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Illicit Trade as a Countervailing Effect: What the FDA Would Have to Know to Evaluate Tobacco Regulations

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Abstract: The Family Smoking Prevention and Tobacco Control Act [P.L. 111-31] gives the US Food and Drug Administration (FDA) the authority to regulate tobacco products, including placing restrictions on product composition, sale, and distribution. A complete accounting of the costs and benefits of any tobacco regulation includes harms from possible illicit trade in tobacco products (ITTP): costs of enforcement, violence, incarceration, etc. Indeed, the law instructs the FDA to take into account the "countervailing effects" of regulation on public health, "such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements." While the law's narrow focus on public health may limit the scope of an inquiry by the FDA compared to a full benefit-cost analysis, aspects of ITTP such as violence and incarceration have substantial health impacts. Illicit markets in drugs such as cocaine, heroin, and methamphetamine, not to mention the grand experiment of alcohol Prohibition in the early twentieth century, illustrate the substantial risks of unwanted side effects of drug prohibition. But taxes, product limitations, access restrictions, and narrowly defined product bans constitute "lesser prohibitions," and are subject to the same kind (if not degree) of risks. All tobacco policymaking should therefore consider ITTP. This article sets forth a research agenda for the FDA to consider in order to estimate the effects of contemplated tobacco-product regulation and ITTP. To carry out fully its legislative mandate, the FDA would have to determine the current size and impacts of ITTP, analyze how these may be expected to change under new regulations, and look for interdependencies among tobacco-product markets that may complicate single-product regulation. A more challenging element of the research agenda would be to develop a better theoretical groundwork for the prediction of the emergence, size, and side effects of illicit markets. We close with discussion of how the proposed research agenda may lead to insights into other policy areas as well.

Keywords: tobacco regulation, food and drug administration, illicit trade, benefit cost analysis, public health, cigarettes

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I. Introduction

Because tobacco use harms health, the Family Smoking Prevention and Tobacco Control Act (TCA) of 2009¹ amended the Federal Food, Drug, and Cosmetic Act (the FDCA) to give the US Food and Drug Administration (FDA) the authority to regulate tobacco products. Such regulation can include restrictions on the sale and distribution of a tobacco product if deemed appropriate for protection of public health. While the FDA lacks the authority to ban any broad class of existing tobacco products, such as cigarettes or cigars, the agency does have the authority to prohibit particular ingredients. The TCA prohibited cigarettes with "characterizing flavors" other than menthol, and instructed the FDA to consider extending that ban to menthol cigarettes.²

A complete accounting of the costs and benefits of tobacco regulation must include assessing possible unintended consequences. One of the risks involved with restricting access to a product through regulation is evasion (Marchese, 2004). Evasion reduces the efficacy of regulations and gives birth to new harms in the form of illicit markets. Illicit trade in tobacco products, hereafter ITTP, creates its own detrimental impacts on the public weal, including the costs of enforcement and the negative effects of incarceration and violence (Prieger and Kulick, 2014, 2015; Kulick, Prieger, and Kleiman, 2015). Indeed, the FDCA instructs the FDA to consider how regulation would affect health risks and benefits to the population at large, not just to tobacco users. In particular, the law instructs the FDA to take into account "the countervailing effects of [a proposed] tobacco product standard on the health of

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¹ Pub. L. 111–31, 123 Stat. 1776.

² While legally the FDA cannot ban tobacco products but instead regulates ingredients, we will loosely refer to the FDA decisions to "ban" particular products such as mentholated cigarettes, since prohibiting the addition of menthol to cigarettes effectively removes the product from the licit market.

³ FD&C §387f (d)(1).

adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements." Such a study can be conducted by the FDA's own personnel (e.g., the agency's experts within its Center for Tobacco Products), by the Tobacco Products Scientific Advisory Committee (TPSAC) established by the FDCA, or by other independent researchers commissioned by the FDA.

While the law's narrow focus on public health may limit the scope of an inquiry by the FDA compared to a full benefit-cost analysis, aspects of ITTP such as violence and incarceration (for example) have substantial health impacts. Illicit markets in drugs such as cocaine, heroin, and methamphetamine, and those during alcohol Prohibition in the early 20th century, illustrate the substantial risks of unwanted side effects of drug prohibition. Outright prohibition, however, is not required for ITTP and its pernicious consequences to occur; regulations restricting access and taxes that increase the price of legal purchases can be thought of as "lesser prohibitions," subject to the same kind (if not degree) of risks (Reuter 2013). A sufficiently high tax is effectively a prohibition. Tobacco policymaking should therefore consider ITTP, since some of the health benefits of regulation may be offset by enforcement costs and the negative impacts of ITTP on illicit-market participants and others.

In the spirit of previous research attempting to identify "what we know and what research is required," (e.g., Van Walbeek et al., 2013), this article sets forth a research agenda for the FDA to consider pursuing to investigate the interaction between tobacco-product regulation and ITTP. The notion that ITTP is entwined with tobacco regulation is not new. Indeed, the TCA lists as one of its goals "to strengthen legislation against illicit trade in tobacco products." In its inquiry into possible regulation of menthol cigarettes, the FDA asked interested parties to comment on whether a ban would lead to a

⁴ TCA, op. cit., Sec. 3(10).

research agenda considered here includes determining the current size and impacts of ITTP, analyzing how they may be expected to change under new regulations, and looking for interdependencies among tobacco-product markets that may complicate single-product regulation. An additional task, formulating a model of price, quantity, and violence determination in illicit markets, would be extremely helpful in providing theoretical grounding for the empirical work. The suggested tasks for research here are not meant to comprehensively cover all costs and benefits of tobacco-product regulation. Rather, our goal is to set forth some of the issues related to one potential cost of regulation—an increase in ITTP—that bear investigation as part of a broader regulatory policymaking process.

II. A Research Agenda for the FDA

The research agenda is laid out in four parts. The first task, described in section A, involves developing an understanding of the current ITTP in the United States. The second part of the agenda, in section B, is to study the likely impacts of additional or stricter tobacco regulation. The third aspect of the agenda, in section C, is to delve into how the various tobacco-product markets are interrelated, and how the outcomes from regulating one market depend on regulations in related markets. The final and most ambitious part of the agenda, proposed in section D, is to improve the theoretical groundwork for the previous analyses by constructing a model that can predict the characteristics and dimensions of the illicit market that will arise in the face of a new regulation or tax, or how an existing market will transform in the face of a change in regulation or taxation. The tasks are summarized in Table 1 and the relationships among them are depicted in Figure 1.

⁵ 78 Fed. Reg. 44485 (July 24, 2013) Sec. II.C.3.

Regulation Consumer attitudes & Licit tobacco preferences market 4 **Enforcement** strategy 3 **Demographic** and economic **ITTP** factors **Enforcement** resources Illicit Social costs: direct, importation by indirect, unintended DTOs, TCOs

Figure 1: Relationships among the regulation, tobacco markets, enforcement, and the proposed research tasks.

Note: The numbers in the figure refer to the research tasks as enumerated in Table 1.

A. Assessing the current situation

To be able to analyze prospectively the outcomes following from particular regulations, the FDA should learn as much as possible about the current state of affairs regarding illicit trade. This effort should include three tasks: 1) Modeling domestic ITTP overall and by locality; 2) Estimating the costs and volume of enforcement actions against ITTP; and 3) Examining state-level capacity to prevent the sale of illicit tobacco.

Table 1: The research tasks in the proposed agenda

No.	Research task	Section of Article	Summary	Policy relevancy
1	Model ITTP by geography to determine who is affected	II.A.1	Estimate the current scale of ITTP at the national and local level. Develop an empirical model linking local sociodemographic factors to ITTP.	ITTP follows from tobacco regulation, and it is important to be able to model where it is likely to occur and who will be affected by it.
2	Assess the social costs of ITTP and enforcement	II.A.2	Examine current enforcement actions against ITTP and their social costs: direct, indirect, and unintended.	The social costs of ITTP must be included in the policy calculus regarding any particular regulatory action.
3	Identify state and local capacity to enforce bans	II.A.3	Discover which regulatory structures and enforcement tactics are effective to combat ITTP, and which states are using them.	Without effective enforcement, additional regulation may fail to achieve its desired effects. Effectiveness requires understanding what works.
4	Survey consumer attitudes toward ITTP	II.B.1	Predict consumer responses to increased regulation by examining attitudes toward ITTP. Identify mechanisms for decreasing the social acceptability of ITTP.	Understanding consumer attitudes is crucial to determining likely responses to new regulation and hence its efficacy.
5	Estimate the enforcement requirements of a ban	II.B.2	Determine how much additional enforcement would be required to blunt the growth of ITTP following new regulation.	Without effective enforcement, additional regulation may fail to achieve its desired effects. Effectiveness requires adequate resources for law-enforcement.
6	Analyze the risks from the import market for illicit product	II.B.3	Identify the organizations (DTOs, TCOs) likely to enter into ITTP. Examine the ramifications for violence, border control, and other illicit activities.	Knowing whether new regulation would spur illegal important would help inform the decision as to whether the public interest would be served.
7	Investigate policy-relevant interdependencies among tobacco products	II.C	Understand interactions among a proposed regulation and all tobacco and related products, not just the one targeted by the new rule.	Consumers' responses to regulation depend on their full set of consumption choices, licit and illicit. Regulatory effectiveness requires understanding how the results of banning one product depend on the alternatives available to consumers.
8	Develop a theoretical framework	II.D	Build a unified model of ITTP to predict market value, conduct, and responses to enforcement.	A model of ITTP that capture the important quantitative features of the black market would be invaluable in conducting regulatory and enforcement simulations.

1. Model ITTP by geography to determine who is affected

The first task is to learn about the scale and local determinants of ITTP. A new ban on a product would create a new set of opportunities for ITTP. Estimating the magnitude of the unintended consequences of a ban therefore requires understanding the current extent and costs of ITTP and anti-ITTP enforcement. Without knowing the magnitude of ITTP, it is impossible to make the best decisions about which regulations work best from an encompassing social perspective. This task addresses the extent and location of ITTP; the following task outlined in section 2 concerns the costs of ITTP and enforcement.

Taxation, regulation, and enforcement efforts influence the level of illicit activity. Given that taxation and regulation vary among locations, illicit activity is not uniform across the nation. For example, communities along borders with high differentials in taxation are likely to be affected more by ITTP due to cross border product flows (Chiou and Muehlegger, 2008; Lovenheim, 2008; Harding et al., 2012). The research task here, therefore, is to map what domestic ITTP looks like at various levels of geography, from the national level down to the state, local, and neighborhood levels. Then, illicit tobacco use can be mapped by jurisdictions as a function of taxation, regulation, and proximity to other higher- or lower-tax states to estimate illicit market share of each state. Finally, to put a human face on the impacts of tobacco regulation and ITTP, the influence of a range of socioeconomic factors on the use and prevalence of illicit tobacco can be investigated. This analysis facilitates better understanding of the distribution of the burdens of illicit tobacco markets and of enforcement against them as a consequence of a ban on particular tobacco products.

a) Background

A complete analysis of the US market for illicit tobacco has not been performed. Frequently quoted figures (e.g., Niquette and Deprez, 2014) suggest that ITTP cost \$5 billion in lost state and federal tax revenues in 2010 and \$7 to \$10 billion in 2014. Accurately describing ITTP is difficult for all the reasons

that observing any illicit activity is difficult: market participants try to hide, may not be available for interview, and have reasons not to be frank in responding to questions. However, it is clear that ITTP in the United States is substantial, with as much as one-fifth of cigarettes smoked in the United States not taxed in the same state where they are consumed (Fix et al., 2014). ITTP is substantial in part because it offers high illicit rewards for relatively low risk compared to other crime (GAO, 2012). Von Lampe, Kurti, and Bae (2014) identify several methods of illicit cigarette supply, including bootlegging (legal purchasing in low-tax jurisdictions for transport and resale in high-tax areas), smuggling (trafficking in untaxed product), and counterfeiting. Any of these can operate both within and across national borders.

State-by-state policy differences have led to different taxation policies even in neighboring states, creating tax differentials across state borders and thus the conditions for profitable smuggling. Smugglers can buy cheap licit product in a low-tax state for illegal resale in a high-tax state; less commonly, smugglers deal in entirely illicit products (i.e., produced without proper licensing or taxation, and perhaps also fraudulently branded) imported from overseas or produced domestically. Accordingly the social consequences of illicit tobacco are felt more acutely in some specific geographic regions than in others. Apart from geography, the use of illicit tobacco and its negative social consequences disproportionately affect certain socioeconomic communities more than others (Delva et al., 2005; Kanjilal et al., 2006).

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⁶ Not every such cigarette is illicit, because it is not illegal to purchase a pack of cigarettes in one state and travel to another state where the pack is consumed. The volume of non-tax-paid cigarettes in many jurisdictions swamps any such casual behavior, however.

⁷ The incidence of such counterfeit or unbranded product is much higher in many foreign countries.

b) Data collection and analysis

Existing studies address the nature and extent of ITTP in the United States (Cummings, Pechacek, and Shopland, 1994; Shelley et al., 2007; Merriman, 2010; Kurti et al., 2013; Fix et al., 2014) and abroad (Wilson et al., 2009; Joossens et al., 2014). These might prove useful in identifying specific areas meriting more detailed investigation. There do not appear to be large-scale studies modeling the illicit market at the levels proposed here.

Many methods of gathering data can be used as inputs for a model of domestic illicit tobacco use in geographic detail. These include novel use of existing large-scale surveys, new surveys, the collection of discarded packs, interviews of law-enforcement agencies, and ethnographic studies. Large-scale traditional surveys that ask about where cigarettes are purchased include the International Tobacco Control (ITC) Project surveys (Guindon et al., 2014) and the TUS-CPS (Chiou and Muehlegger, 2008; Lovenheim, 2008; DeCicca, Kenkel, and Liu, 2013). To augment existing estimates of the size of the illicit tobacco market, surveys of consumers and analysis of discarded cigarette packs (Lakhdar, 2008; Wilson et al., 2009; Merriman, 2010; Davis et al., 2014; Stoklosa and Ross, 2014; Wherry et al., 2014) can be performed. For discarded-pack studies, researchers choose a defined geographic area, collect littered cigarette butts or packs, and examine them for tax stamps and other evidence of legality. Lawenforcement officials currently working tobacco cases are an important potential source of "thick," detailed knowledge about trafficking patterns, including geographic distribution and the demographics of buyers and sellers. Traffickers can also be surveyed, perhaps with ethnographic techniques. Ethnographic approaches provide information about the norms, values, and practices of the subcultures that engage in illicit activity. The qualitative knowledge gained can then inform the creation of data-

collection techniques. Further estimates of the size of ITTP can be based on comparison of tax-paid sales with survey and manufacturing data for total domestic sales and production.⁸

Government agencies with existing interests, programs, and data collection regarding the tobacco industry, enforcement, or ITTP are likely candidates to partner in the research task. Such agencies include the Substance Abuse and Mental Health Services Administration (SAMHSA), ATF, and TTB. Nonprofits such as the American Nonsmokers' Rights Foundation and the Mackinac Center for Public Policy may also be able to contribute data, expertise, or other support for the research. Industry stakeholders, such as tobacco companies whose brand integrity divisions work extensively with lawenforcement agencies involved with ITTP, may be able to provide additional data on ITTP for analysis.

With data in hand, econometric modeling can link the magnitude of ITTP in a state or local area to the various determinants discussed above. Explanatory factors in the analysis can include area characteristics such as the socio-demographic composition of the neighborhoods, the proximity to lower-tax jurisdictions, and the nature of local prohibitions or taxes currently in place. The estimated models can then be used to investigate questions such as what the impacts of ITTP on the community are expected to be, for a community with certain characteristics. If enough data can be collected to accurately estimate the proposed relationship between the explanatory factors and the outcomes, then the models will allow valid out-of-sample prediction for other communities. Such granular geographic analysis can then be aggregated to the state and national level.

2. Assess the social costs of ITTP and enforcement

The next task is to examine the social costs of ITTP and to conduct surveys of present enforcement actions. Among the goals here are to categorize, enumerate, and examine trends in

⁸ The various options to collect data for this research task are described in more detail in the report on which this article is based (Kleiman, Prieger, and Kulick, 2015).

enforcement actions against ITTP, as well as to examine unintended social costs such as incidents of violence. Understanding the costs of ITTP and anti-ITTP enforcement allows estimation of the level of additional enforcement that might be required and the additional social costs of ITTP and enforcement that such a ban would generate.

a) Background

At the federal level, the Jenkins Act, the Contraband Cigarette Trafficking Act (CCTA), the PACT Act, and the TCA all address ITTP. States and localities have enacted a patchwork of laws and regulations. However, the enforcement effort is not currently coordinated or even well measured. Jurisdiction is spread among multiple federal agencies as well as states, counties, and municipalities; ultimately different states and local jurisdictions enforce tobacco regulation on their own terms.

ITTP costs states lost tax revenue from licit trade (Goolsbee, Lovenheim, and Slemrod, 2010).

Illegal activity also generates additional social costs: increased health risks from consuming unregulated or counterfeit products, and increased levels of smoking among youths whose typically lower disposable incomes often prevent them from purchasing legal, taxed tobacco. Other social costs of ITTP to be investigated include law-enforcement costs; crime-related violence; revenue for criminal organizations; and damage to market participants and their families and neighbors from arrest, prosecution, and incarceration.

b) Data collection and analysis

There are no comprehensive quantitative studies of the costs of enforcement or types of enforcement actions against ITTP. The study of anti-ITTP enforcement should have two goals: measuring

⁹ Jenkins Act: 5 U.S.C. §375-378; CCTA: 18 U.S.C. 2341-2346; PACT (Prevent All Cigarette Trafficking) Act: 5 U.S.C. §376; FSP&TCA: 21 U.S.C. §301.

enforcement activities and estimating their budgetary and social costs. Enumerations include the number of dedicated personnel, investigative actions, arrests, prosecutions, convictions, and seizures of contraband and other assets. Measurements include budgetary cost, the number of cigarettes seized, the value of other assets seized, and person-days or person-years served in jail or prison. The confidentiality of enforcement plans and records complicates efforts at gathering data. Furthermore, budgets and activity counts for enforcement efforts against ITTP are hard to disentangle from agencies' other expenditures and activities.

Only a few studies attempt to account for the social costs of crime and violence associated with ITTP (Collins and Lapsley, 2008; Caneppele, Savona, and Aziani, 2013), and fewer still are specific to the United States (Reuter and Majmundar, 2015). Efforts at data collection should begin with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), and the Alcohol and Tobacco Tax and Trade Bureau (TTB). Customs and Border Protection (CBP) should have data on tobacco seizures. The Federal Bureau of Investigation and the Department of Homeland Security will have some information about ITTP and anti-ITTP enforcement where it intersects with concerns about organized crime and terrorism. The Executive Office for US Attorneys collects budget and activity data for the 94 federal prosecutors' offices, and might be able to separate out ITTP cases. State and local enforcement activity may well constitute the bulk of total anti-ITTP enforcement, since state and local activity accounts for approximately 85 percent of total US law-enforcement effort (Kyckelhahn, 2014). Stratified sampling of state and local authorities, of the sort routinely undertaken by the Bureau of Justice Statistics, could provide useful data.

To estimate the harms inflicted by enforcement on offenders and others, and the other social damage done by ITTP, a careful accounting of the many social costs is required. Building a range of reasonable estimates for the size of the illicit tobacco market can follow methods of the social-

accounting exercises for the economic impacts of illegal tobacco or drugs (e.g., Caputo and Ostrom, 2006; Collins and Lapsley, 2008; Joossens et al., 2010). Care needs to be taken to ensure that only the incremental costs of *illicit* tobacco are included. Costs to consider, inter alia, include estimates of the social costs of crimes attributable to ITTP, the incremental harm to health from counterfeit illicit tobacco products (which Stephens, Calder, and Newton (2005) show can be more dangerous than licit product), the forgone productivity of the incarcerated, and other social costs. Since Daudelin, Soiffer, and Willows (2013) warn that participation in ITTP can lead to more involvement in other illegal activities, spillovers to other areas of crime need to be considered.

3. Identify state and local capacity to enforce bans

The capacity of each state to prevent the sale of a tobacco product under consideration for a ban is important to know in advance of regulation. Thus, it is instructive to identify which regulatory structures and enforcement tactics have proven valuable in various jurisdictions and what is the capacity to take on further enforcement responsibility under a new ban. Constraints in enforcement ability and resources will affect the market growth of ITTP that is anticipated to occur under a new ban on a tobacco product.

Many states and localities are unprepared to effectively carry out enforcement against ITTP; ignoring those deficiencies might lead to dramatic underestimates of the social costs of a specific product ban. A study of enforcement capacity is also important for improving the outcomes of a ban. Poorly equipped jurisdictions can be identified and informed of ways to improve controls and effective performers can be offered as examples to others.

a) Background

By influencing the supply side, enforcement can nudge consumers away from illicit purchases with increased prices and search times. Enforcement also provides morality cues to law-abiding citizenry

on the demand side. Thus, adequate enforcement capacity is essential to combating ITTP. However, the states' management of their tobacco-control efforts is far from uniform. States have varying regulatory structures for collecting tobacco taxes; some are easier to evade than others. For instance, California has implemented a new tax stamp and streamlined processes for sanctions against license holders, which the state claims have dramatically increased its ability to prevent and punish resale of illicit tobacco. There is also variation at the level of cities and counties. Only a select few police or sheriff's departments have officers or squads targeted to detecting counterfeit or tax-evaded products, tobacco included.

b) Data collection and analysis

The published literature does not contain a comprehensive review of state- or local-level regulatory and enforcement capacity, nor of the effectiveness of such efforts. Some of the extant literature discusses the strategies available to enforcement agencies seeking to limit ITTP (CTFK, 2014). DiFranza (2005) discusses the cost-effectiveness of various states' enforcement practices regarding limiting youth access to tobacco. However, a comprehensive study evaluating the cost effectiveness of specific actions combatting ITTP has yet to be performed. Indeed, there seems to be a dearth of high-quality academic research that addresses the deficiencies and variations in the capacities of jurisdictions to enforce laws against ITTP.

Data sources for the proposed project can begin with the scant literature detailing enforcement activities and related costs (Alderman, 2012). Then, agencies in each state with responsibilities encompassing ITTP can be identified. Such agencies include taxation authorities, state police, and offices of attorneys general. A sample of local police and sheriff's offices can be contacted and inquiry made about current commitments to combating ITTP (e.g., budget, units, or employees designated to relevant areas) and about policies and processes regarding to detection or reporting. Local agencies can also be

polled as to their willingness and ability to initiate or ramp up enforcement activities related to ITTP in the event of a new ban or other regulations on a particular tobacco product.

The surveys and inquiries should determine which states have the following:

- Difficult-to-counterfeit tax stamp systems;
- Mandatory frequent inspections of retailers;
- Effective case processing and prosecution of illicit-tobacco offenses;
- Effective sanctions for detected violations in terms of deterrence and incapacitation;
- Effective anti-corruption measures with regard to enforcement of tobacco regulations and taxes;
- Capacity for demand reduction, including smoking-cessation campaigns; and
- Any other measures that reduce ITTP.

To identify the effectiveness of various regulatory structures and enforcement tactics, interviewing those responsible for implementing or overseeing programs, including agency personnel and law enforcement, is a natural place to start. Possible partners in the research include ATF, TTB, the US Government Accountability Office (GAO), and state and local tax-enforcement agencies, both in low and high cigarette-tax states. The partners could help identify common obstacles and prerequisites for success. It is important to scrutinize the components of jurisdictional efforts that have managed to keep illicit tobacco and other black markets under control (Allen, 2012). Particular attention should be paid to programs that have managed to minimize deleterious impacts on public safety.

B. Examining the impacts of banning a tobacco product

After learning about the current ITTP and enforcement situation, the FDA should examine the likely impacts of banning a tobacco product. This can include three tasks: 1) Discovering consumer attitudes toward illicit tobacco products and likely responses to banning a particular product; 2)

analyzing the risks of a substantial import market for illicit tobacco product in the face of a ban.

1. Survey consumer attitudes toward ITTP

Consumers' attitudes concerning the purchase of illicit tobacco products are an important part of the policy analysis of a proposed ban, since they determine the likely extent of the resulting illicit activity. In addition to predicting effects on the illicit tobacco market, understanding social attitudes and their relationship to purchasing patterns might help to identify mechanisms for decreasing the social acceptability of illicit tobacco distribution and consumption.

a) Background

Despite the prevalence of tobacco consumption in the United States, relatively little is known regarding users' attitudes toward the illicit market for tobacco. Underlying attitudes toward illicit tobacco consumption likely vary across various socio-economic and demographic factors. It is known, however, that attitudes are not uniform. For example, a quarter of menthol smokers who were surveyed in a recent study claimed that they would seek out illicit menthol cigarettes in the face of a ban (O'Connor et al., 2012). It is unclear how much risk would be required to dissuade illicit purchases, or what illicit demand would be at various possible prices. This segment of the research agenda updates and improves upon existing efforts in this area (e.g., O'Connor et al., 2012).

b) Data collection and analysis

Several studies involve eliciting opinions from smokers and others about contraband, counterfeit, and otherwise illicit tobacco products (Shelley et al., 2007; Moodie, Mackintosh, and West, 2010; Pellegrini, Fry, and Aitken, 2011; Moodie, Hastings, and Joossens, 2012; Stead et al., 2013; Wackowski, Manderski, and Delnevo, 2014). Many of these studies were conducted on subjects outside the United States, which

limits their usefulness for present purposes. Nevertheless, studies from other countries are suggestive. Research in the U.K., for example, finds that working-class communities hold positive attitudes toward illicit cigarette distribution. Respondents thought that distributors provided a valuable service, licit cigarettes were unreasonably expensive, resentment of government rationalizes illicit cigarette use, and smuggling is an everyday practice with social reinforcement (Moodie, Mackintosh, and West, 2010).

Attitudes towards illicit tobacco products can be assessed through surveys and interviews. How users of particular tobacco products would respond to a ban has been estimated by surveys and modeling based on econometric studies of the price responsiveness of demand. For example, response to a ban on menthol cigarettes is examined by Tauras et al. (2010), Winickoff et al. (2011), O'Connor et al. (2012), and Pearson et al. (2012). However, these results remain speculative.

The research here assesses the lengths to which tobacco users would be willing to go when looking for illicit product, as well as the relationship of such willingness to local attitudes about ITTP. Distinctions between specific modes of supply or illicit product may also be important. For example, consumers are not likely to view genuine but smuggled product the same as counterfeit product. In particular, the research should attempt to determine attitudes about illicit sales; tax increases, sale and use restrictions, and bans; actions taken by government, law enforcement, and tobacco companies to limit the illicit market and regulate tobacco; social acceptance of illicit use; and tradeoffs between price, risk, and product quality.

In addition to the qualitative insights such surveying can yield, well-developed methods in the econometric literature can uncover underlying preference relationships from revealed and stated preference data (Morikawa, Ben-Akiva, and McFadden, 2002), which can then be used to determine likely responses to hypothetical regulatory changes. Discrete-choice experiments (an example of

conjoint analysis and contingent valuation)¹⁰ can be conducted with subjects to estimate preferences for alternatives to licit product in the event of a ban. The existing literature provides a useful starting place (Flach and Diener, 2004; Ida and Goto, 2009).

2. Estimate the enforcement requirements of a ban

The task set forth in section A.3 examines current capability and practice in enforcement against ITTP. However, under stricter regulation or new bans, additional law enforcement would be needed. It is therefore necessary to determine how much enforcement would be required to blunt the growth of illicit sales. This research task also includes examination of the effects and costs of these potential changes in state and local law enforcement.

a) Background

Given that a ban would increase the volume of illicit sales activity, it would increase the workload of local and state law enforcement. The extent of that increase has not been estimated.

Various law-enforcement activities should be taken into account when understanding the costs and effects of a ban. These include general street enforcement by non-specialized police units; investigations of large-scale distributors by specialized units; and the costs of prosecution and punishment for violators. Additionally, the costs of training and equipment, as well as coordination across enforcement agencies, should be included.

While interception of illicit shipments entering the United States (interdiction) is mostly handled by the Coast Guard, CBP, and Department of Defense, state and local law enforcement are burdened with monitoring distribution patterns within US borders, including in areas adjacent to borders and

¹⁰ See Agarwal et al. (2014) for an overview of conjoint analysis and seminal citations. Carson (2012) provides a relatively nontechnical discussion of contingent-valuation analysis and the issues involved.

surrounding Indian reservations. In addition, most enforcement efforts to combat the availability of illicit drugs are not interdiction efforts but instead require local resources.

b) Data collection and analysis

There appear to be no current efforts to estimate the enforcement requirements of increased tobacco regulation. An analysis of the problem from the demand side starts by estimating the likely growth in illicit market activity in the absence of any increase in enforcement. Thus, this research task can draw upon the research concerning the behavior of current consumers of tobacco to be performed in section A.1 above. For example, at various price points, what fraction of consumers would be willing to purchase illicit product as opposed to quitting use or switching to other tobacco products?

The simplest next step is to compare the likely size of the post-ban illicit market with the estimated size of the current illicit market, and assume that enforcement would have to scale up proportionately to market size in order to maintain the current level of discouragement of illicit activity. This requires detailed data collection and analysis to estimate the level and costs of current enforcement efforts, as in the task described in section A.2 above. A more ambitious approach uses the "risks and prices" analysis (Reuter and Kleiman, 1986) to compute the level of additional enforcement required to shrink the illicit market back to its current size, given the additional demand from users of the banned product switching from licit to illicit purchase. Even more ambitious is to model the process dynamically, incorporating the range of positive feedbacks characteristic of illicit markets (Kleiman and Kilmer 2009; Prieger and Kulick, 2015).

Another portion of the analysis can model the effects of constraints on enforcement capacity and effectiveness in determining the size and social costs of ITTP. This part of the analysis begins with simulating the effects of different regulatory structures and enforcement practices and resources on the extent of the illicit market. Next, the effect on illicit markets of a ban can be estimated, after accounting

for constraints on enforcement. Computation of alternative scenarios in which enforcement agencies adopt more effective regulatory structures and practices concludes this part of the research.

3. Analyze the risks from the import market for illicit product

The United States risks developing a substantial import market for illicit tobacco if the FDA bans a particular tobacco product. To assess how large a problem importation of illicit product might be, it is necessary to identify the organizations likely to enter into the trade and to examine the ramifications for violence, border control, and other illicit activities. Such considerations will inform the decision as to whether heightened regulation of tobacco would serve the public interest.

a) Background

As discussed above, the substantial ITTP in the United States consists primarily of cigarettes legally produced domestically and then smuggled across state borders. Compared to elsewhere in the world, ITTP in cigarettes produced abroad is relatively rare. This is not to say that illicit importation is unknown; recently the US DOJ convicted an Indian citizen of importing millions of counterfeit Newport cigarettes from India into Miami (USDOJ, 2015). ¹¹ In contrast to the United States, a large export trade in illicit tobacco products already exists within Latin America. In Paraguay, up to 90 percent of their 47 billion annually produced cigarettes are exported internationally (Guevara, Rehnfeldt, and Soares, 2009); large criminal organizations transport illicit tobacco through neighboring countries (Allen, 2011; Interpol, 2014). A ban on a tobacco product might offer that traffic a foothold in the United States, and international smuggling could become the primary source of illicit product.

¹¹ The scale of the operation was large, involving 53,740 cartons of fake Newport cigarettes at a black-market wholesale price of about \$0.5M and a street value of over \$1M (USDOJ, 2015). An equal number of legitimate Newport cigarettes would sell for about \$1.8M in Florida.

Border security alone cannot stop the trade. Already, billions of dollars of drugs are trafficked across the Mexican border into the United States; a tobacco-related ban could bring many more. If even a small portion of current tobacco users were to turn to the black market for imported goods, the potential revenues would likely draw interest from some DTOs, in addition to expanding existing cross-border smuggling networks for tobacco (Daudelin, Soiffer, and Willows, 2013). The effects of a larger trade in imported illicit tobacco products would be far-reaching, given the disorder currently wreaked by Mexican DTOs (Beittel, 2009). The larger of these operations engage in a considerable amount of violence, primarily within Mexico, and the resulting bloodshed (estimated at more than 10,000 deaths per year since 2006) is now devastating parts of that country.

b) Data collection and analysis

Given the increase in ITTP in response to a proposed ban estimated under the research tasks outlined above, the anticipated reactions by DTOs and other transnational criminal organizations (TCOs) can be investigated. To investigate profitable trafficking routes and business models likely to be employed, the literature and available data on DTOs can be reviewed (Natarajan, 2000, 2006; L'Hoiry, 2013; Lyman, 2015). Which organizations are likely to supply demand for illicit product? DTOs are unlikely to enter the trade unless revenues are sufficiently large. However, the revenue requirements for profitability are lower for well-established smuggling networks than they would be for a de novo venture. The former enjoy the advantage of economies of scope, since they have already sunk investments in their infrastructure (Daudelin, Soiffer, and Willows, 2013).

Apart from revenue, costs also figure into the potential profits of DTOs. Costs of illicit suppliers include the cost of production, the cost of labor for distribution, the opportunity costs of capital employed in production and distribution, and the costs of related supplies and proprietors' incomes (whether paid in cash or imputed from managers' opportunity costs) (Reuter and Kleiman, 1986).

Additional costs include the expected value of losses to enforcement (e.g., seizures). Enforcement data from comparable illicit markets might serve as a model for the latter costs. The remaining profit should be compared to other markets and enforcement data to determine whether an illicit market in a banned tobacco product would be lucrative for small and large-scale producers and distributors.

Even if the trade is profitable in the abstract, it is not clear which organizations would enter and compete in that market. Yet some organizations are more dangerous than others. Which organizations are best fit to compete? What are the feasible levels of imported tobacco from Mexico, and at what prices? How would Mexican organizations fare against competition from other potential exporters, such as China or against diversions from Indian reservations? How would the existing domestic infrastructure for interstate smuggling shape international trafficking? All these questions should be investigated. Finally, for policy analysis, expected outcomes as outlined above can be compared under alternative policy formations (e.g., complete ban with or without bans on next-best substitute tobacco products, heavy taxation instead of a ban, etc.).

In addition to the worries about DTOs becoming involved with ITTP is the link between ITTP and funding for terrorism. The U.S. Congress found that ITTP is "linked to organized crime and terrorist groups." ¹² Terrorist organizations consider illicit tobacco a lucrative source of income. Organizations known or strongly suspected to benefit from ITTP include Hamas, Hezbollah, the Taliban, al Qaeda, and the IRA (Billingslea, 2004; Shelley and Melzer, 2008; Brady, 2013). ¹³

Finally, related to the question of importation is the sourcing of tobacco from Native American reservations in the U.S. and First Nations reserves in Canada, some of which straddle the border.

¹² Public Law 111-31, Div. A, sec. 2 (35).

¹³ However, von Lampe (2011) states that "the involvement of terrorist groups who trade in illegal cigarettes to raise funds ... seems to be the exception rather than the rule," at least in Europe, where ITTP is conducted primarily by individuals without previous criminal records instead of known criminals.

Reservations pose a unique problem for tobacco consumption, taxation, and the cross-border transit of tobacco (Daudelin, Soiffer, and Willows, 2013). Even setting aside the aspect of international smuggling, reservations create complications regarding tobacco trade. American Indians are not exempt from paying duties for commercial trading goods when crossing reservation borders. Nevertheless, cigarette production plants operate out of Indian reservations, providing duty-free cigarettes that are sold both to onsite consumers and to distributors who resell throughout other areas, sometimes illegally across borders (Kelton and Givel, 2008).

C. Investigating policy-relevant interdependencies among tobacco products

In the face of a ban on one particular tobacco product, interactions between that and other tobacco products are important to understand. For an example, consider traditional and electronic cigarettes (e-cigarettes). A ban on a type of cigarette (for example, menthols) will present users with a restricted set of choices. Some of those smokers will quit entirely, others will turn to menthols available from the black market, others might switch to non-menthol cigarettes, and others still might switch to menthol e-cigarettes. The advantage of the latter option is reduced rates of traditional-cigarette use and black-market activity, while the disadvantage is a lower rate of complete cessation. The impacts—in either direction—are largest if e-cigarettes remain widely available and allowable to use. Thus the policy decision to ban the one product is inextricably entwined with the question of how to regulate the other. Existing policy-relevant estimates of cross-price elasticities between tobacco-related products include examinations of interdependencies between demand for cigarettes and nicotine replacement therapy (Chandra, Gitchell, and Shiffman, 2011), cigarettes and e-cigarettes (Huang, Tauras, and Chaloupka, 2014), and menthol and non-menthol cigarettes (Tauras et al., 2010).

These considerations affect each of the research tasks outlined above. For example, when examining the risks from the import market for banned product, clearly the product scope of the ban is important. Continuing with the example of e-cigarettes: if allowed, they might steal demand away from illegal imports of the traditional product, but only if e-cigarettes turn out to be substitutes in demand for traditional cigarettes rather than complements. Those factors could be important and should be included in the modeling exercises above as different scenarios.

D. Developing a theoretical framework

There is now a substantial literature on ITTP, along with an even more extensive literature on illicit drug markets and other illicit markets. Considerable attention has been paid to illicit markets and the informal economy in the fields of economics, public policy, criminology, ethnography, and economic sociology (Schelling, 1971; Reuter and Kleiman, 1986; van Ours and Pudney, 2006; Beckert and Wehinger, 2013; Prieger and Kulick, 2014, 2015). Nevertheless, this body of research is of only limited use to policymakers contemplating specific policy changes. Simply put, no existing model predicts the form and scale of illicit markets as a function of policies and circumstances.

Data about illicit markets are so imperfect as to make estimation extraordinarily difficult and prediction virtually impossible (Manski et al., 2001). For example, the estimated inflation-corrected dollar volume in the illicit cocaine market has roughly halved since 1992, while expenditure in the illicit cannabis market is more than two and a half times what it was;¹⁴ neither of those changes was predicted, and there exists no retrospective analysis providing a convincing causal explanation. The

¹⁴ The estimate for cannabis is expenditure of \$11.5 billion in 1992 (Rhodes, Langenbahn, Kling, and Scheiman, 1997) and \$40.8 billion in 2010 (Kilmer et al., 2014). Corrected for inflation, expenditure on marijuana thus grew by 160%. For cocaine, the same sources estimate expenditure of \$41.7 billion in 1992 and \$28.3 billion in 2010. The latter figure is half the former figure in real terms.

desideratum for policymaking would be a well-developed theory capable of predicting quantitatively how changes in laws or enforcement efforts would affect market scale and the conduct of market participants. Here we sketch out what such a theory might entail. Note that this research task is not labeled in Figure 1, since it encompasses every aspect of the illicit trade ecosystem.

1. Background

Simple analyses predict that increased enforcement against illicit markets should drive prices up, and yet the ramping up of the "War on Drugs" in the 1980s and the first half of the 1990s showed that paradoxical outcomes are possible. That period saw greatly increased enforcement effort but also dramatically falling street prices of cocaine and heroin. ¹⁵ That so much enforcement effort was coincident with sharply falling prices is therefore a puzzle. Although some ex-post theoretical modeling suggests reasons for why increased enforcement might lead to lower prices, ¹⁶ some of the modeling efforts are ad hoc, and are often finely tailored to particular features in specific markets, and overall largely unconvincing as uncovering the primary mechanisms driving market outcomes.

Apart from economics, interdisciplinary work on illicit markets, yielding insights from psychology, criminology, sociology, ethnography, and other fields, can help inform the study of preference formation toward illicit goods (Ritter, 2006; von Lampe, 2006; Beckert and Wehinger, 2013). Similarly, careful study of supply conditions can help predict what the costs of supply are likely to be (Reuter and Kleiman, 1986; Hawken, 2013). A complicating factor in the analysis of illicit markets is the presence of positive-feedback effects in illicit activity (Kleiman and Kilmer, 2009; Prieger and Kulick,

¹⁵ Cocaine prices for small users fell from about \$450 per gram in 1981 to below \$200 by 1994. Prices remained low until 2007, when they began to rise again. Heroin prices slid through the 1990s. From 1981 to 1998, annual federal expenditures aimed at reducing the use of illegal drugs through the criminal-justice system, interdiction, and intelligence increased almost seven-fold. See Prieger and Kulick (2015) for sources.

¹⁶ See Prieger and Kulick (2015) for references.

2015). With bandwagon effects on the supply side, outcomes can be "tipped" from high- to low-violation equilibria depending on the likelihood of punishment and on the employment of dynamically concentrated sanctions. This heightens the need to coordinate planned regulatory activity with enforcement agencies.

2. Data collection and analysis

While there is no existing unified theory of value determination in illicit markets, research from many different disciplines is germane (Ritter, 2006; von Lampe, 2005, 2006). There are many "hard" analyses using the tools of economic theory and econometrics of illicit drug and tobacco markets (Becker, Murphy, and Grossman, 2006; Prieger and Kulick, 2014, 2015). Methods from many other disciplines can be brought to bear usefully on the determination of value in illicit markets and its relationship to effective enforcement strategy. Elements of a mixed-methods approach can include the emerging behavioral-economics research linking pharmacological, environmental, and economic factors that contribute to consumption of illicit drugs (Hursh et al., 2005; Caulkins and MacCoun, 2005), ethnographic studies (Natarajan and Belanger, 1998; May and Hough, 2004), and surveys. Given the fundamentals of the market and assumed behavior of participants, economic analysis can be employed to model and predict the magnitudes of prices, quantity, revenue, and profit in an illicit market.

Quantitative analysis can also be used to model the relationship between these market outcomes and the unintended negative consequences of crime, violence, the social aspects of criminalization, etc. Gruenewald et al. (2006) studied the specific empirical relationships between market and demographic characteristics and crime. Sociological aspects of organized crime related to illicit markets, including the aspect of ethnic homogeneity of criminal networks, have been addressed in the "social embeddedness" literature (Kleemans and van de Bunt, 1999; von Lampe, 2002; McIllwain,

2004). The market information and the links to negative consequences can then be used to determine the optimal law-enforcement effort against the illicit market.

Modeling violence in ITTP is also an important aspect of this research task. Unable to resolve disputes in the courts, participants may turn to bloodier methods of dispute resolution. Systematic reviews of the empirical literature show that nearly all studies find evidence of an adverse impact of drug-law enforcement on levels of violence (Werb et al., 2011; Kulick, Prieger, and Kleiman, 2015). Marginal increases in enforcement efforts may tend to increase violence, as illustrated by the enforcement crackdown against the major Mexican drug-trafficking organizations (DTOs) since 2006, the crack markets in many US cities in the 1980s and early 1990s, and the theoretical analyses of Prieger and Kulick (2014, 2015). Intensifying enforcement can increase the risk of getting caught for any given pattern of criminal activity. But insofar as the result is to increase prices, and insofar as demand is relatively inelastic, the result will be to increase total revenue while reducing the number of market participants, thus increasing the rewards for successful dealing. Moreover, individuals and organizations specializing in violence may face less enforcement risk than their competitors because they can intimidate potential witnesses. Thus, while violence provides one justification for increased enforcement efforts, aggressive enforcement may on balance worsen instead of ameliorate the violence problem.

Given a ban on a particular tobacco product, then, does there exist a way to enforce that would uphold the ban without creating a risk of substantial violence in the resulting illicit market? This question cannot be answered on purely theoretical grounds. Some detailed quantitative modeling,

¹⁷ See Prieger and Kulick (2015) for the precise economic conditions under which additional enforcement leads to greater revenue.

informed by the interviews with enforcement officials and traffickers that compose parts of the other research tasks, would be required to make even an informed guess.

III. Conclusion

While the proposed research agenda covers only one aspect of the decision to regulate tobacco—illicit trade and its consequences—it is an important part of the overall decision-making process. Furthermore, despite voluminous research on ITTP, it appears that the topic falls into a blind spot of the FDA. The experience of the FDA's inquiry into menthol cigarettes forms a case to illustrate this.

The FDA commissioned its Tobacco Products Scientific Advisory Committee (TPSAC) to evaluate the public-health impacts of menthol in cigarettes, as required by the TCA. TPSAC reviewed the evidence on whether menthol contributed to smoking initiation, addiction, or harmfulness. The Committee gave very little consideration to the question of illicit markets, though it acknowledged that there exists a potential for contraband menthol cigarettes. Subsequently, the courts prohibited the FDA from using the TPSAC report, ruling that several members of the Committee had financial conflicts of interest. ¹⁸

Now the FDA must reconstitute the TPSAC committee, so that it can again work to produce the required report. A second effort at the TPSAC report provides an opportunity for improvement. The initial report failed to consider all aspects of the Congressional mandate to base regulation on "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." Merely because the

¹⁸ The conflicts of interest were on the part of the tobacco control side, not the tobacco industry. Three TPSAC members stood to gain financially, through their connections with pharmaceutical companies that make smoking-cessation products, from the potentially greater demand for such products following stricter tobacco regulation (Lorillard Inc. et al. v. United States Food and Drug Administration, No. 11-440, July 21, 2014). An appeal of the decision is pending before the US Court of Appeals for the DC Circuit.

social consequences of ITTP are unintended does not mean that they should be ignored in the policy calculus.

The TPSAC report pleaded that "the need to make uncertain assumptions as to the nature and functioning of such a black market" meant that the size and social harms from ITTP "cannot be readily estimated" (Tobacco Products Scientific Advisory Committee, 2011, p. 229). The report's authors can hardly be blamed for that conclusion. The current research literature does not provide sufficient guidance as to many of the key unknowns to allow a responsible estimate. TPSAC recommended the FDA to consult with experts qualified to carry out the analysis relevant to any actions taken in response to the report. If the FDA is to carry out that mandate, then, it faces the need to conduct or commission new research and analysis. The research agenda identified here would generate a clearer answer to questions about the illicit-market effects of banning a tobacco product.

The agenda set forth here is aimed specifically at understanding the countervailing effects of tobacco regulation, but the results of the proposed research would be of indirect benefit to other areas of policy as well. Illicit trade occurs in drugs such as cocaine, methamphetamine, and heroin and otherwise licit pharmaceuticals that are diverted, illegally resold or imported, or counterfeited. Outside of the realm of drug policy, other examples of illicit trade include counterfeit luxury goods and music and video piracy, to name just a few. Some of the research tasks, when performed for ITTP, would provide templates for analyzing similar issues in these other markets. For example, whether the good is tobacco, illegally procured prescriptions drugs, or pirated music, in principle if the required data were available the same modeling that links observed attributes of a local area to the scale and form of ITTP (task 1) can be applied to other illicit activity. Estimating the empirical relationships between the local sociodemographic factors and the illegal behavior can help target enforcement resources, regardless of the particular good. As another example, the methodology and empirical modeling developed to

ascertain consumer attitudes toward ITTP could also be applied—with new data, of course—to other areas of unlawful conduct by consumers. The predicted consumer responses to changes in the legality of other goods (e.g., pharmaceuticals sold online, marijuana, certain types of firearms, etc.) can help policymakers predict and plan for enforcement against attempted circumvention. Finally, the last research task of develop an encompassing theoretical framework for value determination in black markets would have obvious benefits for evaluation of policy in the area of cocaine, heroin, methamphetamine, and other illicit drug markets.

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