More on the regulation of tobacco smoke: how we got here and where next

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Received 15 July 2002; accepted 22 October 2002

The modern cigarette is unnecessarily dangerous. Despite being lower in tar yield, and consequently in squamocarcinogenic polyaromatic hydrocarbons such as benzo[a]pyrene, the nitrosamine yields are often higher than they need to be. Also, reductions in tar levels have not led to the consequential reductions in mortality that were anticipated several decades ago. The modern cigarette is also smoother, easier to smoke and to learn how to smoke, highly addictive and facilitates compensatory smoking. Compensatory smoking leads to excess inhalation of carcinogens and toxins in the hunt for nicotine. Its labelling is misleading in that supposedly low-yielding cigarettes may, due to compensation occurring as a result of cigarette design, lead to inhalation of much higher amounts of nicotine, carcinogens and toxins than the smoker is led to expect. Regulation of the product is needed to provide the persistent smoker with a cigarette lower in risk, accurately labelled, providing a relatively consistent and known dose of nicotine, and less likely to facilitate compensatory smoking. This will not produce a safe cigarette but should result in a reduction in harm if seriously implemented.

Key words: benzo[a]pyrene, compensation, filtration, nicotine, nitrosamines, smoking

Introduction

The modern cigarette is a serious problem [1–3]. It is seemingly as dangerous as its predecessors [1], smoother, easier to smoke and easier to learn to smoke [2] and designed to facilitate compensation [3]. It delivers more nitrosamines than it used to [4] and levels of these vary both between brands and within global brands [5]. The smoke of a selected group of 26 brands in the USA shows differences in delivery of seven-fold for benzo[a]pyrene, eight-fold for arsenic and four-fold for 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) [6].

To date, virtually no country has asserted legislative control over the contents of cigarette smoke. The European Union (EU) has passed legislation setting limits on tar (10 mg), nicotine (1 mg) and additives; this is currently under legal challenge and is not yet in effect. It seems timely to take an overview of what the cigarette of the future should look like. This review will not consider alternative nicotine-delivery devices on the grounds that these should be regulated as pharmaceutical items, for which an extensive system of regulation is in place.

How did we get to this position?

There are really two answers to this question: (i) the original acceptance and endorsement of the Federal Trade Commission (FTC) system of measuring tar and nicotine as an index of dose in 1967 [7]; (ii) the tobacco industry’s policy decision to use this system for marketing purposes rather than as a basis for reducing the harmfulness of its product.

There is little to say about the decision by public health authorities to endorse the low-yield cigarette. It was taken on logical grounds based on the information available at the time and on the assumption that the industry would respond with concern for public health. There was a dose–response effect between cigarettes smoked and disease [8, 9], as well as between the amount of cigarette tar painted on mouse skin and resultant cancers [10]. There was also evidence of risk reversal with cessation [8]. Public health authorities may have responded differently if they had understood nicotine addiction and nicotine compensation as well as the tobacco industry did, and they certainly would have if they had predicted the industry’s response.

There is little doubt that the cigarette could have been, and can be, made somewhat less dangerous. There is no doubt that it cannot be made safe and that, in the long term, it should be replaced as the major form of nicotine dose by tobacco-free products that deliver a similar or lesser ‘fix’ than the cigarette. Products very low in toxicity will be needed to prevent possible net adverse health consequences arising from increased use of any product that offers only modest risk reduction to individuals [11].

The tobacco industry’s response

Faced with the FTC system, which they already used, and official encouragement, the tobacco industry’s sensible response would have been to progressively reduce the carcinogenicity and
toxicity of their products. This did not really happen. Tar was indeed reduced, which did reduce benzo[a]pyrene levels as these correlate quite well with tar [4]. Much of this potential benefit was lost because of compensation by the smoker, although the relative decline in the risk of squamous cell carcinoma [12–17], and some of the decline in risk seen in earlier studies [15, 18–25] and among men under 50 years old in the UK [26], may well be attributed to this factor.

Amazingly, levels of the well-known adenocarcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) [27] were actually increased [4], as were levels of N-nitrosornicotine.

Three other important things happened. The cigarette was rendered more elastic, i.e. it facilitated compensatory smoking. It was also made easier to smoke and to learn to smoke. It seems likely that it also became more efficiently addictive. The role of additives is also an important feature of modern cigarettes.

Compensatory smoking has been well documented since the mid 1970s [28, 29]. It may have always been a feature of cigarette smoking, but knowledge of smoking patterns before ventilated filters were introduced in 1970 is scarce [3], at least in the public arena. It is an important observation that smokers vary considerably in their nicotine needs, many taking relatively low doses, as measured by saliva cotinine, while others take very high doses, although the average dose taken is much the same regardless of the machine-measured yield [28, 30]. A variety of techniques have been used to reduce machine-measured tar and nicotine yields while at the same time making it easier for the smoker to obtain higher doses of nicotine, which brings higher doses of carcinogens and toxins in their wake. Where machine yields vary widely between 0.1 and 1.7 mg per cigarette [4], actual nicotine contained in the cigarette rod (USA) varies only between 7.3 and 13.4 mg [31]. Some brands yielding 0.1 mg by machine contained between 8.7 and 11.2 mg in the rod.

The techniques used by smokers to compensate include increasing puff volume and frequency, to which can be added filter vent blocking by lips or fingers in cigarettes with ventilated filters, and increasing the number of cigarettes smoked. The techniques used by industry to reduce machine-measured yields include decreasing cigarette length, increasing burn rate, filter efficiency and air dilution, decreasing tobacco density and careful tobacco blending [32].

Techniques for increasing ‘smoothness’ [2] include two-stage blending of tobacco, puffing tobacco, humectants, flavourants, filtration and paper specifications. The term smoothness is used as a summary of changes in attributes of ‘after taste, bitterness, mouth sensation and throat scratch’. Remarkably, Camel was re-engineered in the direction of smoothness simultaneously with a marketing campaign using Joe Camel, the ‘smooth character’, during which time its market share among 18-year-olds went from 2.5% to 14%. Filter ventilation also acts to make cigarettes taste lighter [3].

Nicotine is addictive but may be made more or less so by use of chemical manipulations that increase ‘free’ or unprotonated nicotine. One of these is the use of ammonia technology, which increases pH and hence free nicotine levels, leading to quicker absorption and a better ‘kick’ [33]. Other additives have nicotine-enhancing effects. Modern cigarettes may therefore be more efficiently addictive than those of several decades ago.

The roles of the 600-odd additives which are used in modern cigarettes are many and varied [33]. They move from softening harsh impacts, to adding flavour, to bronchodilation, to enhancing nicotine effects. Some, such as acetaldehyde, are carcinogenic. They contribute to making it easier to smoke and to learn to smoke.

It is clear from this material that the modern cigarette is a highly efficient nicotine-delivery device, but is unnecessarily carcinogenic and toxic. It is equally clear that the product should be regulated and that consideration should be given now to how this should be done.

Where next?

The next step is towards regulation of the cigarette itself. This involves a political process, a route that has been tried in the USA [34] but has not succeeded. The EU has begun such a process, some of which is under challenge in the courts. The process may uniquely, involve some coherence between tobacco industry and public health objectives as the industry clearly wants a stable environment and will make some concessions to achieve it; to the extent that Philip Morris (Altria) is calling for regulation [35]. Their Web site lists the following issues: “youth smoking prevention; ingredient and constituent testing and disclosure; text of health warnings on cigarette packages and in advertisements; consistent use of brand descriptors such as ‘light’ and ‘ultra light’; good manufacturing practices for cigarettes; and standards for defining, and for the responsible marketing of any, reduced-risk cigarettes”.

The public health reasons for regulation would include most of these issues, but are somewhat different. They include the need to provide the consumer with the minimum-risk cigarette; one that is correctly labelled, provides a dose of nicotine that is as consistent as possible and carries the lowest possible dose of carcinogens and toxins in its wake.

Some fundamental questions arise here.

- Should limits for carcinogens and toxins be set as low as possible? Can it possibly be justified to add, or allow, higher levels of carcinogens for ‘flavour’ or other purposes?
- The real purpose of the cigarette is to deliver nicotine. It is proven as the fastest (and most addictive) nicotine-delivery system yet known [36]. Should the dose per cigarette be standardised as far as is practicable?
- Should the nicotine dose be ‘satisfying’ without the need for deep and frequent inhalation, which brings with it a larger dose of contaminants?
- If a ‘satisfying’ dose is to be delivered, how should this be measured for regulatory purposes?
- How should the dose be measured (and communicated) for consumer purposes?
- Should additives be allowed without testing for toxicity in both burnt and unburnt form?
- Should each additive be justified on public health grounds?
Abolition of such items as ventilated filters would make compensation more difficult. Is there any reason not to do this?

Should standards be set for filters?

Should standards be set for papers?

It should be recognised that the public health sector lacks laboratories and a solid research base, and also that the manufacturers have more expertise than anyone else. However, this is true of many pharmaceutical products and is no barrier to regulation, which is generally based on the premise that the onus of proof of safety and efficacy lies with the manufacturer. It is therefore not a reason for accepting the status quo. It should also be possible to devise a public health oriented regulatory process which allows the tobacco industry to profitably make cigarettes in a shrinking market. In the long term, it is indeed desirable that the cigarette should lose its place as the preferred source of recreational nicotine, but that time has not yet come.

Measurement

The first response must be to abandon the FTC testing system with all its unintended and misplaced incentives for product modification of the wrong sort. However, since a testing system is needed for regulatory purposes, we propose that it should be replaced with a two-stage test [37] which would provide a nicotine-yield figure that takes into account the degree of compensation likely to occur with the cigarette in question. The second stage of this test would use machine settings which are based on the nicotine yield under FTC conditions, so that a cigarette yielding (FTC) 0.5 mg would be smoked with 60 ml puffs every 40 s, thus simulating the potential compensatory response of the smoker. A cigarette yielding 0.1 mg (FTC) would be smoked with 76 ml puffs every 24 s. The results of the second-stage test could be used for both regulatory and communication purposes.

While the exact parameters of the second-stage test are open to debate, and would need changing if ventilated filters were abolished, the principle of modelling compensation is an essential feature of any future testing system. Further, it is not necessary to wait for global agreement to such a system, any organisation is entitled to carry out and publish its own testing.

Control of carcinogens and toxins

Mainstream smoke contains approximately 4800 [4] constituents, among which Hoffmann and Hoffmann [4] have listed 48 ‘major’ constituents of the vapour phase of cigarette smoke, 51 major constituents of the particulate phase, 13 major toxins and 69 carcinogens. In 1999, the USA tobacco industry performed a ‘benchmark study’ for the Massachusetts Department of Public Health in which 43 smoke constituents were tested [38], these being the ones most widely considered of major consequence. It should be noted that these tests were done using increased puff volumes and frequency, but not using a truly compensatory test as is suggested here.

Very little data exists in the public arena concerning smoke emissions of known brands. However, there is evidence of serious variation in nitrosamines between and within three major global brands [5] varying from three-fold within Camel to nine-fold within Marlboro for a single nitrosamine, NNK. Further, an analysis of the Massachusetts benchmark study [6] revealed variations between 26 selected USA brands of seven-fold for benzo[a]pyrene, eight-fold for lead, 10-fold for arsenic and four-fold for NNK. Such a degree of variation may be perceived as inevitable in a market of 1100 or so brands, but is unacceptable in any sense for public health.

The obvious regulatory response must be to reduce all the selected list of carcinogens and toxins as far as is possible. If the median of the market, as revealed by those 26 brands (considering 34 substances), were set as the upper limit, then only one brand out of the 26 would survive the regulatory blow unscathed [5]. If one brand can be manufactured to meet these criteria, more can clearly be made to do so if required. This approach would incommodate the tobacco industry greatly in the short term, but could be regarded as generous by the public health establishment. The key point is that it is possible, is therefore reasonable and should be accepted. Since this matter is urgent, 2 years ought to be enough for the changes to be made. Later, the process should be repeated more selectively as expertise is built. There is, incidentally, no need for further research before implementing this set of standards—the sample results already in the public arena show what is possible, and that is all that is needed. This approach would work with whatever testing parameters are agreed upon.

Compensation

If the consumer is to receive a standard dose, and to know this, the cigarette has to be re-designed so that compensation is difficult. Abolition of ventilated filters would be a starting point. Approving a relatively small number of filter types and paper specifications, as well as standardising the length of the cigarette, would simplify the problem.

Nicotine

There is, at present, a need for cigarettes delivering low, medium and high doses. This might mean nicotine doses in the rod of between 8 and 13 mg as at present. This could be shown on the packet. Once elasticity is reduced, there would actually be low-, medium- and high-yield cigarettes on the market, and the consumer would know better what is actually being delivered.

In the longer term the question of whether nicotine dose should be progressively reduced in an attempt to reduce addictiveness [39] has to be addressed.

Additives

To regulate additives is likely to interfere in market shares, addictiveness, ease of smoking and, indeed, the whole commercial structure of the industry. This is nevertheless an issue that must be faced and dealt with. A requirement for justification of
every additive with the onus of proof-of-benefit, and the require-
ment to establish safety when burnt, on the manufacturer would
appear to be the minimum. The EU already has legislation along
these lines [40]. Additives that influence nicotine bioavailability
are not acceptable. A small number of taste and harshness modi-
fiers would be acceptable.

Labelling

Labelling cigarettes with the nicotine dose, if it can be done with-
out being misleading, would be appropriate. Existing health warn-
ings as in Australia or Canada would continue to be appropriate.
Carcinogen dose probably need not be on the label as upper limits
would be set, but their presence should be part of the health warn-
ing. Descriptors such as ‘light’ should be forbidden (again the EU
has such legislation, currently under court challenge). Although
this article deals with control of the cigarette, generic packaging
is a major policy objective for other reasons [41].

Research

No such regulation, as proposed here in principle, can be applied
without good laboratory and observational research backup.
There is little doubt that a relatively non-elastic cigarette could be
produced but the industry knows best how to do this. Discussions
between regulators, their advisers, and representatives from
industry would be unavoidable. If, by some miracle, goodwill
could be achieved, then a cigarette that is less dangerous would be
a possibility at an earlier time, but it remains a possibility as soon
as regulatory powers are obtained, assuming regulation is applied
as we propose.

Conclusion

Regulation is inevitable at some stage and it is now time to be
prepared. It would be another tragedy if the tobacco industry were
to achieve the regulation it wants without a viable and preferably
united public health view being influential. Similar regulation
should also be applied to smokeless tobacco products. In the
meantime, and while waiting for regulation, the public health
community should do all it can to test, and inform consumers
about the risks of, current products. For the foreseeable future,
the information for consumers will remain that there is not an
equilibrium to establish safety when burnt, on the manufacturer would
appear to be the minimum. The EU already has legislation along
these lines [40]. Additives that influence nicotine bioavailability
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Acknowledgements

This work was conducted within the framework of support from the Associ-
azione Italiana per la Ricerca sul Cancro (Italian Association for Cancer
Research).

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