Legal - licensing

DRAFT

LICENSING

I. Introduction

ATF has extensive experience in licensing the alcohol, tobacco, and firearms industries for specified statutory purposes. ATF licenses approximately 3,800 distilled spirits plants, wineries, and breweries; 140 manufacturers of tobacco products and cigarette papers; 14,500 alcohol beverage wholesalers and importers; 200 tobacco export warehouse proprietors; and nearly 135,000 firearms and explosives licensees.

II. Issues to Consider in Evaluating the Licensing Provisions of the Proposed Agreement

A. A comprehensive regulatory scheme for retailers requires licensing at all levels of the distribution chain.

Any licensing scheme should be tailored to meet its specific goals. For example, ATF's licensing of tobacco manufacturers serves the primary purpose of collecting and protecting the revenue generated by a production tax collected from the manufacturer. To achieve this goal, there is no need to license wholesalers or retailers. In contrast, ATF licenses the entire distribution chain of the firearms industry because the primary purpose of the gun control laws is to prevent sales of guns to particular classes of persons, such as felons, and comprehensive record keeping on all transactions is essential to the national firearms tracing system.

The proposed settlement suggests that the primary goals of a licensing system are to facilitate FDA regulation with respect to access, advertising, and labeling. These goals require a comprehensive licensing scheme that will provide accountability for compliance with the licensing scheme. Record keeping requirements must be sufficient at each level to enable the licensing agency to trace the commodity from the manufacturer to the retailer. Without these controls, there is a "weak link" in the distribution chain that can result in the diversion of the commodity into the stream of unlicensed commerce or noncompliance with regulatory requirements.

However, the system proposed does not license all levels of the distribution chain. Manufacturers and wholesalers that do not sell to consumers would not require a license. Potential for diversion from points earlier in the distribution chain to illegal consumption or for noncompliance with regulatory requirements would be great, particularly when effective controls are imposed at the retail level.

B. The licensing scheme should have enforceable criteria for obtaining a license.

Setting criteria to limit the distribution system has the prophylactic effect of saving enforcement resources and helping ensure the integrity of the licensing and regulatory system. To avoid illicit trading, licenses should be given only to persons who actually intend to engage in the business the license authorizes. Keeping ineligible persons out of the business can also be achieved through licensing fees and inspections. Several years ago, when firearms licenses cost only $10 per year and there was almost no enforcement of the requirement that licensees actually engage in business, the number of licensees blossomed to over 260,000, making enforcement difficult. Raising the fee to $200 and strictly enforcing the licensing requirements has lead to a decrease of about 60% in the number of licensees over a four year period, greatly enhancing ATF's ability to enforce the gun control laws.

The proposed scheme makes compliance with the proposed legislation a condition of obtaining and holding that license. However, there is no mention of an investigative authority to determine whether an applicant is eligible for a license or, for that matter, to determine whether a licensee is maintaining compliance with the proposed legislation.

C. The licensing system needs an effective enforcement arm.

Because a licensing system produces an incentive to traffic unlawfully in the licensed commodity, a sophisticated enforcement arm is needed to investigate unlawful commerce outside the licensed distribution channels. An effective and fair enforcement arm raises the level of voluntary compliance through education of the licensees and deterrence; in contrast, uneven application leads to resentment and non-compliance on the part of licensees, and ultimately, to litigation.

Certain enforcement tools are necessary to effective licensing enforcement. Periodic inspections ensure that the licensees comply with the system. A sensible range of meaningful sanctions for non-compliance give the licensing agency the needed flexibility to deal with different types of violations. These sanctions can include suspension or revocation of the license, civil fines or penalties, or criminal penalties.

The penalty set out in the proposal for unlawful sale of tobacco products without a license is a misdemeanor. A criminal misdemeanor is not a great deterrent -- particularly if the illicit sale of tobacco products becomes highly profitable. Moreover, it is very difficult to obtain prosecution of a misdemeanor given scarce prosecutorial resources.

It is unclear whether the penalties and other sanctions imposed for the sale of tobacco products to underage persons are criminal or civil in nature. Moreover, it is not clear how to count violations for purposes of imposing these sanctions.

D. The proposal leaves unresolved critical funding and resource issues.

An agency charged with administering a licensing system must have adequate resources to process and investigate applications for licenses to ensure that ineligible persons do not improperly receive them. ATF's experience shows that time spent investigating applicants is repaid many fold by avoiding later enforcement actions. Significant resources must also be devoted to the education and inspection of licensees. Costs associated with data processing support are also significant. Costs of a licensing system are particularly high when enforcement is at the retail level, given the number of potential licensees involved, the frequency of turnover, and the diverse locations where business is conducted.

Resources needed for the proposed scheme will be very substantial. FDA estimates that there are on the order of 700,000 retail dealers in tobacco products in the United States. Given that ATF taxes 450,000 retail liquor dealers (stores, bars , restaurants, etc.), almost all of whom sell tobacco products, this may be an underestimate. Costs relating to the processing and investigation of applications alone will be extensive. Costs associated with investigating violations and taking action against violators could even be greater. For example, ATF regulates nearly 135,000 firearms and explosives licensees, using nearly 430 inspectors and roughly 50 people to process license applications. The cost of administering this licensing system is approximately $38 million per year. This estimate does not include the costs of establishing a new system from scratch, nor does it include litigation costs associated with defending challenges to system; actions to suspend or revoke licenses; or criminal investigations and prosecutions.

The proposal states that the enforcement of the licensing scheme would be funded through industry payments, and that licensing fees would cover the administrative costs of issuing State licenses.

However, the agreement does not appear to contemplate any audit authority to account for payments of monies used to enforce the system, nor does it specify whether the federal government or Indian tribes would recover the costs of non-enforcement aspects of licensing programs they administer..

E. The proposal will require cooperation between the federal government and the States.

In order to avoid confusion, misinformation and duplication of efforts, it is necessary to vest responsibility for licensing in one agency. However, cooperation and communication with other agencies is often essential to ensure the licensing agency has all relevant information. In particular, commodities licensed by the Federal government may also be regulated by State and local governments. Cooperation, information sharing and communication with those State and local agencies is essential in order to regulate a commodity effectively. This is particularly true when enforcement resources are stretched to the limit at both the Federal and State level. ATF has entered into approximately 40 memoranda of understanding with States calling for the exchange of information pertaining to alcohol and tobacco products.

III. Legal Issues

A. Tenth Amendment Concerns with the Imposition of Federal Standards on the States

According to the proposed agreement, Federal legislation would mandate "minimum Federal standards" for a retail licensing scheme. The agreement is ambiguous about how this would be done, but presumably the following are possibilities:

- The Federal government could be the licensor, exercising its power under the commerce clause;
- The Federal government could preempt the field, but allow the states to adopt and enforce their own regulations conforming to the Federal standard;
- The States could design their own licensing schemes with advisory Federal guidance; or
- The spending power could be used to give incentives to the States to comply with the Federal standard.

The language of the proposed tobacco settlement agreement appears to contemplate legislation under which the Federal government would set minimum standards for licensing laws that states would be required to adopt as state law and required to enforce through funding provided by the tobacco industry. In its recent decision striking down certain portions of the Brady act, the Supreme Court made clear that the Tenth Amendment bars the Federal government from requiring states to enact or enforce a Federal mandate. *Printz v. United States*, No. 95-1478, 1997 U.S. LEXIS 4044 (June 27, 1997). Thus, the licensing scheme cannot be implemented simply by the passage of a Federal law requiring states to adopt Federal prescribed licensing laws and to enforce them.

However, there are other constitutionally permissible models for Congress to encourage state participation in a Federal scheme. Congress can make compliance with Federal standards a precondition for continued state regulation in an otherwise preempted field. *Printz, supra.* at 27, *discussing Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U.S. 264 (1981) and *FERC v. Mississippi*, 456 U.S. 742 (1982); *see also New York v. United States*, 505 U.S. 144, 161-3 (1992). There is no question that under its Commerce Clause authority Congress could establish a nationwide Federal licensing system for tobacco products, to be administered by Federal agencies. Under *Hodel*, Congress could then allow states to adopt and enforce their own regulations if they

complied with Federal standards. If the agreement provides for industry payments to the Federal government for licensing, Congress could finance a Federal licensing system through such payments.

A somewhat more difficult question is whether Congress could through Federal legislation condition the receipt of payments from the tobacco industry to the states, or some portion of those payments, on the states' adoption of licensing laws that complied with Federal standards. Under the Spending Clause, Congress may condition the receipt of Federal funds on the States' undertaking certain action. *Printz, supra,* (O'Connor , J. concurring). In *South Dakota v. Dole*, 483 U.S. 203 (1987), the Supreme Court upheld, as a valid exercise of the Spending Power, a Federal law reducing the percentage of Federal highway funds received by States that failed to enact a law barring consumption of alcohol by persons under 21. Likewise, in *New York v. United States, supra.*, the Supreme Court upheld financial incentive provisions of a Federally mandated waste disposal law applying to the States but struck down provisions forcing the State to take title involuntarily to such wastes.

However, the Court has cautioned that if the Federal financial incentive is too powerful it may be deemed not to be a condition but to be impermissible coercion. *South Dakota v. Dole*, 483 U.S. at 211, *citing Stewart Machine Co. v. Davis*, 301 U.S. 548, 590 (1937). The Fourth Circuit, sitting en banc, recently struck down a funding condition imposed by the Department of Education on the receipt of funds under the Individuals with Disabilities Education Act (IDEA). *Comm. of Virginia Dept. of Education v. Riley*, 106 F. 3d 559 (4th Cir. 1997). While the majority held only that the statute did not clearly and expressly authorize the condition imposed, six judges joined an opinion holding that the threat of withdrawal of all IDEA funds if the state did not change its policy of refusing to provide tutors to disabled students expelled from school "begins to resemble impermissible coercion, if not forbidden regulation," in violation of the Tenth Amendment. *Id.* at 569-72. The six seemed moved not only by the size of the amount at issue but also by the area in which the Federal government had sought to influence the state's choice.

Some aspects of the proposed settlement might prove problematic to Federal regulation of state licensing under a Spending Clause approach. First, the industry payments may not be Federal funds subject to the Spending Power -- if, for example, the agreement itself provides for licensing-related payments from the tobacco companies to the states, or otherwise constrains the Federal government's use of the licensing funds. Second, the size of the payments involved may be quite large, so that even in the unlikely event that the states were willing to have industry payments for licensing made to the Federal government and doled out to the states under Federal law, the courts might find the legislation coercive. Finally, not all states are participating in this settlement, and the courts might be particularly skeptical of the legislation as applied to a non-signatory state.

B. Due Process Concerns with Suspension and Revocation

The licensing scheme also provides for a suspension of the retail license (after the first offense) and revocation (after the sixth or subsequent offense). Since a license is a property interest protected by the Fifth Amendment, Due Process requires that the licensees be afford an opportunity for a hearing before the license may be suspended or revoked. *See Bell v. Burson*, 402 U.S. 535 (1971). This applies to both state and Federal licensing procedures because the due process clause is made applicable to the states by the Fourteenth Amendment. Accordingly, the enabling legislation must establish a procedure (administrative and/or judicial) giving the licensee notice of the charges and an opportunity to be heard.

C. Licensing on Native American Lands

Using a framework adopted from the Clean Air Act (a *Hodel* - model scheme), the proposed agreement provides for licensing provisions governing sales on Native American lands and

commerce in tobacco products by members of Indian tribes. The proposed agreement provides that the federal government would decide for each tribe whether the licensing provisions would be set by the federal government, set by the state subject to federal standards, or set by the tribe subject to federal standards which incorporate state law. (*See* Appendix III.)

These provisions do not appear to raise additional Constitutional concerns. First, as discussed above, the *Hodel* model of federal-state interaction appears to have been reaffirmed in the Printz case. We are not aware of any constitutional concerns that would arise from the imposition of a federal licensing system or federal standards on Indian tribes, even if the federal standards incorporated state law. The state could also set the licensing requirements: it is well-established that State taxation and regulatory laws can apply to members of Indian tribes and can apply in Indian country. *See, e.g., New York State Department of Taxation v. Attea*, 114 S. Ct. 2028 (1994) (State can require Indian cigarette traders to register with state and tax cigarettes intended for off-reservation consumption). For example, State liquor licensing laws apply to Indians. *See id.*; *Rice v. Rehner*, 463 U.S. 713 (1983).

Also, the agreement states that federal taxes or fees (such as the tobacco excise tax) would apply to commerce in tobacco by members of Indian tribes or on tribal lands. Again, this does not seem to raise significant legal concerns. Federal statutes of general applicability apply with equal force to Indians unless the law touches on exclusive rights of self-governance in purely intramural matters, the application of the law would abrogate treaty rights, or Congress intended to exclude Indians. *U.S. v. Baker*, 63 F.3d 1478, 1484-1485 (9th Cir.) *cert. den.*, 116 S.Ct. 824 (1996). For example, the Contraband Cigarette Act applies to Indian tribes. *U.S. v. Gord*, 77 F.3d 1192 (9th Cir. 1996).

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However, it might be difficult for a Federal agency or State to enforce a licensing scheme given current sovereignty issues or the volatile nature of investigations occurring on these lands.

PUNITIVE DAMAGES

Provision: All punitive damages claims resolved as part of overall settlement. No punitive damages in individual tort actions. This provision would not apply to suits for relief arising from future conduct -- "i.e., suits claiming injury or damage caused by conduct taking place after the effective date of the Act."

Observations:

- The purpose of punitive damages is to deter and punish. While the aggregate cap on liability provisions in the agreement are very complex, they appear to limit the amount that ultimately will be paid by the participating companies. If this is true, the agreement has the effect of diminishing the impact of diminishing the interrorem effect of punitive damages -- simply put, if punitive damages are awarded, they would effect only the allocation of the amounts contributed by the companies among damage payments and the other purposes envisioned by the agreement, but apparently would not increase the total amount paid by those companies. Perhaps, punitive damage claims for future conduct should not be subject to the annual aggregate cap.

- Query: given the deferral mechanism in the annual aggregate cap regarding judgments above $1 million, would it make sense to prioritize the payment of claims for large compensatory damage judgments/settlements to ensure that their payment is not delayed by the payment of punitive damage judgments/settlements that use up the available aggregate cap for a given year? It particularly seems odd to allow plaintiffs to collect punitive damages for future conduct if it would delay individuals from collecting compensatory damages for past conduct (conduct for which punitive damages are barred under the agreement).

- There may be difficulty in determining whether suits claiming injury or damage relate to conduct taking place after the effective date of the Act, particularly where the injury or damage is caused by continuing conduct taking place both before and after the effective date.

- There does not appear to be any transitional provisions in the agreement regarding pending individual tort actions. If the agreement were deemed to apply to those actions (which seems likely), and to deprive the plaintiffs of punitive damages, it could raise Fifth Amendment issues. The critical question would be whether the plaintiffs would be viewed as having a property interest in a punitive damage claim that had not finally been resolved. While courts have been reticent to find such interests generally, problems could arise if the agreement were deemed to apply to cases pending on appeal, where a plaintiff, at the time of enactment, already had a judgment that included punitive damages.

T – Regulatory

Pros and Cons of a Licensing Scheme

Present Licensing of Tobacco, Alcohol, and Firearms

- All states and the District of Columbia license retail dealers in alcoholic beverages and wholesalers and producers of alcoholic beverages within their jurisdiction. (In addition, 17 states control either parts of the retail sale of alcohol or all or part of wholesale distribution.)

- Thirty states license retail sales of tobacco products and 28 states license vending machine sales.

- In addition, ATF licenses tobacco and alcohol at the manufacturing and export level (approximately 140 tobacco manufacturers and 200 export warehouse proprietors; 3,800 alcohol beverage manufacturers and 14,500 wholesalers and importers) as well as firearms at all levels of the distribution chain-- nearly 135,000 firearms and explosives licensees. Wholesalers and producers of alcoholic beverages are thus licensed by both the state and the federal government.

Possible New Licensing Schemes for Tobacco Products

The pros and cons of a licensing scheme vary to some extent depending on the particular licensing system used. The proposed tobacco settlement seems to envision some role for both the federal and the state governments. There is a spectrum of constitutionally permissible options:

- the federal government establishes and enforces a nationwide licensing program

- the federal government allows states to set up and enforce licensing programs that meet federal standards as an alternative to being subject to the federal program

- the federal government conditions receipt of federal funds (the Industry Payments) on the states' enacting and enforcing a licensing scheme that meets federal standards

- the state and federal governments establish and enforce separate and concurrent retail licensing schemes; a retailer would be required to have both licenses to operate

- the states license tobacco with advisory input from the federal government.

Pros and Cons of a Licensing System

ATF and the FDA have contacted state officials involved in state licensing of alcohol and tobacco, respectively, to collect their impressions of the pros and cons of a licensing scheme and other observations regarding licensing. States have cited the following as specific benefits of a licensing system:

- *The license application process limits the distribution system, saving enforcement resources and helping ensure the integrity of the licensing and regulatory system.* The state observations correspond with ATF's experience in federal firearms licensing: several years ago, when firearms licenses cost only $10 per year and there was almost no enforcement of the requirement that licensees actually engage in business, the number of licensees blossomed to over 260,000, making enforcement of the gun control laws difficult. Raising the fee to $200 and strictly enforcing the licensing requirements has lead to a decrease of about 60% in the number of licensees over a four year period, greatly enhancing ATF's ability to enforce the gun control laws.

  However, the effectiveness of a licensing scheme in ensuring against illegal sales and noncompliance depends in part on the extent to which it covers the distribution chain. Record keeping requirements must be sufficient to enable the licensing agency to trace the commodity from the manufacturer to the retailer. Because the system proposed does not license manufacturers and wholesalers, potential for diversion to illegal consumption or for noncompliance with regulatory requirements would be great, particularly when effective controls are imposed at the retail level.

- *Licensing facilitates identification of retailers for compliance inspections, training and educational programs.* Most states that license alcohol or tobacco products have departments or agencies specifically devoted to enforcing laws relating to the distribution of alcohol or tobacco products and the licensing of dealers in these products. Many jurisdictions also charge these agencies with educating retail dealers on how to comply with the distribution laws. For example, the Illinois Liquor Control Commission (which also regulates the distribution of tobacco products in Illinois) has a program called "Kids Can't Get 'Em Here," designed to educate retail dealers in tobacco products on the regulations relating to distribution of tobacco products, how to assist the Commission in the enforcement of those provisions, how to identify underage purchasers and how properly to check identification. According to the Commission, this program has resulted in a significant increase in retail dealer compliance with Illinois tobacco distribution regulations.

- *The threat of suspending or revoking a license helps to ensure that the retail dealer complies with the State and local laws regulating the product.* Short of revocation, a sensible range of meaningful sanctions for non-compliance gives the licensing agency the needed flexibility to deal with different types of violations. While most states use the threat of suspension or revocation of the license as a way to coerce compliance, many States have added "civil or administrative" fines which are less drastic yet effective ways to achieve compliance. States report that administrative sanctions that can be imposed through an expedited procedure are particularly cost-effective because they can be imposed promptly by the licensing agency.

- *Licensing can. be used to restrict the location of retail dealers.* For example, Massachusetts restricts alcohol licenses from locations near churches or schools.

States have cited the following as the primary difficulties posed by a licensing system:

- *An effective licensing system is expensive and time-consuming to administer and enforce.* An agency charged with administering a licensing system must have adequate resources to process and investigate applications for licenses to ensure that ineligible persons do not improperly receive them. ATF's experience shows that time spent investigating applicants is repaid many fold by avoiding later enforcement actions. Significant resources must also be devoted to inspection, education, and data processing support. Costs of a licensing system are particularly high when enforcement is at the retail level, given the number of potential licensees involved, the frequency of turnover, and the diverse locations where business is conducted. For example, lists of retailers have to be constantly updated or they are useless, but states report that given the number of tobacco product retailers, maintaining the quality and the accuracy of a licensing list in this area requires significant resources.

  FDA estimates that there are on the order of 700,000 retail dealers in tobacco products in the United States. Given that ATF taxes 450,000 retail liquor dealers (stores, bars , restaurants, etc.), almost all of whom sell tobacco products, this may be an underestimate. By way of comparison, ATF regulates nearly 135,000 firearms licensees, using nearly 430 inspectors and roughly 50 people to process license applications. The cost of administering this licensing system is approximately $38 million per year. This estimate does not include the costs of establishing a new system from scratch, nor does it include litigation costs associated with defending challenges to the system; actions to suspend or revoke licenses; or criminal investigations and prosecutions.

  The proposal states that enforcement of the licensing scheme would be funded through industry payments, and that licensing fees would cover the administrative costs of issuing State licenses. However, the agreement does not mention any audit authority to account for payments used to enforce the system, nor does it specify whether the federal government or Indian tribes would recover the costs of non-enforcement aspects of licensing programs they administer.

- *Inadequate or uneven enforcement results in a breakdown of the entire system.* All states surveyed noted the need for adequate enforcement authority. States also noted that proper enforcement can be jeopardized by turf battles between different agencies involved in the process: for example, in some states, lists of tobacco retailers are maintained by the revenue collecting agency but tobacco control public health measures are the responsibility of a different agency, and the exchange of information is less than ideal.

The enforcement authority envisioned by the proposed agreement appears deficient in some respects. There is no mention of an investigative authority to determine whether an applicant is eligible for a license or is maintaining compliance. The penalty set out in the proposal for unlawful sale of tobacco products without a license is a misdemeanor. A criminal misdemeanor is not a great deterrent -- particularly if the illicit sale of tobacco products becomes highly profitable. Moreover, it is very difficult to obtain prosecution of a misdemeanor given scarce prosecutorial resources. Similarly, it is unclear whether the sanctions imposed for the sale of tobacco products to underage persons are criminal or civil in nature. They appear to be less severe than sanctions the FDA can impose under its present authority.

- *Licensing can be perceived as an economic barrier to competition.* Licensing imposes a burden on the retail dealer. The process of getting a license is burdensome, intrusive and costly. Moreover, government limitation of the number of licensed retailers benefits those retailers at the expense of those who do not have a license.

Options other than Licensing

There are other mechanisms besides licensing available to enforce regulations governing the sale of tobacco products. Because they do not involve a licensing scheme, they may be less intrusive on law-abiding manufacturers, wholesalers or retailers and less of an administrative burden on the regulating agency. However, significant enforcement resources would have to be expended to ensure compliance.

- Even without a licensing scheme, the enforcing agency could be authorized to seek civil or criminal sanctions for violations from a court.

- The agency could be authorized to impose administrative sanctions, or even issue a "cease and desist" order, when the agency learns of violations. However, due process concerns would likely require the agency to establish a procedure under which notice and a hearing are provided to the violator either prior to the imposition of the sanctions or shortly after. Additionally, the agency would have to rely on enforcement by a court in the event the violator did not comply with the sanctions.

p. 40 delay of "reduced risk" tobacco products after the effective date is neither admissable nor discoverable

The Tobacco Settlement and Incentives to Develop Reduced-Risk Tobacco Products

July 29, 1997

I. Background

In the past, the tobacco industry has not developed many innovative, reduced risk products -- in large measure because to develop and promote safer products would have been to acknowledge the harm done by existing products. But some innovations, like filters and reduced-tar cigarettes, do appear to have followed the release of adverse health news about smoking. In the current environment, in which companies are admitting that their products are harmful and consumer awareness of smoking's risks is heightened, individual companies may be more likely to view the development of reduced risk products as a profitable endeavor.

The Settlement includes provisions intended to speed the introduction of reduced risk products. According to the Settlement, the goal of these provisions "is to guarantee that a mechanism exists to ensure that products which appear to hold out the hope of reducing risk are actually tested and made available in the marketplace and not held back." The types of innovations expected to be introduced include the removal of toxic constituents from cigarettes, a reduction in the nicotine content in cigarettes, and alternative delivery devices for nicotine that remain attractive to consumers.

II. Provisions of the Settlement

Provisions relating to reduced risk products are in Title I, Section E, Part 4 of the Settlement. Manufacturers will be required to:

- Notify FDA of any technology that they develop or acquire and that reduces the risk from tobacco products, and
- For a "commercially reasonable" fee, cross license all such technology to those companies also covered by the same obligations. Procedural protections will be built in to resolve license fee disputes.

Other provisions include:

- If the technology is in early development stages, manufacturers will be provided confidentiality during the development process.
- The FDA will have the authority to mandate the introduction of less hazardous products that are technologically feasible by requiring the manufacturer who owns the technology to introduce the product or to license the technology to another producer. If no

manufacturer or licensee brings such products to market in a reasonable time frame set by FDA, the U.S. Public Health Service may produce the product, either itself or through a licensing arrangement.

III. The economic tradeoff between dissemination and incentives for R&D

One concern with these provisions is that they effectively eliminate the patent system for tobacco products. Economists have long struggled with the optimal design of a patent system. If new innovation occurred spontaneously -- without the need to invest in R&D -- society's interest would be best served by requiring immediate, full disclosure and licensing of new products and technologies without fee. But innovation generally does require investment -- and full disclosure coupled with free adoption by other firms provides little or no incentive for such investment to be undertaken. The patent system therefore grants a property right to the inventor "to exclude others from making, using or selling the invention."[1] The fundamental tradeoff in the patent system -- inherent in designing the length and comprehensiveness of the patent protection -- is to balance the need to encourage R&D with the desire to disseminate new discoveries as quickly as possible.

IV. The Settlement and incentives

The Settlement's provisions, especially the cross-licensing requirement, are near one extreme of possible patent systems. They ensure rapid dissemination of new discoveries, but provide little incentive for firms to invest further in the processes that could lead to such discoveries. A crucial question to answer is how much of the total possible R&D has been undertaken, and how much remains to be done. In the area of removing toxins from cigarettes, much -- though not all -- is apparently already technologically feasible. Some analysts believe that current knowledge would also allow a reduction of the nicotine content in commercially viable cigarettes within a relatively short period (e.g., 6 months); others believe that such products are a decade away. *A critical technical question for FDA and others to answer is to give a best guess as to how much research remains to be undertaken, and in what specific areas.*

To the extent that most of the relevant R&D has already been undertaken, the incentive problems are not significant. *Enforcing full and even free cross-licensing of extant R&D may not pose the same incentive problems as enforcing cross-licensing of future R&D.* Two potential dangers with cross-licensing existing R&D are (1) it may damage the government's credibility that such a requirement will not be repeated in the future, thus reducing incentives for future R&D; and (2) it may be difficult to define an "existing" innovation (how would a prototype be classified, where the bulk of the costs are bringing it to market?). Despite these potential problems, it may be useful to draw a distinction between cross-licensing of existing R&D and

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[1] Patents are granted for a term of 17 years (14 years for design patents), which may be extended only by a special act of Congress (except for certain pharmaceutical patents). After expiration of the term, the patentee loses rights to the invention.

future R&D.

Another important incentive question is to what extent the firms will be allowed to market their innovations. The FDA and others raise legitimate concerns about allowing marketing of reduced risk tobacco products: by providing a government imprimatur of reduced health risks, allowing such advertising may induce more smoking (either by non-smokers or by those who had intended to reduce their smoking levels). So even if each cigarette is "safer," the public health risk may be expanded because of the increase in total smoking relative to the baseline. *To the extent that advertising of reduced risk products is not allowed, however, firms will have little interest in developing such products.*

One possibility -- which may not be technically feasible -- would be to allow firms to publish "health hazard ratings." For example, cigarette packages could carry health hazard ratings of 90, 95, or 100 depending on the risks profile of the product.[2] It seems unlikely that a product carrying a health hazard rating of "90" would be much more attractive to a non-smoker than one carrying a rating of "100." Such a system could provide firms with some incentives to develop safer products -- because extant smokers would pay attention to the health hazard rating -- while minimizing the potential for perverse results. The system would also facilitate a CAFE-like regulation that cigarette sales by each individual producer could have a mean health hazard rating of no more than some level.

V. Options

The above discussion suggests several possible options:

1. *Maintain current provisions.* The current provisions provide limited incentives for innovation, but strong incentives for diffusion. This solution is acceptable if we believe that most of the knowledge about developing safer products already exists -- and there is therefore more to be gained from disseminating what is known than from trying to develop new knowledge and new products and technology.

2. *Require full (and perhaps free) cross-licensing of existing knowledge but not future discoveries.* As noted above, this option would efficiently diffuse the existing stock of knowledge without affecting firms' incentives for future investments in R&D. Future R&D efforts could be governed by the regular patent system, or one of the options below. One important detail in such a system would be the delineation of existing R&D from future R&D.

3. *Grant patents for a limited period.* The Settlement effectively eliminates the patent period. An intermediate position, which would provide more balance between incentives and dissemination, would shorten the patent period from 17 years to perhaps a few years. At the end

[2] Given the difficulty of distinguishing real health benefits, the scale should only include a few discrete levels -- perhaps 90, 95, and 100 -- instead of being continuous.

of the patent period, other firms would have free access to the knowledge.

4. *Grant patents for a limited period and then have the tobacco fund buy out the patent holder (could be combined with #2).* One solution to the tradeoff between dissemination and incentives is to have the government buy out the patent holder and then license the knowledge to other producers (perhaps for a nominal fee). For example, we could grant a 2-year patent for tobacco products. At the end of the 2-year period, the tobacco fund would compensate the patent holder for some multiple (e.g., 3) of profits from the patent over that period -- a proxy for the present value of the profits from the patent itself. The patent will then expire, and the knowledge could be distributed to other firms for free or for a nominal fee, ensuring relatively rapid dissemination. This structure would maintain incentives for future R&D, encourage patent holders to market their innovations aggressively during the patent period, and ensure dissemination after the end of the patent period.

5. *Eliminate cross-licensing requirements.* Eliminating the cross-licensing provisions would allow companies to profit from innovation as they would in any other industry, thus encouraging future R&D. Concerns about strategic withholding of innovations and the related lack of diffusion could be alleviated by the settlement's provision allowing the FDA to set performance standards. In that way, a minimum level of safety could be set for the entire industry and adjusted as major innovations occurred.

VI. Summary of key points and questions

- Innovation generally requires investment -- and full disclosure coupled with free adoption by other firms provides little or no incentive for such investment to be undertaken.

- Enforcing full and even free cross-licensing of extant R&D may not pose the same incentive problems as enforcing cross-licensing of future R&D. But the government's credibility may suffer, and it may be difficult to define "existing" R&D. ?

- To the extent that the FDA does not allow advertising of reduced risk products, firms will have little interest in developing such products. To counter the potential risk to public health from allowing advertising of "safer" cigarettes, one possibility -- which may not be technically feasible -- would be to allow firms to publish "health hazard ratings."

- The cross-licensing requirements embodied in the Settlement are near one extreme of possible patent systems. Modifications could include limiting cross-licensing to existing R&D, allowing a shorter-than-usual but non-zero patent period, or simply eliminating the cross-licensing requirements and relying on FDA regulations to encourage dissemination.

DRAFT

LICENSING

I. Introduction

ATF has extensive experience in licensing the alcohol, tobacco, and firearms industries for specified statutory purposes. ATF licenses approximately 3,800 distilled spirits plants, wineries, and breweries; 140 manufacturers of tobacco products and cigarette papers; 14,500 alcohol beverage wholesalers and importers; 200 tobacco export warehouse proprietors; and nearly 135,000 firearms and explosives licensees.

II. Issues to Consider in Evaluating the Licensing Provisions of the Proposed Agreement

A. A comprehensive regulatory scheme for retailers requires licensing at all levels of the distribution chain.

Any licensing scheme should be tailored to meet its specific goals. For example, ATF's licensing of tobacco manufacturers serves the primary purpose of collecting and protecting the revenue generated by a production tax collected from the manufacturer. To achieve this goal, there is no need to license wholesalers or retailers. In contrast, ATF licenses the entire distribution chain of the firearms industry because the primary purpose of the gun control laws is to prevent sales of guns to particular classes of persons, such as felons, and comprehensive record keeping on all transactions is essential to the national firearms tracing system.

The proposed settlement suggests that the primary goals of a licensing system are to facilitate FDA regulation with respect to access, advertising, and labeling. These goals require a comprehensive licensing scheme that will provide accountability for compliance with the licensing scheme. Record keeping requirements must be sufficient at each level to enable the licensing agency to trace the commodity from the manufacturer to the retailer. Without these controls, there is a "weak link" in the distribution chain that can result in the diversion of the commodity into the stream of unlicensed commerce or noncompliance with regulatory requirements.

However, the system proposed does not license all levels of the distribution chain. Manufacturers and wholesalers that do not sell to consumers would not require a license. Potential for diversion from points earlier in the distribution chain to illegal consumption or for noncompliance with regulatory requirements would be great, particularly when effective controls are imposed at the retail level.

B. The licensing scheme should have enforceable criteria for obtaining a license.

Setting criteria to limit the distribution system has the prophylactic effect of saving enforcement resources and helping ensure the integrity of the licensing and regulatory system. To avoid illicit trading, licenses should be given only to persons who actually intend to engage in the business the license authorizes. Keeping ineligible persons out of the business can also be achieved through licensing fees and inspections. Several years ago, when firearms licenses cost only $10 per year and there was almost no enforcement of the requirement that licensees actually engage in business, the number of licensees blossomed to over 260,000, making enforcement difficult. Raising the fee to $200 and strictly enforcing the licensing requirements has lead to a decrease of about 60% in the number of licensees over a four year period, greatly enhancing ATF's ability to enforce the gun control laws.

The proposed scheme makes compliance with the proposed legislation a condition of obtaining and holding that license. However, there is no mention of an investigative authority to determine whether an applicant is eligible for a license or, for that matter, to determine whether a licensee is maintaining compliance with the proposed legislation.

C. The licensing system needs an effective enforcement arm.

Because a licensing system produces an incentive to traffic unlawfully in the licensed commodity, a sophisticated enforcement arm is needed to investigate unlawful commerce outside the licensed distribution channels. An effective and fair enforcement arm raises the level of voluntary compliance through education of the licensees and deterrence; in contrast, uneven application leads to resentment and non-compliance on the part of licensees, and ultimately, to litigation.

Certain enforcement tools are necessary to effective licensing enforcement. Periodic inspections ensure that the licensees comply with the system. A sensible range of meaningful sanctions for non-compliance give the licensing agency the needed flexibility to deal with different types of violations. These sanctions can include suspension or revocation of the license, civil fines or penalties, or criminal penalties.

The penalty set out in the proposal for unlawful sale of tobacco products without a license is a misdemeanor. A criminal misdemeanor is not a great deterrent -- particularly if the illicit sale of tobacco products becomes highly profitable. Moreover, it is very difficult to obtain prosecution of a misdemeanor given scarce prosecutorial resources.

It is unclear whether the penalties and other sanctions imposed for the sale of tobacco products to underage persons are criminal or civil in nature. Moreover, it is not clear how to count violations for purposes of imposing these sanctions.

D. The proposal leaves unresolved critical funding and resource issues.

An agency charged with administering a licensing system must have adequate resources to process and investigate applications for licenses to ensure that ineligible persons do not improperly receive them. ATF's experience shows that time spent investigating applicants is repaid many fold by avoiding later enforcement actions. Significant resources must also be devoted to the education and inspection of licensees. Costs associated with data processing support are also significant. Costs of a licensing system are particularly high when enforcement is at the retail level, given the number of potential licensees involved, the frequency of turnover, and the diverse locations where business is conducted.

Resources needed for the proposed scheme will be very substantial. FDA estimates that there are on the order of 700,000 retail dealers in tobacco products in the United States. Given that ATF taxes 450,000 retail liquor dealers (stores, bars , restaurants, etc.), almost all of whom sell tobacco products, this may be an underestimate. Costs relating to the processing and investigation of applications alone will be extensive. Costs associated with investigating violations and taking action against violators could even be greater. For example, ATF regulates nearly 135,000 firearms and explosives licensees, using nearly 430 inspectors and roughly 50 people to process license applications. The cost of administering this licensing system is approximately $38 million per year. This estimate does not include the costs of establishing a new system from scratch, nor does it include litigation costs associated with defending challenges to system; actions to suspend or revoke licenses; or criminal investigations and prosecutions.

The proposal states that the enforcement of the licensing scheme would be funded through industry payments, and that licensing fees would cover the administrative costs of issuing State licenses.

However, the agreement does not appear to contemplate any audit authority to account for payments of monies used to enforce the system, nor does it specify whether the federal government or Indian tribes would recover the costs of non-enforcement aspects of licensing programs they administer..

E. The proposal will require cooperation between the federal government and the States.

In order to avoid confusion, misinformation and duplication of efforts, it is necessary to vest responsibility for licensing in one agency. However, cooperation and communication with other agencies is often essential to ensure the licensing agency has all relevant information. In particular, commodities licensed by the Federal government may also be regulated by State and local governments. Cooperation, information sharing and communication with those State and local agencies is essential in order to regulate a commodity effectively. This is particularly true when enforcement resources are stretched to the limit at both the Federal and State level. ATF has entered into approximately 40 memoranda of understanding with States calling for the exchange of information pertaining to alcohol and tobacco products.

III. Legal Issues

A. Tenth Amendment Concerns with the Imposition of Federal Standards on the States

According to the proposed agreement, Federal legislation would mandate "minimum Federal standards" for a retail licensing scheme. The agreement is ambiguous about how this would be done, but presumably the following are possibilities:

- The Federal government could be the licensor, exercising its power under the commerce clause;
- The Federal government could preempt the field, but allow the states to adopt and enforce their own regulations conforming to the Federal standard;
- The States could design their own licensing schemes with advisory Federal guidance; or
- The spending power could be used to give incentives to the States to comply with the Federal standard.

The language of the proposed tobacco settlement agreement appears to contemplate legislation under which the Federal government would set minimum standards for licensing laws that states would be required to adopt as state law and required to enforce through funding provided by the tobacco industry. In its recent decision striking down certain portions of the Brady act, the Supreme Court made clear that the Tenth Amendment bars the Federal government from requiring states to enact or enforce a Federal mandate. *Printz v. United States*, No. 95-1478, 1997 U.S. LEXIS 4044 (June 27, 1997). Thus, the licensing scheme cannot be implemented simply by the passage of a Federal law requiring states to adopt Federal prescribed licensing laws and to enforce them.

However, there are other constitutionally permissible models for Congress to encourage state participation in a Federal scheme. Congress can make compliance with Federal standards a precondition for continued state regulation in an otherwise preempted field. *Printz, supra.* at 27, *discussing Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U.S. 264 (1981) and *FERC v. Mississippi*, 456 U.S. 742 (1982); *see also New York v. United States*, 505 U.S. 144, 161-3 (1992). There is no question that under its Commerce Clause authority Congress could establish a nationwide Federal licensing system for tobacco products, to be administered by Federal agencies. Under *Hodel*, Congress could then allow states to adopt and enforce their own regulations if they

complied with Federal standards. If the agreement provides for industry payments to the Federal government for licensing, Congress could finance a Federal licensing system through such payments.

A somewhat more difficult question is whether Congress could through Federal legislation condition the receipt of payments from the tobacco industry to the states, or some portion of those payments, on the states' adoption of licensing laws that complied with Federal standards. Under the Spending Clause, Congress may condition the receipt of Federal funds on the States' undertaking certain action. *Printz, supra,* (O'Connor , J. concurring). In *South Dakota v. Dole*, 483 U.S. 203 (1987), the Supreme Court upheld, as a valid exercise of the Spending Power, a Federal law reducing the percentage of Federal highway funds received by States that failed to enact a law barring consumption of alcohol by persons under 21. Likewise, in *New York v. United States, supra.*, the Supreme Court upheld financial incentive provisions of a Federally mandated waste disposal law applying to the States but struck down provisions forcing the State to take title involuntarily to such wastes.

However, the Court has cautioned that if the Federal financial incentive is too powerful it may be deemed not to be a condition but to be impermissible coercion. *South Dakota v. Dole*, 483 U.S. at 211, *citing Stewart Machine Co. v. Davis*, 301 U.S. 548, 590 (1937). The Fourth Circuit, sitting en banc, recently struck down a funding condition imposed by the Department of Education on the receipt of funds under the Individuals with Disabilities Education Act (IDEA). *Comm. of Virginia Dept. of Education v. Riley*, 106 F. 3d 559 (4th Cir. 1997). While the majority held only that the statute did not clearly and expressly authorize the condition imposed, six judges joined an opinion holding that the threat of withdrawal of all IDEA funds if the state did not change its policy of refusing to provide tutors to disabled students expelled from school "begins to resemble impermissible coercion, if not forbidden regulation," in violation of the Tenth Amendment. *Id.* at 569-72. The six seemed moved not only by the size of the amount at issue but also by the area in which the Federal government had sought to influence the state's choice.

Some aspects of the proposed settlement might prove problematic to Federal regulation of state licensing under a Spending Clause approach. First, the industry payments may not be Federal funds subject to the Spending Power -- if, for example, the agreement itself provides for licensing-related payments from the tobacco companies to the states, or otherwise constrains the Federal government's use of the licensing funds. Second, the size of the payments involved may be quite large, so that even in the unlikely event that the states were willing to have industry payments for licensing made to the Federal government and doled out to the states under Federal law, the courts might find the legislation coercive. Finally, not all states are participating in this settlement, and the courts might be particularly skeptical of the legislation as applied to a non-signatory state.

B. Due Process Concerns with Suspension and Revocation

The licensing scheme also provides for a suspension of the retail license (after the first offense) and revocation (after the sixth or subsequent offense). Since a license is a property interest protected by the Fifth Amendment, Due Process requires that the licensees be afford an opportunity for a hearing before the license may be suspended or revoked. *See Bell v. Burson*, 402 U.S. 535 (1971). This applies to both state and Federal licensing procedures because the due process clause is made applicable to the states by the Fourteenth Amendment. Accordingly, the enabling legislation must establish a procedure (administrative and/or judicial) giving the licensee notice of the charges and an opportunity to be heard.

C. Licensing on Native American Lands

Using a framework adopted from the Clean Air Act (a *Hodel* - model scheme), the proposed agreement provides for licensing provisions governing sales on Native American lands and

commerce in tobacco products by members of Indian tribes. The proposed agreement provides that the federal government would decide for each tribe whether the licensing provisions would be set by the federal government, set by the state subject to federal standards, or set by the tribe subject to federal standards which incorporate state law. (*See* Appendix III.)

These provisions do not appear to raise additional Constitutional concerns. First, as discussed above, the *Hodel* model of federal-state interaction appears to have been reaffirmed in the Printz case. We are not aware of any constitutional concerns that would arise from the imposition of a federal licensing system or federal standards on Indian tribes, even if the federal standards incorporated state law. The state could also set the licensing requirements: it is well-established that State taxation and regulatory laws can apply to members of Indian tribes and can apply in Indian country. *See, e.g., New York State Department of Taxation v. Attea*, 114 S. Ct. 2028 (1994) (State can require Indian cigarette traders to register with state and tax cigarettes intended for off-reservation consumption). For example, State liquor licensing laws apply to Indians. *See id.*; *Rice v. Rehner*, 463 U.S. 713 (1983).

Also, the agreement states that federal taxes or fees (such as the tobacco excise tax) would apply to commerce in tobacco by members of Indian tribes or on tribal lands. Again, this does not seem to raise significant legal concerns. Federal statutes of general applicability apply with equal force to Indians unless the law touches on exclusive rights of self-governance in purely intramural matters, the application of the law would abrogate treaty rights, or Congress intended to exclude Indians. *U.S. v. Baker*, 63 F.3d 1478, 1484-1485 (9th Cir.) *cert. den.*, 116 S.Ct. 824 (1996). For example, the Contraband Cigarette Act applies to Indian tribes. *U.S. v. Gord*, 77 F.3d 1192 (9th Cir. 1996).

However, it might be difficult for a Federal agency or State to enforce a licensing scheme given current sovereignty issues or the volatile nature of investigations occurring on these lands.