

URGENT

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From: K.H. Ginzel, MD

To: Senate Committee on Health, Education, Labor and Pensions

Subject: FDA Senate hearing, August 1, 2007

REGULATION OF TOBACCO PRODUCTS

A. THE CASE AGAINST FOOD AND DRUG ADMINISTRATION REGULATION OF TOBACCO PRODUCTS

I am writing to voice my opposition to FDA regulation of tobacco products, including the current S.625/H.R.1108, "The Family Smoking Prevention and Control Act".

My opposition to FDA regulation of recreational tobacco products has not changed since it was first proposed by then FDA commissioner David Kessler, MD. In a letter to Dr Kessler dated May 3, 1994, I raised opposing arguments which turned out to be almost identical to those of US Supreme Court's justice Sandra Day O'Connor's majority opinion six years later, in March 2000, denying the FDA regulation of cigarettes.

O'Connor noted that the FDA has concluded that cigarettes are unsafe and dangerous. As a result, she said, federal law *"would require the FDA to remove them from the market entirely."* She wrote: *"The inescapable conclusion is that there is no room for tobacco products within the (federal law's) regulatory scheme,... if they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit."* Justice O'Connor continued: *"By no means do we question the seriousness of the problem that the FDA has sought to address,the agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States."* Justice O'Connor's March 2000 opinion was echoed by a tobacco industry's lawyer who argued that if FDA regulation were allowed, the government would be forced to ban tobacco products because they have not been shown to be safe. As expected, the tobacco industry sharply opposed FDA involvement.

This, however is no longer true with Bill S.625 that is before you now. S.625 permits, with certain additional restrictions and safeguards, the continued marketing of tobacco products and has thus gained not only the full approval but also the active support of Altria/Philip Morris, PM, the nation's and world's largest tobacco company.

If the FDA is to provide the public with drugs for the treatment and prevention of diseases and disabilities, i.e., with medications that must satisfy the two indispensable criteria of being **safe and effective**, the inclusion in its jurisdiction of cigarettes, a product that kills one out of two of its users, would totally subvert its long-standing avowed mission of protecting and improving public health. Thus - and we are back to O'Connor's analysis - if tobacco products were admitted under FDA overview but not banned in the process, it

would have to be seen as the stamp of federal approval for their continued existence and use in a society ultimately resigned to the prospect of a projected one billion worldwide smoking-related deaths during the 21st century.

Paradoxically, FDA scrutiny that attempts to make cigarettes "safer", as it is intended by S.625, flies in the face of PM's recent blunt admission that "THERE IS NO SAFE CIGARETTE"

(http://www.philipmorrisusa.com/en/health_issues/cigarette_smoking_and_disease.asp).

In fact, this admission is the only compelling conclusion after several decades of tobacco research that has failed to eliminate certain highly toxic and carcinogenic ingredients from tobacco and tobacco smoke (although ulterior motives are clearly involved in PM's unexpected honesty). If S.625 ever succeeds in making cigarettes "safer", it could never create a SAFE cigarette.

If the current momentum to place tobacco under FDA oversight cannot be halted, at least one essential correction in the bill's text is indispensable. It concerns the legal age for buying tobacco products which is currently age 18 and would be retained in S.625.

However, age 18 is unacceptable for the following reasons:

- 1) The proposed regulation specifically prohibits the FDA from raising the legal minimum age for tobacco purchase beyond age 18, as obviously demanded by PM to retain access to high school seniors, many of whom are over 18 and would therefore be able to legally buy tobacco products and pass them on to peers under 18.
- 2) Although the majority of adult smokers started smoking under age 18, 15 to 20 percent may start between 18 and 21. This fringe would probably disappear or diminish if age 21 is adopted as the legal limit. According to CDC, less than 10 percent start smoking after age 21.
- 3) Tobacco use, smoked or chewed, imposes a carcinogenic and toxic burden on the user that is more dangerous for the growing organism than for the adult. Physical growth does not stop at age 18 but continues at least till 21.
- 4) The age at which psychological maturity is attained for making an informed decision about using legal drugs with a high potential for addiction is at least 21, the age adopted for legal purchase of alcoholic beverages.
- 5) The difference between the legal ages of 18 and 21 for purchase of tobacco and alcohol products could be misinterpreted as reflecting a difference in harmfulness.

The American Association of Public Health Physicians, AAPHP, has undertaken an extensive Analysis of S.625/H.R.1108. It states that "*S.625/H.R.1108 is written to perpetuate cigarette consumption for many years, with uncertain benefits after that. Passing this bill would be like turning off a fire alarm without putting out the fire*", and concludes with this pronouncement: "*Finally, and sadly, note that, as seen by AAPHP, no bill at all would be better than S.625 in it's current form*" (AAPHP_Tob_Analysis_20070712.doc).

It is also noteworthy to recall the statements made by the head of the FDA, Dr. Andrew von Eschenbach, a cancer surgeon, in a recent interview with The Associated Press.

Commenting on S.625's intention to lower nicotine levels in cigarettes, he said: *"We could find ourselves in the conundrum of having made a decision about nicotine only to have made the public health radically worse. And that is not the position FDA is in; we approve products that enhance health, not destroy it."* Stressing repeatedly that the issue of regulating tobacco is a complex one, he added: *"What I don't want to see happen is that we are in a position where we are determining that a cigarette is safe"* (<http://www.msnbc.msn.com/id/17483839>).

If the present effort to achieve FDA oversight of tobacco fails or is abandoned for reasons indicated above, what other, and better, options do we have to address the leading preventable cause of disability, disease and death in our society?

B. REGULATION OF NICOTINE BY THE CONTROLLED SUBSTANCES ACT.

In my letter to Dr Kessler of May 3, 1994, I not only opposed FDA regulation of tobacco but also argued in favor of placing nicotine in Schedule II of the Controlled Substances Act that was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Two federal departments, the Department of Justice and the Department of Health and Human Services (which includes the FDA) determine which drugs are added or removed from the various schedules.

In the words of former Surgeon General Koop, the very *"heart of the issue"* is *"not smoking, not tobacco, but nicotine addiction"*. Nicotine addiction was the subject of the 1988 Surgeon General's Report which concluded that nicotine, fulfilling all criteria for drug dependence, is the drug in tobacco products (cigarettes and other forms of tobacco) that causes addiction, and that *"..the pharmacological and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine"*. The 1994 Surgeon General's Report on "Preventing Tobacco Use Among Young People" confirmed that nicotine causes rapid addiction in up to half of all children who experiment with tobacco.

But it is not only the high addictive potential of nicotine that causes increasing concern but also its insidious toxicity, especially the serious harm it can inflict upon the developing and growing organism (Critical Review: Nicotine for the Fetus, the Infant and the Adolescent? J Health Psychol 12(2), 215-224, 2007 (DOI:10.1177/1359105307074240) (see attachment Ginzel_et_al_12_2.pdf).

In light of the accumulated evidence, a legally acceptable option for regulating tobacco products is to place nicotine, the addictive component of tobacco, under the Controlled Substances Act. By including nicotine in Schedule II of the Controlled Substances Act, which contains drugs with a high potential for abuse and dependence but continued medical usefulness, such as cocaine and various opioids, stimulants and hypnotics, the availability of nicotine for the treatment of nicotine addiction, in form of Nicotine

Replacement Therapy, NRT, would be preserved. But nicotine in any other form would be outlawed.

Nicotine would then be back on prescription only, as it had formerly been till 1996. As a Schedule II drug, nicotine dispensed in NRT formulations would then require the same procedure that has to be followed when prescribing other controlled substances. This constraint should help prevent the now uncontrolled, spreading use of NRT for smoking cessation, that is aggressively pursued by the makers of NRT products and those affiliated with them (see attachment Ginzl_et_al_12_2.pdf).

As for the tobacco industry, it could then legally sell only nicotine-free tobacco products which can be expected to lose attraction for the buyer over time. This would bring about the gradual phasing out of tobacco marketing and use, and with it the reduction and eventual elimination of tobacco-related morbidity and mortality. Once this goal is achieved, nicotine can be removed from the Controlled Substances Act.

C. ENDING TOBACCO TRADE BY APPLYING TOOLS PROVIDED IN THE CONSTITUTION.

According to the late Milton Friedman, nobel laureate in economics, corporate officials have only one *"social responsibility,"* i.e., *"to make as much money for their shareholders as possible"*. Maximum profitability is based on product quality and product safety. In the case of tobacco, however, these market forces are suspended by the addictiveness of the products. Here, governmental intervention is necessary to protect the consumer.

In their wisdom, the Framers of the Constitution granted Congress the right to regulate commerce, empowering the U.S. government by the "Commerce Clause" of Article 1, Section 8, of the Constitution to stop the interstate trade of dangerous merchandise. If this authority were exercised in the case of tobacco, it could usher in the beginning of the end of tobacco marketing. Such action must clearly be distinguished from prohibition, since individuals would still be able to grow tobacco locally and strictly for personal use.

D. CONCLUSION.

The reality is simply this: The tobacco industry makes and markets a product that is addictive, toxic and carcinogenic, and it maims or kills when used as intended. The worldwide death toll from cigarette smoking could approach the one billion mark by the end of the 21st century. No other product officially traded on world markets shares this unique notoriety with tobacco (Ginzl, K.H. After Some 100 Million Deaths - What's Next? http://www.acsh.org/healthissues/newsID.574/healthissue_detail.asp).

The continued prosperity of the industry depends on the successful recruitment of children and adolescents into the ranks of smokers. Statistics have convincingly shown

that very few people start to smoke above age 21. This is why the industry has vehemently opposed any legislation that would have raised the legal minimum age for buying tobacco products to age 21. Former FDA Commissioner David Kessler pointedly called smoking "a pediatric disease". The inescapable truth, sadly affirmed by repeated experience over the past half century, is that no stop-gap measures of any kind can be expected to protect children from the onslaught of Big Tobacco. Without them as future customers, tobacco business would be doomed.

Therefore, if government and society honestly want kids not to become victims of tobacco use, the logically compelling choice is to end the commercial marketing of tobacco products. The task would be monumental, but it is the only practical, social, and ethical alternative to allowing the killing to continue. Although only trade within the U.S. would initially be affected, other countries, assisted by WHO's worldwide tobacco control initiative, might soon follow our lead. Indeed, final success would depend on full international cooperation. There are positive indicators that the time is right for such comprehensive action. Some U.S.-based tobacco corporations are already sufficiently diversified in areas other than tobacco to be able to phase out the manufacture of tobacco products while expanding their share in non-tobacco commodities.

Tobacco farmers should be encouraged and assisted to shift from conventional tobacco farming to the cultivation of tobacco plants for the extraction of tobacco protein, which has been shown to be superior to all other plant proteins tested and deserves full-scale development and utilization for food as well as a variety of medicinal purposes (Ginzel, K.H., Protein, An Alternative Tobacco Crop, <http://www.gasp.org/protein.html>). What an intriguing prospect that the same plant that has killed millions of people should also possess the potential and capacity of feeding a protein-starved world and stimulating novel biotechnological research. Neither tobacco nor anything that human ingenuity has brought forth is inherently evil. It just depends on what we, collectively and individually, make of it.

Finally, facing the stark reality laid out in the preceding paragraphs, no nation claiming to uphold the fundamental tenets of civilization can any longer afford not to act.

Respectfully submitted,

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