



An Examination of Strict Criminal Liability Under the Food, Drug and Cosmetic Act of 1938: Is It Time For Change?

The Harvard community has made this article openly available. Please share how this access benefits you. Your story matters.

Citation	An Examination of Strict Criminal Liability Under the Food, Drug and Cosmetic Act of 1938: Is It Time For Change? (1999 Third Year Paper)
Accessed	February 19, 2015 9:33:21 AM EST
Citable Link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:8889485
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA

(Article begins on next page)

An Examination of Strict Criminal Liability Under the Food, Drug and Cosmo

Is It Time For Change?

Breena L. Holt October 18, 1999

Table of Contents

Part I:	Introduction	1
Part II:	Evolution of Strict Criminal Liability in the Food and	2
	Drug Industry	
Part III:	Case History	12
	A. The "Responsible Relation" Standard	12
	B. The "Foresight and Vigilance" Standard and the "Ob-	18
	jective Impossibility" Defense	
Part IV:	Defenses to Criminal Charges for Violations of the Act	29
Part V:	Pros and Cons of Strict Criminal Liability for Violations	32
	of the Act	
Part VI:	Criminal Prosecutions Under the Act	36
Part VII:	Is Strict Personal Criminal Liability Necessary to Achieve	38
	its Desired Goals?	
	A. Corporate Compliance Program Defense	42
	B. Civil Penalties Rather than Criminal Sanctions	47
	C. Negligence Standard	51
Part VIII:	Conclusion	59