

2013 HOUSE HUMAN SERVICES

HCR 3033

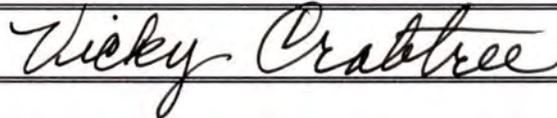
2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HCR 3033
February 25, 2013
Job #19452

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to Legislative Management to study opportunities to reduce the risk of death and disease among smokers who will not quit smoking.

Minutes:

See Testimonies #1-7

Vice-Chair Hofstad opened the hearing on HCR 3033.

Dr. Brad Rodu: Professor of the Dept. of Medicine introduced the bill. (See Testimony #1)

24:50

Rep. Laning: If nicotine isn't the bad actor in smoking, do you contribute any one thing in the smoke to cancer?

Dr. Rodu: When you burn any organic matter you create thousands of chemical agents. Many of those have been measured in smoke, and many are toxic. It is a matter of absorbing toxins over decades of puffing on cigarettes. No one has been able to specific which of those toxins leads to which disease. It is too complex a mixture to focus on specific diseases.

Rep. Laning: You reference E cigarettes and have been looking at some bills to outlaw smoking and E cigarettes. Is there a secondary danger to E cigarettes?

Dr. Rodu: I don't believe second hand vapor is a health risk. I do believe in the absence of a lot of education, North Dakotans seeing someone vaping inside doesn't know what that vapor will do. I see both sides of the issue. A vapor who wants to vapor in his motel room could vapor all day that there is no way to detect that. There is virtually no residual that is in any way toxic from that vapor.

Rep. Laning: Is there enough nicotine from a secondary point of view that could affect somebody?

Dr. Rodu: I can't imagine there is enough nicotine in the exhaled vapor to affect anyone else. The amount of nicotine in the vapor is rather small and can't see where it would affect anyone.

28:37

Rep. Fehr: You began as having no conflict of interest and you don't take any money from the tobacco industry. Is that what you are saying?

Dr. Rodu: The University of Louisville receives unrestricted grants and they benefit my research and support my activities in this area. The university pays my salary through those grants. I'd still have a job if they took the grants away. I can see where that would look a conflict of interest. My travel is supported by the Harland Institute. Joe Bass the president of Harland Institute likes this issue and understands it.

Rep. Fehr: Do you know of any relationship between the Harland Institute and tobacco companies?

Dr. Rodu: I know my relationship with the Harland Institute. They support my issue and that is all that matters to me.

Rep. Fehr: You used the term, "the failed anti-smoking campaign". Giving the quit smoking plan is a more comprehensive effort in terms of media, use of quit lines, nicotine substitutions, and more cognitive therapies. If we accept what you have said, how does your research fit into this more comprehensive plan?

Dr. Rodu: I think it fits beautifully. The current status quo emphasizes only abstinence. This idea says there are safer products that can satisfy your addiction without requiring you to quit everything. It can be an adjunct to all of the current programs. I don't see it as replacing any facet of what is already in existence. I'm only pointing out that what is already in existence isn't working well enough and my evidence of that is the 443,000 dead every year.

Rep. Fehr: You are saying this would fit into a counseling format of trying to get them to quit opposed to get them to move toward a quit smoking?

Dr. Rodu: I think the goal is to quit smoking. This does not emphasize abstinence this emphasizes a replacement rather than complete abstinence.

Rep. Mooney: How does the surgeon general weigh in on this?

Dr. Rodu: He and most medical organizations do not endorse tobacco harm reduction.

Rep. Mooney: Wouldn't we be opening ourselves up to liability?

Dr. Rodu: You may have misunderstood. I've never asked any government to endorse any product.

Rep. Mooney: This is how I interpret the bill, that this is a much better alternative than smoking. Is that right?

Dr. Rodu: You used the word better. Vastly safer.

Rep. Mooney: Some statistics may counter that.

Dr. Rodu: No statistics counter that.

Rep. Mooney: You are saying this is an alternative like nicotine patches or various drugs. Aren't we trying to inflect some form legislation into behavior?

Dr. Rodu: I'm not following you.

Rep. Mooney: We have all types of things that can be purchased so they don't smoke, why would we go towards any form of structured, I'm not understanding this.

Dr. Rodu: I think this calls for study. The purpose of the study is to understand what the risks and benefits are.

Rep. Mooney: Don't we already have professionals in place in ND to come up with that same information?

Dr. Rodu: I'm not intimately familiar with your state's tobacco resources.

Rep. Silbernagel: Do you recognize a risk to smokeless tobacco?

Dr. Rodu: Absolutely.

Rep. Silbernagel: Don't you feel that sending a mixed message on the safety of this product that the end result could be greater use of tobacco products in the long term? Have you done any research in that regard?

Dr. Rodu: Some indications from Sweden that show there is no increase in use from either smokeless tobacco or cigarettes. I don't think we have any evidence that this idea would drive an increase in all tobacco use.

Rep. Marvin E. Nelson: Testified in support of the bill. (See Testimony #2)

Rep. Fehr: Are you supporting or not supporting the resolution?

Rep. Nelson: I am supporting.

OPPOSITION

50:46

Erin Hill-Oban: Executive Director of Tobacco Free ND testified in opposition to the bill. (See Testimony #3)

55:15

Rep. Fehr: Do you know of any research that documents harm from long term use of E cigarettes?

Hill-Oban: I'm not aware of any.

Rep. Laning: You mentioned other groups embarking on what this bill is doing. Do you know if there is a timeline on results for those?

Hill-Oban: As early as April 2013.

Rep. Damschen: Do you think it would be better to keep smoking than trying these alternatives?

Hill-Oban: When harm reduction strategies haven't been proven to be safe or effective, I don't feel that tobacco free ND is going to suggest doing it.

Rep. Mooney: Do you see those as becoming a gateway drug?

Hill-Oban: I don't know.

Kimberlee Schneider: Testified in opposition. (See Testimony #4)

Jeanne Prom: Executive Director of ND Center for Tobacco Prevention and Control Policy. (See Testimony #5)

1:0

Rep. Fehr: If the study is funded, this would not duplicate what you are talking about, correct?

Prom: No it would not, but I feel it would duplicate unnecessarily the work of the USFDA and whatever the feds put into law trumps over state law.

Rep. Fehr: Could you explain what you mean by that?

Prom: But I believe if there is a federal law and system in place, it is a federal law that set up this agency to study tobacco and whatever they determine would take precedence over the state.

Rep. Damschen: Do you think it would be better for a person to keep smoking rather than use the alternatives?

Prom: There are well established health concerns about these products. Until it is proven that use of them would overcome any harm, which there isn't right now, we could not support them.

Rep. Fehr: You said there is research that documents the harm from E cigarette use?

Prom: No, I didn't mean to say that.

Rep. Fehr: You don't know of any research that says of any harm these products do?

Prom: E cigarettes have not been determined as safe or not by the FDA at this point.

Rep. Fehr: You don't know of any other research from any other entity?

Prom: I do not have that with me today.

1:06:39

Ken Tuba: With the American Cancer Society Cancer Action Network handed out Testimony for Deb Knuth (See Testimony #6)

1:08:57

Rep. Fehr: E-cigarettes are not included?

Tuba: You are referring to attachment to the testimony? I believe most of that is in reference to smokeless tobacco products and not the E cigarettes.

1:10

Jack MacDonald: Society of Respiratory Therapists representative testified in opposition. He felt Dr. Rodu was representing tobacco companies.

Vice-Chair Hofstad closed the hearing on HCR 3033.

Handed in Testimony

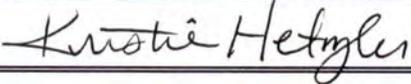
Dr. Jim Hughes: From St. Alexius Heart and Lung Clinic is in opposition of the bill. (See Testimony #7)

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HCR 3033
March 11, 2013
Job 19732

Conference Committee



Explanation or reason for introduction of bill/resolution:

Relating to Legislative Management to study opportunities to reduce the risk of death and disease among smokers who will not quit smoking.

Minutes:



Chairman Weisz: Called the committee back to order on HCR 3033.

Rep. Fehr: It would be such a change in policy that it would almost have to be a two-step procedure. The wording or terms in here would also need to be changed.

Rep. Mooney: We just listed to testimony on substance abuses of all types and to me this is just another way of fueling that. Makes a recommendation, Do Not Pass.

Rep. Laning: Second.

12-1-0

Carried by: Rep. Mooney

Date: 3-11-13
Roll Call Vote #: 1

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 3033

House Human Services Committee

Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: Do Pass Do Not Pass Amended Adopt Amendment
 Rerefer to Appropriations Reconsider

Motion Made By Rep. Mooney Seconded By Rep. Laning

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ			REP. MOONEY		
VICE-CHAIRMAN HOFSTAD			REP. MUSCHA		
REP. ANDERSON			REP. OVERSEN		
REP. DAMSCHEN					
REP. FEHR					
REP. KIEFERT					
REP. LANING					
REP. LOOYSEN					
REP. PORTER					
REP. SILBERNAGEL					

Total (Yes) 12 No 1

Absent 0

Floor Assignment Rep. Mooney

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HCR 3033: Human Services Committee (Rep. Weisz, Chairman) recommends DO NOT PASS (12 YEAS, 1 NAYS, 0 ABSENT AND NOT VOTING). HCR 3033 was placed on the Eleventh order on the calendar.

2013 SENATE HUMAN SERVICES

HCR 3033

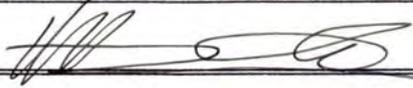
2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

HCR 3033
4/2/13
20765

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

A concurrent resolution directing the Legislative Management to study opportunities to reduce the risk of death and disease among smokers who will not quit smoking, by considering tobacco harm reduction strategies that encourage smokers to switch from cigarettes to less risky tobacco products and by accurately informing the public of the health risks posed by smokeless tobacco products, vapor products, and tobacco-derived products relative to cigarettes

Minutes:

"Attached testimony."

Chairwoman J. Lee opens the public Hearing for HCR 3033

Rep. Blair Thorsten introduces HCR 3033 to the committee. Provides information to the committee **See attachment #1**. **Chairwoman J. Lee** asks if this is a mandatory study. **Chairwoman J. Lee** asks how the State of North Dakota be involved in the study. **Senator Dever** questions about further action. **Chairwoman J Lee** asks about the timing of the bill and the tobacco co. **Senator Larsen** asks for clarification on information provided by Rep. Blair.

Brad Rodu Professor with Department of Medicine James Graham Brown Cancer Center University of Louisville. He was asked to speak by Rep. Blair Thorsten. The research provided is supported by unrestricted grants, from tobacco manufactures to the University of Louisville. The university administers those grants primarily to protect the integrity of the research and the researcher. Mr. Rodu states that he no conflict of interest with respect of these issues, lives on university professors' salary and retire on university professors' pension. See attached **testimony #2**. Testifies in favor of HCR 3033. **Senator Axness** asks about the manufactures of smokeless tobacco and cigarettes and if they are the same. **Senator Larsen** asks about the average life span of an average male and female, and asks for clarification on those on life expectancy of smokeless tobacco.

Nather Marrium chair of the Tobacco Prevention and Control Advisory. Testifies in opposition for HCR 3033. **Senator Dever** talks about the study informing public of health risks and asks if that would be useful. **See attached testimony #3**

Narther Marrium reads the testimony of **Dr. Jim Hughes** from St. Alexius Heart and lung clinic. **See attached testimony #4** 3200

Dr. Eric Johnson Associate Professor in the department of Family and Community Medicine at the UND School of Medicine, a physician consultant for ND Quits, and the board president of Tobacco Free North Dakota. Testifies in opposition for HB 3033. **See attached testimony #5. Senator Larsen** asks about strokes and smoking, questions about medications that were pulled off the market. **Senator Larsen** asks about an oral inhaler and the difference between an E-cigarettes. **Senator Larsen** talks about methadone clinics helping those with addition, 'wouldn't this study be the same. **Senator Dever** asks if FDA has not approved it have they disapproved it. **Senator Dever** asks about Dr. Johnson concerns with study. **Senator Larsen** inquires about not approved FDA, and holistic treatments. **Chairwoman j lee** asks if tobacco is regulated by the federal government. **Senator Axness** asks about the warning on chewing tobacco products.

Jacob Sommerfel, a senior at Century High School, Bismarck ND and a member of SADD, Students against Destructive Decision. Testifies in opposition of HCR 3033, see attached **testimony #6 Chairwoman J. Lee** talks about chewing tobacco. **Senator Larsen** asks how much a can of chew is, and how much is an e-cigarette. **Mandy Jordan with SADD is recognized. Senator Dever** asks the age of buying E-cigarettes **Senator Larsen** asks about fellow students that are smoking and questions if they are changing to smokeless tobacco due to the new law. **Senator Dever** asks if the study revealed that it was harmful that it would be a good thing. **Jessica Paul form SADD is recognized Chairwoman J. Lee** makes a statement about SADD.

Deb Knuth American Cancer Society Cancer Action Network. Shares with the committee about the health risks of smokeless tobacco. Testifies in opposition to HCR 3033. **See attached testimony #7.**

Jack McDonald testifies on behalf of ND Society of Repertory therapists. Testifies in opposition HCR 3033. **Senator Axness** asks if E-cigarettes are allowed in buildings.

Courtney Koeble with ND Medical Association is in opposition to HCR 3033.

June Herman Regional Vice President of Advocacy for the American Heart Association. Testifies in Opposition to HCR3033. **See attached testimony #8**

Chairwoman J lee closes the public hearing on HCR 3033

Dr. Johnson is recognized

Chairwoman J lee asks Dr. Johnson about GI and stomach cancer. **Senator Larsen** asks about price of medications for quitting smoking in comparison of the E-cigarettes. There is a discussion about the cost of smoking.

There is a discussion about starting smoking, and young adults.

Chairwoman J. Lee closes the discussion HCR 3033

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

HCR 3033
4/2/2013
20781

Conference Committee

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution:

A concurrent resolution directing the Legislative Management to study opportunities to reduce the risk of death and disease among smokers who will not quit smoking, by considering tobacco harm reduction strategies that encourage smokers to switch from cigarettes to less risky tobacco products and by accurately informing the public of the health risks posed by smokeless tobacco products, vapor products, and tobacco-derived products relative to cigarettes

Minutes:

Chairwoman j. lee opens the discussion on HCR 3033

Senator Dever states that this is an optional study and does not see the harm in studying it.

Senator Axness discusses that the studies are not free and that the taxpayers shouldn't have to pay for the study. Shares his opinion that the tobacco industry that makes cigarettes is now trying to get study pushed to them off their smoke products on to their smokeless products.

Chairwoman J. Lee discusses about a visit to the CDC, legislators are not trained in science for the research, and the rules that come out of FDA.

Senator Anderson, Comfortable with or without the study. Discusses that the research is going to get done; someone else will do the research.

There is a discussion about the study and the results of the study.

Senator Dever motions for a Do Pass

Senator Larsen seconds

The committee discusses smoking and the risks.

Chairwoman J. Lee shares her opinion about tobacco.

There is discussion about other risky behaviors and amending it to the bill.

Do Pass 3-2-0

Senator Dever will carry.

REPORT OF STANDING COMMITTEE

HCR 3033: Human Services Committee (Sen. J. Lee, Chairman) recommends DO PASS
(3 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). HCR 3033 was placed on the
Fourteenth order on the calendar.

2013 TESTIMONY

HCR 3033



Human Services Committee

North Dakota House of Representatives

Tobacco Harm Reduction Strategies to Reduce Smoking-Attributable Death and Disease

Tuesday February 26, 2013

Prepared Testimony By:

**Brad Rodu, DDS
Professor
Endowed Chair, Tobacco Harm Reduction Research
School of Medicine
University of Louisville**

505 South Hancock Street, Room 208, Louisville, KY 40202
Phone: 502-852-7793; Fax: 502-852-7979; Email: brad.rodu@louisville.edu

Mr. Chairman and members of the committee, I am a professor of medicine, and I hold an endowed chair in tobacco harm reduction research at the University of Louisville. I am a board-certified oral and maxillofacial pathologist, and I was a faculty member at the University of Alabama Birmingham for 24 years. For the past 20 years, my research has focused on tobacco harm reduction, and I have published many studies in prestigious medical and scientific journals on this subject (1). Thank you for the opportunity to provide information about House Concurrent Resolution No. 3033.

Despite limited success, the nearly 50-year old American anti-smoking campaign has not helped sufficient numbers of adult smokers to quit. According to the CDC, smoking kills over 400,000 Americans every year, including almost 900 North Dakotans (2). These smokers were inveterate in the truest sense – they did not quit in time to avoid a deadly illness.

Most Americans understand that nicotine is addictive, but they don't realize that nicotine can be consumed about as safely as caffeine, another addictive drug enjoyed by millions of consumers (3). It is tobacco smoke that kills. Eliminate the smoke, and you eliminate virtually all the risk. This is the essence of harm reduction, which focuses on reducing disease and deaths, instead of eliminating tobacco and nicotine.

Smokeless tobacco has three attributes as a cigarette substitute. First, it delivers nicotine nearly as rapidly and as efficiently as smoking (4). Yes, it is just as addictive as smoking, which is why it is a great substitute.

Second, decades of medical research document that smokeless tobacco use is at least 98% safer than smoking (3, 4). While no tobacco product is absolutely safe, claims about smokeless tobacco risks are often exaggerated by tobacco prohibitionists who cherry-

pick scientific studies for obscure epidemiologic findings. They ignore the overwhelming scientific evidence of little or no risk from smokeless tobacco use. All health risks from smokeless tobacco, including that for oral cancer, are so low as to be barely measurable. Statistically, a consumer of smokeless tobacco has about the same risk of dying from its use as an automobile user has of dying in a car accident.

Third, there is population-level evidence that smokeless is an effective cigarette substitute. I have published a series of scientific studies proving that smokeless is an effective substitute for cigarettes among Swedish men (5,6,7), who for many years have had the lowest smoking rate and the highest rate of smokeless tobacco use in Europe. In fact, over the past 20 years, men in northern Sweden have had lower rates of smoking than women, a pattern different from that of every other society in the world. Other research from Sweden has confirmed my findings (8,9).

The consequences of the Swedish experience are impressive: Lung cancer – the sentinel disease of smoking – among Swedish men is the lowest of 20 European countries. Not so for Swedish women, whose lung cancer rate ranks fifth highest in Europe. In a 2009 study published in the *Scandinavian Journal of Public Health*, I estimated that 274,000 lives could be saved each year in the European Union if men in all EU countries had the smoking prevalence of Sweden (10).

In 2007, the Royal College of Physicians strongly encouraged governments to seriously consider harm reduction strategies to protect smokers (11). That report, which corroborates my position, "...demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of

lives could be saved.” In other words, smokers need harm reduction, and harm reduction needs effective and acceptable cigarette substitutes.

Critics dismiss tobacco harm reduction, instead telling smokers to use FDA-approved nicotine medicines. But research documents that they are successful only 7 percent of the time (12), because they are expensive and provide unsatisfying doses of nicotine.

Inveterate smokers need nicotine, and smoke-free tobacco products are effective cigarette substitutes because they satisfy smokers’ nicotine cravings.

Smokeless tobacco use is often portrayed as a potential problem for children, but this allegation is disingenuous. In North Dakota, tobacco products are not sold to children. Tobacco initiation by young people should be stopped in its tracks, but the relative safety of smokeless isn’t a children’s issue. The 15,500 North Dakotans who will die from smoking-related illnesses in the next 20 years are not children today; they are adults, 35 years and older. Preventing youth access to tobacco is vitally important, but that effort should never be used as a smokescreen to condemn smoking parents and grandparents to premature death.

Most American smokers are terribly misinformed about safer tobacco alternatives, and misperception is pervasive even among health professionals. I published a study showing that 8 of 10 health professional faculty at my university wrongly believe that oral cancer risk is higher for smokeless tobacco than for smoking (13), whereas the risk for smokeless is actually far lower.

In 2011 I launched the first-ever community quit-smoking program based on tobacco harm reduction in Owensboro, Kentucky (14). We informed smokers that they can

achieve nearly all the health benefits of abstinence by switching to smoke-free cigarette substitutes, including smokeless tobacco; snus and electronic cigarettes.

I encourage you to support House Concurrent Resolution No. 3033, which will explore ways to provide North Dakota smokers with accurate information about less-hazardous smoke-free tobacco products, thereby giving them the opportunity to lead longer and healthier lives.

Acknowledgment

My research is supported by unrestricted grants from tobacco manufacturers to the University of Louisville, and by matching funds from the Commonwealth of Kentucky Research Challenge Trust Fund. The terms of the grants assure that the grantors are unaware of the research projects and related activities, and thus have no scientific input or other influence with respect to design, analysis, interpretation or preparation of work products. I have no financial or other personal relationship with regard to any tobacco manufacturer.

Notes and References

1. Rodu B, Abridged Curriculum vitae available at:
<http://www.browncancercenter.org/patients-families/plan-your-visit/physicians-directory/?docId=1753>
2. Centers for Disease Control and Prevention. *Best Practices for Comprehensive Tobacco Control Programs—2007*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; October 2007. Available at: ftp://ftp.cdc.gov/pub/fda/fda/BestPractices_Complete.pdf

3. Rodu B, Godshall WT. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. *Harm Reduction Journal* 3: 37, 2006 (Open Access, available at <http://www.harmreductionjournal.com/content/pdf/1477-7517-3-37.pdf>)
4. Royal College of Physicians of London: Protecting Smokers, Saving Lives: The case for a Tobacco and Nicotine Authority, London, 2002. Available at: <http://bookshop.rcplondon.ac.uk/details.aspx?e=185>.
5. Rodu B, Stegmayr B, Nasic S, Asplund K: Impact of smokeless tobacco use on smoking in northern Sweden. *Journal of Internal Medicine* 252:398-404, 2002.
6. Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K: Evolving patterns of tobacco use in northern Sweden. *Journal of Internal Medicine* 253:660-665, 2003.
7. Stegmayr B, Eliasson M, Rodu B: The decline of smoking in northern Sweden. *Scandinavian Journal of Public Health* 33:321-324, 2005.
8. Furberg H, Lichtenstein P, Pedersen NL, Bulik C, Sullivan PF. Cigarettes and oral snuff use in Sweden: prevalence and transitions. *Addiction* 101: 1509-1515, 2006.
9. Ramstrom LM, Foulds J. Role of snus in initiation and cessation of tobacco smoking in Sweden. *Tobacco Control* 15: 210-214, 2006.
10. Rodu B, Cole P. Lung cancer mortality: comparing Sweden with other countries in the European Union. *Scandinavian Journal of Public Health* 37: 481-486, 2009.
11. Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal

College of Physicians. London: RCP, 2007. Available at:

<http://bookshop.rcplondon.ac.uk/details.aspx?e=234> .

12. Hughes JR, Shiffman S, Callas P, Zhang J. A meta-analysis of the efficacy of over-the-counter nicotine replacement. *Tobacco Control* 12: 21-27, 2003.
13. Peiper N, Stone R, van Zyl R, Rodu B. University faculty perceptions of the health risks related to cigarettes and smokeless tobacco. *Drug and Alcohol Review* 29: 121-130, 2010.
14. Switch and Quit Owensboro. Available at: www.switchandquitowensboro.org .

Tobacco Harm Reduction

Brad Rodu

Professor, Department of Medicine
James Graham Brown Cancer Center
University of Louisville

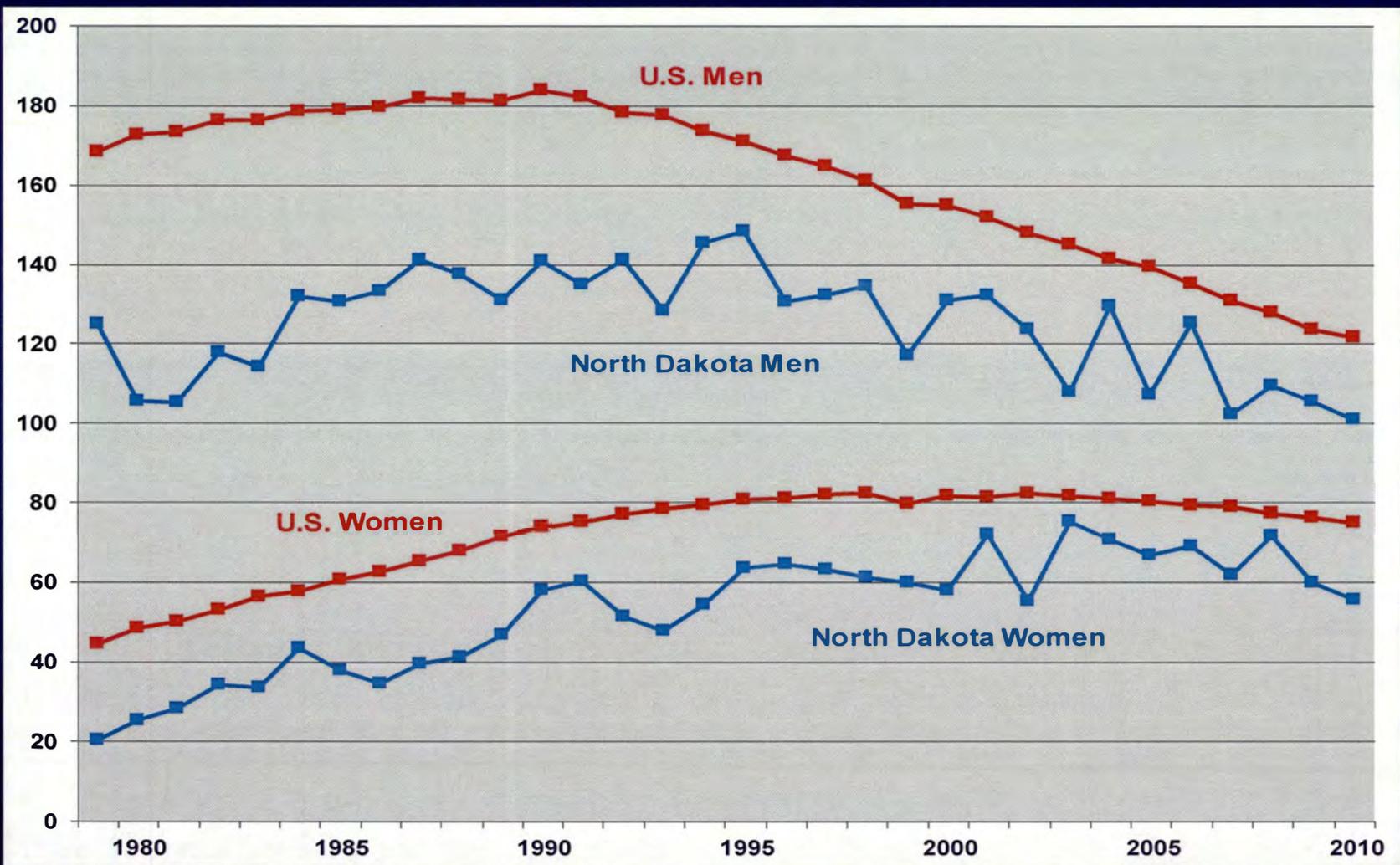
The Smoking Status Quo: Unacceptable

- **The American Anti-Smoking Campaign is
45 Years Old**

- **According to the CDC:
45 million smokers in the U.S.**

**443,000 deaths every year in the U.S.
880 in North Dakota**

Lung Cancer Mortality in Men and Women Age 35+ Years, North Dakota and the US, 1979-2010



If the Status Quo Continues

In the next 20 years:

- **8 million Americans will die from smoking**

All are adults over 35 years of age

None of them are now children

The Failed Anti-Smoking Campaign

- **The Campaign's Only Message:**

Quit Nicotine and Tobacco, or Die

- **The Campaign's Only Quitting Tactics:**

**Ineffective Behavioral Therapy
Ineffective Use of Nicotine**

Rodu and Cole. *Technology* 6: 17-21, 1999.

Rodu and Cole. *International J Cancer* 97: 804-806, 2002.

The Anti-Smoking Campaign- Behavioral Therapy

- NCI Manual for Physicians- Counsel Patients to:
 - "Keep your hands busy- doodle, knit, type a letter"
 - "Cut a drinking straw into cigarette-sized pieces and inhale air"
 - "Keep a daydream ready to go"

Source: How to help your patients stop smoking. NIH Pub. No. 93-3064,
1993

The Anti-Smoking Campaign- Faulted Use of Nicotine

- Temporary – 6 to 12 weeks
- Expensive – per unit and per box
- Very Low Dose – unsatisfying for smokers
- 7% Success* – "Efficacious", "Modest"

*Hughes et al. Meta-analysis in Tobacco Control, 2003.

Comparing Nicotine to Caffeine

Addictive Drugs Can Be Used Safely

Properties of Nicotine and Caffeine

Pleasurable Effects: Enhance concentration and performance
Provide a sense of well being
Elevate mood

Powerfully Addictive: Irreversible for many consumers

Can be Used Safely: Do not cause Cancer, Emphysema,
Heart Diseases

Delivery Systems: Caffeine- Coffee, tea, cola drinks
Nicotine- Smoke versus smokeless

Tobacco Harm Reduction Permanent Nicotine Maintenance

Smokeless Tobacco

- **Nicotine levels comparable to smoking**
- **Vastly safer than smoking (>98%)**
- **Evidence from Sweden – and the U.S. – that smokeless works**
- **Modern products are socially acceptable**

American Smokeless Tobacco



Moist Snuff



Chewing Tobacco

**Powdered
Dry Snuff**



Smokeless Tobacco Use is 98% Safer Than Smoking

- **No risk for emphysema, lung cancer, and heart disease**
- **Mouth cancer risk - Very low in absolute terms***

* 22 studies over 50 years: Rodu and Cole, Oral Surgery 2002.

Smokeless Tobacco and Health: Oral Cancer

Relative Risks

Smoking	~10
Alcohol Abuse	~4

American Smokeless Tobacco*

Chewing tobacco	1.2
Moist snuff	1.0
Powdered Dry Snuff	4.0

Incidence Rate in Long-term ST users (At RR=4):
26 per 100,000 person-years (py)**

* Over 20 epidemiologic studies, reviewed in: B Rodu, P Cole. Oral Surgery 93: 511-515, 2002.

**New England Journal of Medicine 304: 745-749, 1981.

Comparing Risks of Smokeless Tobacco, Automobiles and Cigarettes

Annual Death Rate from:

Powdered dry snuff¹ 12 per 100,000 users

Automobiles² 11 per 100,000 users

Cigarettes³ > 600 per 100,000 users

1. New England Journal of Medicine, 1981.

2. National Highway Traffic Safety Administration, 2009.

3. American Cancer Society data, 1999.

Smokeless Tobacco Has Worked For Swedish Men For 50 Years

- **High** rate of smokeless tobacco use.
- **Lowest** smoking rate in Europe.
- **Lowest** rate of lung cancer and other smoking-related diseases in Europe
- If EU men smoked at the rate of Swedish men, almost **274,000 lives** per year would be saved*

*B Rodu and P Cole. *Scandinavian Journal of Public Health*, 2009.

Tobacco Use in Northern Sweden

From J Int Med 2002; Scand J Pub Health 2005



Growing Discussion about Tobacco Harm Reduction

2002 Royal College of Physicians Report

”...[smokeless] tobacco...10 to 1,000 times less hazardous than smoking...some manufacturers want to market ST as a harm reduction option...may find support for that in the public health community”

2007 Royal College of Physicians Report

Smokers smoke predominantly for nicotine,...nicotine itself is not especially hazardous.

Harm reduction

- a fundamental component of many aspects of medicine and...everyday life...has not been applied to smoking.
- has the potential to save millions of lives, and deserves consideration.

Growing Discussion about Tobacco Harm Reduction

2006 *Addictive Behaviors*, NCI Funded

“...4 million [American] smokers would switch to the low-carcinogen smokeless tobacco.”

American Council on Science and Health

***Harm Reduction Journal*, 2006 and 2011**

”....there is a strong scientific and medical foundation for tobacco harm reduction, which shows great potential as a public health strategy to help millions of smokers.”

Tobacco Harm Reduction The Owensboro, KY Campaign

Dump the smoke.
But keep on lovin' the nicotine.

With cigarettes, it's the smoke that kills. Smoke-free products are proven to be the smarter and safer way to enjoy nicotine – and one of the most effective ways to quit cigarettes:

SwitchAndQuitOwensboro.org

* Reda and Phillips, Harm Reduction Journal 6: 10, 2008

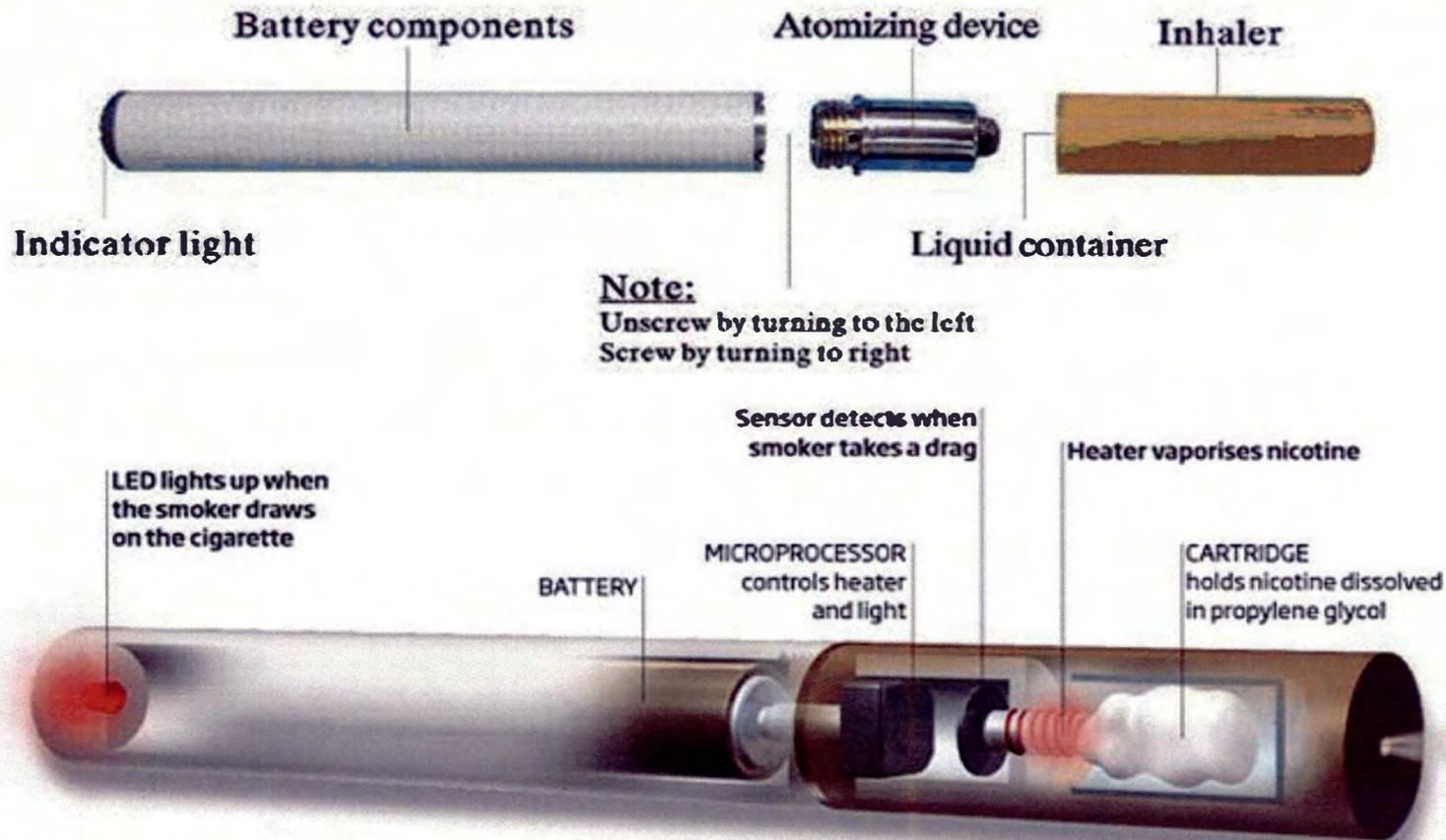


James Graham Brown Cancer Center

UNIVERSITY OF
LOUISVILLE



E-cigarettes



Smoke without fire

Suck on an e-cigarette and it produces a cloud of nicotine-carrying vapour with none of the toxic by-products of burning tobacco

Tobacco Harm Reduction: Moving Forward

- **Eliminate misinformation on state government web pages:**

”There are no studies available detailing what inhaling water vapor, propylene glycol, pure nicotine...will do to human lungs, heart or cardiovascular system.”

<http://www.ndhealth.gov/tobacco/Facts/E-cigs.pdf>

- **Don't "equalize" taxes on smokeless tobacco with those on cigarettes: it denies smokers affordable options**
- **Smokers who switch save essentially as many health care dollars as smokers who quit: state employees and Medicaid recipients**
- **Set insurance rates that don't penalize smokers who switch**

For More Information

www.smokersonly.org

Rodutobaccotruth.blogspot.com

www.SwitchandQuitOwensboro.org

BOARD OF TRUSTEES

February 26, 2013

To: Rep. Robin Weisz, Chairman, House Human Services Committee
Legislative Assembly of North Dakota

From: The American Council on Science and Health
Elizabeth M. Whelan, President

The American Council on Science and Health (ACSH), a consumer education and advocacy nonprofit devoted throughout our 35 year history to the promotion of sound science in public health policy, urges the Legislative Assembly of North Dakota to promote the benefits of Tobacco Harm Reduction (THR) in helping smokers quit and vote in favor of House Concurrent Resolution No. 3033.

Our own research on this subject, published in a peer-reviewed academic journal, as well as many others studies as well as epidemiological data, support our assertion that the methodologies comprising THR — the substitution of low-risk tobacco and nicotine-delivery products for lethal cigarettes — have significant potential benefits in terms of reducing the tragic toll of cigarette smoking by supplying addicted smokers with the substance they crave — nicotine — but at a much reduced cost in terms of adverse health effects.

While we are in full agreement that no form of tobacco use is entirely "safe" and that therefore all recreational tobacco use should be discouraged, it is still necessary to acknowledge the fact that there are 46 million addicted adult smokers in our nation — about 20% of the adult population. Further, while almost three-quarters wish to quit, and half of those do indeed attempt to quit each year, only one in ten (or fewer) succeed. Rarely, smokers quit without cessation aid — cold turkey — but the FDA-approved methods aimed at increasing quit rates (nicotine patches, Zyban, Chantix, etc.) have had an abysmal "success" rate around 15% or less at one year. Yet, these are the only methods touted by our public health authorities, who actively discourage consideration of newer, low-risk alternative cessation aids that have shown promise in helping addicted smokers quit. Now is the time to widely publicize the benefits of THR and make these products more readily available to those who desperately seek to quit smoking.

The established authorities' positions on using reduced risk products to deliver adequate nicotine levels to requite smokers' cravings and help them get off deadly cigarettes is based on long-held mistrust of and contempt for the tobacco companies — well-deserved feelings based on those companies' irresponsible and abusive behavior during the 20th

Nigel Bark, M.D.
Albert Einstein College of Medicine

Robert L. Brent, M.D., Ph.D., D.Sc. (Hon)
Thomas Jefferson University / A. I. duPont
Hospital for Children

Donald Drakeman, J.D., Ph.D.
Advent Ventures Life Sciences

James E. Enstrom, Ph.D., M.P.H.
University of California, Los Angeles

Thom Golab
Media Research Center

Herbert I. London, Ph.D.
New York University / Hudson Institute /
Manhattan Institute

Paul A. Offit, M.D.
Children's Hospital of Philadelphia

Fred L. Smith, Jr.
Competitive Enterprise Institute

Daniel T. Stein, M.D.
Albert Einstein College of Medicine

Elizabeth M. Whelan, Sc.D., M.P.H.
President, ACSH

FOUNDERS CIRCLE

Norman E. Borlaug, Ph.D.
(1914-2009)
(Years of Service to ACSH: 1978-2009)
Father of the iGreen Revolutioni
Nobel Laureate

Fredrick J. Stare, M.D., Ph.D.
(1910-2002)
(Years of Service to ACSH: 1978-2002)
Founder, Harvard Department of
Nutrition

ACSH STAFF

Margareta Becker, CPA
Accountant

Jonathan Bloom, Ph.D.
Director of Chemical and Pharmaceutical
Sciences

Judith D'Agostino
Executive Assistant to the President

Roya Heydari
Research Intern

Ruth Kava, Ph.D., R.D.
Senior Fellow in Nutrition

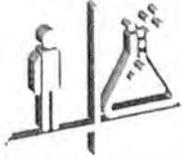
Cheryl Martin
Associate Director

William McCain
Development Associate

Derek Rose
Director of Publications

Gilbert Ross, M.D.
Executive and Medical Director

Ariel Savransky
Research Associate



AMERICAN COUNCIL ON SCIENCE AND HEALTH

1995 BROADWAY, 2ND FLOOR, NEW YORK, NY 10023-5860
TOLL FREE: (866) 905-2694 • TELEPHONE: (212) 362-7044 • FAX: (212) 362-4919
www.acsh.org • acsh@acsh.org

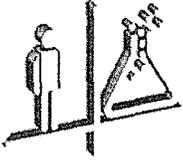
century. But in order to truly help addicted smokers quit, those biases must be put aside and the current facts must be dealt with.

America in the 21st century has developed stringent regulatory oversight over tobacco marketing. The clear (but slow) downward-trend in cigarette sales along with the irrefutable evidence of "the Swedish Experience" (Swedish men have shifted their tobacco use pattern from lethal cigarettes towards much safer "snus," smokeless tobacco), show that it is in tobacco companies' interests for them to market reduced risk products. The fact is that such a shift to reduced-risk products is also in the interests of public health. Further, the tobacco companies could not get away with the nefarious behaviors of the 20th century, even if they had such an inclination.

Those who support the concept of tobacco harm reduction, including ACSH, ask you to rely on the readily available scientific evidence to recommend policies promoting THR. This should include not only snus-type smokeless tobacco aimed at helping addicted smokers quit cigarettes, but also the newer products such as dissolvable tobacco and electronic-cigarettes (e-cigarettes): any product likely to be effective at helping addicted smokers quit cigarettes. We firmly believe that a comprehensive, objective investigation will help you see that the official policies of adhering to the official dogma: "there is no safe tobacco product, so abstinence is the only answer," amounts to a "quit or die" position, the status quo, with the ongoing toll of over 400,000 smoking-related deaths each year. This is no longer an acceptable position from a public health perspective, and we hope you will agree that a creative, flexible new approach is desperately needed, indeed long overdue.

Thank you for your consideration.

P.S. We are pleased to attach a copy of ACSH's peer-reviewed study "Helping Smoker's Quit: The Science Behind Tobacco Harm Reduction" for your consideration.



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1995 BROADWAY, 2ND FLOOR, NEW YORK, NY 10023-5860
TOLL FREE: (866) 905-2694 • TELEPHONE: (212) 362-7044 • FAX: (212) 362-4919
www.acsh.org • acsh@acsh.org

Supporting Studies:

Draft NICE guidance for harm reduction approaches to smoking

<http://www.rcplondon.ac.uk/press-releases/draft-nice-guidance-harm-reduction-approaches-smoking>

The emerging phenomenon of electronic cigarettes.

Caponnetto P, Campagna D, Papale G, Russo C, Polosa R.

<http://www.ncbi.nlm.nih.gov/pubmed/22283580>

Tobacco, nicotine and harm reduction.

Le Houezec J, McNeill A, Britton J.

<http://www.ncbi.nlm.nih.gov/pubmed/21375611>

Contrasting snus and NRT as methods to quit smoking. an observational study

Janne Scheffels 1, Karl E Lund, and Ann McNeill

<http://www.harmreductionjournal.com/content/9/1/10>

Death by regulation: the EU ban on low-risk oral tobacco

<http://www.clivebates.com/?p=434>

#2

Testimony of Representative Marvin E. Nelson House Human Services Committee 2/25/2013

HCR 3033

Mr. Chairman, members of the Committee, HCR 3033 is for the study of products that can be alternatives to tobacco smoking and the potential reduction in health hazards to current smokers. A significant reduction does seem to happen in Sweden. In Sweden, tobacco usage is similar to the rest of Europe, but deaths are significantly lower. This seems to be due to the usage of smokeless tobacco, commonly the moist Swedish product called snus. However, significant differences exist between Sweden and its snus and the United States. In Sweden, the use of additives is strictly regulated, snus is treated like a food product with regulations on both the additives and the methods of manufacture.

Such regulation is lacking in the US, so smokeless tobacco products are different than in Sweden, plus they are changing so it becomes difficult to make solid conclusions.

Similarly, vapor products are also subject to change.

As such, it then becomes very difficult to know exactly what the hazards are since the product line is not stable and the complex interaction of various additives can be changed.

There is also the problem of not letting any lesser danger be misconstrued and thus end up effectively encouraging the use of such products among nonsmokers. In such a situation, the products instead of reducing hazard could actually increase the danger to the public.

The potential of this is seen with the use of blackbull or iqmik (translates as "thing to put in mouth") among Alaskan natives. Blackbull is a mixture of a tobacco product, like Copenhagen, with punk. The punk is normally made from a tree fungus common on birch trees but can be made from other things like willow. While there is additional concern that the punk might interact to increase cancer risk, the fundamental thing is it is quite basic and thus increases the absorption of nicotine. They are freebasing tobacco.

So widespread is this that it is common in some areas for very young children to chew, some start when they are teething. In some parts of Alaska the majority of pregnant women chew blackbull. It is commonly felt that it is more natural and less hazardous than smoking, but it is worth noting that Alaskan natives have the highest rate of being smokers of any group in the United States. So this would be an important area to study. Is the hazard being reduced by their chewing, or is it helping to create the general situation of very high tobacco usage including smoking?

Historically, and today it has been common to see additives like lime or ashes added to chewing tobacco to do the same thing the fungus punk does in blackbull.

So any study of alternative tobacco products really has to be a study of not just tobacco but of tobacco additives and their effects.

***Harm Reduction Strategies for Mitigating Tobacco Risk
Current Recommended Guidelines and Resources for Tobacco Cessation***

Eric L. Johnson, M.D. & Jay Taylor

Chairman Weisz and members of the House Human Services Committee, my name is Erin Hill-Oban. I am the Executive Director of Tobacco Free North Dakota, a non-profit organization focused on education, advocacy and coalition building in support of tobacco prevention, cessation and control. Two members of our TFND Board, Jay Taylor and Dr. Eric L. Johnson have prepared the material I am sharing with you today. Mr. Taylor is a Health Tobacco Education Specialist for Sanford Health, and Dr. Johnson serves as our board president, is an Associate Professor in the department of Family and Community Medicine, and is a physician consultant for ND Quits.

Basic tobacco facts on which we can, and should, all agree:

- Cigarettes are proven and widely known to cause heart disease, stroke, and a number of cancers.
- Smokeless tobacco products, such as spit tobacco and snus, have different sets of health problems, including oral and gastrointestinal cancers.

[This is well-established information, and you may refer to the current U.S. Surgeon General's report, the Centers for Disease Control website, and Mayo Clinic's Nicotine Dependence Center website for a summary of the decades of research in these areas.]

Some brief information on **electronic cigarettes, or e-cigarettes/e-cigs**²:

- E -cigarettes, are battery-operated devices designed to look like regular tobacco cigarettes. Here's how they work: An atomizer heats a liquid containing nicotine, turning it into a vapor that can be inhaled and creating a vapor cloud that resembles cigarette smoke.
- Manufacturers claim that electronic cigarettes are a safe alternative to conventional cigarettes. The FDA, however, doesn't. Some e-cig manufactures have additional problems with the FDA, including five companies in 2010 cited for manufacturing violations.
- Text directly from the label of South Beach Smoke electronic cigarette: *"WARNING: South Beach Smoke products are not smoking cessation products and have not been tested as such. The U.S. FDA has not approved these products for any use and they are not intended to diagnose, cure, mitigate, treat, or prevent any disorder, disease, or physical or mental condition. South Beach Smoke products contain nicotine... [which] is addictive and habit forming, and it is very toxic by inhalation..."*

Harm reduction strategies, simply defined as "using smokeless tobacco to reduce cigarette use", are being proposed to "reduce the overall disease burden of tobacco".

- A considerable amount of harm reduction data, such as substituting smokeless tobacco or e-cigarettes for traditional cigarettes, comes from tobacco company funded research.
- No significant data exists proving that switching from cigarettes to smokeless tobacco products or to e-cigarettes actually leads to cessation.

AS A RESULT, HARM REDUCTION STRATEGIES ARE NOT U.S. FDA OR U.S. PUBLIC HEALTH SERVICE APPROVED STRATEGIES.

The FDA and U.S. Public Health Task Force have provided a number of **proven strategies and medications that are recommended by reputable smoking cessation programs**³. These guidelines include:

- Recommendation of nicotine replacement products such as patches, gum, and lozenges based on proven data for appropriate clients without the negative health consequences of tobacco products. As well, prescription medications such as Chantix and Bupropion are FDA-approved for smoking cessation, unlike e-cigs or substituting tobacco for tobacco. [See “Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation” handout for additional information]
- Counseling is a key component in successful tobacco cessation.
- Abstinence from tobacco is considered a best practice in guideline-based cessation programs. Medically, tobacco addiction is just like addictions to alcohol and other drugs. The cornerstone of all addiction treatment is abstinence, and that, too, is true for tobacco. We don’t tell alcoholics to drink less or that they’d be ok having a single instead of a double, and we don’t advise meth addicts to drink alcohol to get off meth.

North Dakota has many private and public entities – hospitals and ND Quits, North Dakota’s telephone and online quit program, among others – already rely on approved and best practice medical treatments for tobacco addiction, just as they would for the care of any medical condition⁴.

While we absolutely support reducing the harms of tobacco, we do so based on science. Should tobacco users be interested in reducing harms to themselves, there are countless proven, science-based, FDA-approved ways to help. We oppose this proposed study because the appropriate agencies to conduct such a study already exist, and that’s the FDA and U.S. Public Health Task Force. A large body of information already exists.

Contact:

Erin Hill-Oban, Executive Director
Tobacco Free North Dakota
212 N 2nd St
Bismarck, ND 58501
o: 701-223-5613
c: 701-527-1642
erin@tfnd.org

References

1. Surgeon General’s Reports on Smoking and Tobacco Use. (accessed February 24, 2013)
http://www.cdc.gov/tobacco/data_statistics/sgr/index.htm
2. Public Health Focus: Electronic Cigarettes. United States Food and Drug Administration. (accessed February 24, 2013)
<http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>
3. Treating Tobacco Use and Dependence. United States Public Health Service. (accessed February 24, 2013)
<http://www.ncbi.nlm.nih.gov/books/NBK63952/>
4. Tobacco Facts. North Dakota Department of Health. (accessed February 24, 2013)
<http://www.ndhealth.gov/tobacco/Facts.htm>

PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS FOR SMOKING CESSATION

		NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS				BUPROPION SR	VARENICLINE
		GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	
PRODUCT	Nicorette ¹ , Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint, orange	Nicorette Lozenge, ¹ Nicorette Mini Lozenge, ¹ Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CQ ¹ , Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS ² Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution	Nicotrol Inhaler ² Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban ¹ , Generic Rx 150 mg sustained-release tablet	Chantix ² Rx 0.5 mg, 1 mg tablet
	PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ (Rx formulations, category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications or medical conditions known to lower the seizure threshold Severe hepatic cirrhosis Pregnancy³ (category C) and breastfeeding Adolescents (<18 years) <p>Warning:</p> <ul style="list-style-type: none"> BLACK-BOXED WARNING for neuropsychiatric symptoms⁴ <p>Contraindications:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines MAO inhibitor therapy in previous 14 days
DOSING	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette > 30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette > 30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>>10 cigarettes/day: 21 mg/day x 4 weeks (generic) 6 weeks (NicoDerm CQ)</p> <p>14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤ 10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day)</p> <p>One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> – 5 doses/hour or – 40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3–6 months 	<p>6–16 cartridges/day</p> <p>Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3–6 months 	<p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1–2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Can be used safely with NRT Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1–3: 0.5 mg po q AM</p> <p>Days 4–7: 0.5 mg po bid</p> <p>Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> Begin therapy 1 week prior to quit date; alternatively, the patient can begin therapy and then quit smoking between days 8–35 of treatment Take dose after eating and with a full glass of water Dose tapering is not necessary Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS							
	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	BUPROPION SR	VARENICLINE
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> – Lightheadedness – Nausea/vomiting – Throat and mouth irritation 	<ul style="list-style-type: none"> ▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia 	<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ Insomnia ▪ Dry mouth ▪ Nervousness/difficulty concentrating ▪ Rash ▪ Constipation ▪ Seizures (risk is 0.1%) ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)
ADVANTAGES	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to rapidly manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage) 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Might delay weight gain ▪ Can be used with NRT ▪ Might be beneficial in patients with depression 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Offers a new mechanism of action for patients who have failed other agents
DISADVANTAGES	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Patients must use proper chewing technique to minimize adverse effects ▪ Gum chewing may not be socially acceptable 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ Patients cannot titrate the dose to acutely manage withdrawal symptoms ▪ Allergic reactions to adhesive might occur ▪ Patients with dermatologic conditions should not use the patch 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Nasal/throat irritation may be bothersome ▪ Patients must wait 5 minutes before driving or operating heavy machinery ▪ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Initial throat or mouth irritation can be bothersome ▪ Cartridges should not be stored in very warm conditions or used in very cold conditions ▪ Patients with underlying bronchospastic disease must use with caution 	<ul style="list-style-type: none"> ▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ▪ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ May induce nausea in up to one third of patients ▪ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS)
COST/DAY ⁵	2 mg or 4 mg: \$2.25–\$4.41 (9 pieces)	2 mg or 4 mg: \$2.61–\$4.95 (9 pieces)	\$1.87–\$3.52 (1 patch)	\$4.43 (8 doses)	\$7.68 (6 cartridges)	\$3.62–\$7.46 (2 tablets)	\$5.38–\$6.20 (2 tablets)

¹ Marketed by GlaxoSmithKline.

² Marketed by Pfizer.

³ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

⁴ In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a healthcare provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve.

⁵ Average wholesale price from Medi-Span Electronic Drug File. Indianapolis, IN: Wolters Kluwer Health, July 2011.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

Rx for Change: Clinician-Assisted Tobacco Cessation. Copyright © 1999-2011 The Regents of the University of California. All rights reserved. Updated September 24, 2011. Reprinted with permission.

Chairman Weisz and members of the House Human Services Committee, my name is Kimberlee Schneider and I am the Manager of Advocacy and Tobacco Control with the American Lung Association in North Dakota.

House Concurrent Resolution 3033 is a harms reduction resolution that directs legislative management to study opportunities for "harms reduction" measures in tobacco prevention.

Harms reduction is sometimes seen as an accommodating way of dealing with a harmful behavior.

When considering HCR3033 please consider these:

- 1) I hear a lot about smokeless tobacco being a good alternative for adult smokers who don't want to quit using tobacco. Consider this: it is not just adults who use chew. The sweeteners added and new products that have come on the market make it an easy way to addict our next generation to tobacco. North Dakota's youth consume smokeless tobacco at a rate almost twice the national average. (ND, 13.6%, US, 7.7%) In addition, smokeless tobacco is not without its health hazards.
- 2) E-Cigarettes are often touted as a good alternative to tobacco use. We are told by some that the vapor is harmless. This is not true. According to the FDA, electronic cigarettes, or e-cigarettes, are devices that allow users to inhale a vapor containing nicotine or other substances. In initial lab tests, FDA found detectable levels of carcinogens and toxic chemicals, including an ingredient used in anti-freeze, in two leading brands of e-cigarettes and 18 various brands of cartridges. The lab tests also found that cartridges labeled as nicotine-free had traceable levels of nicotine. Experts have raised concerns that e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products. There is still no scientific evidence that the e-cigarettes can help smokers quit. Until and unless the FDA approves a specific e-cigarette for use as a tobacco cessation aid, the American Lung Association does not support any direct or implied claims that e-cigarettes help smokers quit.

Helping people who want to quit is one strategy in a comprehensive tobacco prevention program. Tobacco prevention requires several strategies that, in addition to cessation services, help to keep young people from ever taking up the habit.

Laws that reduce the exposure of youth to tobacco use (smoke free workplace laws, increasing tobacco tax, equalizing tax on all tobacco products, tobacco free school grounds, for example) are sound public policy. Research bears out the results that more people quit, and less people start after public policies such as these are implemented.

Harm reduction is ok for individual taking steps to improve their lives but as public policy it's not the best we can do.

Kimberlee Schneider
American Lung Association
212 N 2nd St
Bismarck, ND 58501
701-223-5613
kimberlee.schneider@lungnd.org



E-Cigarettes

On April 25, 2011, the U.S. Food and Drug Administration (FDA) announced that e-cigarettes will be regulated as tobacco products unless the products are marketed as therapeutic. While FDA made the initial announcement that it intends to regulate most e-cigarettes as a separate class of tobacco products, much more research is needed about the potential health effects of e-cigarettes. The American Lung Association urges FDA to move forward without delay with further regulatory guidance and with additional product research to determine any public health impacts.

What is an E-Cigarette?

- According to the FDA, electronic cigarettes, or e-cigarettes, are devices that allow users to inhale a vapor containing nicotine or other substances.ⁱ
- Unlike traditional cigarettes, e-cigarettes are battery-operated and use an atomizer to heat a refillable cartridge that then releases a chemical-filled vapor.
- E-cigarettes are often available in flavors that may appeal to children and teens, including chocolate, strawberry and mint.ⁱⁱ

Health Effects of E-Cigarettes

- There is currently no scientific evidence establishing the safety of e-cigarettes. No brand of e-cigarettes has been submitted to the FDA for evaluation and approval.ⁱⁱⁱ
- In initial lab tests, FDA found detectable levels of carcinogens and toxic chemicals, including an ingredient used in anti-freeze, in two leading brands of e-cigarettes and 18 various cartridges.^{iv} The lab tests also found that cartridges labeled as nicotine-free had traceable levels of nicotine.
- There is also no evidence that shows the vapors emitted by e-cigarettes are safe for non-users to inhale and we support prohibiting the use of e-cigarettes under smokefree laws. The Lung Association also recognizes that the use of e-cigarettes may complicate efforts to enforce and comply with smokefree laws.
- Some distributors either directly or indirectly market e-cigarettes as tobacco cessation tools. No scientific studies demonstrate safety and efficacy of their use for this purpose.^v

Can E-Cigarettes Help Someone Quit Smoking?

- There is still no scientific evidence that e-cigarettes can help smokers quit.^{vi} The U.S. Public Health Service has found that the seven therapies approved by the U.S. Food and Drug Administration in combination with individual, group or phone cessation counseling is the most effective way to help smokers quit. Until and unless the FDA approves a specific e-cigarette for use as a tobacco cessation aid, the American Lung Association does not support any direct or implied claims that e-cigarettes help smokers quit.

State Laws Pertaining to E-Cigarettes

- Six states – California, Colorado, Minnesota, New Hampshire, Tennessee, and Utah – have enacted legislation prohibiting the sale of e-cigarettes to minors.^{vii}

July 12, 2011

ⁱ U.S. Food and Drug Administration. "E-Cigarettes: Questions and Answers." September 9, 2010. Available at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm>.

ⁱⁱ U.S. Food and Drug Administration. "FDA Warns of Health Risks Posed by E-Cigarettes." July 23, 2009. Available at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>.

ⁱⁱⁱ U.S. Food and Drug Administration. "FDA and Public Health Experts Warn About Electronic Cigarettes." July 22, 2009. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm173222.htm>.

^{iv} U.S. Food and Drug Administration. "Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA." July 22, 2009. Available at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.

^v U.S. Food and Drug Administration. "FDA Acts Against 5 Electronic Cigarette Distributors." September 9, 2010. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225224.htm>.

^{vi} World Health Organization. "Marketers of Electronic Cigarettes Should Halt Unproven Therapy Claims." September 19, 2008. Available at: <http://www.who.int/mediacentre/news/releases/2008/pr34/en/>.

^{vii} American Lung Association. State Legislated Actions on Tobacco Issues (SLATI) online database. Available at: www.lungusa2.org/slati.



FDA Warns of Health Risks Posed by E-Cigarettes

The Food and Drug Administration (FDA) has joined other health experts to warn consumers about potential health risks associated with electronic cigarettes.

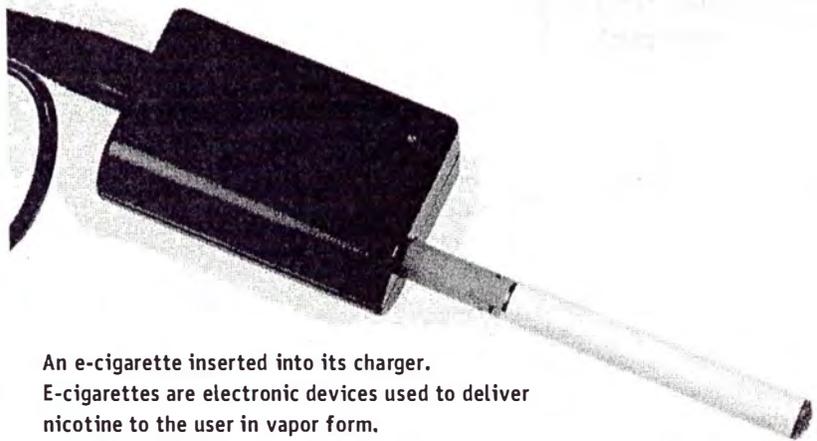
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

Sold online and in many shopping malls, the devices generally contain cartridges filled with nicotine, flavor, and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

"The FDA is concerned about the safety of these products and how they are marketed to the public," says Margaret A. Hamburg, M.D., commissioner of food and drugs.

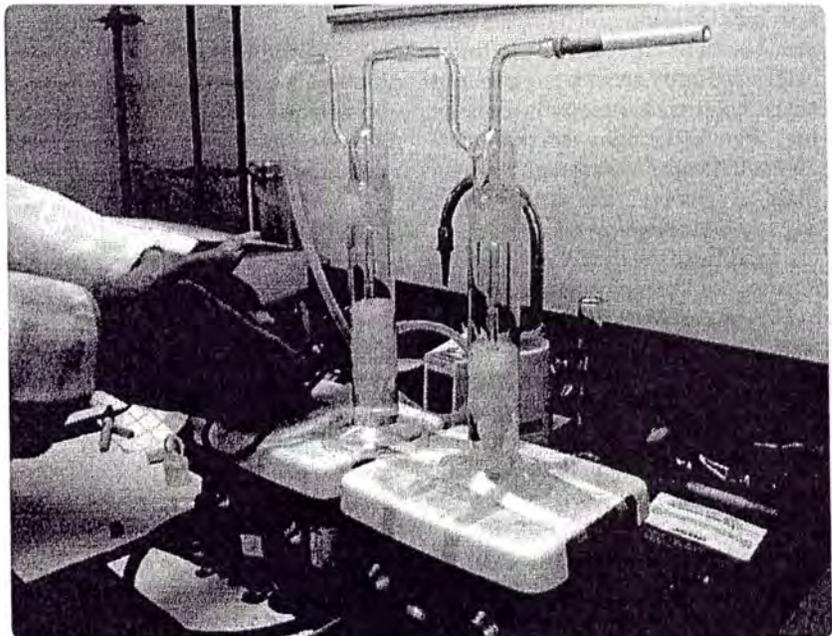
The agency is concerned that

- e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death
- the products may contain ingredients that are known to be toxic to humans
- because clinical studies about the safety and efficacy of these products for their intended use have not been



An e-cigarette inserted into its charger. E-cigarettes are electronic devices used to deliver nicotine to the user in vapor form.

FDA



Air is drawn through an e-cigarette during a laboratory procedure that simulates a smoker taking a puff. The resulting vapor is tested.

FDA

- submitted to FDA, consumers currently have no way of knowing
- whether e-cigarettes are safe for their intended use
 - about what types or concentrations of potentially harmful chemicals, or what dose of nicotine they are inhaling when they use these products

The potential health risks posed by the use of e-cigarettes were addressed in a July 22, 2009, phone conference between Joshua M. Sharfstein, M.D., principal deputy commissioner of food and drugs; Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium; Jonathan Samet, M.D., director of the University of Southern California's Institute for Global Health; and Matthew T. McKenna, M.D., director of the Office on Smoking and Health at the national Centers for Disease Control and Prevention.

Conference participants stressed the importance of parents being aware of the health and marketing concerns associated with e-cigarettes. It was stated that parents may want to tell their children and teenagers that these products are not safe to use.

Of particular concern to parents is that e-cigarettes are sold without any legal age restrictions, and are available in different flavors (such as chocolate, strawberry and mint) which may appeal to young people.

In addition, the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes.

During the phone conference, which was shared with the news media, FDA announced findings from a laboratory analysis that indicates that electronic cigarettes expose users to harmful chemical ingredients.

FDA's Division of Pharmaceutical Analysis—part of the agency's Center for Drug Evaluation and Research—analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarette samples.



An FDA chemist uses a device set to the same temperature as an activated e-cigarette. This helps determine what might be inhaled by users of these products.

One sample was found to contain diethylene glycol, a toxic chemical used in antifreeze. Several other samples were found to contain carcinogens, including nitrosamines.

Agency Actions

FDA has been examining and detaining shipments of e-cigarettes at the border and has found that the products it has examined thus far meet the definition of a combination drug device product under the Federal Food, Drug, and Cosmetic Act.

The agency has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court.

FDA is planning additional activities to address its concerns about electronic cigarettes.

Meanwhile, health care professionals and consumers may report seri-

ous adverse events or product quality problems with the use of e-cigarettes to FDA through the MedWatch program, either online at www.fda.gov/Safety/MedWatch/default.htm or by phone at 1-800-FDA-1088.

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

For More Information

FDA Press Release
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

E-Cigarettes: FDA Web page
www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm



For Consumers

E-Cigarettes: Questions and Answers

[Get Consumer Updates by E-mail¹](#)

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Q: What are electronic cigarettes?

A: Electronic cigarettes are products designed to deliver nicotine or other substances to a user in the form of a vapor. Typically, they are composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor. This vapor can then be inhaled by the user. These products are often made to look like such products as cigarettes, cigars, and pipes. They are also sometimes made to look like everyday items such as pens and USB memory sticks, for people who wish to use the product without others noticing.

Q: What concerns does FDA have regarding electronic cigarettes?

A: FDA has not evaluated any e-cigarettes for safety or effectiveness. When FDA conducted limited laboratory studies of certain samples, FDA found significant quality issues that indicate that quality control processes used to manufacture these products are substandard or non-existent. FDA found that cartridges labeled as containing no nicotine contained nicotine and that three different electronic cigarette cartridges with the same label emitted a markedly different amount of nicotine with each puff. Experts have also raised concerns that the marketing of products such as e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products. Visit FDA's Electronic Cigarettes webpage³ for additional information.

O: What action did FDA take today on electronic cigarettes?

FDA issued warning letters to five distributors of electronic cigarettes for violations of the Federal Food, Drug, and Cosmetic Act (FDCA). These violations included unsubstantiated claims and poor manufacturing practices.

Q: Would it be possible for an electronic cigarette to receive FDA approval?

A: Yes. FDA issued a letter to the Electronic Cigarette Association inviting electronic cigarette firms to work in cooperation with the agency toward the goal of assuring that electronic cigarettes sold in the United States are lawfully marketed. The agency intends to regulate electronic cigarettes and related products in a manner consistent with its mission of protecting the public health.

Q: What products should people who want to quit smoking use?

A: There are a number of FDA-approved smoking cessation aids, including nicotine gum, nicotine skin patches, nicotine lozenges, nicotine oral inhaled products, and nicotine nasal spray that are available for smokers to use to reduce their dependence on nicotine. Free help is available to all smokers who want to quit at 1-800-QUIT-NOW or by visiting www.smokefree.gov⁴.

This article appears on FDA's Consumer Updates page⁵, which features the latest on all FDA-regulated products.

Posted September 9, 2010

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For More Information

- [Family Smoking Prevention and Tobacco Control Act⁶](#)
- [FDA Acts Against 5 Electronic Cigarette Distributors⁷](#)
- [FDA's Electronic Cigarettes web page⁸](#)
- [Letter to the Electronic Cigarette Association \(PDF - 43KB\)⁹](#)



North Dakota Tobacco Prevention and Control Executive Committee

Center for Tobacco Prevention and Control Policy
4023 State Street, Suite 65 • Bismarck, ND 58503-0638
Phone 701.328.5130 • Fax 701.328.5135 • Toll Free 1.877.277.5090

#5

Testimony In opposition to House Concurrent Resolution 3033 February 25, 2013, House Human Services Committee

Good afternoon, Chairman Weisz and members of the House Human Services Committee. I am Jeanne Prom, Executive Director of the North Dakota Center for Tobacco Prevention and Control Policy. The Center is charged with implementing North Dakota's comprehensive statewide tobacco prevention plan, Saving Lives – Saving Money, along with the North Dakota Department of Health, local public health units, and other partners. This work is grounded in science of approaches that are proven to prevent and reduce tobacco use significantly and expediently. These approaches are described in the U.S. Centers for Disease Control and Prevention's Best Practices for Comprehensive Tobacco Control Programs, October 2007.

HCR 3033 is not needed. In the nearly 50 years that have passed since the first Surgeon General's Report on the harms of tobacco, the strong scientific foundation just keeps getting clearer: don't ever start using tobacco, and if you do, quit – completely. We have known for decades what works to avoid and eliminate all harm caused by tobacco and copycat products that mimic, and therefore promote, tobacco use: prevention and cessation of tobacco use.

Again, it's simple:

- 1 – we can avoid the harms of tobacco use by completely preventing tobacco use, and
- 2 – we can eliminate further harm by successfully getting tobacco users to quit for good – whether it's any common form of tobacco, or any other products that encourage sustained tobacco and nicotine addiction.

To reiterate, the science on tobacco harms is well established, overwhelming and clear: completely avoid the harms of tobacco by never starting. If you use tobacco, quit tobacco and any other product that isn't an FDA-approved cessation product.

Keep in mind that previous tobacco industry claims that altered products were less harmful have been proven false. Filtered, "light," or "low-tar" cigarettes were not less harmful.

If tobacco companies want to make the case or claim that a product is less harmful, federal law provides a path for them to do that through the U.S. Food and Drug Administration (FDA).

I urge the House Human Services Committee to reject HCR 3033.

I can respond to any questions or comments.

#6

Testimony

House Human Services Committee
HCR 3033

Deb Knuth
American Cancer Society Cancer Action Network
Monday, February 25, 2013

Tobacco kills nearly half a million Americans every year and is responsible for nearly one-third of all cancers. The American Cancer Society Cancer Action Network is committed to reducing tobacco use in all its forms because we know it will ease the burden of cancer in North Dakota and throughout the rest of the country. We are supportive of any genuine efforts to help cigarette smokers quit their deadly addiction; however, smokeless tobacco products are neither a safe substitute for cigarettes, nor an effective method of quitting smoking. We urge the House Human Services Committee to reject HCR 3033.

There is no need for this study, since both the U.S. Surgeon General and the U.S. Public Health Service, credible, non-conflicted sources, have already studied these products and determined that, at this time, the available reduced harm products do not provide a path to quitting. The State of North Dakota should not spend taxpayer money to fund research that is so closely aligned with – and will be actively distorted by -- tobacco industry interests, particularly since the industry was convicted of racketeering in U.S. District Court as recently as 2006. The misdeeds that caused the industry to be found guilty of racketeering were nothing short of deceiving the public and withholding information that the public deserved to know about the dangers of products that the industry claimed were less harmful. We are concerned that HCR 3033 paves the way for even more misinformation, and the State of North Dakota should distance themselves from tobacco industry bad actors who seek to spin misinformation in order to sell products that do harm.

In fact, HCR 3033 would circumvent the effects of the Family Smoking Prevention and Tobacco Control Act, the historic legislation passed by Congress in 2009 that finally gave the Food and Drug Administration the authority to regulate the manufacture, sale, and marketing of tobacco products. In March 2012, the FDA issued strong draft guidelines requiring tobacco companies to provide scientific proof to support any claims that their products reduce harm to the public, including existing and potential consumers.

To further support your rejection of HCR 3033, we ask you to consider the following:

- **Smokeless tobacco is not a safe product.** Smokeless tobacco products contain as many as 28 known carcinogens and 3-4 times as much nicotine as cigarettes. Long-time users of smokeless tobacco have been shown to be 50 times more likely to develop oral cancer compared to non-users. Smokeless tobacco has also been linked to esophageal and pancreatic cancer, as well as leukoplakia (white sores in the mouth that can lead to cancer), gum disease, and bone loss around the teeth.
- **There is no evidence that smokeless tobacco products help smokers quit.** The 2008 Update of the U.S. Public Health Service Clinical Practice Guidelines regarding tobacco cessation concluded, “the use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit.” In addition, a 2009 study found that it was more likely for American smokeless tobacco users to switch to cigarettes than for smokers to switch to smokeless.
- **Smokeless tobacco may provide a gateway to tobacco use, especially among kids.** Unlike cigarettes, smokeless tobacco is permitted to be sold in flavors such as cherry, grape, peach, and cinnamon. Use of these candy-like flavors alone makes it more likely kids will take up a deadly nicotine addiction. If kids are also getting the message that smokeless products are “not as bad” as cigarettes, the likelihood of beginning tobacco use only increases.
- **There are already proven methods to reduce smoking.** Studies show the most effective means to keep kids from taking up smoking and to encourage current smokers to quit is to increase tobacco taxes, provide adequate funding for evidence-based prevention and cessation programs, and pass comprehensive smoke-free laws.

For these reasons, we urge you to reject HCR 3033. Thank you for your time and considerations.



New and Emerging Smokeless Tobacco Products

Not a Safe Alternative to Cigarettes

Smokeless tobacco products, including snus and dissolvables such as strips, orbs, and sticks, are part of a new series of emerging tobacco products currently being promoted by the tobacco industry as less harmful, more convenient, and more socially acceptable alternatives to traditional cigarettes. However, there is no scientific evidence that smokeless tobacco products are safe and the use of smokeless tobacco products is not considered a safe substitute for, or an effective means of, quitting tobacco use altogether.

The tobacco industry has marketed a new generation of smokeless tobacco products as a temporary way to deal with increasing cigarette taxes and smoke-free policies in public places, thus encouraging dual use (the use of two or more tobacco products) and reducing the incentive to quit.

The Emergence of Smokeless Tobacco Products

- Between 1965 and 2004, cigarette smoking among American adults declined by half, from 42% to 21%. Since 2004, the smoking prevalence has continued to decline, but at a much slower rate.¹
- In 2010, the percentage of Americans who smoke cigarettes fell below 20% for the first time since just after World War I.²
- Cigarette and tobacco manufacturers recognize that a rise in indoor smoking restrictions, smoking-related health concerns, taxes on cigarettes, and reduced social acceptability of smoking has led to a reduction in smoking rates.³
- Since 2005, major cigarette manufacturers have, either through partnership or acquisition, moved into the smokeless tobacco business. Smokeless tobacco products introduce both smokers and non-smokers to new products for use in situations where smoking is restricted, while also providing a means for the tobacco industry to recapture revenue lost as a result of the decline in cigarette smoking.⁴
- Smokeless tobacco products include moist snuff, chewing tobacco, snus (a “spitless, moist powder tobacco pouch”), dissolvables (Orbs, Strips, and Sticks), and a variety of other tobacco-containing products that are not smoked.⁵

Health Risks

Although more research is needed to determine the full scale of health effects from smokeless tobacco products, several risks are currently documented. To date, use of smokeless tobacco has been shown to cause:^{6,7,8}

- Cancer of the mouth, pancreas, and esophagus
- Precancerous mouth lesions
- Dental problems including gum recession, dental carries, and bone loss around the teeth.
- Nicotine addiction

Harm Reduction

Despite the risks, smokeless tobacco products are promoted by the tobacco industry as providing harm reduction, or as an alternative to the abstinence of risky behavior.⁹ Although the tobacco industry, which has been convicted under federal racketeering laws for decades of conspiracy to deceive the public, touts these new products as “reduced harm” or “reduced or modified risk”, and indeed not all tobacco products are equally harmful, there is no such thing as a safe tobacco product.

The tobacco industry survives and profits greatly from selling a highly addictive product that causes diseases, which lead to a staggering number of deaths each year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national healthcare system. In 2010, the combined profits of the six leading tobacco companies was \$35.1 billion, equal to the combined profits of Coca-Cola, Microsoft, and

McDonald's in the same year.¹⁰ However, in order to make these profits, the industry misrepresents and deceives the American public.

- Laboratory analysis by the University of Minnesota revealed the presence of both toxicants and carcinogens in several brands of snus.¹¹
- Chemical analysis by Indiana University – Purdue University Indianapolis scientists found that dissolvable tobacco contains nicotine and a variety of flavoring ingredients, sweeteners, binders, and humectants. Of the flavor compounds identified, ethyl citrate is acutely toxic with oral dosing; cinnamaldehyde is an oral irritant and may increase the risk of gum and mouth disease, and coumarin, which has been banned as a flavoring agent in food for decades, is a liver and kidney toxicant.¹²
- Carcinogenic tobacco-specific *N*-nitrosamines (TSNAs) have been found in smokeless tobacco products.¹³
- To date, none of the products produced by the tobacco industry are recognized by the FDA as either a harm reduction or smoking cessation tool.

Marketing and Use

In 2006, the year that RJ Reynolds and Philip Morris USA began test-marketing their own smokeless tobacco products, spending on advertising and promotions for smokeless tobacco products was \$354.1 million. Just two years later, in 2008, that figure rose 50%, to \$537.9 million.¹⁴ At the same time, cigarette advertising decreased from \$12.49 billion in 2006 to \$9.94 billion in 2008,¹⁵ signaling a distinct shift in focus within the tobacco industry.

Dual use of cigarettes and smokeless tobacco products is of particular concern for public health and of particular interest to the tobacco industry.¹⁶ Dual use of cigarettes and smokeless tobacco products supports revenue streams for tobacco companies while also supplying multiple avenues for nicotine distribution, thus supporting nicotine addiction and, ultimately, continued use of the industry's products.¹⁷

- Many traditional smokeless tobacco users are dual users of cigarettes and smokeless tobacco.^{18,19,20}
- Use of smokeless tobacco products by persons aged 12 or older has increased by more than 51% since 2003.²¹
- While cigarette smoking among youth ages 12-17 declined more than 50 percent between 2002 and 2010, the use of smokeless tobacco products among youth increased 15 percent during that same time period.²²
- According to the 2012 Surgeon General's report, *Preventing Tobacco Use Among Youth and Young Adults*, concurrent use of multiple types of tobacco products is common among teen tobacco users. Among high school

Case Study: Indiana

In 2006, Philip Morris, USA, announced the test marketing of Toboka, a new, "spitless", smokeless tobacco product, in Indianapolis, IN. Between August 2006 and March 2008, Toboka was heavily promoted throughout Indianapolis, widely available, and heavily marketed with signage offering two-for-one deals and the proclamation that Toboka was a safer, more convenient alternative to traditional cigarettes. However, little research existed then, or now, on the safety of Toboka and other similar products, thus leaving a majority of Toboka advertising claims unsubstantiated.

Flashing forward six years, and prompted by the tobacco industry, in 2012 the Indiana General Assembly introduced a bill (H.R. 0059) that would create an interim study committee to consider tobacco harm reduction strategies as a strategy for reducing smoking-attributable death and disease. Tobacco industry lobbyists and their allies made lavish presentations to legislators about the benefits of encouraging the use of smokeless tobacco and other tobacco products that they call "reduced harm".

However, there is a substantial body of objective scientific evidence demonstrating that the three most effective strategies for reducing the death and disease resulting from all tobacco products include:

- 1) Increasing the price of all tobacco products through regular, significant tax increases;
- 2) Implementing 100% smoke-free laws in all workplaces, restaurants, and bars; and
- 3) Fully funding comprehensive state tobacco prevention and cessation programs. These three proven strategies must be considered before the utilization of tobacco products is promoted.

students who use tobacco, nearly one-third of females and more than one-half of males report using more than one type of tobacco product in the last 30 days.²³

- A 2009 study drawn from four nationally representative surveys in the U.S. demonstrated that occasional smokeless tobacco users are more likely to be current daily smokers than any other group, illustrating a pattern of tobacco use that may represent a partial substitution of smoking but a prolonging of dependence on tobacco products.²⁴
- A content analysis of Camel snus advertisements found frequent tie-in cigarette promotions or references to the benefits of using snus relative to cigarettes.²⁵
- An analysis of receptivity to Toboka and Camel snus in the Indiana test market one year after product introduction demonstrated a substantial initial interest in the new products among male smokers, especially those who received promotional mailings from tobacco companies, which often included coupons for free and discounted products.²⁶
- A review of more than eight million internal tobacco industry documents demonstrated that tobacco manufacturers, including cigarette and smokeless tobacco companies, develop products designed to augment cigarette use when smoking is not possible, develop new smokeless tobacco products to exploit smokers and target smokers who would otherwise quit, and attempt to deter quitting by developing products that appear to be less addictive and more socially acceptable.^{27,28}
- Smokers who use smokeless tobacco products as a supplemental source of nicotine to postpone or avoid quitting smoking may increase rather than decrease their risk of lung cancer.²⁹

ACS CAN's Current Views and Recommendations

ACS CAN and the Society support enacting evidence-based, comprehensive tobacco control policies that extend equally to all tobacco products, without any loopholes or exemptions. Specifically, we recommend:

- Eliminating price discrepancies between cigarettes and other tobacco products (OTPs) by increasing the tax on a package of OTPs to an equivalent percentage of the manufacturer's price as the tax on cigarettes.
- Ensuring that the definition of "tobacco product" in new laws is sufficiently broad to include all types of tobacco products, including dissolvable tobacco products and e-cigarettes. ACS CAN and the Society do not support exempting any type of smoked or smokeless tobacco product from smoke-free and tobacco-free laws and policies, tobacco tax increases, or tobacco sales or marketing restrictions.
- Fully funding, promoting, and providing access to all FDA-approved cessation medications.
- While the federal law giving the Food and Drug Administration (FDA) the authority to regulate tobacco products provides a number of restrictions on the manufacturing, marketing, labeling, distribution and sale of tobacco products, it also allows states to further restrict or regulate the time, place and manner (but not the content) of tobacco product advertising or promotions. While some of the regulations in the FDA law apply only to cigarettes, including restrictions on flavored cigarettes and minimum pack size requirements, ACS CAN and the Society support extending appropriate restrictions to all tobacco products.
- Funding and support for increased objective and independent research on OTPs, including evaluation and surveillance of health risks.
- Questions about smokeless tobacco products and their use should be included on national and state-level surveys, particularly those targeting youth and young adults, in order to obtain information about the prevalence and patterns of smokeless tobacco product use. Such information can be used to improve tobacco prevention and cessation initiatives.

References

- ¹ American Cancer Society. (2012). "Cancer Facts and Figures." Atlanta: American Cancer Society.
- ² US Department of Health and Human Services. (1989). "Reducing the Health Consequence of Smoking: 25 Years of Progress. – A report of the Surgeon General." <http://profiles.nlm.nih.gov/ps/access/NNBBXS.pdf>
- ³ Carpenter, CM, et al. (2009). "Developing smokeless tobacco products for smokers: An examination of tobacco industry documents." *Tobacco Control*, 2008; 18:54-59.
- ⁴ O'Connor, R. et al. (2011). "US smokers' reactions to a brief trial of oral nicotine products." *Harm Reduction Journal*, 2011; 8:1. <http://www.harmreductionjournal.com/content/pdf/1477-7517-8-1.pdf>
- ⁵ American Cancer Society. (2012). "Cancer Facts and Figures." Atlanta: American Cancer Society.
- ⁶ Stephanov, I. Ph. D. (2008). "New and traditional smokeless tobacco: Comparison of toxicant and carcinogen levels." *Nicotine and Tobacco Research*, 2008; 10:12.
- ⁷ Benowitz, NL. (2011). "Smokeless Tobacco as a Nicotine Delivery Device: Harm or Harm Reduction." *Clinical Pharmacology and Therapeutics*, Oct 2011; 90:4.
- ⁸ American Cancer Society. (2012). "Cancer Facts and Figures." Atlanta: American Cancer Society.
- ⁹ Sami, M. et al (2012). "Smokers' perceptions of smokeless tobacco and harm reduction." *Journal of Public Health Policy*, 33:2.
- ¹⁰ The World Lung Foundation and American Cancer Society (2012). "The Tobacco Atlas." <http://www.tobaccoatlas.org/>
- ¹¹ Stepanov, I. et al. (2008). "New and traditional smokeless tobacco: Comparison of toxicant and carcinogen levels." *Nicotine and Tobacco Research*, Dec 2008; 10:12.
- ¹² Rainey, CL, et al. (2011). "Chemical Characterization of Dissolvable Tobacco Products Promoted To Reduce Harm" *Journal of Agricultural and Food Chemistry* 2011; 59.
- ¹³ Benowitz, NL. (2011). "Smokeless Tobacco as a Nicotine Delivery Device: Harm or Harm Reduction." *Clinical Pharmacology and Therapeutics*, Oct 2011; 90:4.
- ¹⁴ Federal Trade Commission (2011). "Federal Trade Commission Smokeless Tobacco Report for 2007 and 2008." Accessed on June 28, 2012 at <http://www.ftc.gov/os/2011/07/110729smokelesstobaccoreport.pdf>
- ¹⁵ Ibid.
- ¹⁶ Carpenter, CM, et al. (2009). "Developing smokeless tobacco products for smokers: An examination of tobacco industry documents." *Tobacco Control*, 2008; 18:54-59.
- ¹⁷ Ibid
- ¹⁸ Severson, HH, et al. (2007). "Use of smokeless tobacco is a risk factor for cigarette smoking." *Nicotine and Tobacco Research*, 2007; 9.
- ¹⁹ Tomar, SL, et al (2010). "Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys." *Tobacco Control*, 2010; 9.
- ²⁰ Tomar, SL. (2003). "Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience." *Nicotine and Tobacco Research*, 2003; 5:561.
- ²¹ Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings* 2011. Available at <http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm>
- ²² Ibid.
- ²³ U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults*. A Report of the Surgeon General. Atlanta, GA, 2012.
- ²⁴ Tomar, SL, et al (2010). "Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys." *Tobacco Control*, 2010; 9.
- ²⁵ Timberlake, et al. (2011). "A Content Analysis of Camel Snus Advertisements in Print Media." *Nicotine and Tobacco Research*, June 2011; 13:6.
- ²⁶ Biener, L and Bogen, K. (2009). "Receptivity to Taboka and Camel Snus in a U.S. test market." *Nicotine and Tobacco Research*, Oct 2009, 11:10
- ²⁷ Carpenter, CM, et al. (2009). "Developing smokeless tobacco products for smokers: An examination of tobacco industry documents." *Tobacco Control*, 2008; 18:54-59.
- ²⁸ Ling, P, et al. (2004). "Tobacco Industry Research on Smoking Cessation: Recapturing Young Adults and Other Recent Quitters." *Journal of General Internal Medicine*, 2004; 19.
- ²⁹ Henley, SJ, et al. (2005). "Two large prospective studies of mortality among men who use snuff or chewing tobacco." *Cancer Causes Control*, 2005; 16:4.

#7

HCR 3033 – Submitted written testimony

Chairman Weisz and Members of the House Human Services Committee:

Nicotine exists in nature as an insecticide. Simply stated, it is a poison which kills insects. In veterinary medicine, it has been used to induce respiratory arrest for the purpose of putting down large animals.

Nicotine replacement therapy, used medicinally, is listed as a pregnancy category D. It causes injury, including genetic and epigenetic, to lab animals normally used in drug testing. The effects persist through multiple generations.

There is no safe dose. Nicotine is perhaps the most addictive drug in use today.

Snus is a biological product containing nicotine and other chemicals.

Are you willing to take responsibility to promote the release for wider use of this dangerous material when it will inevitably expose human fetuses to nicotine. It is associated with attention deficit disorder and increased risk of blood vessel damage as an exposed child grows older. It has a direct impact on neurotransmitter activity, and consequently, brain development in mammals, and very likely also in exposed fetuses.

Please exercise your own humanity and do not promote a tax benefit to an addictive substance that does not have adequate testing for what is being proposed in HCR 3033.

Thank you.

Dr. Jim Hughes
St. Alexius Heart and Lung Clinic
Bismarck, ND
701-226-0310

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Editorial

Tobacco harm reduction: How rational public policy could transform a pandemic

Abstract

Nicotine, at the dosage levels smokers seek, is a relatively innocuous drug commonly delivered by a highly harmful device, cigarette smoke. An intensifying pandemic of disease caused or exacerbated by smoking demands more effective policy responses than the current one: demanding that nicotine users abstain. A pragmatic response to the smoking problem is blocked by moralistic campaigns masquerading as public health, by divisions within the community of opponents to present policy, and by the public-health professions antipathy to any tobacco-control endeavours other than smoking cessation. Yet, numerous alternative systems for nicotine delivery exist, many of them far safer than smoking. A pragmatic, public-health approach to tobacco control would recognize a continuum of risk and encourage nicotine users to move themselves down the risk spectrum by choosing safer alternatives to smoking – without demanding abstinence.

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Keywords: Tobacco; Nicotine; Harm reduction; Cigarette smoking; Policy

Introduction

In efforts aimed at reducing the risk of death, injury or disease from any behaviour there are four broad areas of possible intervention. These include efforts to prevent the behaviour ever taking place, efforts aimed at ending the behaviour, efforts aimed at preventing the activity from harming third parties and efforts aimed at reducing the risks of those who engage in the behaviour. The interaction of these four pillars of public health intervention can be seen in everything from pharmaceutical policy, the rules of sport, automobile regulation, workplace safety standards and food processing and preparation regimes.

Interestingly, when dealing with issues of sexual behaviour and the use of licit and illicit drugs there is often strong opposition to efforts aimed at the reduction of risks among those who will engage in the behaviour in question. This schism appears to be the result of a persistent tension between a rational, scientific program and a behavioural, moralistic approach (Brandt, 1987, p. 182).

The conflict over means traces to a fundamental disagreement about aims: Is the purpose of an intervention to make people healthier or safer? Or is it to create better moral souls, to make people less “bad”? The availability of ‘risk reduction’ among accepted interventions can be seen as a

key distinguishing feature between scientific public health interventions whose aims are pragmatic, and moralistic ones, whose aims are impossible to measure.

If the goal of public policy interventions on tobacco is to achieve the greatest possible reduction in deaths, injury and disease, then it is necessarily pragmatic. Therefore, it is necessary for policy makers to seriously consider the role of risk reduction for continuing users of tobacco/nicotine products. This does not mean that risk reduction strategies must replace other strategies any more than protection of third parties needs to replace cessation strategies. An ideal public health approach rationally combines the various possible interventions in pursuit of the greatest achievable reduction in deaths, injuries and disease.

The case for applying harm reduction strategies to public health interventions on tobacco

It is estimated that cigarette smoking resulted in the deaths of roughly 100 million people in the last century, and that at current trends in consumption will kill 10 times that many this century (Peto & Lopez, 2001). Roughly half of long-term smokers will die as a direct result of diseases caused by their smoking, and half of those deaths will occur during

middle age. In terms of drug related deaths cigarettes dwarf the toll from other drugs.

The primary reason for smoking cigarettes is to obtain nicotine. The cigarette is an effective – but almost uniquely hazardous – delivery device for the drug, nicotine. As with the use of other drugs the pursuit of nicotine can be attributed to a combination of recreation, addiction and self-medication. The extent of each of these motivations will vary over time and between smokers just as the reasons behind the pursuit of alcohol or caffeine will vary between consumers and change over time.

We stress that nicotine is the primary cause of tobacco consumption. But it is not the nicotine that causes the harm: the inhalation of tobacco smoke is responsible for the pandemic of cancers, heart disease, respiratory diseases and other deadly results of tobacco consumption. Nicotine itself is comparatively benign. A fatal dose of nicotine would require roughly 60 mg for an average person, but, as with a fatal dose of caffeine, such a quantity is far more than is sought or attained by consumers (Fagerstrom, 2005). Were the world's 1.3 billion cigarette smokers acquiring their nicotine from clean delivery systems rather than through repeated inhalation of smoke, nicotine use would likely not rank much higher than caffeine use as a public health priority.

Given the projected death rates associated with smoking and the fact that these deaths can largely be explained by the recognition that 'it's the smoke, stupid', harm reduction interventions are essential. The case for harm reduction is made all the stronger when one considers that there already are various alternatives to cigarettes that are markedly less toxic and clearly acceptable to large numbers of consumers (See Table 1).

In Sweden a smokeless tobacco product known as 'snus' has come to dominate the tobacco market, with sales rising as cigarette sales have fallen. Many former smokers have switched to snus, far more males use snus than smoke, and snus sales amongst females – which had long lagged male usage – is now evidently growing rapidly. As a result Sweden has the lowest level of tobacco related disease in males among OECD countries, and has reported male smoking prevalence that has now hit single digit percentages in parts of the country.

Table 1
Examples of western world smoke-free alternatives to cigarettes

Transdermal nicotine patch (of various strengths and regimens)
Nicotine chewing gum (range of flavours and 2 strengths)
Nicotine inhaler ['puffers']
Nicotine nasal spray
Medicinal nicotine lozenges (range of flavours and 3 strengths, including sublingual)
Ultra-low nitrosamine tobacco lozenges [Ariva, Stonewall]
Swedish snus
Hard tobacco [Oliver Twist]
Moist snuff [Skoal, Copenhagen]
Spit-free tobacco pouches
Chewing tobacco

Norway and the United States have also in recent years seen a rapid increase in sales of smokeless tobacco products, and these sales trends are ascribed at least in part to growing awareness that non-combustible products are massively less hazardous than smoking (Morgan Stanley Research North America, 2006). Many countries also now have experience with medicinal nicotine (gum, patches, lozenges and 'inhalers') meeting the needs of smokers not just for short-term cessation efforts but for longer term use as a replacement for smoking.

Smokeless tobacco products do cause disease – but at very low rates compared to cigarettes. The disease risk of smokeless tobacco can be made lower still through changes in manufacturing techniques that reduce toxins such as tobacco-specific nitrosamines. It has been estimated that modern smokeless tobacco products are least 90%, and perhaps closer to 99%, less deadly than smoking cigarettes (Levy et al., 2004; RCP, 2002). While there is popular recognition that 'smokeless tobacco causes oral cancer' few recognize that the risk of oral cancer from the sort of high nitrosamine smokeless products that used to be on Western markets (and upon which the oral cancer risk was based) was actually considerably lower than the risk of the disease from smoking. Nor is there widespread recognition that low nitrosamine products such as Swedish snus do not appear to cause oral cancer at all.

Medicinal nicotine products appear to be significantly less hazardous even than smokeless tobacco. These products have been subjected to rigorous evaluation by drug regulatory authorities in many countries and been in use for decades. The major risk of such products is not inherent dangers, but the fact that they are not used at a sufficient dosage for a sufficient length of time and so result in users reverting to cigarette smoking. In part this underutilization of medicinal nicotine can be attributed to government regulations that restrict the nature and availability of such products out of an expressed concern that there is a potential for 'abuse'. This cautious approach to medicinal nicotine, combined with assorted attacks on tobacco and nicotine that demonize nicotine and fail to distinguish inter-product risks helps to explain why a vast number of smokers incorrectly believe that nicotine itself causes cancer.

Current cigarettes and cigarette-like products are at the high end of a continuum of risk. Moving down the continuum, but still very likely to be high risk are alternative 'cigarette' designs that primarily heat rather than burn tobacco. These products are undoubtedly more hazardous than non-combustion-based delivery, but very likely less hazardous than smoking. Even tinkering with the toxicity levels of cigarettes, through such things as lowering nitrosamine levels in the tobacco leaf, has potential to reduce mortality. Non-combustion products, and particularly low nitrosamine smokeless tobacco and medicinal nicotine products are at the least hazardous end of this risk continuum.

The relative safety of smokeless tobacco and other smoke-free systems for delivering nicotine demolishes the claim that

abstinence-only approaches to tobacco are rational public-health campaigns. This is not to say that all smokers would or should necessarily switch to snus or current forms of medicinal nicotine. But it does mean that cigarettes need not be seen as the only way consumers can obtain their nicotine. This also means that it need not be that the only alternative to continued cigarette smoking must be complete cessation of nicotine in any form.

Alternative nicotine delivery devices will still entail risks. But as nothing in life is devoid of risks it is nonsensical to dismiss an alternative to a tremendously harmful activity by claiming the alternative is not absolutely 'safe', or to claim that the pursuit of a less hazardous alternative implies that the alternative is "virtually harmless" (Gray & Henningfield, 2006).

As more alternatives to conventional cigarettes are considered it is clear that there is a wide range of possibilities on the continuum of risk. The variation of risk among interchangeable products creates a strong basis for regulatory intervention aimed at shaping the market. It should also be the basis for accurate communications to consumers. The fact that alternative products can meet the needs of some significant number of those who would likely otherwise smoke cigarettes also raises key issues about just what sort of products might be available, what sort of information consumers can be given about relative risks and what sort of policy environment could achieve maximum public health benefits through the greatest transition of smokers to less toxic alternatives.

The critical issue in looking at consumer safety, and one that makes tobacco/nicotine an ideal area for harm reduction interventions, is that smokers are capable of moving down the risk continuum when offered alternative products and accurate information on relative risks. A pragmatic goal would be to move current smokers as far down the continuum of risk as possible, without depriving consumers of all choice. The consumer who rejects (or cannot achieve) abstinence but will use a product that reduces risk by 90% should not be prevented from making that preferred choice. Indeed, it is exactly the forced choice between smoking and abstinence that reinforces the current dominance of cigarettes.

Fitting harm reduction into existing public health interventions on tobacco

Comparing tobacco control interventions with efforts that have historically been directed at reducing the toll associated with other potentially dangerous consumer products reveals how tobacco and the harms of smoking it, are positioned in the consumer culture. With products such as food, pharmaceuticals, automobiles, electrical goods, toys, sports equipment and caffeine products, reform movements embraced risk reduction. Though this often came after a fight between pragmatists and 'absolutists' (Young, 1989), the transition was not nearly as drawn out or heated as

is currently the case on tobacco/nicotine. More than 40 years after the U.S. Surgeon General's Report on the Health Consequences of Smoking opened the protracted public-health campaign to stamp out smoking-related disease, no public-health approach to tobacco has emerged that can fully counteract smoking-promoted morbidity and mortality. While many tobacco-control interventions have reduced smoking rates and prevented millions of deaths, that success is limited: Even today, policy makers refuse to deal directly with the nature of nicotine itself by giving viable alternative delivery systems to smokers. The result is that millions of tobacco users, unable to quit, are not encouraged – or simply not told – that they might be safer by moving down the "risk continuum" to an alternative nicotine-delivery system.

Current debates within tobacco control circles more closely resemble those found on issues such as alcohol, illicit drugs and sexual practices rather than the dangers of consumer items. In regard to substance use and sex, the pragmatism that marks the typical harm-reduction approach to product safety collides with moralistic approaches to human behaviour. The conflicts over drug use, especially in the context of deadly viral infections potentially spread through drug delivery systems (i.e., needle and syringe), are well known. In many countries, battles still rage over what to tell people – especially adolescents – about sex and in particular whether to encourage them to use condoms or simply to abstain from sex outside of marriage. While tobacco use has not yet elicited the same emotional intensity as have concerns about addiction and teen sex, the failure to establish a rational and evidence-based public-health approach to tobacco use can be traced to similar sorts of pragmatism–moralism debates.

And the situation with tobacco might be even more complicated than the debate over illicit drug use. One of the challenges facing tobacco control efforts is that the advocates pushing for social change include both public health pragmatists who are genuinely concerned about reducing tobacco-associated illness and death caused by smoking and moral absolutists whose concern is with the bad habit of substance (nicotine) use. They find common ground on elimination of smoking and doing battle with the tobacco companies. But, as seen in the history of the Pure Food movement in the United States in the 1800s it might be impossible to get absolutists to endorse risk reduction interventions. Those with an abstinence-only view on nicotine (or tobacco) might never change their view regardless of the science, as their views are possibly not actually based on scientific principles any more than the Christian Right's opposition to condoms is primarily based on science.

Can advocates of change in existing policies work together without undermining each other? If so, how? We see two ways in which efforts to reduce tobacco harms are unusual, even in the context of public-health approaches to use of other substances such as heroin or alcohol.

For one, the nature of the marketplace and the increasingly rapid dissemination of information of interest to consumers will undoubtedly see an acceleration of market changes that

will likely marginalize those tobacco control advocates who adhere to an abstinence-only orientation (Meier & Shelley, 2006). That still leaves those who simply do not yet recognize that risk reduction is, along with prevention, cessation and protection of third parties, one of the four pillars of public health interventions.

The other is that, thus far, tobacco harm reduction has not been backed by the liberal public health establishment. In other contexts, the liberationist and social-justice sentiments of the public-health profession worked in favour of promoting harm-reduction interventions for sex-related harms (condoms) and drug-injection-related harms (syringe exchange), rather than insist that people cease engaging in activities that are potentially risky but impossible to eradicate. To a pragmatist – that is, to the public-health professional – the reason for a behaviour is less important than the fact that the behaviour is going to continue. The public-health profession supported the harm-reduction stance on sex and illicit-drug use even before the safety of those interventions had been established. With tobacco, by contrast, the public-health profession has yet to support tobacco HR despite the strong, consistent, and increasingly extensive evidence that many alternative nicotine delivery systems would be safer than smoking.

An understanding of the public-health profession's position is important, because its voice would sound loud in the policy debate were it to renounce its support of cessation-only approaches. We see two ingredients to the public-health establishment's reluctance to embrace the concept of a continuum of risk and advocate non-cessation approaches for nicotine users.

First, the public-health establishment, at least in the U.S. where much of the policy fight is centred, is inclined to be distrustful of big business in general and Big Tobacco in particular. Two of the foundations of public health, occupational hygiene and worker safety, were built on direct opposition to industry; another, environmental monitoring and maintenance, has depended on advocacy to overcome industry standards that tolerated pollution. And the collusion of private business with government regulators that has produced serious public-health disasters – the Triangle fire in New York, the Bhopal disaster in India, mad cow disease in the U.K. – increases the profession's antipathy.

Second, the tobacco industry has played into the hands of its critics by its attempts to suppress information on the harms of smoking and cover up evidence of its own awareness, from early on, that it was making an intrinsically hazardous product.

The paradoxical, and lamentable, outcome of the public-health profession's anti-industry stance is that government and non-profit public-health agencies will generally not fund the research that would define the continuum of risk for nicotine delivery devices, and thereby allow for rational and evidence-based decision making on behalf of the public's health. Instead, in the U.S. (whose research budget dwarfs other countries'), virtually the only substantive research

on alternative delivery systems now being carried out is funded by industry: research on smokeless tobacco products is financed by the tobacco companies, and research on nicotine replacement is financed by the pharmaceutical industry. To public-health advocates whose *idée fixe* is that industry is singularly self-interested, venal, and treacherous, these funding streams serve to discredit the researchers who are doing what would, otherwise, be the essential work of determining how best to serve the public's health. The consequent situation is this tautology: the only nicotine- or tobacco-related research that is recognized as valid is research funded by the government or non-profits; the government and non-profits will fund only research on smoking cessation; only smoking cessation is a valid public-health intervention.

Using policy levers to reduce the risk of tobacco/nicotine use

The potential for tobacco harm reduction interventions is clarified by examining how risk reduction strategies have been applied elsewhere. The long battles to establish regulations pertaining to the manufacturing of food products or to replace 'snake oil' with science-based pharmaceutical products offer examples of how advances in science and a proliferation of alternative products can combine with changing corporate vested interests and political pressure to fundamentally 'morph' a market. The fundamental change with respect to pure foods and pharmaceuticals did not come with legislation *per se* (e.g., the U.S.'s Food and Drug Act of 1906), but from two broader cultural phenomena: the growth and professionalization of the craft of medicine, and changes in the social contract that demanded more public responsibility from private manufacturers (with concomitantly expanded compliance by the courts). In America, the medical trade advocated for greater regulation of products having to do with health so that it might dominate the market in health-risk avoidance. The movement for purer foods developed in tandem with awareness of nutritional public health, positioning food regulation across both the medical and consumer arenas. Thus, the role of both the health-care industry and the public-health agencies was essential to the development of policies that reduced food- and prescription-drug-associated harms.

The example of food and pharmaceuticals might be promising for nicotine regulation, since nicotine remains a legal drug and tobacco is a consumer product with recognized appeal. But it also highlights the importance of swaying the medical and public-health professions to embrace harm reduction for nicotine users. And, the need to implement tobacco regulation in ways that will cohere with evidence-based public-health strategies.

There are many regulatory strategies that could be reasonably expected to reduce the present levels of tobacco related morbidity and mortality. A key step would be measures that would put the most hazardous products at the greatest market-

place disadvantage. As Sweden has long done in dealing with cigarettes versus snus and many other countries have done in dealing with leaded versus unleaded petrol, differential taxation could dramatically change the market. Combustion-based products could be taxed so as to be, for example, at least twice as expensive as non-combustion alternatives. Cigarettes could also be subjected to more rigorous marketing restrictions and package health labelling. In addition, manufacturing standards could require reductions in known toxins without allowing these changes to be used in promotional efforts by the companies in question. Such efforts would simultaneously promote prevention, cessation, and protection of third parties as well as achieving viable harm reduction for continuing nicotine users.

Conclusion

We can reduce tobacco related death and disease far more rapidly than we can reasonably expect to reduce nicotine use by focusing on the fact that people smoke for the nicotine but die from the smoke. Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.

References

- Brandt, A. M. (1987). *No magic bullet: A social history of venereal disease in the United States since 1880*. Oxford University Press.
- Fagerstrom, K. (2005, June). The nicotine market: An attempt to estimate the nicotine intake from various sources and the total nicotine consumption in some countries. *Nicotine & Tobacco Research*, 7(3), 343–350.
- Gray, N., & Henningfield, J. (2006, September 9). Dissent over harm reduction for tobacco. *Lancet*, 368, 899–901.
- Levy, D. T., Mumford, E. A., Cummings, K. M., Gilpin, E. A., Giovino, G., Hyland, A., et al. (2004). The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: Estimates of a panel of experts. *Cancer Epidemiology, Biomarkers & Prevention*, 13, 2035–2042.
- Meier, B., & Shelley, D. (2006, September–October). *The fourth pillar of the framework convention on tobacco control: Harm reduction and the international human right to health* (Vol. 121, pp. 494–500). Public Health Reports.
- Morgan Stanley Research North America. (2006, September 19). *UST: Further from the precipice, but still significant L-T issues*. Morgan Stanley.
- Peto, R., & Lopez, A. D. (2001). Future worldwide health effects of current smoking patterns. In C. E. Koop, C. Pearson, & M. R. Schwarz (Eds.), *Critical issues in global health* (pp. 154–158). San Francisco: Jossey-Bass.
- Tobacco Advisory Group of the Royal College of Physicians (2002). *Protecting smokers, saving lives: The case for a Tobacco and Nicotine Authority*. London.
- Young, J. H. (1989). *Pure food: Securing the Federal Food and Drugs Act of 1906*. Princeton University Press.

David Sweanor
Faculties of Law and Medicine,
University of Ottawa, Canada

Philip Alcabes*
School of Health Sciences, Hunter College,
City University of New York, United States

Ernest Drucker
Montefiore Medical Center/Albert Einstein College of
Medicine and Mailman School of Public Health,
Columbia University, NY, United States

* Corresponding author. Tel.: +1 212 481 5111.
E-mail addresses: dsweanor@uottawa.ca (D. Sweanor),
palcabes@hunter.cuny.edu (P. Alcabes)

4 October 2006

Tobacco Harm Reduction

Brad Rodu

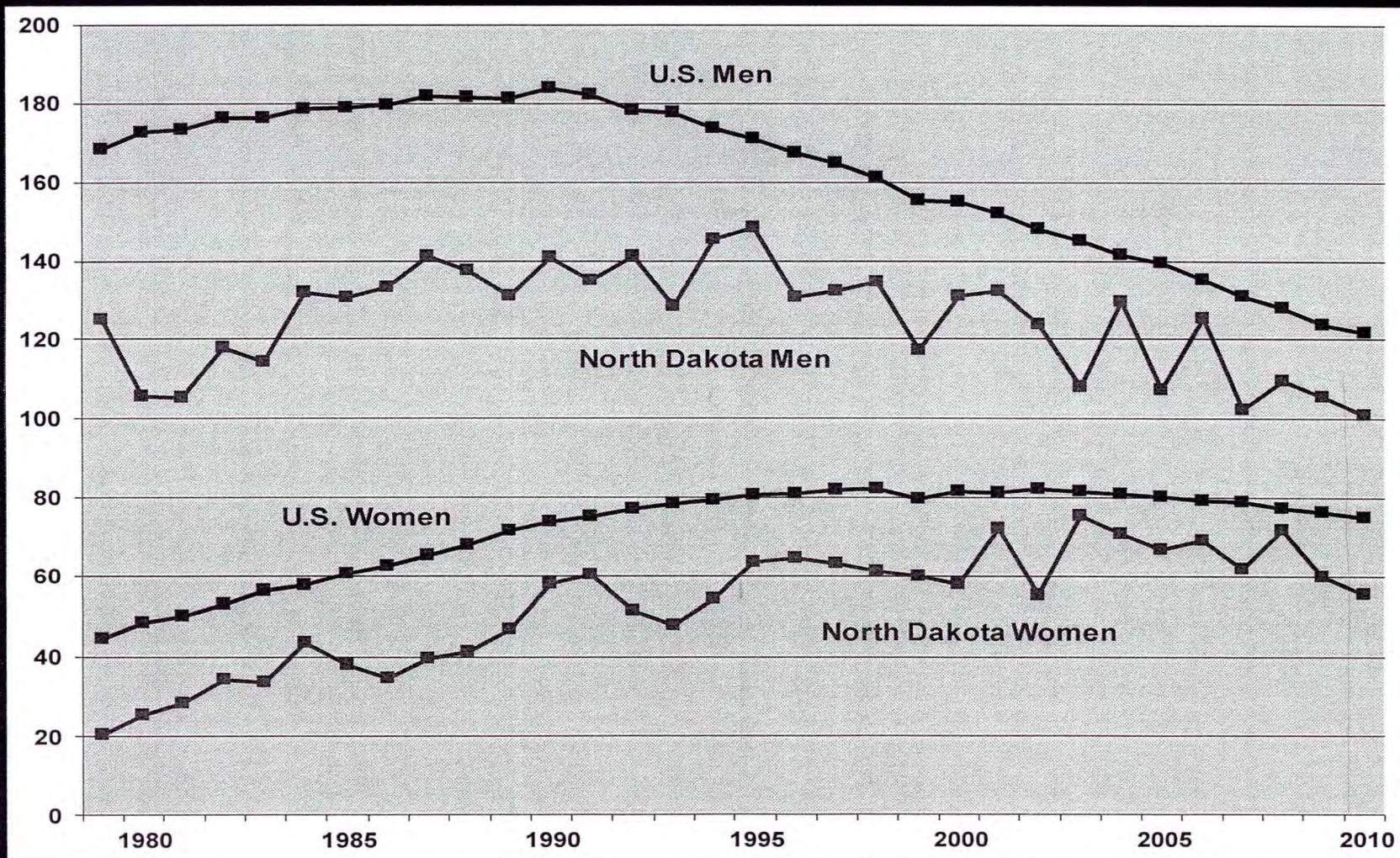
Professor, Department of Medicine
James Graham Brown Cancer Center
University of Louisville

The Smoking Status Quo: Unacceptable

- **The American Anti-Smoking Campaign is
45 Years Old**
- **According to the CDC:
45 million smokers in the U.S.**

**443,000 deaths every year in the U.S.
880 in North Dakota**

Lung Cancer Mortality in Men and Women Age 35+ Years, North Dakota and the US, 1979-2010



If the Status Quo Continues

In the next 20 years:

- **8 million Americans will die from smoking**

All are adults over 35 years of age

None of them are now children

The Failed Anti-Smoking Campaign

- **The Campaign's Only Message:**

Quit Nicotine and Tobacco, or Die

- **The Campaign's Only Quitting Tactics:**

**Ineffective Behavioral Therapy
Ineffective Use of Nicotine**

Rodu and Cole. *Technology* 6: 17-21, 1999.

Rodu and Cole. *International J Cancer* 97: 804-806, 2002.

The Anti-Smoking Campaign- Behavioral Therapy

- NCI Manual for Physicians- Counsel Patients to:
 - "Keep your hands busy- doodle, knit, type a letter"
 - "Cut a drinking straw into cigarette-sized pieces and inhale air"
 - "Keep a daydream ready to go"

Source: How to help your patients stop smoking. NIH Pub. No. 93-3064,
1993

The Anti-Smoking Campaign- Faulted Use of Nicotine

- **Temporary – 6 to 12 weeks**
- **Expensive – per unit and per box**
- **Very Low Dose – unsatisfying for smokers**
- **7% Success* – ”Efficacious”, ”Modest”**

*Hughes et al. Meta-analysis in Tobacco Control, 2003.

Comparing Nicotine to Caffeine Addictive Drugs Can Be Used Safely

Properties of Nicotine and Caffeine

Pleasurable Effects:	Enhance concentration and performance Provide a sense of well being Elevate mood
Powerfully Addictive:	Irreversible for many consumers
Can be Used Safely:	Do not cause Cancer, Emphysema, Heart Diseases
Delivery Systems:	Caffeine- Coffee, tea, cola drinks Nicotine- Smoke versus smokeless

Tobacco Harm Reduction Permanent Nicotine Maintenance

Smokeless Tobacco

- **Nicotine levels comparable to smoking**
- **Vastly safer than smoking (>98%)**
- **Evidence from Sweden – and the U.S. – that smokeless works**
- **Modern products are socially acceptable**

American Smokeless Tobacco

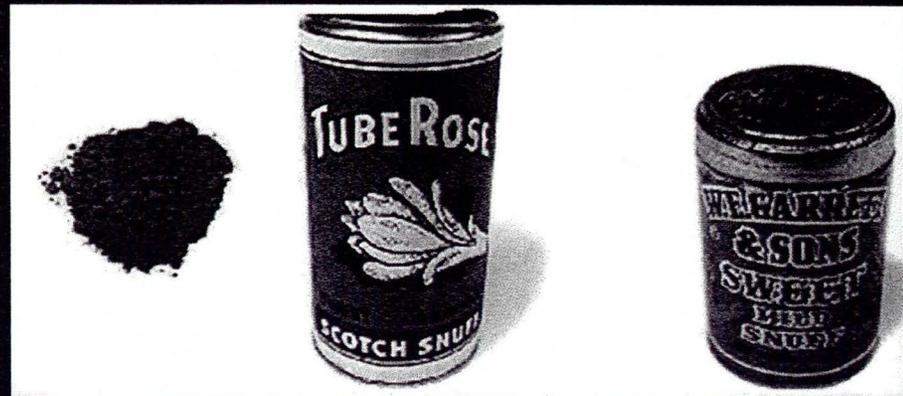


Moist Snuff



Chewing Tobacco

Powdered
Dry Snuff



Smokeless Tobacco Use is 98% Safer Than Smoking

- **No risk for emphysema, lung cancer, and heart disease**
- **Mouth cancer risk - Very low in absolute terms***

* 22 studies over 50 years: Rodu and Cole, Oral Surgery 2002.

Smokeless Tobacco and Health: Oral Cancer

Relative Risks

Smoking	~10
Alcohol Abuse	~4

American Smokeless Tobacco*

Chewing tobacco	1.2
Moist snuff	1.0
Powdered Dry Snuff	4.0

Incidence Rate in Long-term ST users (At RR=4):
26 per 100,000 person-years (py)**

* Over 20 epidemiologic studies, reviewed in: B Rodu, P Cole. Oral Surgery
93: 511-515, 2002.

**New England Journal of Medicine 304: 745-749, 1981.

Comparing Risks of Smokeless Tobacco, Automobiles and Cigarettes

Annual Death Rate from:

Powdered dry snuff¹ 12 per 100,000 users

Automobiles² 11 per 100,000 users

Cigarettes³ > 600 per 100,000 users

1. New England Journal of Medicine, 1981.

2. National Highway Traffic Safety Administration, 2009.

3. American Cancer Society data, 1999.

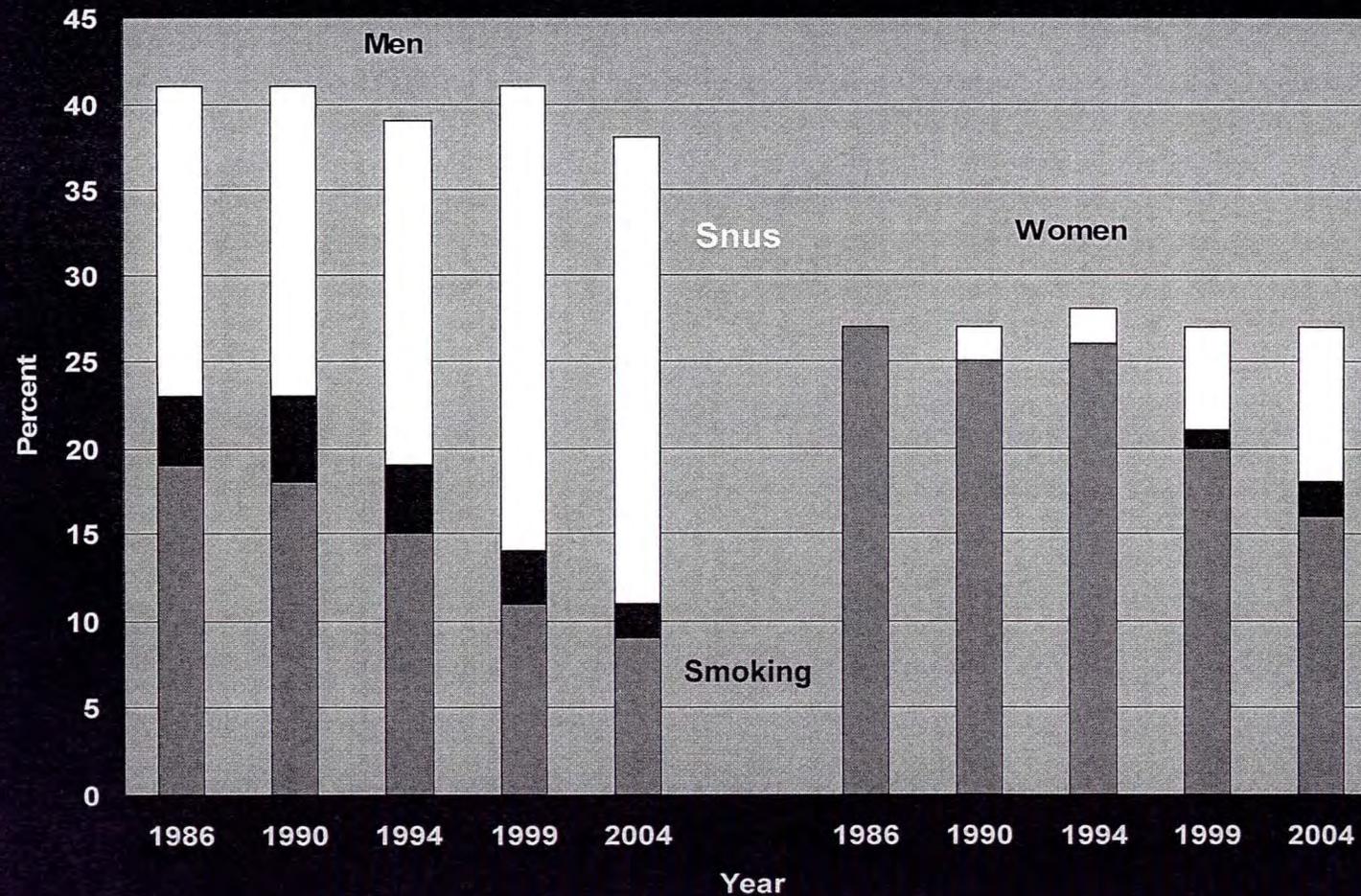
Smokeless Tobacco Has Worked For Swedish Men For 50 Years

- High rate of smokeless tobacco use.
- Lowest smoking rate in Europe.
- Lowest rate of lung cancer and other smoking-related diseases in Europe
- If EU men smoked at the rate of Swedish men, almost 274,000 lives per year would be saved*

*B Rodu and P Cole. *Scandinavian Journal of Public Health*, 2009.

Tobacco Use in Northern Sweden

From J Int Med 2002; Scand J Pub Health 2005



Growing Discussion about Tobacco Harm Reduction

2002 Royal College of Physicians Report

”...[smokeless] tobacco...10 to 1,000 times less hazardous than smoking...some manufacturers want to market ST as a harm reduction option...may find support for that in the public health community”

2007 Royal College of Physicians Report

Smokers smoke predominantly for nicotine,...nicotine itself is not especially hazardous.

Harm reduction

- a fundamental component of many aspects of medicine and...everyday life...has not been applied to smoking.**
- has the potential to save millions of lives, and deserves consideration.**

Growing Discussion about Tobacco Harm Reduction

2006 *Addictive Behaviors*, NCI Funded

“...4 million [American] smokers would switch to the low-carcinogen smokeless tobacco.”

American Council on Science and Health

***Harm Reduction Journal*, 2006 and 2011**

”....there is a strong scientific and medical foundation for tobacco harm reduction, which shows great potential as a public health strategy to help millions of smokers.”

Tobacco Harm Reduction The Owensboro, KY Campaign

**Dump the smoke.
But keep on lovin' the nicotine.**

With cigarettes, it's the smoke that kills. Smoke-free products are proven to be the smarter and safer way to enjoy nicotine – and one of the most effective ways to quit cigarettes.

SwitchAndQuitOwensboro.org

* Reda and Phillips, Harm Reduction Journal 5, 18, 2009

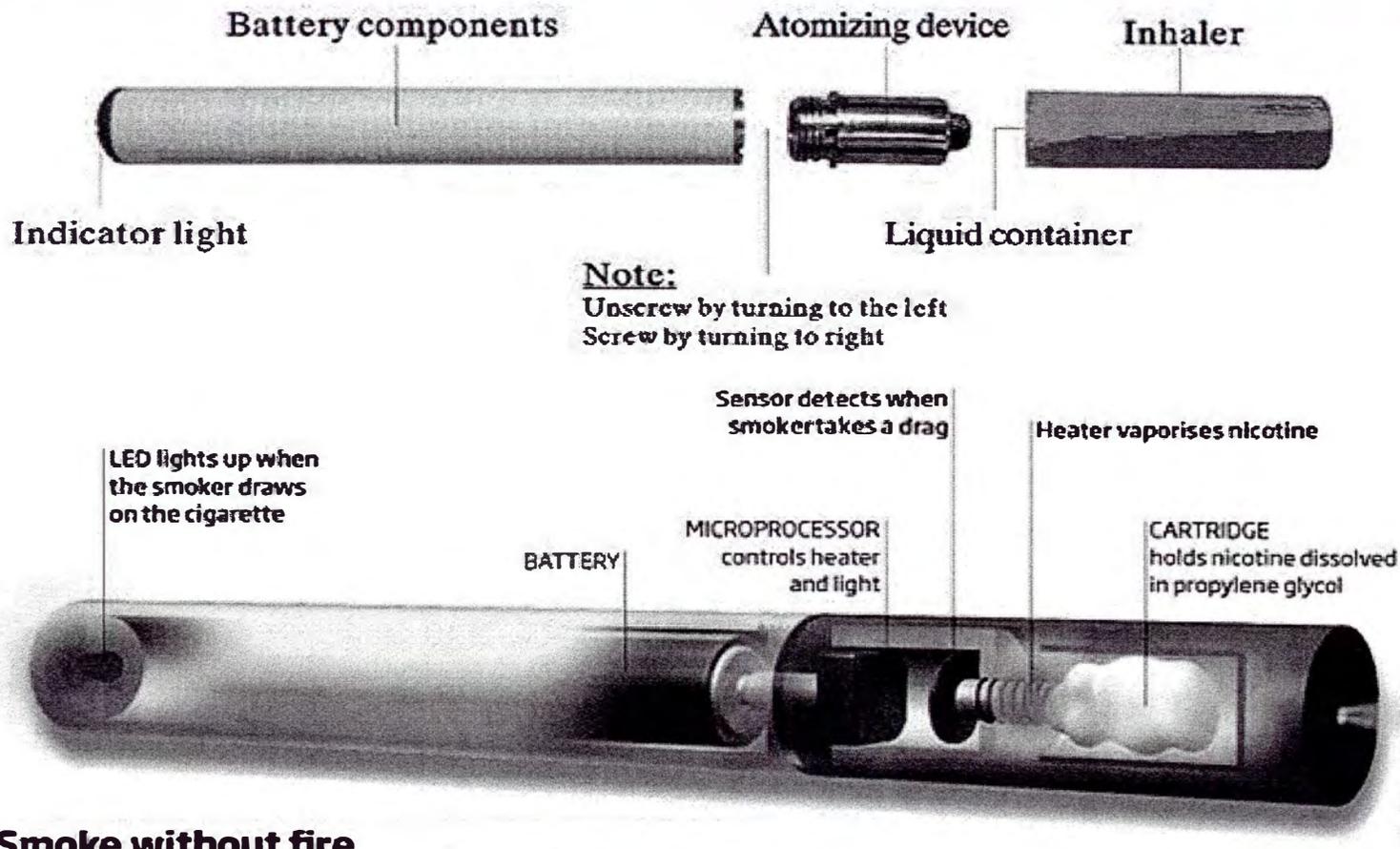


James Graham Brown Cancer Center

UNIVERSITY OF
LOUISVILLE



E-cigarettes



Smoke without fire

Suck on an e-cigarette and it produces a cloud of nicotine-carrying vapour with none of the toxic by-products of burning tobacco

Tobacco Harm Reduction: Moving Forward

- **Eliminate misinformation on state government web pages:**

”There are no studies available detailing what inhaling water vapor, propylene glycol, pure nicotine...will do to human lungs, heart or cardiovascular system.”

<http://www.ndhealth.gov/tobacco/Facts/E-cigs.pdf>

- **Don't "equalize" taxes on smokeless tobacco with those on cigarettes: it denies smokers affordable options**
- **Smokers who switch save essentially as many health care dollars as smokers who quit: state employees and Medicaid recipients**
- **Set insurance rates that don't penalize smokers who switch**

For More Information

www.smokersonly.org

Rodutobaccotruth.blogspot.com

www.SwitchandQuitOwensboro.org



North Dakota Tobacco Prevention and Control Executive Committee
Center for Tobacco Prevention and Control Policy
4023 State Street, Suite 65 • Bismarck, ND 58503-0638
Phone 701.328.5130 • Fax 701.328.5135 • Toll Free 1.877.277.5090

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**Testimony
In opposition to HCR 3033
April 2, 2013
Senate Human Services Committee**

Good morning, Chairman Lee and Members of the Senate Human Services Committee. I am Nathan Marion, chair of the Tobacco Prevention and Control Advisory Committee.

I am a student at Bismarck State College and have witnessed nicotine's grip among my college peers. Many of these students fall into the dual use trap, where they use other tobacco products, such as chewing tobacco and snuff, in places where smoking is not allowed.

For these students, smokeless tobacco use is not a substitution for cigarettes, but serves as a bridge to increasing the number of dual tobacco users within our state. While smoke free laws encourage quit attempts, tobacco companies respond by aggressively introducing more smokeless products to the market as a way for smokers to fulfill their need for nicotine in places where they cannot smoke.

Do not be fooled by House Concurrent Resolution 3033. This tobacco company strategy undermines quit attempts by smokers and leads to higher dual usage among tobacco users. Tobacco companies are using this strategy to increase sales, not reduce harm.

HCR 3033 – Submitted written testimony

Chairman Lee and Members of the Senate Human Services Committee:

Nicotine exists in nature as an insecticide. Simply stated, it is a poison which kills insects. In veterinary medicine, it has been used to induce respiratory arrest for the purpose of putting down large animals.

Nicotine replacement therapy, used medicinally, is listed as a pregnancy category D. It causes injury, including genetic and epigenetic, to lab animals normally used in drug testing. The effects persist through multiple generations.

There is no safe dose. Nicotine is perhaps the most addictive drug in use today.

Snus is a biological product containing nicotine and other chemicals. Electronic cigarettes contain huge amounts of nicotine.

Are you willing to take responsibility to promote the release for wider use of this dangerous material when it will inevitably expose human fetuses to nicotine?

It is associated with attention deficit disorder and increased risk of blood vessel damage as an exposed child grows older. It has a direct impact on neurotransmitter activity, and consequently, brain development in mammals, and very likely also in exposed fetuses.

Please exercise your own humanity. Do not promote harm reduction strategies or addictive substances that receive tax benefits, neither which have adequate testing for what is being proposed in HCR 3033.

Thank you.

Dr. Jim Hughes
St. Alexius Heart and Lung Clinic
Bismarck, ND
701-226-0310

**HCR 3033 - Harm Reduction Strategies for Mitigating Tobacco Risk
Current Recommended Guidelines and Resources for Tobacco Cessation**

Chairwoman Lee and members of the Senate Human Services Committee, my name is Dr. Eric L. Johnson. I'm here to share some of my expertise as a physician, as someone dedicated to helping North Dakota smokers quit, and to provide a perspective based on my own personal experiences with nicotine and its harmful effects. I am an Associate Professor in the department of Family and Community Medicine at the UND School of Medicine, a physician consultant for ND Quits since its inception in 2004, and the board president of Tobacco Free North Dakota. I received training in tobacco cessation strategies at the Mayo Clinic course. In addition, I am a former smoker and am currently recovering from a stroke I suffered in September 2012 which, quite frankly, possibly could have been prevented had I never put a cigarette in my mouth starting at the age of 14 and smoked for over 25 years after that.

Basic tobacco facts on which we can, and should, all agree:

- Cigarettes are proven and widely known to cause heart disease, stroke, and a number of cancers.
- Smokeless tobacco products, such as spit tobacco and snus, have different sets of health problems, including oral and gastrointestinal cancers.

[This is well-established information, and you may refer to the current U.S. Surgeon General's report, the Centers for Disease Control website, and Mayo Clinic's Nicotine Dependence Center website for a summary of the decades of research in these areas.]

Some brief information on **electronic cigarettes, or e-cigarettes/e-cigs**²:

- E-cigarettes, are battery-operated devices designed to look like regular tobacco cigarettes. Here's how they work: An atomizer heats a liquid containing nicotine, turning it into a vapor that can be inhaled and creating a vapor cloud that resembles cigarette smoke.
- Manufacturers claim that electronic cigarettes are a safe alternative to conventional cigarettes. The FDA, however, doesn't. Some e-cig manufactures have additional problems with the FDA, including five companies in 2010 cited for manufacturing violations.

Harm reduction strategies, simply defined as "using smokeless tobacco to reduce cigarette use", are being proposed to "reduce the overall disease burden of tobacco".

- A considerable amount of harm reduction "data", such as substituting smokeless tobacco or e-cigarettes for traditional cigarettes, comes from tobacco company funded research.
- No significant data exists proving that switching from cigarettes to smokeless tobacco products or to e-cigarettes actually leads to cessation.

AS A RESULT, HARM REDUCTION STRATEGIES ARE NOT U.S. FDA OR U.S. PUBLIC HEALTH SERVICE APPROVED STRATEGIES.

The FDA and U.S. Public Health Task Force have provided **proven strategies and medications that are recommended by reputable smoking cessation programs**³. These guidelines include:

- A number of safe, FDA-approved smoking cessation products that are prescribed every day. Recommendation of nicotine replacement products such as patches, gum, and lozenges based on proven data for appropriate clients without the negative health consequences of tobacco products. As well, prescription medications such as Chantix and Bupropion are

FDA-approved for smoking cessation. [See “Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation” [handout for additional information](#)]

- Counseling, which, in North Dakota, is offered through ND Quits, a telephone and online quit program, is a key component in successful tobacco cessation.
- Abstinence from tobacco is considered a best practice in guideline-based cessation programs. Medically, nicotine addiction is just like addictions to alcohol and other drugs. The cornerstone of all addiction treatment is abstinence, and that, too, is true for tobacco. We don’t tell alcoholics to drink less or that they’d be ok having a single instead of a double, and we don’t advise meth addicts to drink alcohol to get off meth.

North Dakota has many private and public entities – hospitals and ND Quits, among others – that already rely on approved and best practice medical treatments for tobacco addiction, just as they would for the care of any medical condition⁴. If smokeless tobacco products and e-cigarettes deserve to be treated as effective cessation products, the FDA will let us know. If these products were currently proven to be safe and effective for cessation, doctors, myself included, and other health care professionals in North Dakota, would already be using them as such.

On its face, this resolution has a nice ring to it, and I guarantee that after your recommendation is given and this comes for a full vote of the Senate, someone will stand up on the Senate floor and say this is a way to help people stop smoking. It’s your responsibility to carry this message and respond with the truth.

The fact is, this resolution was submitted at the request of the tobacco industry and supported in the House Human Services Committee by only two people – one of the resolution’s co-sponsors, who voted AGAINST it on the House floor, and a man from Kentucky who is flying all over the country on the tobacco industry’s dime requesting this exact same thing of other state legislatures.

In my opinion, this resolution is just a wolf in sheep’s clothing. While we absolutely support reducing the harms of tobacco, we do so based on science. Tobacco companies have a right to sell their products, but they shouldn’t do it under false pretenses. They want the state of North Dakota to help market their products under this false pretense of research.

I oppose this study and ask this committee to save North Dakota taxpayers’ time and money, to trust health care professionals and the FDA, and to give HCR 3033 a “Do Not Pass” recommendation.

Eric L. Johnson, M.D.
Grand Forks, ND
701-739-0877
dead734@yahoo.com

References

1. Surgeon General’s Reports on Smoking and Tobacco Use. (accessed February 24, 2013) http://www.cdc.gov/tobacco/data_statistics/sgr/index.htm
2. Public Health Focus: Electronic Cigarettes. United States Food and Drug Administration. (accessed February 24, 2013) <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>
3. Treating Tobacco Use and Dependence. United States Public Health Service. (accessed February 24, 2013) <http://www.ncbi.nlm.nih.gov/books/NBK63952/>
4. Tobacco Facts. North Dakota Department of Health. (accessed February 24, 2013) <http://www.ndhealth.gov/tobacco/Facts.htm>

PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS FOR SMOKING CESSATION

		NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS				BUPROPION SR	VARENICLINE
		GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	
PRODUCT	Nicorette¹, Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint, orange	Nicorette Lozenge,¹ Nicorette Mini Lozenge,¹ Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CQ¹, Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS² Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution	Nicotrol Inhaler² Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban¹, Generic Rx 150 mg sustained-release tablet	Chantix² Rx 0.5 mg, 1 mg tablet
	PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ (Rx formulations, category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications or medical conditions known to lower the seizure threshold Severe hepatic cirrhosis Pregnancy³ (category C) and breastfeeding Adolescents (<18 years) <p>Warning:</p> <ul style="list-style-type: none"> BLACK-BOXED WARNING for neuropsychiatric symptoms⁴ <p>Contraindications:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines MAO inhibitor therapy in previous 14 days
DOSING	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>>10 cigarettes/day: 21 mg/day x 4 weeks (generic) 6 weeks (NicoDerm CQ)</p> <p>14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><u>≤ 10 cigarettes/day:</u> 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day)</p> <p>One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> – 5 doses/hour or – 40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3–6 months 	<p>6–16 cartridges/day</p> <p>Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3–6 months 	<p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1–2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Can be used safely with NRT Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1–3: 0.5 mg po q AM</p> <p>Days 4–7: 0.5 mg po bid</p> <p>Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> Begin therapy 1 week prior to quit date; alternatively, the patient can begin therapy and then quit smoking between days 8–35 of treatment Take dose after eating and with a full glass of water Dose tapering is not necessary Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients

		NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS				BUPROPION SR	VARENICLINE
		GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> – Lightheadedness – Nausea/vomiting – Throat and mouth irritation 	<ul style="list-style-type: none"> ▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia 	<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ Insomnia ▪ Dry mouth ▪ Nervousness/difficulty concentrating ▪ Rash ▪ Constipation ▪ Seizures (risk is 0.1%) ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)
	ADVANTAGES	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to rapidly manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage) 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Might delay weight gain ▪ Can be used with NRT ▪ Might be beneficial in patients with depression
DISADVANTAGES	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Patients must use proper chewing technique to minimize adverse effects ▪ Gum chewing may not be socially acceptable 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ Patients cannot titrate the dose to acutely manage withdrawal symptoms ▪ Allergic reactions to adhesive might occur ▪ Patients with dermatologic conditions should not use the patch 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Nasal/throat irritation may be bothersome ▪ Patients must wait 5 minutes before driving or operating heavy machinery ▪ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Initial throat or mouth irritation can be bothersome ▪ Cartridges should not be stored in very warm conditions or used in very cold conditions ▪ Patients with underlying bronchospastic disease must use with caution 	<ul style="list-style-type: none"> ▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ▪ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ May induce nausea in up to one third of patients ▪ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS)
	COST/DAY ⁵	2 mg or 4 mg: \$2.25–\$4.41 (9 pieces)	2 mg or 4 mg: \$2.61–\$4.95 (9 pieces)	\$1.87–\$3.52 (1 patch)	\$4.43 (8 doses)	\$7.68 (6 cartridges)	\$3.62–\$7.46 (2 tablets)

¹ Marketed by GlaxoSmithKline.

² Marketed by Pfizer.

³ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

⁴ In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a healthcare provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve.

⁵ Average wholesale price from Medi-Span Electronic Drug File. Indianapolis, IN: Wolters Kluwer Health, July 2011.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

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HCR 3033
Senate Human Services Committee Hearing
4-2-2013

Good morning, Chairwoman Lee and members of the Senate Human Services Committee. My name is Jacob Sommerfeld, and I am a senior at Century High School here in Bismarck. I am a member of the SADD, Students Against Destructive Decisions, and I'm here with three fellow SADD members Amanda Jordan, Jessica Paul and Amber Jordan, as well as our SADD Advisor, Mrs. Laurie Foerderer.

We are here to provide a young person's thoughts and to show you the faces of the people you will affect and INFLUENCE with the decision you make on this resolution.

We have been taught from a young age about the harms of using tobacco and the effects it would have on our health if we started. We all agreed that we've probably been taught the most about cigarettes, the science proving what's in them, and why they're so bad for us. We have also been taught about smokeless tobacco, or chew. And because these two specific products have become fairly widely known, we know that education is working for prevention and hope that continues.

But now the tobacco industry is coming out with new products because we're catching on to their old ones, and they're continuing to advertise to and target our friends and classmates by spending millions of dollars a day telling us how cool and safe these new products are. And now we've learned that the tobacco industry is sending people up to our state to ask you, our legislators, to tell us how safe they are too.

One of the newest products released by the tobacco industry are electronic cigarettes. These can be bought right across the street from Century High at the gas station where we buy pop, TCBY and Happy Joe's Pizza. Celebrities are endorsing them as a "cool new product" even though studies by the FDA haven't even been completed yet, so we don't even know what is in them. How can anyone, with a straight face, claim these are "safer" than other products when the FDA hasn't even finished studying them?

While we pass a couple examples of e-cigarettes around for you to see, let me read you the labels from both an e-cigarette and from a can of chew:

From South Beach Smoke, an e-cigarette: "South Beach Smoke products are not smoking cessation products and have not been tested as such. The U.S. FDA has not approved these products for any use and they are not intended to diagnose, cure, mitigate, treat, or prevent any disorder, disease, or physical or mental condition. South Beach Smoke products contain nicotine, a chemical known... to cause birth defects or other reproductive harm. Nicotine is addictive and habit forming, and it is very toxic by inhalation... Physical effects of nicotine may include increased heart rate and accelerated blood pressure."

And from a can of Wintergreen Copenhagen: *“WARNING: This product can cause mouth cancer.”* And, *“WARNING: This product is not a safe alternative to cigarettes.”*

Our point is simple. This is a bad road to go down. I know they’re just asking for a “study”, but a study legitimizes the idea. Would you feel comfortable telling us, or your children or grandchildren, to just use chew or smoke e-cigarettes instead of regular cigarettes? If you pass this, that’s the message we feel you are sending us.

We are members of SADD because we want to discourage our friends from making destructive decisions. We are here today to discourage you from endorsing a destructive decision.

Thank you. We appreciate the chance to be here today and will try to answer any questions.

Jacob Sommerfeld, Jessica Paul, Amber Jordan and Amanda Jordan
Century High School SADD students
Bismarck, ND



New and Emerging Smokeless Tobacco Products

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Not a Safe Alternative to Cigarettes

Smokeless tobacco products, including snus and dissolvables such as strips, orbs, and sticks, are part of a new series of emerging tobacco products currently being promoted by the tobacco industry as less harmful, more convenient, and more socially acceptable alternatives to traditional cigarettes. However, there is no scientific evidence that smokeless tobacco products are safe and the use of smokeless tobacco products is not considered a safe substitute for, or an effective means of, quitting tobacco use altogether.

The tobacco industry has marketed a new generation of smokeless tobacco products as a temporary way to deal with increasing cigarette taxes and smoke-free policies in public places, thus encouraging dual use (the use of two or more tobacco products) and reducing the incentive to quit.

The Emergence of Smokeless Tobacco Products

- Between 1965 and 2004, cigarette smoking among American adults declined by half, from 42% to 21%. Since 2004, the smoking prevalence has continued to decline, but at a much slower rate.¹
- In 2010, the percentage of Americans who smoke cigarettes fell below 20% for the first time since just after World War I.²
- Cigarette and tobacco manufacturers recognize that a rise in indoor smoking restrictions, smoking-related health concerns, taxes on cigarettes, and reduced social acceptability of smoking has led to a reduction in smoking rates.³
- Since 2005, major cigarette manufacturers have, either through partnership or acquisition, moved into the smokeless tobacco business. Smokeless tobacco products introduce both smokers and non-smokers to new products for use in situations where smoking is restricted, while also providing a means for the tobacco industry to recapture revenue lost as a result of the decline in cigarette smoking.⁴
- Smokeless tobacco products include moist snuff, chewing tobacco, snus (a “spitless, moist powder tobacco pouch), dissolvables (Orbs, Strips, and Sticks), and a variety of other tobacco-containing products that are not smoked.⁵

Health Risks

Although more research is needed to determine the full scale of health effects from smokeless tobacco products, several risks are currently documented. To date, use of smokeless tobacco has been shown to cause:^{6,7,8}

- Cancer of the mouth, pancreas, and esophagus
- Precancerous mouth lesions
- Dental problems including gum recession, dental carries, and bone loss around the teeth.
- Nicotine addiction

Harm Reduction

Despite the risks, smokeless tobacco products are promoted by the tobacco industry as providing harm reduction, or as an alternative to the abstinence of risky behavior.⁹ Although the tobacco industry, which has been convicted under federal racketeering laws for decades of conspiracy to deceive the public, touts these new products as “reduced harm” or “reduced or modified risk”, and indeed not all tobacco products are equally harmful, there is no such thing as a safe tobacco product.

The tobacco industry survives and profits greatly from selling a highly addictive product that causes diseases, which lead to a staggering number of deaths each year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national healthcare system. In 2010, the combined profits of the six leading tobacco companies was \$35.1 billion, equal to the combined profits of Coca-Cola, Microsoft, and

McDonald's in the same year.¹⁰ However, in order to make these profits, the industry misrepresents and deceives the American public.

- Laboratory analysis by the University of Minnesota revealed the presence of both toxicants and carcinogens in several brands of snus.¹¹
- Chemical analysis by Indiana University – Purdue University Indianapolis scientists found that dissolvable tobacco contains nicotine and a variety of flavoring ingredients, sweeteners, binders, and humectants. Of the flavor compounds identified, ethyl citrate is acutely toxic with oral dosing; cinnamaldehyde is an oral irritant and may increase the risk of gum and mouth disease, and coumarin, which has been banned as a flavoring agent in food for decades, is a liver and kidney toxicant.¹²
- Carcinogenic tobacco-specific N-nitrosamines (TSNAs) have been found in smokeless tobacco products.¹³
- To date, none of the products produced by the tobacco industry are recognized by the FDA as either a harm reduction or smoking cessation tool.

Marketing and Use

In 2006, the year that RJ Reynolds and Philip Morris USA began test-marketing their own smokeless tobacco products, spending on advertising and promotions for smokeless tobacco products was \$354.1 million. Just two years later, in 2008, that figure rose 50%, to \$537.9 million.¹⁴ At the same time, cigarette advertising decreased from \$12.49 billion in 2006 to \$9.94 billion in 2008,¹⁵ signaling a distinct shift in focus within the tobacco industry.

Dual use of cigarettes and smokeless tobacco products is of particular concern for public health and of particular interest to the tobacco industry.¹⁶ Dual use of cigarettes and smokeless tobacco products supports revenue streams for tobacco companies while also supplying multiple avenues for nicotine distribution, thus supporting nicotine addiction and, ultimately, continued use of the industry's products.¹⁷

Case Study: Indiana

In 2006, Philip Morris, USA, announced the test marketing of Toboka, a new, "spitless", smokeless tobacco product, in Indianapolis, IN. Between August 2006 and March 2008, Toboka was heavily promoted throughout Indianapolis, widely available, and heavily marketed with signage offering two-for-one deals and the proclamation that Toboka was a safer, more convenient alternative to traditional cigarettes. However, little research existed then, or now, on the safety of Toboka and other similar products, thus leaving a majority of Toboka advertising claims unsubstantiated.

Flashing forward six years, and prompted by the tobacco industry, in 2012 the Indiana General Assembly introduced a bill (H.R. 0059) that would create an interim study committee to consider tobacco harm reduction strategies as a strategy for reducing smoking-attributable death and disease. Tobacco industry lobbyists and their allies made lavish presentations to legislators about the benefits of encouraging the use of smokeless tobacco and other tobacco products that they call "reduced harm".

However, there is a substantial body of objective scientific evidence demonstrating that the three most effective strategies for reducing the death and disease resulting from all tobacco products include:

- 1) Increasing the price of all tobacco products through regular, significant tax increases;
- 2) Implementing 100% smoke-free laws in all workplaces, restaurants, and bars; and
- 3) Fully funding comprehensive state tobacco prevention and cessation programs. These three proven strategies must be considered before the utilization of tobacco products is promoted.

- Many traditional smokeless tobacco users are dual users of cigarettes and smokeless tobacco.^{18,19,20}
- Use of smokeless tobacco products by persons aged 12 or older has increased by more than 51% since 2003.²¹
- While cigarette smoking among youth ages 12-17 declined more than 50 percent between 2002 and 2010, the use of smokeless tobacco products among youth increased 15 percent during that same time period.²²
- According to the 2012 Surgeon General's report, Preventing Tobacco Use Among Youth and Young Adults, concurrent use of multiple types of tobacco products is common among teen tobacco users. Among high school

students who use tobacco, nearly one-third of females and more than one-half of males report using more than one type of tobacco product in the last 30 days.²³

- A 2009 study drawn from four nationally representative surveys in the U.S. demonstrated that occasional smokeless tobacco users are more likely to be current daily smokers than any other group, illustrating a pattern of tobacco use that may represent a partial substitution of smoking but a prolonging of dependence on tobacco products.²⁴
- A content analysis of Camel snus advertisements found frequent tie-in cigarette promotions or references to the benefits of using snus relative to cigarettes.²⁵
- An analysis of receptivity to Toboka and Camel snus in the Indiana test market one year after product introduction demonstrated a substantial initial interest in the new products among male smokers, especially those who received promotional mailings from tobacco companies, which often included coupons for free and discounted products.²⁶
- A review of more than eight million internal tobacco industry documents demonstrated that tobacco manufacturers, including cigarette and smokeless tobacco companies, develop products designed to augment cigarette use when smoking is not possible, develop new smokeless tobacco products to exploit smokers and target smokers who would otherwise quit, and a ttempt to deter quitting by developing products that appear to be less addictive and more socially acceptable.^{27,28}
- Smokers who use smokeless tobacco products as a supplemental source of nicotine to postpone or avoid quitting smoking may increase rather than decrease their risk of lung cancer.²⁹

ACS CAN's Current Views and Recommendations

ACS CAN and the Society support enacting evidence-based, comprehensive tobacco control policies that extend equally to all tobacco products, without any loopholes or exemptions. Specifically, we recommend:

- Eliminating price discrepancies between cigarettes and other tobacco products (OTPs) by increasing the tax on a package of OTPs to an equivalent percentage of the manufacturer's price as the tax on cigarettes.
- Ensuring that the definition of "tobacco product" in new laws is sufficiently broad to include all types of tobacco products, including dissolvable tobacco products and e-cigarettes. ACS CAN and the Society do not support exempting any type of smoked or smokeless tobacco product from smoke-free and tobacco-free laws and policies, tobacco tax increases, or tobacco sales or marketing restrictions.
- Fully funding, promoting, and providing access to all FDA-approved cessation medications.
- While the federal law giving the Food and Drug Administration (FDA) the authority to regulate tobacco products provides a number of restrictions on the manufacturing, marketing, labeling, distribution and sale of tobacco products, it also allows states to further restrict or regulate the time, place and manner (but not the content) of tobacco product advertising or promotions. While some of the regulations in the FDA law apply only to cigarettes, including restrictions on flavored cigarettes and minimum pack size requirements, ACS CAN and the Society support extending appropriate restrictions to all tobacco products.
- Funding and support for increased objective and independent research on OTPs, including evaluation and surveillance of health risks.
- Questions about smokeless tobacco products and their use should be included on national and state-level surveys, particularly those targeting youth and young adults, in order to obtain information about the prevalence and patterns of smokeless tobacco product use. Such information can be used to improve tobacco prevention and cessation initiatives.

References

- ¹ American Cancer Society. (2012). "Cancer Facts and Figures." Atlanta: American Cancer Society.
- ² US Department of Health and Human Services. (1989). "Reducing the Health Consequence of Smoking: 25 Years of Progress. – A report of the Surgeon General." <http://profiles.nlm.nih.gov/ps/access/NNBBXS.pdf>
- ³ Carpenter, CM, et al. (2009). "Developing smokeless tobacco products for smokers: An examination of tobacco industry documents." *Tobacco Control*, 2008; 18:54-59.
- ⁴ O'Connor, R. et al. (2011). "US smokers' reactions to a brief trial of oral nicotine products." *Harm Reduction Journal*, 2011; 8:1. <http://www.harmreductionjournal.com/content/pdf/1477-7517-8-1.pdf>
- ⁵ American Cancer Society. (2012). "Cancer Facts and Figures." Atlanta: American Cancer Society.
- ⁶ Stepanov, I, Ph. D. (2008). "New and traditional smokeless tobacco: Comparison of toxicant and carcinogen levels." *Nicotine and Tobacco Research*, 2008; 10:12.
- ⁷ Benowitz, NL. (2011). "Smokeless Tobacco as a Nicotine Delivery Device: Harm or Harm Reduction." *Clinical Pharmacology and Therapeutics*, Oct 2011; 90:4.
- ⁸ American Cancer Society. (2012). "Cancer Facts and Figures." Atlanta: American Cancer Society.
- ⁹ Sami, M. et al (2012). "Smokers' perceptions of smokeless tobacco and harm reduction." *Journal of Public Health Policy*, 33:2.
- ¹⁰ The World Lung Foundation and American Cancer Society (2012). "The Tobacco Atlas." <http://www.tobaccoatlas.org/>
- ¹¹ Stepanov, I, et al. (2008). "New and traditional smokeless tobacco: Comparison of toxicant and carcinogen levels." *Nicotine and Tobacco Research*, Dec 2008; 10:12.
- ¹² Rainey, CL, et al. (2011). "Chemical Characterization of Dissolvable Tobacco Products Promoted To Reduce Harm" *Journal of Agricultural and Food Chemistry* 2011; 59.
- ¹³ Benowitz, NL. (2011). "Smokeless Tobacco as a Nicotine Delivery Device: Harm or Harm Reduction." *Clinical Pharmacology and Therapeutics*, Oct 2011; 90:4.
- ¹⁴ Federal Trade Commission (2011). "Federal Trade Commission Smokeless Tobacco Report for 2007 and 2008." Accessed on June 28, 2012 at <http://www.ftc.gov/os/2011/07/110729smokelesstobaccoreport.pdf>
- ¹⁵ Ibid.
- ¹⁶ Carpenter, CM, et al. (2009). "Developing smokeless tobacco products for smokers: An examination of tobacco industry documents." *Tobacco Control*, 2008; 18:54-59.
- ¹⁷ Ibid
- ¹⁸ Severson, HH, et al. (2007). "Use of smokeless tobacco is a risk factor for cigarette smoking." *Nicotine and Tobacco Research*, 2007; 9.
- ¹⁹ Tomar, SL, et al (2010). "Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys." *Tobacco Control*, 2010; 9.
- ²⁰ Tomar, SL. (2003). "Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience." *Nicotine and Tobacco Research*, 2003; 5:561.
- ²¹ Substance Abuse and Mental Health Services Administration. Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings. 2011. Available at <http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm>
- ²² Ibid.
- ²³ U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA, 2012.
- ²⁴ Tomar, SL, et al (2010). "Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys." *Tobacco Control*, 2010; 9.
- ²⁵ Timberlake, et al. (2011). "A Content Analysis of Camel Snus Advertisements in Print Media." *Nicotine and Tobacco Research*, June 2011; 13:6.
- ²⁶ Biener, L and Bogen, K. (2009). "Receptivity to Taboka and Camel Snus in a U.S. test market." *Nicotine and Tobacco Research*, Oct 2009, 11:10
- ²⁷ Carpenter, CM, et al. (2009). "Developing smokeless tobacco products for smokers: An examination of tobacco industry documents." *Tobacco Control*, 2008; 18:54-59.
- ²⁸ Ling, P, et al. (2004). "Tobacco Industry Research on Smoking Cessation: Recapturing Young Adults and Other Recent Quitters." *Journal of General Internal Medicine*, 2004; 19.
- ²⁹ Henley, SJ, et al. (2005). "Two large prospective studies of mortality among men who use snuff or chewing tobacco." *Cancer Causes Control*, 2005; 16:4.

Testimony

Senate Human Services Committee
HCR 3033

Deb Knuth
American Cancer Society Cancer Action Network
Tuesday, April 2, 2013

Tobacco kills nearly half a million Americans every year and is responsible for nearly one-third of all cancers. The American Cancer Society Cancer Action Network is committed to reducing tobacco use in all its forms because we know it will ease the burden of cancer in North Dakota and throughout the rest of the country. We are supportive of any genuine efforts to help cigarette smokers quit their deadly addiction; however, smokeless tobacco products are neither a safe substitute for cigarettes, nor an effective method of quitting smoking. We urge the Senate Human Services Committee to reject HCR 3033.

There is no need for this study, since both the U.S. Surgeon General and the U.S. Public Health Service, credible, non-conflicted sources, have already studied these products and determined that, at this time, the available reduced harm products do not provide a path to quitting.

In fact, HCR 3033 would circumvent the effects of the Family Smoking Prevention and Tobacco Control Act, the historic legislation passed by Congress in 2009 that finally gave the Food and Drug Administration the authority to regulate the manufacture, sale, and marketing of tobacco products. In March 2012, the FDA issued strong draft guidelines requiring tobacco companies to provide scientific proof to support any claims that their products reduce harm to the public, including existing and potential consumers.

To further support your rejection of HCR 3033, we ask you to consider the following:

- **Smokeless tobacco is not a safe product.** Smokeless tobacco products contain as many as 28 known carcinogens and 3-4 times as much nicotine as cigarettes. Smokeless tobacco has also been linked to esophageal and pancreatic cancer, as well as leukoplakia (white sores in the mouth that can lead to cancer), gum disease, and bone loss around the teeth.
- **There is no evidence that smokeless tobacco products help smokers quit.** The 2008 Update of the U.S. Public Health Service Clinical Practice Guidelines regarding tobacco cessation concluded, “the use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit.” In

addition, a 2009 study found that it was more likely for American smokeless tobacco users to switch to cigarettes than for smokers to switch to smokeless.

- **Smokeless tobacco may provide a gateway to tobacco use, especially among kids.** Unlike cigarettes, smokeless tobacco is permitted to be sold in flavors such as cherry, grape, peach, and cinnamon. Use of these candy-like flavors alone makes it more likely kids will take up a deadly nicotine addiction. If kids are also getting the message that smokeless products are “not as bad” as cigarettes, the likelihood of beginning tobacco use only increases.
- **There are already proven methods to reduce smoking.** Studies show the most effective means to keep kids from taking up smoking and to encourage current smokers to quit is to increase tobacco taxes, provide adequate funding for evidence-based prevention and cessation programs, and pass comprehensive smoke-free laws.

For these reasons, we urge you to reject HCR 3033. Thank you for your time and considerations.



American Heart Association | American Stroke Association

Learn and Live.

HCR 3033

Senate Appropriations

AHA Testimony

Good afternoon Chairman Lee and members of the Senate Human Services Committee. For the record, I am June Herman, Regional Vice President of Advocacy for the American Heart Association. I ask for your Do Not Pass recommendation on HCR 3033.

As the bill title states*, Legislative Management is being asked to take on the work typically provided by the FDA for medical product review and by national science review groups for medical treatment recommendations. For the state to undertake a tobacco use statement and medical advisory role without sufficient product review and vetting by medical science and treatment advisory groups could place the state in a position of significant liability. Such statements of reduced harm have not worked for the tobacco industry in the past, with significant liability court costs and settlement dollars.

HCR 3033, the reduced tobacco harm study resolution goes far beyond studying how to implement consensus, science based medical treatments, and for that reason, should receive your Do Not Pass recommendation to the full Senate. This scope is beyond the typical legislative study review, and is a direction the state of North Dakota should not travel. Systems exist through which scientific bodies review promising medical treatments, and make recommendations for treatment standards. Practice guidelines are clinical documents of high methodological rigor, which facilitate evidence-based decision making. They reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. Appropriately constructed practice guidelines intend to minimize harm, reduce inappropriate practice variations, and assist in producing optimal health outcomes for patients. Give HCR 3033 a Do Not Pass.

*A concurrent resolution directing the Legislative Management to study opportunities to reduce the risk of death and disease among smokers who will not quit smoking, by considering tobacco harm reduction strategies that encourage smokers to switch from cigarettes to less risky tobacco products and by accurately informing the public of the health risks posed by smokeless tobacco products, vapor products, and tobacco-derived products relative to cigarettes.



Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines

June 2010

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1. Overview of Methodology

1.1. Importance of ACCF/AHA Guidelines

The Institute of Medicine defines clinical practice guidelines as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.” (1990) Evidence-based medicine is a coherent approach to clinical decision making. The Institute of Medicine defines evidence-based medicine as the “integration of best researched evidence and clinical expertise with patient values.” (*Institute of Medicine (2001). Crossing the quality chasm: A new health system for the 21st century. Washington, DC: National Academies Press*). Well-developed guidelines have the potential to enhance the appropriateness of clinical practice, improve the quality of cardiovascular care, lead to better patient outcomes, improve cost effectiveness, and identify areas of further research needs.

The creation of clinical practice guidelines has been a joint activity between the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) since the 1980s. Practice guidelines are clinical documents of high methodological rigor, which facilitate evidence-based decision making and incorporate group values and patient preferences. The development of these guidelines is intended to be evidence-based, transparent, and systematic. Guidelines advance the missions of both organizations by providing clinical recommendations to healthcare providers for the purpose of improving cardiovascular health.

ACCF/AHA Guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. These guidelines attempt to define practices that meet the needs of most patients in most circumstances. They reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. These guidelines may be used as the basis for regulatory/payer decision making; however, the ultimate goal is quality of care and serving the patient’s best interests. The

final judgment regarding the care of a particular patient must be made by the healthcare provider and patient in light of circumstances specific to that patient.

Appropriately constructed practice guidelines intend to minimize harm, reduce inappropriate practice variations, and assist in producing optimal health outcomes for patients. Patient centric guidelines will be a keystone of patient-centered care.

The following nonexhaustive list includes important common uses of ACCF/AHA Practice Guidelines:

- Improve patient outcomes
- Synthesis of latest clinical research
- Determine whether practice follows the current evidence-based recommendations
- Reduce practice variation
- Influence policy
- Promote efficient resource usage
- Identify gaps in the evidence base
- Serve as a basis for development of Performance Measures and Appropriate Use Criteria

1.2. Purpose and Scope of the Manual

To continue as a leader in the field of clinical practice guidelines, the ACCF/AHA Task Force on Practice Guidelines (Task Force) has overseen the creation of this manual to assist guideline writing committees in navigating guideline development. This manual is intended to assist guideline authors with crafting recommendations that will influence care or assess performance and/or quality. The recommendations can then be translated into action or activity that can be implemented and measured.

The bulk of this manual consists of tools to assist guideline writers in interpreting and applying the methodology. A flowchart highlighting the key steps in the development of evidence-based guidelines (**Figure 1**) serves as the basis for organizing the manual. **Section 8** describes general

operating procedures that are integral to the guideline development process. These include relationships with industry and other entities (RWI), confidentiality agreement, copyright assignment and license agreement and the ACCF/AHA editorial response policy.

The Task Force understands the challenges in applying a uniform methodology to guidelines that represent diverse diseases, conditions, diagnostics, and interventions. In all cases, writing committee members should familiarize themselves thoroughly with the manual, as these policies and standards provide the framework for guideline development. However, if warranted, the Task Force may allow exceptions to the written policies.