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FDA in-vitro testing for abuse-deterrent opioids is **fatally flawed** and has resulted in the **misbranding** of opioid products.

Abuse-deterrent labeled OxyContin provides no meaningful abuse-deterrence to the primary known route of abuse, **oral consumption**.

“The vast majority of deaths associated with OC (original OxyContin) were related to oral consumption”

“…relative to original OxyContin, there is an increase in the ability of OxyContin to resist crushing, breaking, and dissolution using a variety of tools and solvents.”

- OxyContin Label

Table 4: Summary of Maximum Drug Liking (E_{max}) Data Following Intranasal Administration

VAS Scale (100 mm)*		OXYCONTIN (finely crushed)	Original OxyContin (finely crushed)	Oxycodone HCl (powdered)
Drug Liking	Mean (SE)	80.4 (3.9)	94.0 (2.7)	89.3 (3.1)
	Median (Range)	88 (36-100)	100 (51-100)	100 (50-100)
Take Drug Again	Mean (SE)	64.0 (7.1)	89.6 (3.9)	86.6 (4.4)
	Median (Range)	78 (0-100)	100 (20-100)	100 (0-100)

* Bipolar scales (0 = maximum negative response, 50 = neutral response, 100 = maximum positive response)

“Upon chewing vigorously, OFR [reformulated OxyContin] and OC products are bioequivalent with respect to oxycodone Cmax and AUC.”

- FDA Review

“The controlled-release properties of ORF (reformulated OxyContin) can be overcome with chewing and swallowing.”

- FDA Review

The FDA should **stop** using friability tablet testing to support abuse-deterrent properties, as it is **not representative** of breaking strength for abuse-deterrence.

“When subjected to an aqueous environment, OxyContin gradually forms a viscous hydrogel (i.e., a gelatinous mass) that resists passage through a needle.”

- OxyContin Label

“These features also render the product almost impossible to dissolve, syringe, and inject.”

- Dr. Rappaport, Division Director of DAAAP

“OCR gradually forms a viscous hydrogel (i.e. a gelatinous mass) that resists passage through a needle. The in vitro testing was sufficient to demonstrate that OCR (reformulated OxyContin) prevents oxycodone from being drawn into a syringe to any meaningful extent.”

- Dr. Throckmorton, Deputy Director for Regulatory Programs (CDER)

In an aqueous environment, OxyContin can be easily extracted to **high purity** and **high label claim** by an unskilled person **in minutes**, with a viscosity similar to water.

The extract can be drawn into a syringe and **prepared for injection**.

Using **alcohol**, OxyContin can be easily extracted to **high purity** and **high label claim** by an unskilled person.

The extract can be converted into a **crystalline form** for **distribution and sale**.

The FDA needs to explain their choice of 40% alcohol over other **common**, **inexpensive**, and **optimal** alcohol options which are **more effective solvents**.

Citizen Petition, Docket ID: **FDA-2016-P-0645**

“FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials.”

- FDA Response