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## SMOKING: PREVALENCE AND REGULATIONS

JOSÉ AGENOR ÁLVARES DA SILVA

“If tobacco was introduced in society now, certainly it would be considered illegal, because of the accumulated knowledge about the damage caused by its use. Therefore, its legality is the product of a historical mistake” (Brazil, 2002, our translation).

### FROM THE GLAMOR OF “SMOKING I WAIT” TO THE LARGEST CAUSE OF PREVENTABLE DEATH IN THE WORLD

Until the middle of last century, smoking was synonymous with glamor, social status, even if it was a prosaic straw cigarette from Minas Gerais’ countryside, manufactured with the corn straw, softened by moisture of the tongue in a typically rustic gesture, interwoven through the ring and middle fingers and hold by the pinky and index finger<sup>1</sup>. Made with artisan refinement, using sharp knife and roll-your-own cigarette (preferably the one called *capoeirinha*), chopped and mixed with mastery in your palm, having a small talk and coffee – filtered through a strainer cloth and made in a wood burning stove – this type of cigarette is known as “pito mouth”. The mastery in the making of this cigarette, even today, especially in the countryside, is not to let any of the manipulated ingredients, all at the same time, escape from the hands - often calloused by daily blue-collar work, by those who did and still do this act as daily dilettantism to satisfy the desire for a drag supposedly necessary for relaxing

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1 In popular parlance, the fingers are known as pinky, your neighbor, the father of all, cake ruiner and lice killer.

or bringing emotional well-being, thanks to that smoke that encompasses the lungs. What a serene peace.

In a diverse environment of the simplicity of the straw cigarette, the industrialized cigarette, cigar, cigarillo or pipe gave its users the glamor of “smoking I wait”, in a reference to words of a tango of the 1950s. These products were refined by industries just to be seen as providers of benefit and personal success to its users. After all, nothing more charming and elegant than to hold between your index and middle fingers, with that triumphant air of Sierra Maestra, a Cohiba from Cuba. Or to enjoy the exciting aroma of refined tobacco imported and placed in a pipe brought from the UK, made from the most legitimate of English rose stem, which gave that intellectual aura, closer to the British nobility than the Geraldinos’ environments<sup>2</sup> frequented by sons of this land. That is, a consumer dream finally realized.

The inspired person who designs the cigarette, makes it a male instrument in the hand of man, a feminine instrument in woman’s hand, sophisticated for the sophisticated ones [...] for young people, a touch of rebellion, for the elderly, a tranquility tool, a warm ally in the moments of action and a solitary companion during reflection (Cruz apud Heartier, 1993).

However, time goes by, dreams fade away, science advances and reality finally arrives. What was a guarantee of success for people turned into a disease. Studies by several research institutions, from the 1950s, began to warn of the harm caused by nicotine and the many substances used in the manufacture of tobacco, most carcinogenic. When trying to deceive the user and mitigate the awful taste of pure nicotine, the industry adds adjuvants to facilitate the absorption of that substance and foster the loyalty of the unwary to their brands, especially youth and adolescents.

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2 Geraldino is a football metaphor for fans attending regular seats at soccer stadiums. These places were not comfortable, without any protective equipment against bad weather and where the games were seen standing. The discomfort posture was offset by the joy of being close to watch their beloved team, not to mention ticket prices, affordable to low-income workers. Happy times that came to an end with FIFA following the demand of modern multipurpose arenas to house the elite of football.

The subservience to the elegant “habit” is soon felt. It is the beginning of chemical addiction and not healthy habit, as does the aggressive industry-marketing machine makes it sound. It is not something that is under user control, easily discarded in a magic trick.

Researchers and scholars on the scientific evidence and consequences of smoking on the human body consider important to differentiate the conceptual understanding of habit, addiction and dependence. For the industry, I repeat, it is all a prosaic and wholesome recreational habit.

“A habit means [...] a permanent or frequent, regular or expected form of acting, feeling, behaving; mania” (Houaiss; Villar; Franco, 2013). I.e., a matter of mania, which, because it is a mania, will be easy to face and overcome. It is the feeling of absolute control over the situation. Silly mistake. Regarding smoking, this logic does not apply so easily. The famous images of the Marlboro man, riding a pompous stallion in the American West, then on his deathbed, affected by lung cancer, speak for themselves.

Addiction, according to the Aurélio dictionary (2004, p. 2058), means “severe defect that makes a person or thing improper for certain purposes or functions”. Today, the smoker who does not respect the rights of non-smokers, especially in collective environments, inappropriate to the use of tobacco products, is considered, from the behavioral point of view, as an antisocial person. The question is how this individual posture should be portrayed, since smoking is characterized as addiction.

Finally, addiction is characterized “by the use and the need, both physical and psychological, of a psychoactive substance, despite the knowledge of its detrimental health effects”. “Substances or psychoactive drugs are those that change the user state of consciousness” (AMB, 2013). Nicotine is considered a psychoactive substance.

Therefore, smoking is an addiction characterized by physical and psychological dependence on nicotine consumption. It is included in the group of mental and behavioral disorders resulting from psychoactive substance use, according to the Tenth Revision of the International Classification of Diseases (ICD-10). Tobacco dependence is:

A cluster of physiological, behavioral, and cognitive phenomena that develop after repeated use and has features such as the strong desire

to smoke, difficulty in controlling use, persisting in use despite harmful consequences, increased tolerance to nicotine and state of abstinence (OMS, 1997, p. 313-14).

Smoking is the leading cause of preventable death worldwide. Six million lives are lost every year because of tobacco-related diseases, according to the World Health Organization (WHO). In Brazil, there are more than 200,000 deaths annually. This number is alarming and clearly indicates that the national authorities in their respective territories should commit to reducing the prevalence of smoking, in addition to associate with other countries to contain the spread of this evil that devastates the world.

Today the mortality caused by tobacco-related diseases exceeds the mortality of AIDS, cocaine, heroin, alcohol, suicides and traffic accidents combined (Shafey et al., 2009). About 90% of smokers become addicted to nicotine between 5 and 19 years of age (Instituto Nacional do Câncer, 2004). On the one hand, this dependence is considered a pediatric disease; on the other, a true pandemic, with a unique feature: the transmission vector of this disease is an industry. Not just any industry, but the powerful tobacco industry, with its economic and coercive tentacles. With a shameless performance on various actors of world society without any political embarrassment, it aims only to ensure the profusion of its business and rejects any protective measure of the population health that can affect its profits.

## FIGHTING TOBACCO ADDICTION – AN INTERNATIONAL PACT

The worsening of the NCDs worldwide led the WHO to propose, for the first time in history, an international pact in the public health sector to combat smoking, known as the Framework Convention on Tobacco Control (FCTC). Approved in 2003 by the 52nd WHO World Health Assembly, after extensive discussion by State Members, it was ratified by Brazil in 2006 - currently, 178 countries have ratified the convention. The objective of the FCTC is “to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure” (OMS, 2003, p. 4).

This treaty, binding on all signatories, provides some guidelines, which aim at reducing tobacco consumption, without, however, disregarding the political conditions of each country. These guidelines are organized into three sets of measures (Cavalcante, 2014):

- Measures related to consumption: emphasis on protection against passive smoking, pricing and taxes on tobacco products, as well as guidance to ban advertising, promotion and sponsorship by industries. In Brazil, the Ministry of Finance has set the minimum price of R\$ 3.00 (US\$ 0.93) per cigarette pack<sup>3</sup>;
- Measures related to the demand: control of illicit trade and sales ban to minors under 18 years;
- Transverse measures: calls the participation of civil society in the fight against smoking.

In Brazil, several measures have been taken in compliance with the guidelines of the Framework Convention. Some of these measures, inclusive, are reference for the formulation of policies to combat smoking in other countries. The highlight of these measures, within the framework of post-FCTC regulation, was the restriction of the use of tobacco products.

Tobacco control, despite the legitimacy of the actions developed for the benefit of society as a whole, regardless of social class and gender, has direct repercussions for a segment that is part of the productive tobacco complex and that the State cannot relegate to a secondary plan. The raw material, tobacco leaves, obviously is a part of the nuclear field of the production complex of tobacco products, without which the industry would be feasible. This production is originated mainly in the field of family farming, consisting of small farmers with estates, mostly up to 15 hectares, dependent on this agricultural commodity for survival (Delgado, 2014).

In the beginning of the last century, the boom of the exporting agricultural model encouraged farmers, especially from the South, to focus on the production of tobacco leaves. It was a trendy product. Even the coat of

<sup>3</sup> The minimum price is due to the approval of the Law no 12,546, of December 14, 2011, establishing the Special Regime of Reinstatement of Tax Amounts for Exporting Companies (Reintegra). Please note that this law, an authentic legal and tax monster, stipulated the minimum price for the cigarette pack and raising taxes for the industrial segment as compensation for the reduction of the tax for white goods - not to join the government guidelines to combat smoking.

arms of the Republic portrays the importance of this culture, which, along with coffee production, symbolized the power of Brazilian agriculture. In the coat of arms are portrayed as a symbol of nationalism and importance to the economy of the country back then the coffee leaf on one side and the tobacco leaf on the other.

The Framework Convention did not omit the situation of farmers who grow tobacco leaves in producer countries. Besides the restrictive measures on consumption, it dedicates part of its regulation for the appointment of nation states to adopt economic measures to ensure the conversion of production of tobacco leaf for other cultures. In addition, it states that economic performance guarantees are given according to the needs of family farmers and consistent with the gains with the cultivation of this crop.

## SMOKING PREVALENCE

*“All epidemics have a type of contamination, a vector that causes disease and death. For the tobacco epidemic, the vector is not a virus, a bacteria or other microorganism - it is an industry and its business strategy” (OMS, 2008 p. 21 apud Brazil, 2014).*

International research has pointed to a significant decrease in the prevalence of smoking in various parts of the world, including Brazil. Several factors can be considered as causes of this decline. Among them: education campaigns about the risks of smoking, restrictions to smoke in public or private places, regulation of tobacco products, advertising restriction, warning labels about the side effects of these products, legislative actions taken by some states and counties, etc. These factors have contributed to a considerable decline in smoking rates in Brazil over the last 25 years, despite being one of the world’s largest tobacco producers.

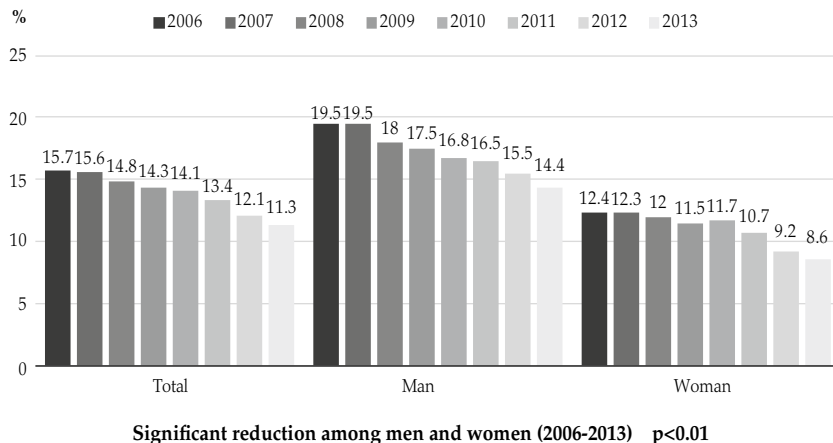
In 1989, smoking prevalence in Brazil was 39.4% among men and 23.9% among women, according to the Brazilian Survey on Nutrition and Health conducted by IBGE. These data are significant and alarming and support the government’s decision to intervene in this pathogenic

chain led by tobacco use in order to reduce morbimortality derived from tobacco-related diseases.

From 2002 to 2003, the household survey on risk behaviors and morbidity of diseases to non-communicable diseases, conducted by the Brazilian Cancer Institute (INCA) in 16 Brazilian capitals, confirmed the decline in smoking prevalence. In these capitals, the prevalence ranged from 16.9% to 28.2% among men and from 10% to 22.9% among women. One information about that research has drawn attention: the prevalence of cigarette smoking was higher among men than women considered all social strata. However, in the regions of higher income and higher education, the prevalence between genders was similar (Brazil, 2004).

While there may not be a direct comparison, given the universe in which the two surveys were conducted, a sharp decline in smoking prevalence over the years was proved. In the figure that follows, this downward trend is evident among men and women in the period between 2006 and 2013.

**Figure 1. Smoking prevalence by gender in Brazil – VIGITEL 2006-2013**



Source: Cavalcante, 2014.

According to VIGITEL data for 2011, 11.3% of the Brazilian population uses tobacco products regularly; among the male population, this percentage reached 14.4% (Brazil, 2012).

The decline in smoking prevalence is also confirmed in the 2013 National Health Survey (PNS) by IBGE. With minor differences between the results of the two surveys, the PNS shows the steady decline in smoking prevalence across the country, compared to the beginning of this research. This 2013 survey showed a prevalence of 12.7%; 16.2% among males and 9.7% among females. It also showed the difference in prevalence between urban and rural population. In urban areas, it was 12.5%; in the countryside, 14%.

Tobacco use is responsible in Brazil for about 95% of cases of oral cancer, 90% of breast inflammation, 80% of the incidence of lung cancer, 97% of cases of laryngeal cancer, 50% of skin cancer cases, 45% of deaths from coronary heart disease and 25% of deaths from cerebrovascular disease. There are more than 50 diseases associated with tobacco use (Brazil, 2010).

According to an international survey conducted by several institutions, such as INCA, among 20 countries, Brazilians are the people who most regret having started smoking (91% of respondents). Among Brazilian smokers, 63% support campaigns and laws against smoking and 82% report that smoking has caused them some sort of health problems (NÚMERO..., 2010, online).

World Bank reports indicate that the available evidence shows that poorer individuals tend to smoke more. For them, the money spent on tobacco represents a high opportunity cost: this money is not invested in crucial goods for the family. Tobacco and poverty form a vicious circle, which is difficult to escape from, unless tobacco users are encouraged and receive the support required to quit smoking.

This trend has been observed also in national surveys that correlate higher prevalence of smoking among people with less education, not only in rural areas but also in urban centers. That is, the prevalence of smoking today is more relevant in population extracts more fragile socially and economically, a very vicious circle, as highlighted by the World Bank report.



The Brazilian Plan of Action for Management of Chronic Non-Communicable Diseases, launched by the Ministry of Health in 2010, projects a target of reducing smoking prevalence to 9% for 2022. Considering the speed of the downward trend seen in recent polls, both official or from non-governmental organizations, reaching this goal is quite feasible. This tendency is also due to the engagement of the population in a kind of spontaneous campaign organized worldwide without explicit coordination to combat the harmful effects of smoking.

Given the sharp decline in smoking prevalence, the global tobacco industry seeks aggressive strategies to gain new users. The most prominent is the co-opting of youth, children and adolescents for early initiation, producing advertisements for decades, some subliminal and others not so much, verified in documents of the industries made public.

The age of initiation is an important factor to be considered by government authorities in the formulation of public policies to combat smoking.

The young are particularly vulnerable to becoming users and once dependent they tend to remain so for many years. And advertising and packaging, which make tobacco use seem less harmful than it really is, when exposed to young people and adolescents, increase the positive perception of tobacco derivatives and the curiosity to consume, which increases the probability of youth and adolescents to start smoking (WHO, 2013).

The co-optation of youth and adolescents is a key strategy for flourishing the businesses of the companies producing tobacco derivatives. The main counterpoint of health authorities around the world is to inhibit the initiation of these products. "Today's teenager is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens [...] The smoking patterns of teenagers are particularly important to Philip Morris" (Morris, 1981). In other words, the strategy involves replacing consumers that died, often prematurely, due to a number of diseases caused as consequences of smoking addiction.

Parallel to tobacco-related diseases, widely known and disseminated, other illness, not publicized by the media in this world increasingly globalized, is affecting the families of the farmers who grow tobacco leaf: Green Tobacco Sickness, caused by dermal absorption of nicotine due to unhealthy working conditions. Without any personal protective equipment, given the socioeconomic conditions of the families, cropping and transporting tobacco leaf happen in direct contact with the skin of farmers and this favors the absorption of nicotine in infinitely greater amount of nicotine present in the products derived from the leaf.

A 2007 survey of the Ministry of Health, in producing areas of Arapiraca, in the state of Alagoas, and Candelária, in Rio Grande do Sul, denounced the gravity of the situation, notably due to the contamination of children that even during school years are used to harvest because of the high demand for labor for families. Urine tests established the presence of nicotine among the examined groups, even for non-smokers, in higher proportion than found in habitual smokers. The main symptoms of the disease are headache, dizziness, nausea, and cramping, among others. Even not knowing yet the future consequences of this disease, this is another concern of health authorities, not only in Brazil, due to the cruelty of working conditions and the economic exploitation of farmers producing tobacco leaves (Oliveira et al., 2010).

However, as in many similar situations to that of Green Tobacco Sickness, this problem does not affect indiscriminately rich or poor regions. It is a specific problem caused by unhealthy working conditions of the poorest regions, of small farmers forced to use all family members to help. The devastating effects of this disease, as evidenced by the survey of the Ministry of Health, are another harm that directly affect small farmers engaged in the production of tobacco leaf. This disease will be counted as another neglected disease, or more neglected, to be incorporated into the portfolio of developing countries, along with so many others. What about the State? Will it once again demonstrate insensitivity and omission?

## REGULATION OF TOBACCO PRODUCTS: THE HAPPINESS QUOTIENT

“Tobacco is a unique consumer product. If it were a new product today, it would not be allowed on the market. Tobacco is toxic, carcinogenic, and addictive. No other consumer product legally available on the market kills when used exactly as the manufacturer intends, and there is no safe level of consumption. For these reasons, tobacco merits legislative and regulatory treatment different from all other products” (Cunningham; Kyle, 1995, p. 85).

Brazil’s Federal Constitution consecrate health as a citizenship right of public importance. The state regulation in industrial production in certain areas of strong connection with health issues, especially for those sectors responsible for products that spread risk factors for chronic conditions, is legitimate and highly relevant to the promotion and protection of human health (NETHIS, 2013). In this regard, the Director-General of WHO believes that:

Efforts to prevent non-communicable diseases go against the business interests of powerful economic operators. [...] All of these industries fear regulation, and protect themselves by using the same tactics. Research has documented these tactics well. They include front groups, lobbies, promises of self-regulation, lawsuits, and industry-funded research that confuses the evidence and keeps the public in doubt. Tactics also include gifts, grants, and contributions to worthy causes that cast these industries as respectable corporate citizens in the eyes of politicians and the public. They include arguments that place the responsibility for harm to health on individuals, and portray government actions as interference in personal liberties and free choice. This is formidable opposition. Market power readily translates into political power (Chan, 2013).

Chan’s speech is a warning against attempts to prevent State action to protect human health. Currently, not only in Brazil but also in other countries there is a real crusade against this mission. Some question the legitimacy of the State to interfere, even if only with guidance, on citi-

zens' personal lives to clarify the use of certain products, proven harmful to health. It is the false contradiction between the role of the modern State opposed to individual rights, free will and freedom of expression. The representatives of these industries use all media to proclaim that the citizen does not need clarification regarding his health or warnings about the risks of any product available on the market. They mix up freedom of expression with marketing trickery to mislead the population deliberately (Silva, 2014).

Tobacco control in Brazil dates back to 1986 and great progress has been made since then. Advertising ban and warning labels on packages of tobacco products began to set the tone of the regulatory agenda of a public policy that transcends the transience of extemporaneous governments to turn into a State policy. The result was a decline in smoking prevalence in the country as already highlighted.

Regulation of tobacco products is a big controversy in any part of the world. An emblematic subject, so to speak. Legally commercialized since the early days, these products are the only ones that do not have, anywhere in the world, any reference to its quality or certification of alleged advantages for its use. When the registration of a product is granted by any regulatory State, whether a drug or medical use equipment, for example, one assumes that, if used according to the manufacturer orientation and following current health precepts, the user can achieve some benefit.

In the case of tobacco products, what happens is exactly the opposite. There is no benefit and no orientation from the manufacturer about its use, which induces one to think that the industry itself considers it a lethal product, although legal. That is why Brazil only registers the brand and does not grant the product a full registration. It is the opposite of the regulatory activity of the State. I.e., there is a complete reversal of the regulatory flow – it is an anti-regulation or a reverse regulation, so to speak.

Due to the intrinsic organoleptic characteristics of tobacco products, reverse regulation means guarding the interests of society against the dangers of these products. It can be understood as a set of guidelines issued by the State to regulate a legal product, but admittedly lethal, in order to prevent gimmicks used in industrial production and creative business marketing to trick the user and draw attention to the product.

The regulation of additives used in the production of derivatives of tobacco, undertaken by the Brazilian Health Surveillance Agency in 2010, caused moments of great political tension due to the explicit lobby of the tobacco industry among parliamentarians, the judiciary<sup>4</sup>, segments of the executive branch and retail trade. The industry also manipulated small producers co-opted to industry interests with blackmailing them about the possibility of extinguishing their crops. Public consultation on the subject received worldwide the highest number of officially sent answers known in history about this type of consultation, by either email, mail or direct delivery.

There were 127,388 answers to public consultation. After evaluating each response, some unusual facts were found. Of the total, 97,156 letters had the same pattern printed in by a company; there were various irregularities, such as same participant, same handwriting or identical texts. Hundreds were posted in the city of Rio de Janeiro, using the same type of brown envelope, of the same size, same pattern of the stamp indicating the recipient and same post office. This fact drew attention of the Postal Corporation in Rio de Janeiro, who made a telephone consultation to the technical area on the meaning of that flood of correspondence.

The amount of correspondence on this issue also drew attention not only of the Anvisa board, as well as a number of public health protection agencies. Associated with this, in an unusual decision without any legal base that would justify it, a judge from Rio Grande do Sul suspended a scheduled public hearing and, at the height of his arrogance, determined the hearing should take place in a room that could fit at least a thousand people. In the Democratic Rule of Law, each power must be respected and therefore the court order was promptly obeyed. After all, justice is blind.

The hearing was held in a gymnasium in Brasilia, the Nilson Nelson, with a capacity of 15,000 seats, coincidentally, the same place where they held the VIII National Health Conference in 1986. More than 800 people attended the hearing, mostly farmers from the south of the country, brought by tobacco industries. Other groups against and in favor of the

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4 Even after the sharp reduction in smoking prevalence, Brazil remains the second largest producer and exporter of tobacco leaf in the world. Around 85% of Brazilian production is exported, according to the Brazilian Association of Tobacco Industry.

measure, such as parliamentarians, medical organizations, health professionals, researchers, universities, ministries, international organizations, the tobacco industry, and consumer organizations and those who protect public health also participated. It lasted four hours. There was an intense debate, in which all without distinction, according to the rules, could present reasons against and in favor of the rule in consultation in an authentic democratic coexistence and respect for conflicting positions. However, most of the arguments defended population health.

However, tensions aside, creativity in regulatory activity may surprise with truly original and unusual arguments, not to say insane. The attempt to bring highly subjective and immeasurable parameters for the objective reality of a regulatory impact analysis draws attention.

In August 2014, the US agency in charge of regulating tobacco products, the F.D.A. (Food and Drug Administration), surprised the United States after introducing in its regulatory impact analysis, in a procedure for granting registration to electronic cigarettes, a totally abstract and surprising concept to offset the economic impact of banning these products in the US market: the happiness quotient. F.D.A. linked this quotient to happiness in order to compensate for the loss of pleasure that smokers had when stopped smoking as opposed to reducing the risk of illness, disability and death. The alleged economic losses from the industrial segment in question must be compensated up to 70% in a cost-effective relation between the product and its consumption restrictions<sup>5</sup>.

This proposal became known by the American population through a public hearing made by the FDA and was much debated among economists, including the Nobel Economics Prize Winners, and health professionals across the country. The normative activity of that agency, or, more properly, the privilege of the economic impact on the defense of health, was widely debated, and a warning was explicit: the vulnerability that the use of such a factor could represent in litigations against the tobacco industry. It was so controversial that The New York Times published a story with a warning about the impact that the introduction of this parameter

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<sup>5</sup> Adapted from comments received via e-mail by Alberto Araujo, coordinator of the Center for the Study and Treatment of Smoking (Federal University of Rio de Janeiro) and member of the Tobacco Commission of the Brazilian Medical Association.

could represent to any measure of protection to public health if taken into account for other products, equally harmful, as alcoholic beverages. Said the newspaper:

Buried deep in the federal government's voluminous new tobacco regulations is a little-known cost-benefit calculation that public health experts see as potentially poisonous: the happiness quotient. It assumes that the benefits from reducing smoking – fewer early deaths and diseases of the lungs and heart – have to be discounted by 70 percent to offset the loss in pleasure that smokers suffer when they give up their habit. [...] The idea of lost happiness is new for health regulation. But it has surfaced as part of a longstanding requirement – first codified under President Bill Clinton – that every set of federal regulations with more than \$100 million effect on economy needs and analysis to prevent the adoption of regulations with high costs and low benefits (Tavernise, 2014, online).

I.e., the guarantees of security of products for domestic consumption associated with quality of life are considered to be of low benefit over the alleged economic losses of companies in the sector. It never fails to amaze the introduction of exotic and subtle criteria to meet the dictates of industrial sectors fallacious of their economic prerogatives. It is the explicit confrontation of exacerbated power to challenge the cost-benefit ratio between the most expensive use of value to people, life, and the commercial value of a proven harmful product searching for space in the consumer market, with the illusion to compensate for alleged losses of citizens' personal welfare. It is an authentic marketing deception of what is considered the greatest villain of humanity. An authentic Nosferatu coming from the ghostly depths of Transylvania.

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