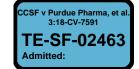


TE-SF-02463.00001



© 2016 Johns Hopkins University Press All rights reserved Published 2016 Printed in the United States of America on acid-free paper 987654321

Johns Hopkins University Press 2715 North Charles Street Baltimore, Maryland 21218-4363 www.press.jhu.edu

Library of Congress Cataloging-in-Publication Data

Names: Lembke, Anna, 1967-

Title: Drug dealer, MD: how doctors were sluped, patients got hooked, and why it's so hard to stop / Anna Lembke, MD.

Description: Baltimore : Johns Hopkins University Press, 2016. | Includes bibliographical references and index.

Identifiers: LCCN 2016010031 | ISBN 9781421421407 (pbk. : alk. paper) | ISBN 1421421402 (pbk.: alk. paper) | ISBN 9781421421414 (electronic) | ISBN 1421421410 (electronic)

Subjects: LCSH: Analgesics. | Medication abuse. | Physician and patient. | Drugs— Prescribing. | Drug addiction.

Classification: LCC RM319 .L46 2016 | DDC 615.7/83- -dc23 LC record available at http://lccn.luc.gov/2016010031

A catalog record for this book is available from the British Library.

Special discounts are available for bulk purchases of this book. For more information, please contact Special Sales at 410-516-6936 or specialsales@press.jhu.edu

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Big Pharma Joins Big Medicine

class and randomly, by drawing names from a hat, divide the students into two groups: half to play soccer and half to sit at the arts and crafts table and make hand puppets. At the end, you use some measure to assess whether kids are happier and better behaved when they play soccer or when they do art. That is a classic randomized study design.

Now suppose that instead of the above, you make all the kids play soccer every day at lunch for two weeks first, before randomizing them to different groups. Naturally, the kids who already like soccer or are more athletic or have higher energy will probably enjoy this. The kids who are naturally unathletic, low-energy, or disinclined to play sports will not like this. In fact, quite a few of them may simply refuse to participate and may even bring in notes from their parents asking that they be allowed to sit out during lunch. At the end of the two weeks, you might have only half the number of kids still playing soccer because the rest have dropped out of the study. All clinical studies have subjects who drop out, ending with many fewer subjects than when the study started.

With the kids left, most of whom enjoy soccer, you now randomly assign half to soccer, and half to arts and crafts. The kids who get randomized to soccer are happy. The ones who get randomized to arts and crafts are not so happy. They miss soccer and are now also fidgety and restless because their bodies had gotten used to getting exercise during lunch. Your study results unequivocally show that kids who play soccer are much happier and better behaved than kids who do arts and crafts, and every school in the district, as a result of your work, has mandatory soccer at lunchtime.

The FDA has made some limited innovations to target the prescription opioid epidemic, but for every step forward, they've taken two back. In 2014, the FDA reclassified Vicodin, among the most misused pain-killers in the 1990s and early 2000s, to schedule II, making it harder for doctors to prescribe it and hence for patients to get it. ¹⁰⁷ But nearly simultaneously, in 2013, the FDA approved Zohydro, a long-acting version of Vicodin that is likely to be as addictive as or more addictive than

Vicodin. The FDA is meanwhile keeping drugs like Opana on the market. Opana was approved in 2011 as an "abuse-deterrent" opioid painkiller, but since then has proven to be highly addictive when injected. It was recently tied to a 2015 outbreak of HIV in rural Indiana, as well as a surge in hepatitis C infections in Kentucky, Tennessee, West Virginia, and Virginia.

The Engine and the Caboose

In 2007 three of Purdue's top executives pleaded guilty to "misbranding" OxyContin as less addictive than it is, and Purdue paid \$634 million in fines, the eleventh largest fine paid by a pharmaccutical firm in the history of the US Department of Justice. Of the fines paid by Purdue in 2007, about \$160 million went to reimburse the federal government and some states for damages suffered by Medicaid programs, the government health insurer for the poor.¹⁰³

Kentucky, one of the states especially hard hit by the prescription opioid epidemic, refused its reimbursement of \$500,000, the only state to do so, deciding instead to file its own class action lawsuit against Purdue. Similar class action suits have been filed by Illinois and California. When Kentucky's suit against Purdue goes to trial, it will be an unprecedented event. Purdue Pharma has never gone to trial for Oxy-Contin and has succeeded in dismissing more than four hundred personal injury lawsuits related to the use of OxyContin. If Kentucky wins, Purdue is facing an extraordinary fine, comparable to the class action suits that cost Big Tobacco billions in the 1990s. Unfortunately, it's too little too late for the 175,000 people who have died from prescription opioid overdose between 1999 and 2013, not to mention the lives lost before and after.

Manufacturers of opioid painkillers have contributed to the opioid epidemic that has ravaged the United States, but blame cannot be placed on Big Pharma alone. Blame lies with doctors as well, especially those in academia and other positions of leadership who ignored the