The Synar Program: A Tobacco Control Success Story

Jennifer Wagner
Susan Marsiglia Gray, M.P.H
SAMHSA
Tobacco Use

*Tobacco addiction is the single most preventable cause of death in our society.*

Centers for Disease Control and Prevention
Addiction Rates
The younger a person starts smoking, the stronger the addiction.¹

Tobacco Use is a Pediatric Disease
80 percent of adult smokers who are nicotine dependent report that they started smoking before they were 18 years old.²

¹ CDC, 1994 Surgeon General’s Report—Preventing Tobacco Use Among Young People.
² 2009 National Survey on Drug Use and Health.
The History Behind the Synar Legislation

- The Synar legislation reflects former Oklahoma Congressman Michael Synar’s vision for reducing youth access to tobacco products.

- The Synar Amendment and its implementing Regulation require States to enact and enforce laws prohibiting the sale and distribution of tobacco products to individuals under the age of 18.
Implementing the Synar Amendment

To implement the Synar Amendment, SAMHSA issued the Synar Regulation in January 1996 requiring States to:

- Have in effect laws prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual younger than age 18.
- Enforce their laws.
- Conduct annual random, unannounced inspections in a way that provides a valid probability sample of outlets accessible to minors.
- Negotiate interim targets and a date to achieve a noncompliance rate of no more than 20 percent.
- Submit an Annual Synar Report detailing State activities to enforce their laws.
Penalty for Noncompliance

• States that do not comply with the Synar requirements are subject to a penalty of 40 percent of their Federal Substance Abuse Prevention and Treatment (SAPT) Block Grant funding.

• However, in practice, since 2000 Congress has provided an alternative penalty mechanism by which a State can avoid the 40-percent reduction in its SAPT Block Grant if the State stipulates that it will spend its own funds to improve compliance with the law.
Alternative Penalty—213/214/218/212 Provision

- Section 213/214/218/212 provision provides a penalty alternative for States not meeting the Synar target rate:
  - Commit new State funds for tobacco access compliance activities
  - Supplement and not supplant existing funds for tobacco prevention and compliance activities
  - Provide reports to the Secretary of DHHS on all State resources for prevention and compliance activities.
State Synar Program Compliance
The State must have a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing tobacco products to any individual under the age of 18.
Enforcement

The State must enforce youth tobacco access laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.
Random, Unannounced Inspections and Valid Probability Sample

The State must conduct random, unannounced inspections of youth-accessible tobacco outlets using a valid probability sample to assess tobacco retailer compliance with State law.
Retailer Violation Rate Compliance

The State’s retailer violation rate (RVR) must not be greater than 20 percent.
Reporting

- The State must submit an annual report detailing State activities (Annual Synar Report).
- The State’s report must be made available for public comment prior to submission.
Synar Is a Success

• In FFY 2010, all 50 States, the District of Columbia, and Puerto Rico met the 20-percent retailer violation target rate.

• Youth tobacco use prevalence rates have dropped, but are beginning to level off.

Synar is a critical component of the success of youth tobacco prevention efforts.
National Weighted Retailer Violation Rate

FFY 1997–FFY 2010

<table>
<thead>
<tr>
<th>Federal Fiscal Year</th>
<th>Violation Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>40.1</td>
</tr>
<tr>
<td>1998</td>
<td>25.4</td>
</tr>
<tr>
<td>1999</td>
<td>20.5</td>
</tr>
<tr>
<td>2000</td>
<td>20.0</td>
</tr>
<tr>
<td>2001</td>
<td>17.5</td>
</tr>
<tr>
<td>2002</td>
<td>16.3</td>
</tr>
<tr>
<td>2003</td>
<td>14.1</td>
</tr>
<tr>
<td>2004</td>
<td>12.8</td>
</tr>
<tr>
<td>2005</td>
<td>11.6</td>
</tr>
<tr>
<td>2006</td>
<td>10.8</td>
</tr>
<tr>
<td>2007</td>
<td>10.5</td>
</tr>
<tr>
<td>2008</td>
<td>9.9</td>
</tr>
<tr>
<td>2009</td>
<td>10.9</td>
</tr>
<tr>
<td>2010</td>
<td>9.3</td>
</tr>
</tbody>
</table>
Breakdown of States Achieving the 20-Percent Retailer Violation Rate (FFY 2010)

- 9 states with ≤5 retailer violation rate
- 25 states with 5.1-10 retailer violation rate
- 14 states with 10.1-15 retailer violation rate
- 3 states with 15.1-20 retailer violation rate
- 0 states with >20.1 retailer violation rate
Practices for Reducing Access Reported by Successful States

- Regular and statewide enforcement of merchant compliance with youth tobacco access laws

- Policy and regulatory approaches:
  - Enacting and enforcing tobacco license laws
  - Required merchant education
  - Attorney General Assurances of Voluntary Compliance
Practices for Reducing Access Reported by Successful States

• Merchant education, including nonenforcement compliance checks conducted by community members to warn noncompliant merchants about youth access laws and provide positive reinforcement to compliant merchants

• Community education and support through:
  o Media-led public education campaigns
  o Support for community-led prevention activities
## How FDA and the Synar Program Differ

<table>
<thead>
<tr>
<th>Synar Program</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory program tied to receipt of the Substance Abuse Prevention and Treatment Block Grant</td>
<td>Contract</td>
</tr>
<tr>
<td>Conduct annual, random, unannounced inspections using a valid probability sample</td>
<td>Conduct two types of inspections (advertising and labeling and undercover buys), frequency varies</td>
</tr>
<tr>
<td>Sets a performance target with an incentive to comply</td>
<td>Takes enforcement action against retailers found to be in violation</td>
</tr>
<tr>
<td>Applicable States, DC, 8 US Territories, Not Tribes</td>
<td>Contract with States, DC, 5 US Territories and Tribes to the extent feasible</td>
</tr>
<tr>
<td>Requires States to have laws prohibiting sale/distribution of tobacco products to individuals younger than 18</td>
<td>FDA laws and regulations</td>
</tr>
</tbody>
</table>
Using FDA Inspection Data for Synar Reporting

- Inspections must be completed at retailers randomly sampled using State’s CSAP-approved sampling methodology.
- Any work associated with analyzing and reporting Synar data may not be paid for using FDA contract funds.
- Need to collect additional data points required for Synar reporting:
  - Gender of youth inspector
  - Age of youth inspector
  - Reason for non-completion of sampled outlet (SSES disposition code)
Using FDA Inspection Data for Synar Reporting

- Must follow FDA inspection protocol
  - Consummated buy
- If this protocol differs from State’s CSAP-approved inspection protocol, work with CSAP State Project Officer to amend Synar inspection protocol
- Important Note: States still need to enforce State youth access laws in order to comply with the Synar regulation – enforcement of Federal youth access laws under the FDA contract does not meet this requirement
SAMHSA and FDA Coordination

- Monthly coordination meetings
- Data collection coordination
- FDA participation and presentations at 11th National Synar Workshop and planned for 12th National Synar Workshop
- SAMHSA/CSAP presentation at FDA 1st National Program Coordinator’s Conference
- Publication of “A Strategic Partnership: The FDA’s Tobacco Retail Compliance Inspection Contracts and SAMHSA’s Synar Program”
Does Enforcement of Youth Tobacco Access Laws Reduce Tobacco Sales to Youth and Youth Smoking?
Synar Noncompliance Rate and Perceived Availability of Cigarettes by 8th and 10th Graders, FYs 1997–2010

Source: Monitoring the Future, 2010
Synar Noncompliance Rate and 30-Day Cigarette Use by 8th, 10th, and 12th Graders, FYs 1997–2010

Source: Monitoring the Future, 2010
Does enforcement reduce tobacco sales to youth: What does the peer-reviewed literature say?

- Sales of cigarettes to youth can be reduced through active enforcement of youth access laws
Does enforcement reduce youth smoking: What does the peer-reviewed literature say?

- Small community studies have shown mixed results on effectiveness of enforcement on reducing youth smoking
Does enforcement reduce youth smoking: What does the peer-reviewed literature say?

• First national study of the impact of tobacco sales law enforcement on youth smoking was published in 2009 (DiFranza JR, Savageau JA, Fletcher KE. Enforcement of underage sales laws as a predictor of daily smoking among adolescents – a national study. BMC Public Health 2009; 9:107-113.)

  – Examined association between merchant compliance with youth access laws and current daily smoking while controlling for cigarette prices, state restaurant smoking policies, anti-tobacco media and demographic variables.

  – Higher average state merchant compliance with youth access laws from 1997-2003 predicted lower levels of current daily smoking among adolescents when controlled for all other factors.

  – Odds ratio for daily smoking was reduced by 2% for each 1% increase in merchant compliance.
Strong Enforcement Makes the Difference

• Which interventions against the sale of tobacco to minors can be expected to reduce smoking? (DiFranza JR. Tobacco Control (2011). Doi:10.1136/tobaccocontrol-2011-050145.)
  – Review of all studies that evaluated the impact on youth tobacco use of efforts to disrupt the sale of tobacco to youth
    • Little evidence that enacting a law without sufficient enforcement had any impact on youth tobacco use
    • No evidence that merchant education without enforcement had any impact on smoking among youth over the age of 12
    • No evidence that weak enforcement efforts that failed to reduce the sale of tobacco to minors had any impact on youth smoking
    • All enforcement programs that reduced the sale of tobacco to minors reduced smoking by youth and this effect was greater the more sales to youth were reduced (i.e. the lower the retailer violation rate)
• Active enforcement of youth tobacco access laws is an important component of a comprehensive youth tobacco prevention program and leads to reductions in youth smoking but should not be done in isolation.
Take Home Message

• Enforcement should be combined with other efforts to reduce youth access:
  – Community mobilization to reduce minors’ access
  – Stronger restrictions on retailer sales of tobacco products
  – Restrictions directed at youth purchase, possession or use
  – Retailer education

• All efforts to reduce youth tobacco access should be combined with other efforts to reduce youth tobacco use:
  – Increasing the price of tobacco products
  – Smoking bans
  – Mass media campaigns
Kentucky’s Progress

Your work is making a difference!
Kentucky Synar Noncompliance Rate and 30-Day Cigarette Use by High School Youth 1997-2012

Percentage

FFY

97' 98' 99' 00' 01' 02' 03' 04' 05' 06' 07' 08' 09' 10' 11' 12'

30- Day Use

Non-Compliance Rate
For More Information

- Synar Web Site
- Jennifer Wagner
  Jennifer.Wagner@samhsa.hhs.gov
- Susan Marsiglia Gray
  Susan.Marsiglia@samhsa.hhs.gov
  240-276-2568