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Countervailing Effects: What the FDA Would Have to Know to Evaluate Tobacco Regulations

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Countervailing Effects

What the FDA Would Have to Know to Evaluate Tobacco Regulations

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Countervailing Effects

What the FDA Would Have to Know to Evaluate Tobacco Regulations

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 20th century, illustrate the substantial risks of unwanted side effects of drug prohibition. But taxes, product limitations, access restrictions, and narrowly defined product bans constitute

Acronyms

ATF: Bureau of Alcohol, Tobacco, Firearms and Explosives, United States Department of Justice

CBP: Customs and Border Protection, United States Department of Homeland Security

CCTA: Contraband Cigarette Trafficking Act of 1978

CTFK: Campaign for Tobacco Free Kids

DTO: drug-trafficking organization

FDA: Food and Drug Administration, United States Department of Health and Human Services

FDCA: Federal Food, Drug, and Cosmetic Act

GAO: United States Government Accountability Office

ITC: International Tobacco Control Project

ITTP: illicit trade in tobacco products

NRC: National Research Council

NT: nominative technique

PACT: Prevent All Cigarette Trafficking Act of 2009

RRT: randomized-response technique

“lesser prohibitions,” and are subject to the same kind (if not degree) of risks. All tobacco policy-making 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. We argue that, to carry out fully its legislative mandate, the FDA would have to determine the current size and impact 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.

Acronyms, cont.

SAMHSA: Substance Abuse and
Mental Health Services
Administration, United States
Department of Health and
Human Services

TCA: Family Smoking Prevention
and Tobacco Control Act of
2009

TCO: transnational criminal
organization

TPSAC: Tobacco Products Scientific
Advisory Committee

TTB: Alcohol and Tobacco Tax and
Trade Bureau, United States
Department of the Treasury

TUS-CPS: Tobacco Use Supplement
to the Current Population
Survey, United States Census
Bureau

UCT: unmatched-count technique

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. The TCA banned cigarettes with “characterizing flavors” other than menthol, and instructed the FDA to consider extending that ban to menthol cigarettes. The FDCA also instructed the FDA to consider how regulation would affect health risks and benefits to the population at large, not just to tobacco users.² In particular, the law instructs the FDA to take into account “the countervailing effects of [a proposed] tobacco product standard on the health of 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.

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

¹ Pub. L. 111–31, 123 Stat. 1776.

² FD&C §387f (d)(1).

its own detrimental impacts on the public weal, including the costs of enforcement and the negative effects of incarceration and violence (Hawken, Kulick, and Prieger 2013; Prieger and Kulick, 2014a,b). 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 (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.”³ In its inquiry into possible regulation of menthol cigarettes, the FDA asked interested parties to comment on whether a ban would lead to a

³ TCA, op. cit., Sec. 3(10).

significant problem of illicit trade and, if so, what would be the impact on public health.⁴ The proposed research agenda considered here includes determining the current size and impact 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 be comprehensive, covering all possible 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 three research projects involved here are to estimate the current costs of enforcement actions against ITTP, to see how ITTP varies by locality, and to assess state-level regulatory capability to prevent ITTP. The second part of the agenda, in section B, is to study the likely impacts of additional or stricter tobacco regulation. Tasks here include learning what consumer attitudes and intentions are toward illicit tobacco products, estimating the enforcement requirements of a specific tobacco-product ban at state and local levels, and analyzing the risks of a substantial import market for ITTP in the face of a ban. 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

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

most ambitious part of the agenda, proposed in section D, would be 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.

A. Assessing the current situation

To be able to prospectively analyze 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) Estimating the costs and volume of enforcement actions against ITTP; 2) Modeling domestic ITTP by state and local geography; and 3) Examining state-level regulatory capacity to prevent the sale of illicit tobacco.

1. Assess the current enforcement against and violence from illicit trade

The first tasks to enable accurate assessment of the current state of affairs regarding illicit trade are to learn about the scale of ITTP and to conduct surveys of present enforcement actions. The goal of the work is to enumerate and categorize types of enforcement actions against ITTP, such as arrests and incarceration. Examination of phenomena related to enforcement such as incidents of violence would also be useful. As part of the data collection and analysis, trends in these variables can be estimated.

This proposed research task is highly relevant to the policy calculus regarding banning a tobacco product. Contemporary ITTP in the United States involves primarily interstate transactions that exploit tax differentials across states. A new ban on a product would create a new set of opportunities for ITTP participants. Estimating the magnitude of the unintended consequences of a ban therefore requires understanding the current extent and costs of ITTP and anti-ITTP enforcement. This 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

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. Precisely describing the enforcement effort against ITTP is difficult partly due to the confidentiality of enforcement plans and records. Furthermore, in the absence of specialist anti-ITTP enforcement units, budgets and activity counts for enforcement efforts against ITTP are hard to disentangle from other expenditures and activities. Moreover, insofar as higher taxes and tighter regulations risk increasing the costs associated with ITTP, disagreements about the extent of ITTP have policy relevance and may be motivated by *a priori* preferences for policies that high or low estimates might argue for. This aspect lends a partisan edge to what otherwise would be neutral differences of scientific opinion.

However, it is clear that ITTP in the United States is substantial. A recent analysis based on discarded cigarette packs concludes that as much as one-fifth of cigarettes smoked in the United States are not taxed in the same state where they are smoked (Fix et al., 2014).⁵ ITTP is substantial in part because it offers high illicit rewards for relatively low risk compared to other crime (GAO, 2011).

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. Thus ITTP encompasses both tax evasion and illegal manufacturing. Any of these can operate both within and across national borders. The social costs of ITTP to be investigated include:

⁵ Of course, not every such cigarette is by definition illicit—it is not illegal to purchase a pack of cigarettes in one state and travel to another state where the pack is consumed. The latter activity is tax *avoidance*, which can be distinguished from tax *evasion*. But the volume of non-tax-paid cigarettes in many jurisdictions swamps any such casual behavior.

- Increased levels of tobacco use compared to fully enforced regulation and taxation, especially among users with lower disposable incomes, including adolescents;
- Lost tax revenues;
- Law-enforcement and prosecution costs;
- Incarceration costs and harms suffered by those incarcerated;
- Disorder and crime, including violence among and against ITTP participants; and
- In the case of counterfeit products, potentially increased health risks to tobacco users.

b) Data collection

(1) ITTP volume and conduct

To estimate the size of the illicit tobacco market, data can be gathered from surveys and sources used to produce existing estimates of illicit market size. To augment and update existing estimates, novel surveys and analysis of discarded cigarette packs (Lakhdar, 2008; Wilson et al., 2009; Merriman, 2010; Davis et al., 2013; Stoklosa and Ross, 2014; Wherry et al., 2014) can be performed. New surveys of consumers on illicit tobacco purchases can be conducted in the field or by telephone. Traffickers and enforcement agencies can also be surveyed, the latter 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 survey instruments, other data-collection techniques, or modeling construction to be employed for quantification. For discarded-pack studies, researchers choose a defined geographic area, collect littered cigarette butts or packs, and examine them for tax stamps, health warnings, and other evidence of legal purchase and consumption. The various options to collect data for this research task are similar to those discussed in sections d) and 2.b) below; see those sections for a more complete description of

each. 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.

(2) Anti-ITTP enforcement

The study of anti-ITTP enforcement should have two goals: measuring enforcement activities and estimating their budgetary and social costs. Enumerations include the number of dedicated personnel; investigative actions (surveillance, undercover purchase, intercepted communications, search warrants served); arrests, prosecutions, and convictions (broken out between felonies and misdemeanors); 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.

No single source of data covers enforcement actions directed against ITTP, much less on violence associated with enforcement. Law-enforcement and crime data, generally, suffer from inconsistent definitional and reporting standards across local, state, and federal agencies. Efforts at data collection should begin with the two federal agencies with principal responsibility for federal tax collection and enforcement: the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), and the Alcohol and Tobacco Tax and Trade Bureau (TTB). These agencies may be able to provide some data on enforcement at the state and local levels, at least insofar as that enforcement involves joint operations with federal agencies. Customs and Border Protection (CBP) should have data on tobacco seizures; although illegal imports are a small share of the domestic black market, some portion of CBP's activities and expenditures can be credited to tobacco enforcement. The Federal Bureau of Investigation and the Department of Homeland Security will have some information about ITTP and anti-ITTP enforcement that intersects with concerns about organized crime and terrorism. The Executive Office for US

Attorneys collect 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). Generating estimates of state and local enforcement against ITTP requires the compilation of data not yet collected, using some combination of interviews and sample surveys. With over 3,000 counties, and many times that number of local police jurisdictions, a census represents an almost insurmountable data-collection challenge. However, stratified sampling, perhaps designed with certainty strata⁶ of the counties and localities (fewer than 100 in total) that account for approximately half of all felony arrests and prosecutions nationwide, could provide useful data. This is the sort of inquiry routinely undertaken by the Bureau of Justice Statistics, which has well-developed relationships with state and local authorities.

c) Analysis

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 based on the data described above 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). These studies can provide a methodological starting point, although 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

⁶ In complex survey design, certainty strata contain population elements that are sampled with certainty (i.e., all elements within the strata will be included in the final sample).

products (which Stephens, Calder, and Newton (2005) show can be more dangerous than licit product), the foregone productivity of the incarcerated, and other social costs. Some steps have been taken in the literature to account for social costs related to illicit drugs, alcohol, or other goods requiring enforcement of restrictions in access or use, and some of the studies address the types of costs discussed here, although rarely with use of specific data. Since Daudelin, Soiffer, and Willows (2013) warn that participation in ITTP can lead to more involvement in other illegal activities,⁷ spillovers to other areas of crime need to be considered. There are no comprehensive quantitative studies of the costs of enforcement or types of enforcement actions against ITTP.

d) Existing or ongoing studies

Past estimates of the incidence of black-market cigarette purchases and the characteristics of purchasers are available at a range of geographic scales. The estimates are computed using a variety of methods to collect data, including collection of empty discarded packs, consumer surveys, seizure data, and other methods. Numerous studies, beginning with Lakhdar (2008), perform discarded-pack studies (Wilson et al., 2009; Merriman, 2010; Barkans and Lawrance, 2013; Davis et al., 2013; Stoklosa and Ross, 2014; Wherry et al., 2014). Many types of surveys can ascertain the prevalence of illicit tobacco purchases, including telephone surveys of areas near Indian reservations (Hyland et al., 2004) and convenience samples of self-identified smokers at bus stops (Wherry et al., 2014). Pack-collection surveys ask respondents to provide a pack of cigarettes of the type usually consumed (Fix et al., 2014), to show all opened packs in the household to the researcher (Stoklosa and Ross, 2014), or to show the

⁷ Daudelin, Soiffer, and Willows (2013, pp. 22–3) argue that the “illegal nature of the trade and the need to launder and spend its proceeds put pressure on those involved to become more involved or to engage in other illegal activities. In addition, groups ... can use illicit tobacco to support more ambitious and dangerous criminal and political endeavors.... [Connections with criminal organizations and well established operational procedures would make it relatively easy to diversify away from tobacco if circumstances warranted.”

most recent pack opened (Joossens et al., 2014). One field study in South Africa employed teams of researchers to make “dummy purchases” at cigarette stands and shops, gathering data on licit and illicit brands offered for sale (Wherry et al., 2014).

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). Stehr (2005) used publicly available data from the Behavioral Risk Factor Surveillance System (BRFSS) to estimate the prevalence of tax avoidance in cigarette purchasing. Estimates of the incidence of consumption of illicit cigarettes can vary widely across geography, time, and research methodology. The methodologies themselves are subject to accusations of bias (Barkans and Lawrance, 2013; Calderoni, 2013; Guindon et al., 2014; Stoklosa and Ross, 2013). And there are few estimates of a change in black-market share in response to a policy change other than a tax increase (Scollo et al., 2014).

Few studies attempt to account for the social costs of crime and violence associated with ITTP. Most of the few that address the crime problem are specific to areas outside the United States (Collins and Lapsley, 2008; Caneppele, Savona, and Aziani, 2013).

2. Model ITTP by geography to determine who is affected

Kilmer et al. (2014) argue that sensible policymaking regarding illicit markets requires that policymakers have some idea of the scale of those markets. Without knowing the magnitude of ITTP, it is impossible to make the best decisions about which regulations work best from an encompassing social perspective. Therefore, the next research task in the agenda 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.

The modeling incorporates features of local enforcement efforts against ITTP as well. Then, using GIS software, 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.

Taxation, regulation, and enforcement efforts and their geographic variation influence the level of illicit activity. Given that taxation and regulation vary between states, it follows that illicit activity similarly is not uniform across the nation, but disproportionately affects communities where the conditions support the illicit market. For example, communities along borders with high differentials in taxation are likely to be affected more by ITTP, given that the literature finds evidence for cross border product flows in such case (Chiou and Muehlegger, 2008; Lovenheim, 2008; Harding et al., 2012).

Understanding the region-specific effects of today's ITTP allows forecasting of how a state, region, community, or neighborhood might respond to regulatory changes in the future. This information is invaluable not only for projecting the social costs of regulatory changes but also for tailoring law-enforcement approaches to maximize impact in the most vulnerable areas.

a) Background

A complete analysis of the US market for illicit tobacco has not been performed. Frequently quoted figures suggest that ITTP cost \$5 billion in lost state and federal tax revenues in 2010 and \$7 to \$10 billion in 2014.⁸ Illegal activity also generates additional social costs: increased health risks from

⁸ The figures are typically found in media articles (e.g., Fields, 2009; Niquette and Deprez, 2014) with general attribution to ATF or particular ATF officials, although we have not found actual studies supporting these figures published by that agency. For comparison, Davis et al. (2013) find that illicit cigarette trafficking in just five cities cost about \$700 million annually in lost tax revenue. See also Jones (2003). Here, ITTP includes several varieties:

consuming unregulated and un-branded products; increased levels of smoking among youths whose typically lower disposable incomes often prevent them from purchasing legal, taxed tobacco; 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.

At the federal level, the Jenkins Act, the Contraband Cigarette Trafficking Act (CCTA), the PACT Act, and the TCA all address ITTP.⁹ States and localities have enacted a patchwork of laws and regulations. However, the enforcement effort is not currently well 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. 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.¹⁰ The combination of high profitability with comparatively lenient penalties for smuggling makes illicit tobacco trade a low-risk crime (GAO, 2011). Accordingly the social consequences of illicit tobacco are felt more acutely in some specific geographic regions than in others.

direct smuggling of tobacco products into the country; re-introducing export-only products into the American domestic market; manufacturing tobacco products without a license; buying products in one state for illegal resale in another; buying cigarettes on Indian reservations for illegal resale to non-tribal members; and buying from websites that do not charge taxes.

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.

¹⁰ The incidence of such counterfeit or unbranded product is much higher in many foreign countries.

Geography is just one important factor in mapping the illicit tobacco market in the United States. Like legal smoking, 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).

b) Data collection

Difficulties in collecting data on ITTP notwithstanding (Joossens and Raw, 2012), at least five methods of gathering data can be used as inputs for a model of domestic illicit tobacco use in geographic detail. These are the collection of discarded packs, novel use of existing large-scale surveys, new surveys, interviews of law-enforcement agencies, and ethnographic studies.

(1) Discarded-pack collection

In discarded-pack studies, teams of researchers are sent out to find all discarded cigarette packs. Packs may then be examined for the absence of mandated tax stamps for the local area, or of health warnings, or other telltale signs that indicate an illegal purchase or location of consumption (Lakhdar, 2008; Wilson et al., 2009; Merriman, 2010; Davis et al., 2013; Stoklosa and Ross, 2014; Wherry et al., 2014). The packs can also be classified by type of tobacco product. These methods do not rely on getting individuals to accurately report their own illegal behavior, which is problematic. However, discarded- pack studies are labor-intensive and necessarily location-specific, and interpreting them depends on unverified assumptions about whether packs that are publicly discarded are representative of all packs consumed.

(2) Use of existing large-scale surveys

Existing data from studies such as the TUS-CPS could be “mined” for geographically disaggregated data if the Census Bureau agreed to make disaggregated results available. Even without

such cooperation, there are enough data in such surveys that fairly precise mappings from individual characteristics (income, age, marital status, race, etc.) to the propensity to use various sorts of tobacco products as well as the propensity to purchase from the Internet or out of state can be estimated. Then the mappings can be used to estimate the incidence of tobacco use and illicit purchases in other areas, as a function of area demographics.

(3) New consumer surveys

Since all existing surveys have some limitations for the task at hand, designing and commissioning new surveys is a promising avenue to gather data on tobacco-product use and illicit tobacco consumption. The information desired includes, among other items, which specific tobacco products are consumed, where the products are typically (or most recently) purchased, the price paid, and various demographic information about the respondent and the neighborhood. These could be field or telephone surveys, perhaps employing randomized-response technique (RRT)¹¹ or related techniques to minimize social-desirability bias (Krumpal, 2013).¹²

¹¹ The RRT, in which the respondent uses a randomizing device to indicate whether a truthful or false answer should be given, increases the validity of answers to sensitive questions such as those regarding drug use (Goodstadt and Gruson, 1975). RRT works because the interviewer does not know if the respondent answered truthfully, and so the questioner need not feel stigmatized by giving a truthful answer (in cases where the randomizer indicates that the questioner should answer truthfully). Statistical methods are then used in data analysis to uncover the population prevalence of the socially undesirable behavior.

¹² Other survey methods in this vein include the unmatched count technique (UCT) and the nominative technique (NT). With UCT, respondents look at a list of behaviors and state in how many they have engaged, without saying which ones. With NT, respondents answer questions on behalf of other, unidentified persons (relatives or friends) about illegal behavior. In each case, whether RRT, UCT, NT, or similar other methods, there is no deterministic link between the respondent's answers and the respondent's actual behavior, so social desirability bias is reduced. Nevertheless, in each case a statistical method can uncover the prevalence of the behavior at issue.

(4) Interviews and surveys of law-enforcement officials

Law-enforcement 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 (Holloway, 1997). Semi-structured interviews could be used to elicit hypotheses that could then be tested with larger-scale formal surveys.

(5) Ethnographic studies

A final approach to gathering information on the prevalence and location of ITTP is to perform ethnographic studies. While sometimes the term is used loosely to refer to any qualitative study performed by anthropologists or other social science researchers, ethnographic study is more precisely defined as fieldwork requiring the researcher to “immerse him or herself fully in the chosen field of study, learning the day-to-day and extraordinary stuff of social and cultural life by ‘being there’” (Lewis and Russell, 2011, p.400). While there are apparently no ethnographic studies yet of illicit tobacco consumption, the approach has been used in a few instances of research of tobacco-control programs (Schultz, Bottorff, and Johnson, 2006; Lewis and Russell, 2011). There are a few difficulties with ethnographic research. The amount of time required for the researcher to embed with and gain the trust of the studied subjects is the most obvious limitation. Therefore, an ethnographic study may best be employed in this research to inform the research team about the forms that illicit tobacco takes and the norms involved with the subculture of those who participate in black markets. The qualitative knowledge gained can then inform the creation of the survey instruments or other data-collection techniques to be employed for quantification.¹³

¹³ See also Simpson (2011) for other practical difficulties with ethnographic research.

c) 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 on the community of ITTP 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 allow valid out-of-sample prediction for other communities for which neighborhood characteristics are known but the scale of ITTP is not. Such granular geographic analysis can then be aggregated to the state and national level.

d) Existing or ongoing studies

Existing data and literature address the nature and extent of ITTP in the United States (Cummings, Pechacek, and Shopland, 1994; Eriksen and Mackay, 2012; Fix et al., 2014) and abroad (Joossens et al., 2014), and discuss the various laws in place, as well as enforcement agencies (e.g., Alderman 2012). Other sources detail the extent of illicit tobacco in a specific region or city (e.g., Shelley et al., 2007; Wilson et al., 2009; Merriman, 2010; Kurti et al., 2013). These might prove useful in identifying specific areas meriting more detailed investigation.

In some cases there are multiple sources detail a single aspect of the illicit market. For example, many sources investigate youth access to illicit tobacco (e.g., Forster et al., 1998), although their value in estimating the overall scale and distribution of illicit tobacco sales is limited. There is at least one large study on tobacco use (ITC Project, 2014). Many of the large-scale studies on tobacco in the United

States (e.g., SAMHSA, 2013) do not cover illicit tobacco. There do not appear to be large-scale studies modeling the illicit market at the levels proposed here.

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 law-enforcement agencies involved with ITTP, may be able to provide additional data on ITTP for analysis.

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.

As part of this research task, inquiry into which states have the following is helpful:

- 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;

- High-quality relationships between law enforcement and communities, and good access to reliable intelligence on illicit activities;
- Public appetite for tougher regulation, including a larger police presence, stricter enforcement, and increased arrests;
- Cultural distaste for illegal activity, or a public-relations apparatus capable of discouraging consumption of illicit products and participation in black markets;
- Capacity for demand reduction, including smoking-cessation campaigns; and
- Any other measures that reduce ITTP.

Estimating the social costs of any proposed regulatory change requires accounting for its unintended consequences. These cannot be estimated with any certainty without understanding the capacity of state and local governments to enforce the laws against ITTP. Those capacities, though always important, will become more so in the face of a ban on a particular tobacco product. A ban would create new demand for illicit product from those users who do not quit and who prefer illicit purchase to switching to legal tobacco substitutes. Limiting the increase in ITTP that would naturally result from such a change would require effective enforcement. Enforcement can nudge consumers away from illicit purchases by influencing the supply side by increasing prices and search times for illicit products. Enforcement also provides morality cues to law-abiding citizenry on the demand side. Yet 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

The scale of ITTP is substantial nationally but highly concentrated in some states and neighborhoods. Many factors account for that regional variation. States with high rates of tobacco use are at special risk. So, too, are high-tax states close to low-tax states, especially if they also have weak enforcement capacity.

Effective regulatory structures and adequate enforcement capacity are essential to combating ITTP. But the way states manage 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 claims to have dramatically increased its ability to prevent and punish resale of illicit tobacco. The state has implemented a new tax stamp and streamlined processes for sanctions against license holders. Furthermore, a unit within the state's Board of Equalization regularly (and more frequently than in earlier years) investigates and prosecutes large illicit-tobacco-trafficking schemes. 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.

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.

b) Data collection

Data sources for the proposed project can begin with existing surveys or other work in the literature detailing enforcement activities and related costs (Alderman, 2012). Then, in each state, agencies with responsibilities encompassing ITTP can be identified. Such agencies include taxation authorities, state police, and offices of attorneys general, from which information can be requested on active programs relevant to ITTP. 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.

c) Analysis

A primary task of this analysis is to determine 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, along with reviewing the literature relevant to particular programs. It is helpful also to work with outside experts, including retired law-enforcement personnel, to gain additional insight into the effectiveness of anti-ITTP programs from a variety of perspectives. Possible partners in the research include ATF, TTB, the US Government Accountability Office (GAO), and state and local tax-enforcement agencies, both in low cigarette-tax states such as North Carolina, Virginia, and Georgia and in high cigarette-tax states such as New Jersey, New York, and Washington. The partners could help identify common obstacles and prerequisites for success, and the structure of the partnership can be informed by past research on agency cooperation to combat ITTP (McNeill et al., 2013). Analysis of data relating to purchases or sales of illicit tobacco products, detected violations, and enforcement actions helps quantify the relative sizes of need and capacity to enforce against ITTP. 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.

A more formal portion of the analysis can model the effects of constraints on enforcement capacity and effectiveness in determining the size and social costs of ITTP. Several aspects of the

modeling are similar to research tasks posed above, with the difference here being a primary focus on enforcement capacity. Elements of this part of the analysis include the following:

- Construction of a modeling framework capable of estimating the extent of ITTP, using as inputs both anticipated demand and law-enforcement response. The modeling can draw on the results of the analysis conducted on the scale of ITTP described above in section 1.b)(1) and section 2.
- Estimation of the range of anticipated demand-side market growth in response to a ban on the tobacco product in question. The estimation can rely on the work performed for the research task proposed in section B.1 below.
- Simulation of the effects of different regulatory structures and enforcement practices, and in enforcement resource levels, on the extent of the illicit market.
- Estimation of the effect on illicit markets of a ban, after accounting for constraints on enforcement.
- Computation of an alternative scenario, in which more effective and harmonized regulatory structures and practices are adopted by enforcement agencies nationwide.

d) Existing or ongoing studies

Some of the extant literature addresses the nature and extent of the US illicit tobacco trade (Fix et al., 2014), and discusses the various laws in place, as well as affected regulatory and enforcement agencies (e.g., Alderman, 2012). There are also discussions of the strategies available to enforcement agencies seeking to limit ITTP (CTFK, 2014). Some of the literature identified addresses the cost-effectiveness of various states' enforcement practices regarding limiting youth access to tobacco (DiFranza, 2005). However, a comprehensive study detailing the precise actions taken by each state combatting ITTP in general or evaluating the cost effectiveness of such efforts 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.

B. Examining the impacts of banning a tobacco product

After learning about the current ITTP situation with the research tasks identified in the previous section, the FDA should examine directly 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) Estimating the enforcement requirements of a specific product ban at state and local levels; and 3) Analyzing the risks of a substantial import market for illicit tobacco product in the face of a ban. Note that several aspect of the tasks outlined in the previous section also relate directly to the prospective impacts of a tobacco-product ban, since the point of examining past efforts against ITTP is to learn about the impacts of future proposed enforcement (see, for example, the analysis proposed in section A.2.b)(5) above).

1. Survey consumer attitudes toward ITTP

The attitudes of consumers about the purchase of illicit tobacco products are an important part of the policy analysis of a proposed ban. Examining attitudes toward illicit tobacco consumption is necessary to determine the likely extent of the increase in illicit activity resulting from a ban. An informed assessment must take stock of underlying attitudes toward illicit tobacco consumption across various demographics, as well as the social and financial contexts of those who would be affected. 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. This segment of the research agenda updates and improves upon existing efforts in this area (e.g., O'Connor et al., 2012).

a) Background

Attitudes held by individuals and communities toward illicit tobacco use do not appear to be uniform, but instead vary across the population. Actual behavior of consumers in the tobacco market is likely to depend not only on the attitudes of the individual but also on the perceived attitudes of others. Furthermore, factors such as individual wherewithal and local availability of illicit products are also important determinants of participation in ITTP. Despite the prevalence of tobacco consumption in the United States, relatively little is known regarding users' attitudes toward the illicit market for tobacco. 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), yet it is unclear how persistent they would be, how much risk would be required to dissuade them, or what their demand would be at various possible prices.¹⁴

b) Data collection

Awareness of, and attitudes towards, illicit tobacco products are best assessed through surveys and interviews. Respondents can be recruited from communities with high rates of smoking or use of the tobacco product in question. 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

¹⁴ Note that the economic way of thinking suggests that answers to general poll questions such "what would you do if product x were banned" are nearly meaningless, because behavioral responses to specific policies depend on the prices and availability of substitutes to the licit good (Gruber, 2001). While it is possible to view such answers as incorporating consumers' expectations regarding the likelihood of the various price-availability scenarios after a ban, the data are of limited use for policy-related prediction and evaluation without modeling explicitly the dependence of behavior on prices.

counterfeit product, and attitudes toward such may vary by city or ethnic group. A survey also inquires into the reasons for participants' inclination towards or against illicit activity, informing measures to limit demand for illicit products in the event of a ban.

In particular, survey questions and focus-group discussions should attempt to determine attitudes about and general perceptions of:

- 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;
- Prevalence of illicit use within the community;
- Social acceptance of illicit use, including the impression of attitudes of others within peer groups;
- Tolerable risk in purchasing illicit tobacco products; and
- Tradeoffs between price, risk, and product quality (i.e., perceived marginal rates of substitution among these).

c) Analysis

In addition to the qualitative insights such surveying can yield, well-developed methods in the survey and econometric literature can uncover underlying preference relationships (e.g., a utility function) from revealed and stated preference data (Morikawa, Ben-Akiva, and McFadden, 2002). Discrete-choice experiments (an example of conjoint analysis and contingent valuation)¹⁵ can be conducted online or on the telephone to estimate and assess preferences for alternatives to licit product

¹⁵ 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.

in the event of a ban. The existing literature provides a useful starting place (Flach and Diener, 2004; Ida and Goto, 2009).

d) Existing or ongoing studies

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 from other countries, however, with no claims to or assessment of external validity. Given that the incidence and dynamics of smoking and other tobacco use vary widely among countries, this is problematic. Furthermore, no existing study of tobacco users combines the elicitation of stated preferences with the sort of rigorous econometric analysis necessary to identify the structural elements of the individuals' preferences. This limits the usefulness of existing research for purposes of predicting consumer behavior under prospective, counterfactual scenarios.

Nevertheless, studies from other countries suggest expected results and provide a starting point for designing new studies as proposed here. For example, a majority of young smokers surveyed in the UK are aware of the illicit tobacco market (Moodie, Mackintosh, and West, 2010). A considerable minority had been offered illicit cigarettes, slightly over half of whom reported having bought illicit cigarettes within the last six months. The limited research suggests that working-class communities have relaxed and even positive attitudes toward illicit cigarette distribution: distributors provide a valuable service, licit cigarettes are unreasonably expensive, resentment of government rationalizes illicit cigarette use, and smuggling is an everyday practice with social reinforcement. This research focuses on especially disadvantaged areas and might not be representative of low-income or other communities generally. More-expansive surveying across a range of demographics and regions helps to place these

findings within the broader context of public attitude toward illicit cigarettes. On the positive side, several studies suggest that even those who condone ITTP are nevertheless concerned about the risk of exposure of children to tobacco. This concern offers a potential target for public-awareness efforts to foster opposition to illicit cigarette distribution—one that has already shown mildly promising results and benefits from further investigation.

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, the FDA inquiry into regulation of menthol cigarettes led to many empirical studies in this vein (Tauras et al., 2010; Compass Lexecon, 2011; Winickoff et al., 2011; O'Connor et al., 2012; Pearson et al., 2012). However, these results remain speculative.

2. Estimate the enforcement requirements of a ban

If a tobacco product is banned, upholding the regulation would require law-enforcement actions. In order to properly consider the unintended consequences of a ban, it is necessary to determine how much enforcement would be needed to prevent or 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. Knowledge of such costs and impacts is necessary when examining the merits of a potential ban on a particular tobacco product.

a) Background

A ban would be expected to increase the workload of local and state law enforcement, but the extent of that increase has not been estimated. A ban would tend to increase the volume of illicit sales activity where it is already prevalent and perhaps to create new illicit markets where none now exist. In particular, there is the risk of substantial illicit imports of both genuine and counterfeit product (as is common in Europe), giving tobacco enforcement more of an international aspect than it now has. The

size of the illicit market and attendant costs and effects of enforcement are unlikely to be uniform. They may vary depending on factors such as geographic location, existing demand for the tobacco product at issue, and the preexisting degrees of enforcement and ITTP in those regions.

Various law-enforcement activities should be taken into account when understanding the costs and effects of a ban. These include:

- Patrols, seizures, local arrests, and general street enforcement by non-specialized police units;
- Investigations of large-scale distributors, including sting operations and facility raids by specialized units;
- Costs of prosecution, court processing, and punishment for those violators of the ban;
- Costs of training and equipment (e.g., detection and recognition of contraband product, advanced tax-stamp readers, patrol and search dogs); and
- Need for coordination across US agencies and with foreign enforcement agencies.

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 surrounding Indian reservations. In addition, most enforcement efforts to combat the availability of illicit drugs are not interdiction efforts and instead take place on the local level, and therefore require local resources.

b) Data collection and analysis

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. This requires estimation of (or assumptions about) the behavior of current consumers of the tobacco product under consideration.

Thus, this research task can draw upon the research to be performed in the previous section (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, and thus the research from the task described in section A.1 above can be drawn upon.

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, 2014b).

c) Existing or ongoing studies

We are not aware of any effort to estimate the enforcement requirements of a ban, or to propose an approach to doing so.

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. One particularly worrisome possibility is that a new trade in importing the banned product would encourage further international trafficking of other illicit

tobacco products, as traffickers develop infrastructure and organizational capacity. The risks involved with illicit import trade and its associated acts of violence and disorder ought to be weighed against the possible public-health benefits of eliminating legal access to the tobacco product in question. Aspects of this research task include estimating the size of the potential market for smuggled product after a ban, investigating plausible reactions by Mexican drug-trafficking organizations and their competitors, and identifying profitable trafficking routes and business models likely to be employed. Such considerations will inform the decision as to whether such a ban would, on balance, serve the public interest.

a) Background

The United States already supports a substantial ITTP, consisting primarily of cigarettes legally produced domestically and then smuggled across state borders. Compared to elsewhere in the world, imported cigarettes are relatively rare; counterfeit cigarettes are also uncommon but not unknown on the black market in the United States. In contrast, an 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. In that case, international smuggling could become the primary source of illicit product, with secondary contributions by illicit domestic manufacture, which is barely an issue today. Another concern is that, once trafficked tobacco products begin to stream in across the borders, it may be hard to shut off the flow after supply channels develop.

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. Today's market for many tobacco products is larger than the illicit markets for heroin or

methamphetamine.¹⁶ For such products, if even a small portion of current users were to turn to the black market for imported goods, the potential revenues would likely draw interest from some DTOs. Existing cross-border smuggling networks for tobacco (Daudelin, Soiffer, and Willows, 2013) could also be expanded greatly.

The effects of a larger trade in imported illicit tobacco products would be far-reaching. One consequence is the risk of inflaming 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. In 2011, the Treasury listed one such group, Los Zetas, as a “significant transnational criminal organization” (TCO) subject to asset controls. Another revenue flow would only exacerbate that disorder, including making it harder for US law enforcement to detect and control the traffic in other illicit substances, such as methamphetamine and heroin.

b) Data collection and analysis

The research task begins with a review of the literature related to the size of the market for the tobacco product at issue. To estimate the size of the potential market for smuggled product post-ban, the next step is to model how users are likely to change their habits in the face of a ban. This research is required by the FDCA, which says the FDA shall take into account “the increased or decreased likelihood that existing users of tobacco products will stop using such products” when considering regulation.¹⁷ The literature, at least for many tobacco products, can be consulted for existing evidence on cessation

¹⁶ The US cigarette- and tobacco-manufacturing market had revenue of \$39.9 billion, and the next step in the supply chain, cigarette- and tobacco-products wholesaling, had revenue of \$122.0 billion, both in 2014 (IBISWorld database, queried February 2, 2015). The estimated sizes of the heroin and methamphetamine markets in the US are \$27 billion and \$13 billion, respectively (Kilmer et al., 2014).

¹⁷ FD&C §387f (d)(1)(A).

(actual and intended), switching to other tobacco products, and intentions toward black-market participation. These aspects of the research task obviously overlap with the tasks outlined in sections A.1, A.2, and B.1 above.

To investigate anticipated reactions by DTOs and other TCOs and identify profitable trafficking routes and business models likely to be employed, the literature and available data on DTOs can be reviewed. These range from comprehensive analyses (Lyman, 2015) to case studies and ethnographic work (Natarajan, 2000, 2006; L’Hoiry, 2013). The data sources and methods of analysis employed for the research described in sections A.3 and B.2 are relevant here as well. There are several considerations in this regard to be examined. For example, ultimately the unintended consequences of a ban on a tobacco product might come down to specific details about the competitiveness of Mexican DTOs, and how they react to the opportunity to import illicit tobacco. Details that bear investigation include: Which organizations are likely to supply demand for illicit product? By which trafficking routes? With what consequences? It is important to attempt to quantify the potential stakes of the decision to ban a good.

These considerations are interrelated. DTOs are unlikely to enter the trade unless revenues are sufficiently large. On the other hand, well-established smuggling networks enjoy the advantage of economies of scope since they have already sunk investments in their infrastructure (Daudelin, Soiffer, and Willows, 2013), and thus the revenue requirements to expand into a new line of business are lower than they would be for a *de novo* venture. Under different assumptions about how current users react to a ban—e.g., if they quit use entirely, switch to other tobacco products, or turn to illicit sources—one can estimate a feasible range for market demand. Research proceeds by identifying the total annual revenue of the current market, which is then multiplied by the fraction of consumers who would be willing to buy product illegally (see O’Connor et al., 2012 for such estimates for menthol cigarettes).

To attract DTOs, the business would also need to be profitable. According to Reuter and Kleiman (1986), costs of illicit suppliers include the cost of production (or cost of procuring supply of the illicit product, depending on the supplier's position in the supply chain), 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). These should be subtracted from total revenue, along with the expected value of losses to enforcement (e.g., seizures),¹⁸ which can be measured as the financial costs of such losses times their probabilities. While such probabilities might be difficult to measure, enforcement data from comparable illicit markets might serve as a model. 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 menthols 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? In the United States, interstate smugglers have already established expertise and effective trafficking routes; how would that existing infrastructure 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.).

¹⁸ Relying on expected values tacitly assumes the DTOs operate as risk-neutral economic agents.

c) Existing or ongoing studies

Some investigation has centered on the relationship between ITTP and funding for terrorism. The TCA states as a “finding of Congress” that ITTP is “linked to organized crime and terrorist groups.”¹⁹ Terrorist organizations consider illicit tobacco a lucrative source of income, given the large profits and relatively little success at (or interest in) prevention by law enforcement. Organizations known or strongly suspected to benefit from ITTP include Hamas, Hezbollah, the Taliban, al Qaeda, and the IRA (Billingslea, 2004; Horwitz, 2004; Shelley and Melzer, 2008; Brady, 2013; Daudelin, Soiffer, and Willows, 2013).²⁰

Research and basic economic reasoning suggest that criminal organizations are willing to supply illicit products to virtually any community that demonstrates sufficient demand. Factors that appear to influence the situation include local social norms regarding ITTP, effectiveness of the national or local legal system in punishing those apprehended, and ambition of law enforcement in pursuing illicit tobacco.

Related to the question of importation is the sourcing of tobacco from Native American reservations in the US and First Nations reserves in Canada. Reservations pose a unique problem for tobacco consumption, taxation, and the cross-border transit of tobacco. Canadian authors Daudelin, Soiffer, and Willows (2013) conducted a thorough analysis of the smuggling and crime problems associated with cross-border ITTP between eastern Canada and the United States through a Mohawk reserve straddling the border. Their study may provide a model for an examination from the US perspective. Even setting aside the aspect of international smuggling, reservations in the US create

¹⁹ Public Law 111-31, Div. A, sec. 2 (35).

²⁰ 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.

complications regarding tobacco trade. The US Court of Customs ruled in 1937 that American Indians are not exempt from paying duties for commercial trading goods when crossing reservation borders; yet some reservation residents assume that they are entitled to produce and sell duty-free cigarettes, believing that since they are sovereign they are exempt from national regulations. Both registered and unregistered production plants operate out of Indian reservations, providing duty-free cigarettes that are sold both to consumers onsite and to distributors who resell throughout other areas, sometimes 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.

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, and criminology (Schelling, 1971; Reuter and Kleiman, 1986; Rydell and Everingham, 1994; Levitt and Venkatesh, 2000; Miron, 2003; van Ours and Pudney, 2006; Werb et al., 2011), as well as in other fields such as ethnography and economic sociology (Ritter, 2006; von Lampe, 2006; Beckert and Wehinger, 2013). Nevertheless, this body of research is of only limited use to policymakers contemplating specific policy changes. No existing model predicts the form and scale of illicit markets as a function of policies and circumstances. For example, between 1980 and 1990 prices of illicit heroin and cocaine fell drastically; since 1990, the estimated dollar volume of the U.S. illicit cannabis market has grown approximately fourfold, while the volume of the cocaine market has shrunk by approximately 50%. Cocaine-dealing violence exploded between the early 1980s and the mid-1990s, then fell away equally dramatically. None of those changes was predicted in advance, and no model exists today to retrospectively explain them in quantitative terms. Even the shape of the supply curve remains an open question, with some analysts arguing for a downward-sloping curve as a result of enforcement swamping (i.e., growing markets face lower enforcement pressure per unit of physical volume). The 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. While we do not develop such a theory here, we sketch out what it might entail.

1. Background

Illicit markets have been studied fruitfully using the tools of economics, under the assumption that such markets obey the laws of supply and demand (Reuter and Kleiman, 1986; UNODC, 2004; Becker, Murphy, and Grossman, 2006; Prieger and Kulick, 2014a,b). Given well-estimated demand and supply relationships, the price, quantity, revenue, and profit garnered in an illicit industry can be determined. Economic analysis derives these relationships from consumer preferences and producer technology and costs, and these preferences and costs of the market are typically taken as given in existing theoretical work. In principle, econometric estimation can provide the demand and cost functions. However, data about illicit markets are so imperfect as to make estimation extraordinarily difficult and prediction virtually impossible (NRC, 2001). For example, the estimated dollar volume in the illicit cocaine market has roughly halved since 1992, while the volume in the illicit cannabis market has roughly trebled; neither of those changes was predicted, and there exists no retrospective analysis providing a convincing causal explanation (derived from Rhodes, Langenbahn, Kling, and Scheiman, 1997 and Kilmer et al., 2014).

Furthermore, existing analyses of particular illicit markets tend to focus on one aspect of the market at a time (the role of prices in a competitive market, competition among suppliers in noncompetitive black markets, vertical relationships among players in the supply chain, enforcement swamping, etc.) while holding other things constant—the economist’s beloved assumption of *ceteris paribus*. In reality, of course, many factors change at once and many forces operate to drive market outcomes. 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.²¹ 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 (Lee, 1993; Skott and Gepsen, 2002; Poret, 2003; Caulkins and Reuter, 2006; Jacobsson and Naranjo, 2009), 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, drawing on both economics and other fields (e.g., as in Hawken, 2013), can help predict what the costs of supply are likely to be. A full accounting of costs must incorporate the risks borne by suppliers due to participating in an illegal activity (Reuter and Kleiman, 1986).

Even with adequate information on consumer preferences and supply-side costs, additional factors will render predictions about illicit markets and their consequences unreliable. Externalities created by the market may include the costs of violence stemming from the illicit market, corruption of officials tasked with enforcement, and the expansion of organized crime into the illicit market. Other social impacts may include the criminalization of a large new class of consumers and a degradation of

²¹ This section draws on the discussion in Prieger and Kulick (2014b); see that work for additional sources. Cocaine prices for small users fell from about \$450 per pure gram in 1981 to below \$200 by 1994. Prices largely remained low until 2007, when they began to rise again. Changes in the street price of heroin were less dramatic. Heroin prices slid more slowly than cocaine prices during the 1980s but continued to fall through the subsequent decade. 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.

respect for the authorities among illicit-market participants. All of these are related to the magnitude of the illicit market, although the nature of the relationships requires study.

Another complicating factor in the analysis of illicit markets is the presence of positive-feedback (i.e., “tipping” or “bandwagon”) effects in illicit activity (Kleiman and Kilmer, 2009; Prieger and Kulick, 2014b) and other non-standard economic phenomena (Caulkins and Reuter, 2006). 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 (Kleiman and Kilmer, 2009). This heightens the need to coordinate planned regulatory activity with enforcement agencies. On the demand side, attitudes toward “victimless” illicit behaviors are likely to soften as the prevalence of those behaviors grows.

2. Data collection and analysis

Methods from many disciplines can be brought to bear usefully on the determination of value in illicit markets and its relationship to effective enforcement strategy. As described for other parts of the research agenda above, elements of a mixed-methods approach can include ethnographic studies, surveys, and “hard” analyses using the tools of economic theory and econometrics. In addition to other studies discussed above, studies applying insights from behavioral economics and psychology (theories of addiction, limited rationality, etc.) can also be helpful to augment the demand and supply sides of the modeling of ITTP. 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. The market information and the links to negative consequences can then be used to determine the optimal law-enforcement effort against the illicit market. Even in the absence

of a precise prediction of market size, various scenarios can be examined (e.g., small, medium, and large illicit markets) to inform enforcement policy.

Violence is one possible consequence of illicit markets, and modeling violence in ITTP is an important second aspect of this research task. Unable to resolve disputes in the courts, participants may turn to bloodier methods of dispute resolution. Presumably, there is some tendency for the level of violence to vary directly with the level of market activity; virtually complete enforcement success in suppressing a market should reduce the level of violence to near zero. However, evidence from the US illicit drug markets suggests that they can persist, at large scale, even in the face of extremely vigorous enforcement.²²

Unfortunately, it may not be true that marginal increases in enforcement efforts leading to somewhat lower volumes in illicit markets will tend to decrease violence. The opposite may be true, as illustrated by the enforcement crackdown against the major Mexican drug-trafficking organizations (DTOs) since 2006, by the crack markets in many US cities in the 1980s and early 1990s, and by the theoretical analyses of Prieger and Kulick (2014a,b). 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.²³ As Thomas Schelling (1971) has put it, enforcement agencies and organized criminals both prefer higher prices for illicit goods. Moreover, individuals and organizations specializing in violence may face less enforcement risk than their competitors because they can intimidate potential witnesses. Thus, while violence

²² The United States has over 300,000 people behind bars in federal and state prisons for drug offenses at any one time (Carson, 2014).

²³ See Prieger and Kulick (2014b) for the precise economic conditions under which additional enforcement leads to greater revenue.

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 level and distribution of enforcement effort that would enforce 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, informed by interviews with enforcement officials and traffickers, would be required to make even an informed guess.

3. Existing or ongoing studies

While there is no existing unified theory of value determination in illicit markets, research from many different disciplines is germane (Ritter, 2006; von Lampe, 2006). Von Lampe, Kurti, and Bae (2014) provide an excellent overview of current illicit cigarette markets in the United States. There are many economic treatments of value determination in illicit drug and tobacco markets and of implications for policy given the supply and demand relationships (Rydell and Everingham, 1994; Caulkins et al., 1997; Moore et al., 2005; Becker, Murphy, and Grossman, 2006; Prieger and Kulick, 2014a,b). More fundamental or nuanced treatment of demand for illicit goods is examined by Marchese (2004) and the emerging behavioral-economics literature linking pharmacological, environmental, and economic factors that contribute to consumption of illicit drugs (Hursh et al., 2005). Ethnographic studies have also been employed to research demand for tobacco and tobacco-control programs (Schultz, Bottorff, and Johnson, 2006; Lewis and Russell, 2011). Supply-side analysis that moves beyond simple supply curves includes behavioral modeling of drug dealers operating under limited rationality (Caulkins and MacCoun, 2005) and a host of ethnographic and qualitative studies (e.g., Natarajan and Belanger, 1998; May and Hough, 2004). Ethnographic studies can also be combined with subsequent economic analysis of the market data, as in Levitt and Venkatesh (2000). The delineation of the

geographic extent of drug markets is studied by Eck (1995) and may also be approached with general methods from antitrust economics (Dobbs, 2003). Von Lampe (2005), with the benefit of hindsight, attempts a holistic explanation of why tobacco smuggling arose in Germany in the early 1990s.

Many have studied the empirical relationships among illicit drug markets, violence, and crime. 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; Hawken, Kulick, and Prieger, 2013). 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; McIlwain, 2004).

III. Conclusion

While the research agenda proposed above 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.²⁴ 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 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.

²⁴ Contrary to what some readers may expect, the conflicts of interest were on the part of the anti-tobacco 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.

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