven to be true, their truth or falsity is irrelevant. All that is required for the FDA to have jurisdiction over a product is for claims related to health benefits and/or quitting to be made which they clearly are.

The extent to which these claims may later prove to be true may relate to the types of regulations which are appropriate for the FDA to impose. For example, while reducing tars may lessen the cancer risk, if inhaling nicotine creates serious dangers for those at heightened risk of cardiovascular problems like heart attacks and/or strokes, a special health warning addressed to those people may be warranted, even if switching does in fact reduce the overall risk of death.

No company should be permitted to put new nicotine delivery devices on the market, and make health- and cessation claims for them which have not been subject to some sort of independent review. That is the job of the FDA, and the FDA should do it without further delay.

Otherwise, the FDA's ability to act to prevent current smokers, who might otherwise have to quit (for reasons of health, cost, etc.), from switching to a product which appears to pose some dangers of a magnitude yet to be determined would be nonexistent, and many may die trying to quit using e-cigarettes rather than other methods which do not involve inhaling nicotine.

Also, a failure to act quickly could compromise the legal authority of the FDA to act.

V. Having been put on notice by the wide-spread publicity about the product, a failure to even formally assert jurisdiction could stymie the FDA's power in the future by legal arguments in the nature of estoppel, laches, lack of clean hands, and unfairness especially if the agency's failure to act were challenged in court.

While everyone, including judges, may understand that the FDA has to take a reasonable amount of time in accordance with its established procedures to study how far and how best to regulate a new drug or new medical [drug delivery] device under its jurisdiction, judges and others may have a far harder time understanding why the FDA did not take even the preliminary step of asserting its jurisdiction in a timely fashion while the product was being widely sold.

This is especially true when the agency's jurisdiction is so clear based upon its prior assertion of jurisdiction over a wide variety of nicotine administering devices, including one which is very close to identical to e-cigarettes. Favor. Certainly the agency cannot claim to be unaware of the many health-type claims now being made for the product which true or false further support the FDA's jurisdiction.

Finally, the agency can hardly claim to any judge who has read the Brown ruling that the decision in any way undercut or otherwise affected the FDA's jurisdiction over devices which are obviously not tobacco products, and as to which there is no history whatsoever of prior Congressional regulation.

For all of these reasons, any judge called upon to determine what steps the agency can take regarding e-cigarettes may well be sympathetic to a company which (it will probably claim) marketed a product which it thought in good faith was safer than cigarettes and was designed to benefit the public health especially if the FDA stood idly by while that company invested large amounts of money, time, human resources, etc. into building its distribution chain without even a hint from the FDA that the product was subject to its jurisdiction.

Without delineating the precise legal arguments for fear, among other things, that they might be copied by the manufacturers and/or distributors legal arguments in the nature of estoppel, laches, lack of clean hands, and unfairness can certainly be anticipated.

The FDA's position would be even further compromised if some person or entity e.g., a U.S. Senator, an antismoking or other public health organization, etc. were to promptly challenge in court this agency's apparent failure to take any action whatsoever as to a medical device clearly within its jurisdiction, and making very persuasive health claims, is left free to market a product whose key ingredient is a highly addictive substance with known health risks to all users, and perhaps even to those (including children) who inhale the nicotine-laden vapor secondhand.

Whether the agency claims in court that its jurisdiction over the new product was uncertain, or, on the contrary, that it was sure of its jurisdiction but took its time taking action, there is bound to be considerable sympathy for a company which can claim that it was unfairly ambushed by this federal agency, and an additional loss of credibility and respect by a public which depends on the FDA to take action without delay where the public health is affected.

VI. Any failure by the FDA to react decisively would also seriously undermine its credibility, and do so at a time when it has been widely criticized for failing to take decisive action regarding many other different products also clearly within its jurisdiction.

As this agency knows all too well, its credibility and respect have suffered severely over the past several years as it has apparently failed to protect the public from a wide variety of threats to the public health from a variety of sources. But the agency can at least argue that virtually all of those failures occurred under the prior administration, and that the new and newly-revitalized FDA under the new Obama administration is very different and far more effective.

The issue of e-cigarettes may then present the first major and very public test of whether the FDA has changed fundamentally, or whether it is still content to sit on the sidelines. At a time when the public (as well as many Members of Congress) want if not demand proof that the new FDA is a significant improvement on the old one under the prior administration, the e-cigarette appears poised to provide a crucial benchmark of its success or failure.

If the agency continues to vacillate on this issue and product, which potentially affects tens of millions of current smokers and perhaps even children who might be tempted to try some hits and get a nicotine kick or nicotine high without the risks posed by many of the toxins in tobacco smoke from a real cigarette it will undermine its credibility at a time when it needs it most, even if no user ever experiences a health problem.

But it seems likely, if not inevitable, that some e-cigarette user will suffer from a heart attack or stroke or other condition where the ingestion of nicotine from the e-cigarette could plausibly be attacked as a significant factor, thereby arguably triggering potential tort liability and a law suit which could prove embarrassing to the FDA.

While the FDA might possibly argue that this occurred before it was able to decide exactly what level and type of protection was appropriate and necessary, any argument that it didn't even know if it had jurisdiction, and/or was too busy to even issue a public warning about possible or potential risks, will sound hollow an echo of the failed FDA of the prior administration.

Whether or not the FDA should follow the suggestion of U.S. Senator Lautenberg and others that the FDA should immediately take these products off the market until they are proven safe, or whether some less intrusive steps e.g., requiring health warnings at least on an interim basis, restricting the sale to persons over 18, etc. might be sufficient while the medical evidence and other issues are further studied, one thing is clear: to continue to do absolutely nothing at all while this dangerous and addicting device multiplies its customer base is not an option.

To continue to do nothing will imperil the agency's already-shaky credibility, respect, and public support, as well as potentially place at risk millions of users who will be ingesting a drug this very agency has declared is both addictive and toxic, as well as possibly endangering totally innocent bystanders including young children in whose presence this device is likely to be used by parents, grandparents, and other care givers. This is obviously unacceptable.

VII. Since nicotine is a deadly and addictive drug, there is at least a reasonable probability that it could be causing harm both to the users and to others in the vicinity who inhale the vapor, and therefore the product should be appropriately regulated without further delay.

Both the FDA and the U.S. Surgeon General have concluded and reported that nicotine is a highly addictive drug which is largely responsible for the huge number of people who continue smoking tobacco despite the known health hazards. Thus, there is a very real concern that the use of e-cigarettes could create at least two major problems based upon addiction alone.

First, many smokers who might otherwise quit (and eliminate all the risks) if there were no readily available alternative might be tempted to take a shortcut by switching to e-cigarettes, and thereby continue to be exposed to the cardiovascular and other risks from nicotine.

Second, some people (especially children) might be tempted to use an e-cigarette to get a nicotine high (lift, buzz, etc.) or in the hopes of relieving tension. Once begun, they could become addicted to nicotine, and possibly even go on to smoking tobacco.

Nicotine is also known to be a toxic drug which can trigger, and/or at least contribute to, a variety of very serious cardiovascular problems including heart attacks, strokes, etc. While these concerns may be small when nicotine is very slowly released from gum and patches, the risks are far greater when the drug is inhaled and instantly absorbed into the bloodstream of the user.

In this connection it must be noted that the vapor containing nicotine is reportedly exhaled into the air by the user, apparently even in areas where smoking (i.e., the use of lit tobacco products) is prohibited. That means that many people including the elderly, those with a variety of serious pre-existing conditions, etc. will be exposed to some concentrations of this drug.

Since so many people smoke cigarettes and other tobacco products in close proximity to children, often even when they are holding the child or even breastfeeding an infant, it is virtually certain that a significant percentage of e-cigarette users will likewise use this new product in close proximity to children especially if they become convinced from the advertising or otherwise that the exposure does not present any significant risks. Thus very young children, whose bodies and bodily defenses are still developing, and including many with pre-existing conditions, will also be exposed to this toxic drug. These are all major concerns which cannot be ignored any longer.

The FDA obviously cannot deny that it is well aware of these risks, and shares many of the concerns expressed in this document. For example, consider the following:

"We're concerned about the potential for addiction to and abuse of these products," says FDA spokeswoman Rita Chappelle. "Some people may mistakenly perceive these products to be safer alternatives to conventional tobacco use."
<http://www.prurient.com/2009-04-13/pressrelease35790.htm>

Thus, any further delay in at least taking some action perhaps even tentative action like a public statement, requiring health warnings, etc. could have very serious health consequences, in addition to possibly compromising the agency's legal position, and damaging its credibility and that of the new administration.

VIII. Even if the FDA later holds that e-cigarettes harmful effects are outweighed by their benefits as it has with nicotine gum and patches the FDA may nevertheless find it appropriate to require health-related warnings, and/or limit its sales (e.g., to adults upon presentation of proof of age, etc.)

In cases involving other nicotine delivery devices, the FDA took initial action, and then once more information could be obtained relaxed its restrictions. For example, even though makers of nicotine gum and patches were required to satisfy the FDA with medical evidence that the products were safe and effective, they originally could be purchased only with a prescription. Subsequently, in the light of new evidence, over-the-counter sales were permitted, but only with appropriate warnings and other safeguards.

In this very closely related example (Favor smokeless cigarettes), the FDA did not hesitate to require similar proof, and did not permit the product to continue to be marketed in the absence of such evidence.

In the instant situation, there appear to be genuine differences of opinion among those concerned with the problems of smoking, nicotine replacement, etc., and ultimately the FDA will have to address them in light of the best available evidence. But, as it did with all of these other nicotine products, the agency should at least take the first step of asserting its jurisdiction, and, by doing so, put the manufacturers and sellers on notice.

Even if mild, and even if adopted on only an interim basis, some regulatory steps appear to be required by both law and FDA precedent. Some may argue that an agency which is unwilling to assert a jurisdiction which already clearly exists and to confront a tiny company is not to be trusted to regulate not only all novel nicotine drug-delivery products, but also tobacco products, as a bill now before Congress would require.

To prove itself worthy of this proposed dramatic expansion of its power to protect the public from the most dangerous product ever made (tobacco cigarettes), as well as to regain its public credibility, the FDA should unambiguously assert jurisdiction over e-cigarettes.

RELIEF REQUESTED

For all of the reasons set forth in this legal petition, the FDA should immediately issue a public statement and provide notice to the manufacturer, distributors, and others directly affected that the device falls within the FDA's jurisdiction as a drug or, more likely, as a drug delivery device (medical device). The FDA should also initiate, at its very earliest possible convenience, any and all appropriate regulatory proceedings, including those which might lead to interim regulations while the issues are studied more fully.

Respectfully submitted,

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