ABSTRACTS OF PRESENTATIONS MADE AT THE 2010 CORESTA CONGRESS IN EDINBURGH, SCOTLAND PLENARY SESSION

Invited Speakers

ASHLEY D.L.

CORESTA Congress, Edinburgh, 2010, Plenary Session, Invited Paper 1

The role of science in achieving the public health goals of tobacco product regulation.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law by President Obama on June 22, 2009. It created the Center for Tobacco Products (CTP) as part of the U.S. Food and Drug Administration. Under the statute, CTP is given a broad range of authorities to protect the public health through the regulation of tobacco products. CTP is the primary Federal regulatory authority regarding the manufacture, marketing, distribution, and sale of tobacco products. CTP's goals are to prevent youth tobacco use, help those who use tobacco to quit, promote public understanding of the contents and consequences of use of tobacco products, develop the science base to regulate tobacco products in order to reduce the toll of tobacco-related disease, disability, and death. Because the goal of the Tobacco Control Act is to improve public health, the status quo, in which millions of people worldwide die each year from tobacco use, cannot continue. The cost in medical care and lost productivity and the pain and suffering of tobacco users and their families is unacceptable and preventable.

The Office of Science at CTP is responsible for identifying, developing, and applying the science that informs and supports regulation of tobacco products in a manner that will have the greatest impact on improving public health. In fact, several authorities in the Tobacco Control Act specifically govern the scientific review and regulation of tobacco products. For example, FDA is authorized to establish tobacco product standards that are appropriate for the protection of public health. The statute provides broad authority to develop standards regarding many provisions including additives, smoke constituents, and other properties of the tobacco product.

Traditionally, tobacco product smoke constituents have been tested in a manner that, because of cigarette engineering changes, did not correctly refl ect risk to the user or public health outcomes. Limiting analysis to only a few constituents measured under conditions of minimal use provided information to consumers that gave false perceptions of lower risk. CTP will have the opportunity to change this paradigm because the Tobacco Control Act grants FDA authority to require testing, reporting, and public disclosure of information in a manner that clearly and accurately communicates the harmful and potentially harmful constituents of tobacco products.

New tobacco products, unless they are substantially equivalent to certain previously marketed products, will require premarket review of complete applications by CTP, including full reports from investigations into the health risks of the products. New tobacco products must meet a public health standard before they are marketed.

Premarket review is required for tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease when compared to commercially marketed tobacco products. These "modified risk tobacco products" will be evaluated for their impact on both individual and population risk. Because of previous experiences with public misconceptions of modified-risk claims, substantial scientific evidence will be required to support approval.

In implementing these and other provisions of the Tobacco Control Act, we will consider the potential benefit to the public health, including both users and not-users of tobacco products. This will be our measure of success. The application of a public health standard into a venue in which people are dying daily means that morbidity and mortality must decrease. Every effort will be focused on preventing this outcome.

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BALLIN S.D.

CORESTA Congress, Edinburgh, 2010, Plenary Session, Invited Paper 2

"Toto, I have a feeling we're not in Kansas anymore" (The Wizard of Oz)

Tobacco, nicotine and alternative products in the 21st century - opportunities for reducing the harm caused by tobacco.

The days of the 'tobacco wars' as we have known them over the last 40 years have dramatically changed even though many in tobacco control and the tobacco industry still prefer to keep those 'wars' going. Unfortunately, such thinking may in fact be doing more public health harm than good. In today's environment it is the science that must now be driving the policy and regulatory decisions rather than emotion and rhetoric. But it is also how that science is discussed and used that will be tantamount to determining whether the policies and regulations are, or will be effective in reducing disease and death caused by the use of tobacco. The past misuse and abuse of the science by the tobacco industry must come to an end, if any progress is to be forthcoming. Similarly those engaged in public health, and in tobacco control must recognize that they cannot use science merely as a public relations tool -- using it when it's convenient and ignoring it when it is not. Many highly respected public health authorities have stated that harm reduction, if done carefully, can be a viable and effective strategy for reducing disease caused by tobacco. Thus it is no longer a question of whether harm reduction strategies should be discussed and implemented but more importantly how. The issues surrounding tobacco, nicotine and alternative products are becoming increasingly complex and are rapidly changing the discussions between and amongst many of the various stakeholders. Harm reduction isn't just about tobacco (i.e. cigarettes vs. smokeless tobacco), it is also about a growing spectrum of other products that are appearing on the market and which along with tobacco should be evaluated based on their risks and relative risks, and their potential for helping reduce disease and death caused by tobacco. All parties including public health and tobacco control advocates, tobacco manufacturers, pharmaceutical companies, researchers, and governmental agencies must be willing to accept that this is a "new era".

In addition to reviewing some of the past history, that has fostered and perpetuated a climate of distrust and animosity, this presentation will outline some of the major challenges, barriers but more importantly the opportunities for moving forward and changing the way in which we deal with the development and regulation of tobacco, nicotine and other alternative products. It will also focus on how we can establish ongoing dialogues in both the public and private sectors to promote a dialogue that will allow for the transparent and honest discussion of issues without compromising goals and objectives.

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Intergroup Papers

VERRIER J-L.(1); WIERNIK A.(2); STAAF M.(2); ONILLON M.(1); LAURENT T.(1)

CORESTA Congress, Edinburgh, 2010, Plenary Session, abstr. IG01

TSNA accumulation during post-cure storage of air-cured tobacco: Results of a 2009 experiment.

In Burley and dark tobacco, tobacco specific nitrosamines (TSNA) are formed during air-curing. A further accumulation may occur post-cure, before threshing and re-drying. The experiment reported here investigates this post-cure accumulation in leaves from the Dark Malawi Western, and the Burley ITB 573, produced at Bergerac in 2009, stored in the following conditions:

- A: immediate threshing after end of cure (no re-drying). Strips and stems kept in boxes at 14 °C constant.
- B: same as A, basal part of the leaves (butts) removed before threshing,
- C: reference, baled whole leaves kept in the curing shed (av. temperature 8.5 °C).
- D: same as C, butts removed before baling,
- E: delayed taking down. Tobacco left hanging in the same shed as C,
- T10, T16, T20, T25, T32: baled whole leaves, stored at constant temperature, respectively 10, 16, 20, 25 and 32 °C.

Storage lasted 3 months, from November 2009 to January 2010.

TSNA concentrations before storage were less than 0.5 ppm in lamina and approximately 1 ppm in stems. After storage, average concentrations were higher than at the start in all treatments, varieties and organs. Consistent with previous experiments, the highest increases were found with the T32 and E treatments.

This involves NNK and NAT as well as NNN. In particular, NNK concentrations in stems showed a 4 fold increase with the T32 treatment.

Butt removal was associated with a slightly lower increase (statistically non significant). The treatment showing the more stability during storage was D, in which butts were removed and the average temperature was 8.5 °C. Results from T10 to T32 suggest that 3 month storage temperatures above 20 °C may produce a more than 2 fold increase, at least when the TSNA levels at the start of storage are low (<2 ppm).

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CORESTA Congress, Edinburgh, 2010, Plenary Session, abstr. IG01

The "attractiveness" and "addictiveness" of ingredients added to tobacco products.

The draft guidelines for the implementation of articles 9 and 10 of the WHO FCTC are expected to highlight attractiveness, addictiveness and toxicity as the key drivers for tobacco product regulation, with a focus on the role played by ingredients. In Europe, DG SANCO has requested a scientific opinion on "the addictiveness and attractiveness of tobacco additives" from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). While a common framework of understanding exists by which to examine changes in toxicity, the concepts of attractiveness and addictiveness are poorly-defined and so any possible influence on tobacco smoking remains unclear. Nevertheless it has been claimed that certain ingredients added to tobacco products "attract" individuals to use tobacco, are in themselves "addictive" or can enhance the "addictiveness" of nicotine. However, the alleged mechanisms by which attractiveness and addictiveness operate may be challenged. Moreover, if these claims were to be supported, the use of tobacco ingredients should be associated with (i) earlier/higher rates of initiation, (ii) increased/more intensive use of tobacco products and (iii) delayed/lower rates of cessation. A review of scientific studies which have examined these endpoints shows that, while gaps remain, there is no evidence to suggest that ingredients at levels currently used in tobacco products influence initiation, use or cessation. Without such *a priori* evidence, there is no apparent rationale for the WHO FCTC or DG SANCO to recommend the regulation of tobacco ingredients on the basis of their attractiveness or addictiveness.

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Prize Winner

PERFETTI T.A.(1); RODGMAN A.(2)

CORESTA Congress, Edinburgh, 2010, Plenary Session, Prize Winner

The complexity of tobacco and tobacco smoke.

Tobacco and tobacco smoke are both complex mixtures. We previously reported 8430 unique chemical components identified in these complex mixtures but two years later our updated number is 8877. Our previous number of 4992 identified tobacco components is now 5204; our previous number of 5311 identified tobacco smoke components is now 5679. An operational definition of a complex mixture is as follows: A complex mixture is a characterizable substance containing many chemical components (perhaps thousands) in inexact proportions. Detailed knowledge of the amount and type of each component within the substance is uncertain even with today's analytical technology. Although it has been estimated that as many as 100,000 components are present in these complex mixtures, their analyses of indicate that the vast majority of the mass of each of these complex mixtures accounts for the 8430 compounds reported previously. Over 98.7% of the mass of tobacco has been accounted for in terms of identified components in tobacco. Greater than 99% of the mass of whole smoke has been accounted for based on identified chemical components. Certainly, many more tobacco and tobacco smoke components are present in these complex mixtures but the total mass of these components obviously is quite small.

One of the significant challenges we face as a scientific community is addressing the problems of determining the risk potential of complex mixtures. Many issues are associated with toxicological testing of the complex mixture of tobacco smoke. Conducting valid experiments and interpreting the results of those experiments can be quite difficult. Not only is the test agent a complex mixture but also the tests are performed on species that have complicated life-processes. Interpretations of test results are often paradoxical. Significant progress has been made in the toxicological evaluations of complex mixtures in the last 80 years. The challenges we face in terms of testing the biological properties of tobacco smoke are substantial. The statement by DIPPLE et al. in their summary of the research on polycyclic aromatic hydrocarbons from the 1930s through 1980 is equally true today for the cigarette smoke situation:

> "… many important questions remain unanswered … many questions persist despite the considerable progress that has been made."

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