

Science to the Rescue

BY GEORGE GAY

Coresta's research should help counter misperceptions about e-cigarettes.

Just before I started to write this story, I was reading a piece by a U.S. health worker entitled: “Value, harm of e-cigs unsubstantiated.” The piece started with the usual claim that 480,000 people in the U.S. die each year from tobacco-related illnesses, and it then went on to ask, “Are electronic cigarettes or e-cigarettes safer than conventional cigarettes?” The writer said the U.S. Food and Drug Administration (FDA) had “tested two popular brands of e-cigarettes and found variable amounts of nicotine, a number of impurities and detectable levels of cancer-causing substances.” And she concluded that “the potential health risks are unknown.”



The writer then ended her piece with some advice, which I quote here in full: “The FDA recently announced that it will start to regulate e-cigarettes and, until more is known about the safety of e-cigs, it is probably best to avoid them. So, if you don’t smoke or ‘vape,’ don’t start. If you are trying to quit smoking and need assistance, talk with your health care provider. There are FDA-approved medications and smoking-cessation counseling [services] that are safe and effective in assisting you with kicking the habit.”

The writer is a registered nurse, so what she says might not carry the same weight as that of a health care professor associated with a university, at least in the eyes of academics. But her piece, which was published in the *Bismarck Tribune*, was not, I assume, aimed at academics. Rather it was aimed at grassroots smokers, so in that sense it carried a great deal of weight.

I think there are two major problems with the advice given. The first is that it plays on the fear that most people suffer when faced with the unknown. It is like a script from an old science fiction movie where the aliens land and are immediately blasted with nuclear weapons before there is time to find out whether they had come in peace, bearing and willing to share the knowledge of how to cure cancer. And it does this despite the reference point of 480,000 annual premature deaths having been laid at the feet of smoking, and without even taking a shot at comparing the dangerous compounds found in tobacco smoke with those found in the vapor from e-cigarettes.

The other major problem is the piece doesn’t address smokers—the majority of smokers, if I understand things correctly—who want to give up smoking and who have tried and failed even with the support of the sorts of services suggested by the writer.

It would be relatively easy to dismiss the nurse’s piece if it were the only such story doing the rounds, but it is one of

hundreds of tales spreading fear about alien products. The e-cigarette company Totally Wicked complained in January that a California Department of Public Health campaign had been written in such a way that it appeared to be designed to spread fear about e-cigarettes. The company said that it was saddened and dismayed at the extent of what appeared to be “a deliberate misinformation and smearing campaign against e-cigarettes.”

COUNTERING MISINFORMATION

It is difficult to know why misinformation is fed into the public domain, and I can only assume that it is a result of a mindset that calls for the nuclear option whenever faced with something unknown. So how can such a mindset be countered in order to stop the fear of alien invasion from convincing governments to load the nuclear codes, to help regulators make choices that don’t render e-cigarettes ineffectual and to prevent vulnerable smokers from being scared off? Well, for many people the answer lies in using good, science-based research to prove the relative safety of e-cigarettes and their efficacy in helping people to quit smoking. This is where the Cooperation Center for Scientific Research Relative to Tobacco (Coresta) has stepped up to the mark. For two years it has been assessing the research into e-cigarettes that has been carried out around the world, compiling standardized e-cigarette terminology, researching the analysis of e-liquids and e-cigarette aerosols, and devising a provisional recommended puffing regimen for the machine testing of these products.

This is encouraging because Coresta is a well-respected, noncommercial organization that is focused only on advancing scientific knowledge. It has well-established procedures for developing research methods, it is well-versed in the coordination of inter-laboratory studies to recommend analytical



methods, and it offers global interdisciplinary expertise encompassing different sectors.

The story began in January 2013 when Coresta's Scientific Commission decided to set up the E-Cigarette Task Force under the leadership of coordinator Dr. Charles Garner, senior director of the regulatory oversight group at Reynolds American Inc. Services Co. The task force's objectives were threefold:

1. To create a document on worldwide product definition and definitions of terms to support the harmonization of nomenclature
2. To gather and share preliminary data on analysis relevant to e-cigarettes worldwide with a view to making recommendations for product testing
3. To define the relevant categories of products for potential further Coresta studies

The task force, which includes representatives of e-cigarette companies, tobacco companies and contract laboratories, draws its membership of about 55 people from 45 organizations based in 15 countries in North America, Europe and Asia. It has held four meetings, including one during Coresta's biennial Congress in Quebec, Canada, in October 2014. The next meeting is scheduled for June 10 in Toronto, Ontario, Canada.

In its review of e-cigarette literature, which sought to uncover work directed at the methods for, and the results of, the analysis of e-liquids, mainstream aerosol and environmental emissions, the task force discovered 55 sources comprising peer-reviewed articles, presentations and commercial product analysis reports. Articles were reviewed for their contributions to several priority areas, including: smoking regimes, topography, analytes, reporting units, analytical methods, device design, and reference products or materials.

In addition, the task force undertook e-liquid and aerosol studies. As part of the former, it sought to determine the consistency of the results obtained by nine laboratories using their own methods for the analysis of the same set of 11 e-liquid samples, including a study control, in respect of nicotine, glycerin, propylene glycol and water. The laboratory results were said to have shown a high degree of accuracy and precision.

Meanwhile, in respect of e-cigarette aerosols, the task force sought to determine the consistency of results between laboratories using the same puffing regimen and their own methods for analysis. Four laboratories conducted a puffing parameters evaluation that ended by recommending, in May 2014, a 55 ml puff

volume, three second puff duration, a 30 second puff interval and square wave puff profile. These parameters were then evaluated by 14 laboratories that tested the same eight samples for nicotine, glycerin, propylene glycol, water and total yield, using the recommended puffing parameters. The results across most laboratories were said to be "very consistent."

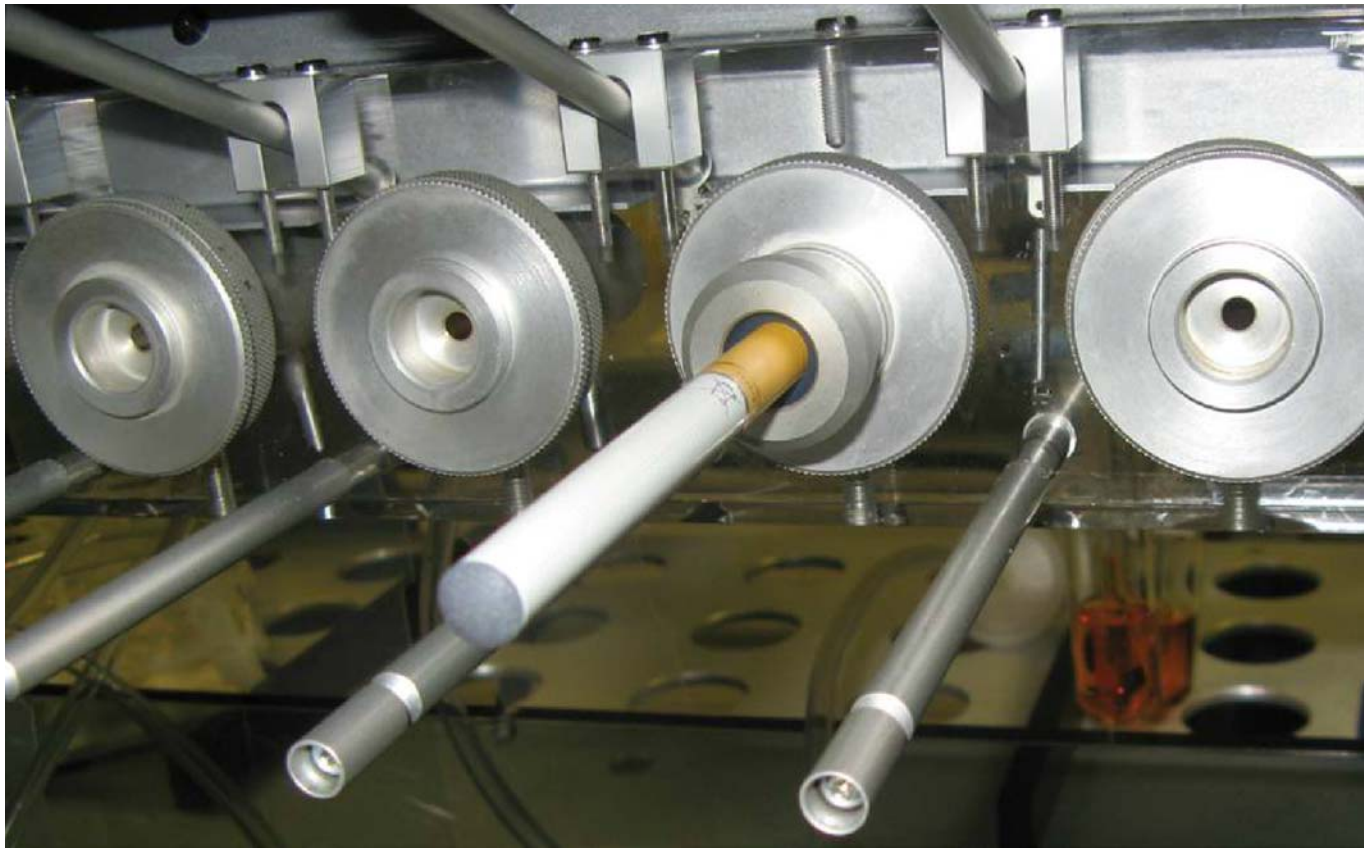
NEXT STEPS

So now, with the work of its task force more or less complete, the question arises as to where Coresta goes from here, a question that, among other matters, Coresta's Scientific Commission met to discuss during the week starting Jan. 19. The issue is involved because the task force was set up to make recommendations about developing official Recommended Methods but not to develop them. Developing such methods would be the job of either the Product Testing Methods subgroup or the Routine Analytical Chemistry subgroup, but, for the time being, e-cigarette expertise remains in the hands of the task force. So a final decision on the future of the task force had not been taken by the time of this writing, though more should be known by mid-February (after publication of this article), by which time the commission will have presented its work sharing recommendations to the Coresta board.

What seems not to be in doubt is that Coresta will continue its work on e-cigarettes. After all, interest in e-cigarettes is huge, and while Coresta is a scientific body, it is one that focuses its science on what is happening in the real world. For instance, as is suggested above, Coresta might want to develop a Recommended Method for machine vaping of e-cigarettes, a process that, as Garner explained, would require further, more-formalized work than has been done to date, with testing across multiple laboratories using a more rigorous test protocol and recognized statistical evaluation of the results. The work involved would be extensive and more complex than in the case of combustible cigarettes because e-cigarettes tend to be more variable, and they require an activation period during which the heater warms to the point where the liquid is vaporized.

It might want also to test a wider range of e-cigarettes than those that were tested by the task force, which included only various cigalike products. And it might want to develop specific methods for the analysis of other compounds in aerosols.

Another project might look at how the results of standard testing methods should be expressed. Should the results be based on 10 puffs, which would roughly align the testing of e-cigarettes with those of traditional cigarettes? Or would it be better to test e-cigarettes to exhaustion—up to 400 puffs in some cases, perhaps? ►



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WIDER COMMUNITY

One complicating factor that the commission will have had to have considered is that other organizations are looking at developing methods for the evaluation of e-liquids and e-cigarettes. As I understand it, the International Organization for Standardization (ISO) has made a proposal to set up methodologies for the evaluation of nicotine in e-liquids. And CEN, the European Committee for Standardization, has proposed setting up a new technical committee on e-cigarettes and e-liquids with the aim of developing European standards dealing with safety aspects for both e-cigarettes and e-liquids, as well as analytical methods that provide a basis for the determination and quantification of all chemical components stated in the requirements of the revised EU Tobacco Products Directive.

But such work need not cause Coresta to retreat. Coresta doesn't do this sort of work solely on behalf of itself or its members, and it is keen to make the results of its research available to any interested parties. The organization has been looking for some time at widening its membership to include more regulatory and other bodies, and it has had some success in attracting such representation to its meetings. In the past, Coresta has had its methods validated and adopted by ISO for various test regimes for traditional cigarettes. And there is some commonality of membership in Coresta and CEN; so a number of companies that have input into Coresta would also have input into CEN.

The idea that Coresta is part of a wider community looking at e-cigarettes was made a number of times during a conversation

I had with Robert Burton, the director of corporate and regulatory affairs of White Cloud E-Cigarettes, which has taken part in the task force. Burton is keen that the task force talks to the regulators to explain what it has done, partly to prevent the wheel's being reinvented. And he wants the task force to approach the regulators in advance of new projects to find out what it needs to do to meet the objectives of the regulators.

One of the reasons why White Cloud had become involved in the task force, said Burton, was because it felt it was important to be part of a credible organization that approached things in a scientific way and that was developing the sorts of test regimes and standards that would potentially find their way into the regulatory authorities' methods of testing and measuring. If regulators set standards, e-cigarette companies needed methods for demonstrating they were meeting those standards, and those methods needed to be ones that were recognized by regulatory authorities, such as the FDA, as coming from a credible body.

Most of the experience with these products lay with industry itself, said Burton, but there was an opportunity for Coresta and the regulators to make sure that everybody was working toward a common goal—a public health benefit. “I'd rather work with the regulators than have the regulators regulate [e-cigarettes] out of existence,” he said. “E-cigarettes are the biggest public health opportunity to combat smoking that has come along since the [traditional] cigarette was invented. The last thing we want is for someone to come along and regulate them just because they think that no one else is doing anything about it.” **V**