

## II. TOBACCO MANUFACTURERS "INTEND" THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS.

The FDCA, FDA's regulations, and judicial decisions interpreting the Act and analogous provisions in other public welfare statutes all demonstrate that "intended to" and "intended for," as used in the Act, denote objective intent, as that term has become commonly understood by the courts. Objective intent may be determined by what a reasonable person would understand in the circumstances presented, or whether a "reasonable person would believe" that the defendant's conduct would lead to certain events. See, e.g., United States v. Articles of Banned Hazardous Substances . . . Baby Rattles, 614 F. Supp. 226, 231 (E.D.N.Y. 1985) ("[t]he only rational interpretation of the word 'intended' in the statute calls for an objective test of intent: whether a reasonable person would believe that the object is a toy"); W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 8, at 36 (5th ed. 1984) ("relying on circumstantial evidence, [one] may infer that the actor's state of mind was the same as a reasonable person's state of mind would have been").

The courts have also described objective intent in terms of foreseeability. For example, in United States v. Focht, the Third Circuit held that the intent requirement in the "intended to produce [banned] fireworks" language of the regulations implementing the Federal Hazardous Substance Act (FHSA) could be satisfied by a demonstration that it was "foreseeable" that the components sold by the defendant would be used to build banned products. 882 F.2d 55, 59-60 (3d Cir. 1989); see 15 U.S.C. § 1261(q). Similarly, in defining discriminatory intent in a voting rights case, the Fifth Circuit held that "[o]bjective intent . . . presumes that a person intends the natural and foreseeable consequences of his voluntary

actions." Lee v. Lee County Bd. of Ed., 639 F.2d 1243, 1267 (5th Cir. 1981).<sup>4</sup>

Subsection A, infra, demonstrates that an objective intent standard is the appropriate standard under the FDCA. The evidence in subsection B, infra, demonstrates that tobacco manufacturers "intend" cigarettes and smokeless tobacco products to affect the structure or any function of the body within the meaning of the FDCA.

#### A. OBJECTIVE INTENT IS THE APPROPRIATE STANDARD.

The FDCA is a consumer protection statute which has as its explicit purpose the "prohibit[ion of] the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics." Pub. L. No. 75-717, 75th Cong. 3d. Sess. (1938); see also H.R. Rep. No. 2139 at 1-2, reprinted in 6 Legislative History at 300-01 ("this act seeks to set up effective provisions against abuses of consumer welfare"; "the old law . . . contains serious loopholes [and] is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions"; the 1938 Act "amplifies and strengthens the provisions [of the 1906 act] designed to safeguard the public health and prevent deception, and it extends the scope of the old law to include . . . certain drugs that now escape regulation").

Given the Act's focus on consumer welfare and public health protection, interpreting

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<sup>4</sup> Subjective intent, on the other hand, considers the actual state of mind of the responsible actor. *See, e.g., Ellington v. Metropolitan Life Ins. Co.*, 696 F. Supp. 1237, 1242 (S.D. Ind. 1988) (a subjective intent test requires a determination that the defendant actually foresaw the result of his conduct and persisted nonetheless). This standard, which focuses on the actor's actual desires and knowledge, has been applied in certain areas of criminal law when the critical issue is the culpability of a particular actor. *See, e.g., Morissette v. United States*, 342 U.S. 246, 250-52 (1952). It is not used as a standard of proof for intent in public health and welfare statutes such as the FDCA.