INTRODUCTION

Through marketing and promotion, the tobacco industry (TI) is the vector of an exclusively anthropogenic pandemic: tobacco addiction. TI has a long history of targeting youth to ‘replace’ smokers and ensure the continuity of its markets. Exposure to tobacco marketing and products has been associated with an increase in smoking among adolescents. The development of attractive packaging is one of the many marketing strategies used to promote tobacco products among youth, increase brand appeal, and create misleading impressions about tobacco products. Reviews of TI documents show how cigarette packs are designed to target consumers and increase product appeal, including in Brazil.

To counterattack this strategy, the use of pictorial health warning labels (HWLs) is one of the best...
policies available. Besides decreasing the appeal of tobacco packaging, HWLs also inform consumers about the risks of smoking and stimulate quitting attempts\textsuperscript{9}. The WHO Framework Convention on Tobacco Control (FCTC) recommends a series of characteristics to develop effective packaging and labelling of tobacco products\textsuperscript{10}.

Considering the existing evidence on the efficacy of regulating packaging and labelling of tobacco products, including health warning labels, the Brazilian Health Regulatory Agency (ANVISA) published in 2010 a public consultation to establish new HWLs requirements and to ban the display of tobacco products at the point-of-sale (POS). This study reviews the approaches used by the TI as a response to the public consultation and analyzes the arguments used to prevent the implementation of the proposed regulations.

\textbf{METHODS}

We conducted a retrospective, qualitative analysis between January and June 2019. First, we conducted a literature review in PubMed (MEDLINE). Our search strategy included the terms: [tobacco industry] AND [HWLs], which resulted in 145 articles; and [tobacco industry] AND [display bans], which resulted in 88 articles. Our inclusion criteria were: a) papers published in English, Spanish or Portuguese; and b) papers about strategies used by the TI to undermine the implementation of HWLs and/or display bans. After screening, our final sample comprised 34 articles published between 2000 and 2019. The same search strategy was used in SCIELO; however, it did not result in any additional articles.

In order to identify additional documents related to the approaches used by the TI to prevent or minimize the HWLs, we employed snowball search techniques\textsuperscript{11} combining qualitative content techniques with interactive strategies\textsuperscript{12} at the ‘Truth Tobacco Industry Documents’ (TTID) library\textsuperscript{13}. All approaches identified via TTID were described in the scientific articles.

We also examined websites hosted by the TI or its allies, tobacco control organizations, and the federal government; in addition, we reviewed newspapers from Brazil’s main tobacco producer region as well as national newspapers to identify other sources of information related to the public consultation and TI’s reactions to it. We monitored legislative activity related to the public consultation via the official websites from the House of Representatives and the Federal Senate and additional internet search\textsuperscript{14,15}. We also obtained official material directly from ANVISA regarding the public consultation, including lawsuits, via the Access to Information Law\textsuperscript{16}.

When internal TI documents were cited by one of the sources, we triangulated the information with other documents (e.g. scientific papers, governments reports, FCTC documents) in order to ensure data reliability and reproducibility.

The TI strategies are presented following existing taxonomies on tobacco industry interference as described in Ulucanlar et al.\textsuperscript{17}. We chose this taxonomy, because it is internationally accepted and because it has already been used to present and describe IT strategies in Brazil\textsuperscript{18}.

\textbf{RESULTS}

All the approaches used by the TI to undermine the new regulations proposed by ANVISA had been previously reported, and most of them were used to oppose a public consultation held by ANVISA during the discussion on banning additives to tobacco products\textsuperscript{18}.

\textbf{TI resistance to the public consultation}

Brazil was the second country in the world to implement pictorial HWLs on tobacco packaging and is recognized as one of the world leaders in tobacco control. Despite its tobacco control pioneering spirit, the TI has been a fierce opponent with a long history of strategies to prevent or minimize HWLs in tobacco products\textsuperscript{19}. In 2010, ANVISA initiated the process to improve Brazil’s HWLs by organizing a public consultation\textsuperscript{20} on a proposed resolution to new HWLs.

Published on 28 December 2010, the public consultation, CP 117/2010, invited the population to provide comments to a draft proposal to Resolution 335/2003. The proposal included new tobacco packaging requirements, such as increased HWLs and new warning messages, and a ban on the display of tobacco products at the POS. The consultation lasted from January to April 2011, being the second longest public consultation in ANVISA’s history to date (behind only the public consultation regarding tobacco additives)\textsuperscript{18,21}. The draft proposal, in short,
contained the following provisions:

• New warning message occupying 50% of the front of the pack: ‘Smoking is a disease. You are entitled to treatment’.
• Larger health warning messages on both sides of the pack.
• Mandatory HWLs to secondary packaging.
• Specific warning message to cigars and little cigars: ‘These products cause mouth, tongue, and gum cancer and physical and chemical dependency. There are no safe levels to consume these substances’.
• Information provided by TI restricted only to brand name, manufacture date, type of product, quantities, manufacture (or importer) information, bar codes and contacts.
• Ban the use of words, images or any graphic features that could be used to promote or associate the product to: health benefits, relaxing proprieties, added value, promoting (directly or indirectly) the consumption, sexuality, product characteristics, commemorative dates, sports, inducing the use in prohibited places, expressions in languages other than Portuguese.
• New HWLs messages should occupy 60% of advertising material when displayed at the POS.
• Ban the display of tobacco products at POS, except at tobacco shops.
• Ban the promotional approach of tobacco products.

Contributions to the public consultation were mailed, emailed or hand-delivered to ANVISA. A valid contribution was determined using the same approach of previous work about TI in Brazil.

Of the 140754 letters received by mail/hand-delivered, only 28 were, in effect, a contribution. Of the 1020 participations received by email, 301 were in effect contributions. This public consultation along with the one to ban additives on tobacco products are those that have received more contributions in total. This is of concern because it has been previously reported that this is an approach used by the TI to delay the analysis of the public’s comments and, as a result, the implementation of the proposed resolution. The analysis of the documents obtained from ANVISA revealed that:

1. Printed forms were used by the TI and supporters to contest the new regulations. These forms contained instructions on how to be filled in. Despite the theme not directly correlated to tobacco cultivation, more than 95% of participants identified themselves as tobacco growers.
2. Approximately 2000 were blank forms sealed sent directly from the print shop.
3. Most forms were not filled in, preventing the correct identification of the responsible for the contribution.

The TI paid a series of advertisements targeting tobacco growers, small business owners and the general population to spread the idea that the measures proposed by CP 117/2010 would increase illicit trade, negatively affect small business and farmers, affect the product information directed to consumers, and interfere in the consumers’ freedom of choice. One of these advertisements published on a national newspaper, in a reference to the letters sent to ANVISA, stated: ‘Everybody has their own opinion. In this case, 150000 have the same’.

These strategies could explain the massive participation of tobacco growers in the public consultation (more than 95% of participants), who were concerned about the impact of the display ban and larger HWLs.

Similar to one of the approaches used during the additive ban public consultation, a bill was proposed in the national congress (PDC 454/2011) to stop CP 117/2010; in addition, the bill’s author used the same argument as to the previous consultation that the resolution interfered with National Congress authority. In 2014, the bill proponent received BRL 40000 (about US$15000, in 2014 Brazilian Real) from the tobacco company Alliance One. In 2013, the author dropped the bill.

The public hearing to discuss CP 117/2010 and CP112/2010 was postponed due TI interventions.

Table 1 details the approaches used by the TI during the public commentary process.

TI use of junk science
The same study conducted by the Getulio Vargas Foundation (FGV) in 2011 to dispute the additive ban, funded by the TI and groups linked to it, concluded that a ban on the display of tobacco products at the POS would increase illicit trade, unemployment and criminal activity, and would result
in tax revenue losses; therefore, it would not result in any public health benefit. The Pan-American Health Organization (PAHO) reviewed the study and concluded it was biased, the authors had conflicts of interest, and that the arguments were not supported by references. The study was also reviewed by other independent researchers, who presented a similar conclusion to PAHO.

**TI interference in the National Congress**

In the second half of 2011, a provisional measure on the taxation of tobacco products was approved by federal deputies, receiving several amendments beyond tax, including one that supported the implementation of frontal HWL, but without the message ‘Smoking is a disease. You are entitled to treatment’. However, the provisional measure still allowed the display of tobacco products at the POS.

According to some authors, the provisional measure was controversial because some of the proposed amendments were regressive in relation to already established tobacco control polices in

| Discursive strategy | Domain | Argument |
|---------------------|--------|----------|
| Unanticipated costs to economy and society | Economy | Loss of jobs (farmers and POS employees) and sales reduction due to tobacco display ban |
| | Law enforcement | Rise of illicit trade – the tobacco display ban and the increase of health warning message will facilitate the illicit trade |
| | Legislation | ANVISA has no mandate to display ban, change the size and the HWLs and define POS |
| Intended public health benefits | There is not enough evidence | There is no scientific evidence about the relation between tobacco display and tobacco use |
| Unintended benefits to undeserving groups | Smuggling will profit | The measures will not prevent smoking initiation among children |
| Expected tobacco industry costs | The tobacco display ban and increased HWLs with new messages will reduce sales and jobs | The measures will rise illicit trade |

| Instrumental strategy | Technique | Description |
|-----------------------|-----------|-------------|
| Coalition management | Constituency recruitment | TI associations complain and argument to impede the public consultation |
| | Constituency fabrication | Growers’ and restaurants, bars and small shops association complain about the public consultations |
| Information management | Amplification | Dissemination of TI arguments in newspapers and other media |
| | | Dissemination of misleading information |
| | Suppression | ‘Scientific studies’ funded by TI contesting the tobacco display ban and increased HWLs with new messages efficacy |
| Direct involvement and influence in policy | Incentives and threats | Political campaign funding a political party that defends TI interests |
| | Actor in legislative processes | Congressman supported by TI made an amendment in a provisional measure blocking the implementation of the measures |
| | Congressman supported by TI tried to cancel the public consultation through legislative measures |
| Key actor in government | Ministry of agriculture hosts a sectoral group of tobacco chaired by TI |
| Litigation | Legal action to contest/obstruct regulations | Injunction to cancel the public hearing |

POS: point-of-sale. TI: tobacco industry. "Based on the work of Ulucanlar et al."
the country. For example, one of the amendments would allow smoking in bars and restaurants, which had been prohibited since 1996. None of the regressive amendments was approved; however, the final provisional measure included the new HWL as indicated and did not ban the display of tobacco products at the POS.

The new legislation expressly allowed the display of tobacco products at the POS, preempting ANVISA’s proposal being discussed in the public consultation CP 117/2010, which ended up being archived. In the end, all efforts related to the consultation did not result in any new tobacco control measure, and the TI successfully prevented the implementation of new HWLs and the display ban in Brazil.

One of the arguments used by a tobacco company against the use of the expression ‘Smoking is a disease. Entitled to treatment’ was that there was no evidence that another health warning would help to clarify smokers because Brazilian smokers are very well informed about the harms of smoking, and there would be no references to make such a statement.

Table 2 summarizes the key arguments used by TI and its allies and provides comments about each argument.

**DISCUSSION**

The approaches used by the TI to interfere with the implementation of a tobacco display ban are the same as described in the literature. Approaches used by the TI to deter the implementation of the display and new requirements to HWLs were the same as reported in Brazil and in other countries. Nevertheless, in most of the other cases, the TI employed intensive strategies after the implementation of a certain prohibition and not in order to stop a regulation, such as in Brazil.

The TI has used similar approaches to undermine evidence-based public health policies. In Brazil, the TI used similar approaches, suggesting that its actions are highly coordinated and organized. Considering that tobacco companies are mostly transnational, the use of similar approaches across the globe is not surprising.

Scientific evidence did not support the main arguments (economic damage and increase of illicit trade) used by the TI and its allies against the tobacco display ban and new requirements to HWLs, which was part of the FGV study funded by the TI. The lobby used to delay the public consultation process, as a mechanism to thwart regulations, has been described elsewhere, including lobbying activities during the public consultation as a strategy to prevent or at least delay regulation (in other areas of tobacco control policy). Nevertheless, it is worthwhile mentioning that the high number of contributions submitted to ANVISA during the public consultation is unique. Transparency and disclosing conflicts of interests are key measures in policy making, which includes the public’s participation. Litigation was used once to avoid the public hearing at the National Institute of Cancer.
Strengths and limitations

This was the first study describing a successful TI strategy to prevent tobacco display ban and the larger and more undermining HWLs in Latin America and the Caribbean region. It can explain why almost all countries in this region have not implemented tobacco display bans. The argument analyzed could be helpful to other countries to take countermeasures against the TI strategies used in the display ban process in Brazil. The present study describes how the lobby was an important tool used by TI to prevent the implementation of tobacco control policies.

However, not all documents were available, and limitations about the search and indexing of the gray literature involved in this process imposed challenges and difficulties to describe the strategy.

Some information was only available informally or unofficially, which makes its use and discussion impossible. It was not possible to identify all strategies used by IT, especially when it comes to lobbying or the use of front groups.

CONCLUSIONS

HWLs and a tobacco display ban are evidence-based measures to contain the tobacco epidemic. Despite not presenting solid scientific arguments, the TI was able to stop the implementation of these measures. Countries considering the implementation of HWLs and a ban on the display of tobacco products should learn from Brazil’s failure in order to prepare themselves to face fierce and extensively documented opposition from TI. Countries must adopt procedures to guarantee transparency, especially to avoid conflicts of interest between the industry and public health policymakers. In this case, the TI was successful through its lobbying activities, thus pro-health lobby strategies and popular campaigns could be used as a response. The approaches used by TI are extensively known and tobacco control supporters should consider strategies to counterattack those of the TI before they even happen.

The TI strategies are global and very similar around the world; this reinforces the need to share experience and strength and apply FCTC Articles 20 (Research, surveillance, and exchange of information), 21 (Reporting and exchange of information), and 22 (Cooperation in the scientific, technical and legal fields and provision of related expertise).

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