

## McKinsey Documents – Simultaneous Work for Opioid Manufacturers and the U.S. Food and Drug Administration

### Summary and Sample Documents Explained:

McKinsey advised pharmaceutical companies while simultaneously working with the key federal agency that regulates them, the U.S. Food and Drug Administration (FDA). It did not disclose this conflict to the FDA, but it emphasized its access to regulators as it marketed its services to Purdue.

### Sample Documents:

**Document Title:** [Outcomes for OxyContin range from business-as-usual to withdrawal]

**OIDA ID:** <https://idl.ucsf.edu/opioids/docs/#id=hxhk0255>

**Date:** 2008-10

**Description:** This PowerPoint presentation advises Purdue on how to respond to the FDA's proposed Risk Evaluation and Mitigation Strategy (REMS) program for OxyContin. Options presented include acceding to the FDA's request, delaying the FDA through legal means, taking some high-dose versions of OxyContin off the market and working with other pharmaceutical companies to counter "strict treatment" by the FDA.

**Document Title:** [Email from McKinsey to Purdue about capabilities]

**OIDA ID:** <https://idl.ucsf.edu/opioids/docs/#id=jxhk0255>

**Date:** 2014-01

**Description:** This email to Purdue's CEO, [Mark Timney](#), from McKinsey Senior Partner [Rob Rosiello](#) emphasizes McKinsey's work with federal regulators, including the FDA. Rosiello claims that "McKinsey brings an unequalled capability based on who we know and what we know."

**Document Title:** [A transition memorandum: Setting the course for the US Department of Health and Human Services]

**OIDA ID:** <https://idl.ucsf.edu/opioids/docs/#id=snhk0255>

**Date:** 2018-01

**Description:** This memo was sent to the incoming Secretary of Health and Human Services (HHS), [Alex Azar](#). It highlights "strategic priorities" for HHS, including "tackling the opioid epidemic" and "ensuring the value of pharmaceuticals."

**Document Title:** Timeline FDA Activities Opioid Abuse.pdf

**OIDA ID:** <https://idl.ucsf.edu/opioids/docs/#id=qkyn0256>

**Date:** 2018-06

**Description:** This timeline charts the FDA's approvals and other efforts regarding the epidemic from 1987 to 2017. This is a copy of a document first published on the FDA's website.

**Document Title:** [Opioids: Transition team support document]

**OIDA ID:** <https://idl.ucsf.edu/opioids/docs/#id=mxhk0255>

**Date:** 2018-12

**Description:** After the November 2018 elections, McKinsey made presentations to various governors' transition teams about the SUPPORT Act, a new federal law authorizing billions in spending to ease the epidemic. This presentation to New Mexico officials focuses on funding available to states and shows how the Ohio governor's office coordinated its own efforts.

**Document Title:** [New Drugs Regulatory Program Modernization Technical Proposal]

**OIDA ID:** <https://idl.ucsf.edu/opioids/docs/#id=hmhk0255>

**Date:** 2019-03

**Description:** This document is a proposal of work to the FDA's Center for Drug Evaluation and Research, detailing how McKinsey would help the Center to "modernize" its processes, documentation and organizational structure.

### Additional Documents

- [ysgk0255](#)
- [sfxk0255](#)
- [ytgk0255](#)
- [stgk0255](#)
- [ztgk0255](#)
- [mfhk0255](#)
- [nfhk0255](#)
- [gghk0255](#)
- [qghk0255](#)
- [nhhk0255](#)
- [shhk0255](#)
- [thhk0255](#)
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