

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

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

Select Documents of Relevance

Document Title: [Purdue’s strategic options]

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 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, Alex Azar. It highlights “strategic priorities” for HHS, including “tackling the opioid epidemic” and “ensuring the value of pharmaceuticals.”

Document Title: Timeline of Selected FDA Activities & Significant Events Addressing Opioid Misuse & Abuse

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: RE: Tomorrow

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=kmhk0255>

Date: 2019-02

Description: This email to McKinsey partner Jeffrey Smith, from McKinsey associate Sarah Nam, reflects on the practice's work and impact on public health in light of recent news coverage. Nam is surprised by the lack of communication from leadership on this topic and seeks Smith's input while acknowledging "I know you lead work in combating the opioid crisis with public health institutions and regulators (on the complete other side)."

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.

OIDA Identification Numbers for Additional Relevant Documents

- ysgk0255
- sfxk0255
- ytgk0255
- stgk0255
- ztgk0255
- mfhk0255
- nfhk0255
- gghk0255
- qghk0255
- nhhk0255
- shhk0255
- thhk0255
- gxhk0255
- jxhk0255
- kxhk0255
- lxhk0255
- mxhk0255
- yxhk0255
- zxhk0255
- fjhk0255
- hjhk0255
- jjhk0255
- gmhk0255
- hmhk0255
- qnhk0255
- qthk0255
- mflm0256
- qlpm0256
- qkyn0256
- qsmn0255
- zjbw0256
- hgyw0257
- fhwg0257