

Researcher says pharma industry's ability to deliver new drugs may be coming to an end

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Credit: Washington University in St. Louis

From reading and hearing news accounts, the general public has a vague impression that some things are amiss with the pharmaceutical industry—one word: Epipens. But few might consider it an industry in a

state of collapse.

Michael Kinch tries to convince otherwise in "Prescription for Change," his history and review of the industry. Kinch is the associate vice chancellor and director of the Center for Research Innovation in Biotechnology at Washington University in St. Louis, and he brings to this book (University of North Carolina Press) many decades of research and harrowing personal experience with pharma.

The book starts with some classic tales of the struggle to make sure drugs weren't poisons and actually did what they were said to do. One early antibiotic, for example, was mixed in a sweet syrup whose main ingredient was antifreeze: 106 died, mostly children.

The pace quickens as the struggle between innovation and regulation becomes fiercer. The industry spins off, Kinch notes, into new territories, such as patent extensions, me-too drugs, generics, pay-for-delay, orphan drugs and compendium expansion.

Companies found ways to game the system by gaining FDA approval for an orphan [drug](#) under favorable terms and then conducting a small clinical trial that would allow the drug to be approved for another indication, called "compendium expansion." This was lucrative, Kinch explains, because [orphan drugs](#) could command high "price points" without insurance companies squealing, but the expansion drugs made up for the small number of patients with orphan indications.

Kinch repeatedly emphasizes that decisions like these are rational and not based on "dark motivations." And the point of the book is really that the high cost of bringing a new drug to market (\$2.6 billion) is largely the unintended consequence of the desire to make sure drugs are safe.

By chapter 10, the author is describing how such high costs led

[pharmaceutical companies](#) to cut costs, dismantled their own research and development wings but were forced to replenish their drug pipelines by buying one another and then biotechnology start-ups.

Altogether, Kinch says, the biotechnology sector was responsible for more than two-thirds of all new medicines in the past decade.

But Kinch says this finesse is already failing. The number of successful biotech companies peaked at 141 in 2000 and had fallen to 60 by the end of 2014. It is simply easier and less risky for venture capitalists to invest in two guys in a garage writing code, says Kinch, than in a large, complex biotech lab. As a result, the entire industry, Kinch says, may be "fading to black."

To make sure the reader understands the stakes, Kinch mentions three looming crises in drug therapy. One is antibiotic resistance, which, some experts say, will break the surface and come to widespread public notice in 2017.

A similar problem, but one that has received less attention, is the emergence of resistance to AIDS drugs. One in five AIDS patients had a virus that was resistant to at least one component of the current drug cocktail, Kinch says. Seven of the 10 companies that successfully developed AIDS drugs have dropped research in this area.

And then there is Alzheimer's. Fully 99.6 percent of experimental drugs designed to treat Alzheimer's failed in clinical trials, according to a 2015 report that Kinch cites. Many pharmaceutical companies, not surprisingly, have reduced or completely eliminated programs that had been focused on Alzheimer's disease and other neuroscience indications.

What can be done? To survive the current crisis, Kinch says, "we will need to fundamentally reconsider all aspects of how [new medicines](#) are

created." To get the ball rolling, he ends his book with a few ideas. For example, he suggests the potential elimination of the requirement for costly Phase III clinical trials.

To those familiar with the history of drug toxicities and side effects, that may seem like an outrageous proposition. But Kinch would argue that it is better than running off the cliff that seems to be in front of us—hence, the reference to the expression already used in some places around the industry "The Valley of Death."

Provided by Washington University in St. Louis

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