Author's response to reviews

Title: Smokers' Reactions to FDA Regulation of Tobacco Products: Findings from the 2009 ITC United States Survey

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Author's response to reviews: see over
Reviewer's report
Title: Reactions to FDA Regulation of Tobacco Products: Findings from the 2009 ITC United States Survey
Version: 1 Date: 27 September 2011
Reviewer: adam goldstien
Reviewer's report:
Interesting paper with some useful data, but also some methodological and other concerns as below. Thank you for the opportunity to provide peer review.

The premise is a problem- that smokers would be aware of new law less than six months after the law’s passage. Recommend toning down this point and focusing on other issues.

RESPONSE: The authors agree that a low level of awareness should be the expectation given the dates of the legislation and the survey fieldwork.

The following paragraph has been added to the background section of the manuscript:

“The current manuscript reports data from a nationally representative sample of smokers measuring their attitudes and beliefs on specific issues relevant to the FSPTCA. Data were collected shortly after the passage of FSPTCA and prior to the enactment of any of the specific regulatory measures.”

Additionally, we added the following to the conclusions section of the manuscript:

“The study is limited since it only includes adult smokers and because this supplemental survey was conducted shortly after the passage of FSPTCA and prior to the implementation of any of the components of the regulations. Thus, it is not surprising that awareness of these new regulatory measures was low.”

Please make more clear why the attitudes of smokers about FSPTCA is relevant. Please make the case stronger in the intro.

RESPONSE: A paragraph outlining why this study is relevant has been added to the background section.

“While the FSPTCA was landmark legislation for tobacco control in the United States, there is limited public opinion data assessing general attitudes toward FDA tobacco regulation. A June 2009 Gallup Poll indicated that 46% of all Americans and only 28% of
smokers approved of FDA tobacco product regulation in concept [5]. The current manuscript reports data from a nationally representative sample of smokers measuring their attitudes and beliefs on specific issues relevant to the FSPTCA. Data were collected shortly after the passage of FSPTCA and prior to the enactment of any of the specific regulatory measures. Levels of support or opposition for specific regulations could be used by the FDA to inform methods for increasing consumer knowledge of tobacco related regulations.”

Not sure why you combined the evaluation of smoker packs with the analysis of smoker attitudes. These seem like fairly different topics. It seems like that in abstract and even more so in results. Would recommend removing that analysis from the paper and perhaps make it a separate analysis/letter.

RESPONSE: Both reviewers suggested removing the analysis from the pack collection component of the study from this manuscript. The authors agree with this suggestion. We have removed all references to the pack collection component of this study including the description in the methods section and observations in the results section.

It is also unclear why the researchers had smokers return packs of cigarettes to see about compliance with FDA. Why not simply go to the store and look at the packs?

RESPONSE: The initial aim of the pack collection was to assess the prevalence of contraband tobacco products. The change in descriptive terms in advance of the FDA legislation was merely an interesting observation. We have removed this analysis from the manuscript.
How do you know the packs sent for analysis were not bought before the FSPTCA law was passed?

RESPONSE: At the suggestion of both reviewers, we have removed this analysis from the manuscript.

The discussion about the terms such as “light” being used inappropriately by tobacco manufacturers, based on your survey in late 2009, but they did not have to quit using such terms until July, 2010. Please explain as it applies to your work and results.

RESPONSE: At the suggestion of both reviewers, we have removed this analysis from the manuscript.

Your intro focuses broadly on FDA potential interventions under FSPTCA, such as new warning labels, but your research has little to do with that intervention. Please tie your introduction to most relevant data to your study- e.g. why surveys of smokers can inform policy. It is perhaps clear to you why baseline data from sample of smokers about these issues is relevant, but you do not make the case.

RESPONSE: The authors agree and have removed from the background any text related to interventions that we are not assessing in this study.
You do say that this current survey is useful to measure baseline attitudes of smokers for the FSPTCA, but it appears you have annual surveys of smokers since 2002, so it is a little confusing (see above comment). How does this study relate, if at all to prior surveys?

RESPONSE: The questions measuring attitudes toward the FSPTCA were not asked prior to the 2009 survey. These questions were added to the 2009 US survey to measure attitudes around the time that the legislation was passed.

The authors have added this detail to the methods section of the manuscript.

“The ITC United States Supplemental Survey was conducted between November 2009 and January 2010 of the existing cohort at the previous wave of the ITC United States Survey (Wave 7, which had been conducted between October 2008 and July 2009). This supplementary survey included the addition of focused questions around issues pertinent to the FSPTCA in order to measure baseline knowledge and attitudes about the FSPTCA around the time that the Act was passed.”

What stopped potential participants from simply going out and buying a pack of cigarettes to get the $25?

RESPONSE: We have removed this analysis from the manuscript.

It is a little unclear how eligibility for participating in cigarette pack analysis was determined and why only 69% were eligible. Only a third of sample ultimately completed pack analysis (and less than 50% of eligible smokers). Why is this the case? What impact does this have on results?

RESPONSE: We have removed this analysis from the manuscript.
Can combine T2 and T3 (3 q’s total) into one table or eliminate T3 and simply put into text. Could also eliminate T4, 5 & 6, as results can simply be summarized in text.

RESPONSE: The authors appreciate this suggestion, but elected to leave all of the tables in the manuscript “as-is”. It was difficult to combine tables, as many of the questions had different response options.

You did several analyses by gender, income and education, but you do not mention them in your discussion anywhere. It would also be good to analyze the results by levels of smoking?

RESPONSE: The authors appreciate this suggestion and have included these details in the conclusions section. We analyzed the results by heaviness of smoking index (HSI) found no differences in levels of support. In other words, support for FDA regulations was generally strong, even among heavy smokers. We have added the following to the conclusions section:

“Support for potential regulations foreshadowed in the FDA legislation was generally stronger than for some of the more novel possibilities. Support for many FDA proposals was consistent among all smoker subgroups examined, including heavy smokers. Of the small number of statistically significant comparisons, most were related to age. When compared to older participants, 18-24 year olds were less likely to believe that their brand has been evaluated by the government, more likely to support a ban on tobacco company promotions, and were more likely to believe that light cigarettes are just as dangerous as regular strength cigarettes. This suggests a need to better target educational campaigns toward older smokers.

The finding that support is generally strong among heavy smokers, and comparable to that of light smokers, could be particularly important because it suggests that degree of nicotine dependence is not motivating opposition to regulation.”
It is necessary to mention limitations to your study. It would be good to discuss these for the reader.

RESPONSE: The authors agree and have added the following paragraph to the conclusions section:

“These findings from a nationally representative sample of smokers provide an indication of support for the specific provisions of the FSPTCA. The study is limited since it only includes adult smokers and because this supplemental survey wave was conducted shortly after the passage of FSPTCA and prior to the implementation of any of the components of the regulations. Thus, it is not surprising that awareness of these new regulatory measures was low. Future waves of the ITC United States Survey will continue to monitor how smokers’ beliefs and attitudes related to FDA regulation of tobacco products may change over time.”

Despite reading the paper twice, I am left with a “so?” sort of reaction. I think you need to make a case stronger for the rationale for this study, and why your results are important. I think it is a good study, but can be stronger.

RESPONSE: The authors have added the following paragraph to the background section.

“While the FSPTCA was landmark legislation for tobacco control in the United States, there is limited public opinion data assessing general attitudes toward FDA tobacco regulation. A June 2009 Gallup Poll indicated that 46% of all Americans and only 28% of smokers approved of FDA tobacco product regulation in concept [5]. The current manuscript reports data from a nationally representative sample of smokers measuring their attitudes and beliefs on specific issues relevant to the FSPTCA. Data were collected shortly after the passage of FSPTCA and prior to the enactment of any of the specific regulatory measures. Levels of support or opposition for specific regulations could be used by the FDA to inform methods for increasing consumer knowledge of tobacco related regulations.”

We also added the following two paragraphs to the conclusions section:

“It is clear from this study that smokers need to be better informed about the implications of FDA regulation. A large scale public education campaign from the FDA about the dangers of tobacco use and the regulatory powers they now have that is
coordinated with other national, state, and local partners would be useful. Because reducing nicotine levels has the potential to reduce addictiveness, thereby increasing consumer autonomy, such efforts to educate the public about this possible regulatory action would be important.”

These baseline data were collected shortly after the passage of the FSPTCA and prior to the enactment of any specific regulatory measures. These initial levels of support or opposition for specific policy measures can be used by the FDA to inform policy development and the need to educating smokers and the public at large about the purpose behind the regulation and of the kinds of regulatory controls the public are looking for. As specific regulatory measures of the FSPTCA are enacted, it will be important to assess any changes in knowledge and attitudes related to specific components of the regulations.”

How will this “baseline” data be useful in the future?

RESPONSE: The authors have added the following paragraph at the end of the discussion section:

“These baseline data were collected shortly after the passage of the FSPTCA and prior to the enactment of any specific regulatory measures. These initial levels of support or opposition for specific policy measures can be used by the FDA to inform policy development and the need to educate smokers and the public at large about the purpose behind the regulation and of the kinds of regulatory controls the public are looking for. As specific regulatory measures of the FSPTCA are enacted, it will be important to assess any changes in knowledge and attitudes related to specific components of the regulations.”

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I declare that I have no competing interests.
Reviewer's report
Title: Reactions to FDA Regulation of Tobacco Products: Findings from the 2009 ITC United States Survey
Version: 1 Date: 17 October 2011
Reviewer: Richard Edwards
Reviewer's report:
Reviewer report on “Reactions to FDA Regulation of Tobacco Products: Findings from the 2009 ITC United States Survey” by Brian V. Fix et al for BMC Public Health.

Richard Edwards, Oct 12 2011

This is a report from a cross-sectional sample of smokers from the US ITC cohort. The main focus is on describing attitudes towards potential FDA regulatory actions on tobacco products. There is also a sub-study of packs returned by regular smokers.....

I am broadly supportive of the publication of this paper, as it is important to document levels of support for important and topical tobacco control measures. This study provides some baseline data about levels of support for these measures which may be used to assess change (probably an increase) over time as debate about the FDA regulations develops.

BMC Public Health Questions
1. Is the question posed by the authors well defined? Yes, mostly
2. Are the methods appropriate and well described? Yes, mostly
3. Are the data sound? Yes
4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes, mostly
5. Are the discussion and conclusions well balanced and adequately supported by the data? Yes
6. Are limitations of the work clearly stated? No, not much on limitations
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? Yes, mostly
8. Do the title and abstract accurately convey what has been found? Yes, mostly
9. Is the writing acceptable? Yes
Compulsory revisions:

1. The last para of the background states “In the US, there is little data from a nationally representative sample of smokers to provide baseline measures [i.e. about support for the FDA regulatory powers]. I think this needs to be more explicit. Is there any published public opinion data from smokers or the general population? If so it should be referenced and any strengths/weaknesses/gaps noted. If this is the first such survey, then clearly it is of more interest as a paper.

RESPONSE: The following text has been added to the background section:

“While the FSPTCA was landmark legislation for tobacco control in the United States, there is limited public opinion data assessing general attitudes toward FDA tobacco regulation. A June 2009 Gallup Poll indicated that 46% of all Americans and only 28% of smokers approved of FDA tobacco product regulation in concept [5]. The current manuscript reports data from a nationally representative sample of smokers measuring their attitudes and beliefs on specific issues relevant to the FSPTCA. Data was collected shortly after the passage of FSPTCA and prior to the enactment of any of the specific regulatory measures. Levels of support or opposition for specific regulations could be used by the FDA to inform methods for increasing consumer knowledge of tobacco related regulations.”

2. There is no description given for the sampling methods (e.g. sampling frame and recruitment methods) for the US ITC sample. No reference is made to a published methods paper/report about the US ITC sample, for readers wanting further methodological detail.

RESPONSE: The authors re-formatted the entire methods section to provide more details on the sampling methods.

“The data source for this study is the International Tobacco Control (ITC) United States Supplemental Survey. The ITC United States Survey—as all ITC Surveys being conducted across 20 countries—includes questions to assess smoking behavior, attempts at cessation, and attitudes and beliefs about tobacco products, as well as questions pertaining to each of the demand reduction policies of the WHO Framework Convention on Tobacco Control (FCTC) (e.g., warning labels, smoke-free laws,
advertising/promotion, price/taxation) and a set of important psychosocial mediators and moderators of tobacco use and of cessation (e.g., perceived risk, quit intentions, time perspective). In general, the ITC Surveys are designed to evaluate the psychosocial and behavioral effects of national-level and sub-national tobacco control policies [6].

The ITC United States Survey began in 2002 and has been conducted approximately annually, in conjunction with ITC surveys in Canada, United Kingdom, and Australia; to date, 8 waves have been conducted. The ITC United States Survey utilizes random digit dialing to recruit a sample of randomly selected adult (≥ 18 years) smokers. Cohort members who are lost to follow-up are replaced with newly recruited participants from the same sampling frame to preserve the overall sample size from wave to wave. Thus, there is a longitudinal component and a representative cross-sectional component at each wave of every ITC survey.

The ITC United States Supplemental Survey was conducted between November 2009 and January 2010 of the existing cohort at the previous wave of the ITC United States Survey (Wave 7, which had been conducted between October 2008 and July 2009). This supplementary survey included the addition of focused questions around issues pertinent to the FSPTCA in order to measure baseline knowledge and attitudes about the FSPTCA around the time that the Act was passed. Further details of the sampling design used in the ITC survey can be found in a technical report, available on the ITC Project website at http://www.itcproject.org/ [7].

The total eligible sample size for the 2009-10 survey was 912 participants who at the preceding wave of the ITC United States Survey (Wave 7) reported being a daily smoker of 10 or more cigarettes per day, reported that they regularly smoked a particular variety of cigarettes, and provided the type of location where they usually purchase their cigarettes. These inclusion criteria facilitated a component of the study where unopened cigarette packs were collected from participants (results not reported in this manuscript). These data collection methods were reviewed and approved by the Roswell Park Cancer Institute Institutional Review Board and the University of Waterloo Human Research Ethics Committee.”
3. There are no confidence intervals given for the point estimates of support.

RESPONSE: The authors have added 95% confidence intervals around the point estimates of policy support to all of the tables in the manuscript. These are presented within parentheses in each cell in all the tables. A description of how the confidence intervals were calculated has been added to the methods section.

Discretionary revisions:

1. The purpose of the paper is described as to provide baseline measures of attitudes and beliefs in these areas (proposed and implemented FDA regulations) among smokers. The pack collection study rather seems to be a test of manufacturer compliance with the light and mild descriptor ban, and does not fit with the main purpose of the paper. I suggest this could be omitted and possibly submitted as a separate short report.

RESPONSE: Both reviewers suggested removing the analysis from the pack collection component of the study from this manuscript. The authors agree with this suggestion. We have removed all references to the pack collection component of this study including the description in the methods section and observations in the results section.

2. In the abstract, over half of the results section is taken up with the findings from the packs study (NB also see point 1 above). This seems unbalanced given the main paper focuses much more on the findings from the survey of smoker attitudes and support for tobacco control measures.

RESPONSE: We have removed all references to the pack collection component of this study including the description in the abstract.
3. In the background section, first page, the fourth bullet point is difficult to interpret e.g. are all of the listed to be banned? Which of the preceding list are currently stayed pending the outcome of litigation?

RESPONSE: The fourth bullet point has been changed for clarity.

“July 2010: banned specific types of advertising and marketing including vending machines and self service displays in non adult only venues, branded product tie-ins (e.g., Marlboro t-shirts), free cigarette samples, outdoor advertising within 1000 feet of schools, event sponsorship, and tombstone only advertising in magazines and point of sale in non-adult only facilities and magazines with youth readerships. These actions related to advertising and marketing are currently stayed pending the outcome of litigation.”

4. Some of the background material doesn’t seem that relevant e.g. the detail about previous research on the impact of GHWs. The smokers were not asked about GHWs in this study, so other than a brief statement that the FDA has introduced new requirements about GHWs, I am not sure much more information is needed.

RESPONSE: The authors agree with this point. The details regarding previous research on the impact of graphic health warnings, along with other irrelevant background materials, have been removed from the manuscript.
5. Where the dates for data collection are given, I think it would be worth stating that this occurred prior to any of the specific FDA regulation measures described in the bullet points in the background being implemented.

RESPONSE: The authors agree that this is information worth stating. The following sentence has been added to the last paragraph of the background section:

“The current manuscript reports data from a nationally representative sample of smokers measuring their attitudes and beliefs on specific issues relevant to the FSPTCA. Data were collected shortly after the passage of FSPTCA and prior to the enactment of any of the specific regulatory measures.”

6. Discussion could mention that this is baseline data, before there was much awareness of FDA regulatory powers; and that follow up data will be required to track support over time.

RESPONSE: The following was added to the conclusions section:

“These findings from a nationally representative sample of smokers provide an indication of support for the specific provisions of the FSPTCA. The study is limited since it only includes adult smokers and because this supplemental survey wave was conducted shortly after the passage of FSPTCA and prior to the implementation of any of the components of the regulations. Thus, it is not surprising that awareness of these new regulatory measures was low. Future waves of the ITC United States Survey will continue to monitor how smokers’ beliefs and attitudes related to FDA regulation of tobacco products may change over time.”

7. Last paragraph of the discussion seems a bit of a hot potch, and doesn’t really round off the paper.

RESPONSE: The authors have re-formatted this paragraph and added an additional paragraph to wrap the paper up.

“It is clear from this study that smokers need to be better informed about the implications of FDA regulation. A large scale public education campaign from the FDA
about the dangers of tobacco use and the regulatory powers they now have that is coordinated with other national, state, and local partners would be useful. Because reducing nicotine levels has the potential to reduce addictiveness, thereby increasing consumer autonomy, such efforts to educate the public about this possible regulatory action would be important.

These baseline data were collected shortly after the passage of the FSPTCA and prior to the enactment of any specific regulatory measures. These initial levels of support or opposition for specific policy measures can be used by the FDA to inform policy development and the need to educate smokers and the public at large about the purpose behind the regulation and of the kinds of regulatory controls the public are looking for. As specific regulatory measures of the FSPTCA are enacted, it will be important to assess any changes in knowledge and attitudes related to specific components of the regulations.”

Minor Essential Revisions

1. There is a typo where ‘higher education’ is repeated in footnote 2 for table 1”

RESPONSE: This has been corrected.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: No, except I have been an occasional collaborator and co-author with Ron Borland over the last 5-6 years.