

# BIDEN ADMINISTRATION PROPOSAL: REDUCTION OF NICOTINE CONTENT IN CIGARETTES

**Natalie R. Beylin, BS; Anna Song, PhD**

One of the preliminary proposed rules included in the Biden Administration's Spring 2022 Unified Agenda of Regulatory and Deregulatory Actions agenda is a "tobacco product standard that would establish a maximum nicotine level in cigarettes and certain finished tobacco products".<sup>1</sup>

## WHAT IS THE PURPOSE OF THIS RULE?

This initiative was proposed to reduce the amount of tobacco related deaths and illness.

- Over 480,000 people die in the United States per year from smoking-related disease, including 41,000 secondhand smoke deaths, and over 16 million Americans live with a smoking-related disease.<sup>2</sup>

## HOW WILL IT WORK?

Nicotine is the addictive chemical in cigarettes and is the driving force behind the difficulties of quitting smoking.<sup>3</sup>

- More than half of adult cigarette smokers report having tried to quit in 2020.<sup>4</sup>
- Fewer than 10% of adult cigarette smokers succeed in quitting each year.<sup>4</sup>
- In 2021, 65.3% of youth who currently used tobacco reported wanting to quit.<sup>5</sup>

Thus, limiting the amount of nicotine in these products can help a) addicted smokers quit and b) to prevent youth from initiating use and becoming regular smokers.<sup>6</sup>

- Majority of adults favor reducing nicotine levels in cigarettes, including 8/10 smokers.<sup>7</sup>
- Simulation models show that reduced nicotine content in cigarettes would lead to significant reduction in tobacco-related deaths.<sup>8</sup>
  - o Estimated prevention of 2.8 million tobacco-related deaths by 2060.<sup>8</sup>

## WOULD PEOPLE SMOKE MORE TO COMPENSATE FOR THE LOWER NICOTINE LEVELS?

- Results from clinical trials testing low-level reductions in nicotine to 0.4mg or less nicotine/g tobacco show participants smoking less cigarettes per day with less withdrawals and more motivation to quit.<sup>9-13</sup>
  - o Only moderate-level nicotine reductions, such as 5.2mg per gram of tobacco, have been reported to lead to compensatory smoking.<sup>11,12,14</sup>
  - o Suggests nicotine reductions should be low-level; not moderate.



### WHAT WILL BE THE MAXIMUM NICOTINE LEVEL IN CIGARETTES IF THIS PROPOSAL IS ENACTED?

- Although still undisclosed, FDA's Center for Tobacco Products has previously suggested a "sweet spot" range of 0.2- 0.7 mg nicotine per gram of tobacco cigarette to reduce amount of cigarettes smoked, addiction likelihood, dependence levels, and increased cessation rates without increased compensatory smoking, cravings, or withdrawals.<sup>15</sup>
- It is important that the maximum level set be not too high for several reasons:
  - Although varying amounts of reduced nicotine levels (2.4, 1.3, or 0.4mg) can contribute to decreased smoking frequency, quit attempts were much more likely to occur in individuals using the 0.4mg nicotine cigarettes.<sup>9</sup>
  - Some smokers still preferred the cigarettes with slightly higher levels of nicotine (2.4mg) per tobacco gram than the lowest level (0.4mg).<sup>16-18</sup>
  - Compensatory smoking only occurred in moderate level reductions.<sup>11,12,14</sup>
- Research suggests a 0.4mg per gram of tobacco level would be most efficient and effective.<sup>19</sup>

### WHAT ARE THE NEXT STEPS?

- FDA to issue the proposed rule by May 2023.<sup>20</sup>

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