Consent Decree, Why, How, and What to Do?

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Overview

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What’s a Consent Decree?
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• A Consent Decree is a legal agreement between a company and a US regulatory agency that is enforced by the US Department of Justice after court approval.

• In exchange for agreeing to the terms of the Consent Decree, a company is generally allowed to continue manufacturing and selling products, but under heightened regulatory scrutiny and with significant limitations on how and when product can be released to customers.

• A Consent Decree is often a result of one or more inspections or investigations by the regulatory agency.
A Company Under Consent Decree
A Company Under Consent Decree

• In some cases production is halted completely at the impacted sites until the remediation efforts are concluded.

• The FDA normally requires a third-party oversight at the manufacturer’s expense, and they may increase the frequency and duration of their inspections.

• In certain circumstances, civil and criminal legal actions are being directed, not just at corporations, but also at individuals for non-compliance with the law and regulations.
The Impact of a Consent Decree
The Impact of a Consent Decree

• Financially

• The organization’s cultural foundation and its customers’ and patients’ health and welfare for years to come

• Employee morale can be impacted by a hostile environment and people may start leaving

• Dozens of contractors and/or new employees may join the organization and roles and responsibilities will rapidly change
Causes of a Consent Decree

Practical Examples
Abbott

• Start Date: 1999
End Date: still pending

• Cited for nonconformance with quality system regulations for \textit{in vitro} diagnostic products at an Illinois facility

• An initial \textit{$100$-million} fine was followed by a \textit{$112$ million} penalty after the company failed a follow-up inspection
Actavis

Start Date: 2008
End Date: still pending

- GMP violations in all of the products made at the three New Jersey facilities. The FDA blocked all production at the plants. Required to retain a 3-rd party expert to ensure GMP compliance

- Management team at its Little Falls plant was replaced (Oxycodone products)

- Oxycodone production resumed in 2009

Financial penalties: none
Nonconformance issues at a Georgia facility prompted this consent decree, which is comparatively mild given its three-year timeframe and lack of financial penalty.

Issues included inadequate equipment maintenance and lack of testing and final validation.
Eli Lilley

Start Date: 1989
End Date: Still pending

Financial penalties: none

• GMP violations at a facility in Puerto Rico. A reorganization yielded groups within the company designed to prevent conflict of interest

• Although no financial penalty was assessed, Eli Lilly suffered the delayed approval of two drugs when inspectors found GMP issues during a pre-approval inspection in 2001

• The company and FDA agreed on fixes in 2002, but subsequent violations have left the matter unresolved
• Started with manufacturing quality problems

• GMP violations discovered during a fall 2008 inspection led to a Warning Letter in February 2009

• Real trouble started when a virus contaminated a bioreactor, leading to a plant shutdown for decontamination. The shutdown seemed to roll into a consent decree remediation effort, which ultimately involved an operations restructuring

• Genzyme can trace its current takeover bullying by Sanofi to the consent decree issued this past May. Sanofi’s offer is pinned to the company's post-consent-decree valuation, rather than the higher pre-decree valuation that Genzyme prefers

• A subsequent shortage of one of the drugs led the FDA to ask a Genzyme competitor to offer its experimental treatment under an expanded access program
GSK

Start Date: 2005  Financial penalties: $650 million bond
End Date: still pending

• GSK's failed to meet quality standards for the diabetes medication Avandia and the antidepressant Paxil that it manufactured in Cidra, Puerto Rico

• The regulator began investigating the plant in 2002, and U.S. Marshalls raided it in 2005 seizing inventory

• GSK ultimately closed the plant in 2009
The scope and fines give this decree legendary status, and it embodied in 2002 an aggressive FDA posture that's similar to its posture today around executive prosecutions.

"The agency has allowed itself to get into this situation of issuing Warning Letter after Warning Letter to the same company, without taking any action," said Eric Blumberg, the FDA's deputy chief counsel for litigation, in May 2002 when he signed the consent decree. He also said, "It's clear we're not getting the job done with large, monetary settlements. Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress."

The consent decree affected four manufacturing sites and 125 products, about 90% of the drugmaker's offerings. Production was suspended for 73 of them.

In addition to the financial penalties levied, the FDA withheld approval of the company's allergy medication Clarinex. Company shares fell 15 percent in a day, and investors filed a $165-million class action suit.
Warner Lambert

Start Date: 1993
End Date: 2005

- Warner Lambert pleaded guilty to charges of intent to defraud and mislead the government
- Decrees often spare the company from any admission of wrongdoing
- Conditions included 3rd-party certification of manufacturing process compliance with GMPs
- Certification by consultants also was required for facility laboratories, and lab workers were retrained

Financial penalties: $10 million
Warning Letters 2013

• Wockhardt Limited regulations for finished pharmaceuticals 11/25/13
• Agila Specialties Private Limited 9/9/13
• Sentiss Pharma Pvt. Ltd. (Formerly Promed Exports Private Limited) 8/9/13
• Aarti Drugs Limited 7/30/13
• Contract Pharmaceutical Services of Australia Pty Ltd 5/17/13
• Boehringer Ingelheim Pharma GMBH & Co manufacture of APIs and the CGMP regulations for finished pharmaceuticals 5/6/13
• Kanebo Cosmetics, Inc. 4/1/13
• Wyeth Lederle S.p.A. 3/27/13
• Apotex, Inc. 2/21/13
How to Operate under a Consent Decree?
How to Operate under a Consent Decree? (1)

- Accept that the company will be asked to contract with an expert 3\textsuperscript{rd}-party. They will be your biggest ally or your worst nightmare, based on your selection.

- Just because the consulting firm is large and promises you the world, does not mean that they can deliver.

- Select people with “executive experience” as well as hands-on compliance experience – in Operations, in the QC Lab, in the Warehouse, etc. You will need both, especially the executive level.
How to Operate Under a Consent Decree? (2)

• Senior management has to accept that things will not be better for a long, long time. There are no easy ways out; no amount of “experience” will prepare you for the wrath of putting the FDA into a position to seeking a Consent Decree

• As the company CEO, you should limit the inner circle to the experts who can make decisions and follow through on the actions needed
How to Operate Under a Consent Decree? (3)

• Open communication with the employees. Your co-workers will be worried— and rightly so. If there will be a reduction in force, determine who and when – do this action quickly

• Also pay a good attention to the communications with clients and other market players
How to Operate Under a Consent Decree? (4)

- Expect to find more issues; many more issues that have to be resolved. Your company has done a lot to get into a Consent Decree.

- The Project Manager(s) and Team(s) are very critical for success. Hire experienced Project Managers (executive levels).

- Prepare for significant disruption in your production schedule (prepare your customers too).
• Prepare the company for serious training. The executive team should know the everyday procedural training or annual GMP training.

• This training is for everyone; not just the operators or QC/QA. The executives should be “very” involved in the training.

• Determine the kind of data (critical progress parameters) that you should see on weekly basis to monitor progress, real progress. Get feedback.
How to Operate Under a Consent Decree? (6)

- Some of these meetings are long and boring; the executive team have to demonstrate strong by-in and support.

- Your visit and communication with the FDA is very important. Be well prepared.

- Establish standard meeting times with your district to review your progress. Be open, honest, and forthcoming.
How to Avoid a Consent Decree?
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• Compliance culture and practices
• Embrace Quality by Design
• Continue to improve quality systems
• Adopte forward looking compliance metrics (KPI) and emphasize a culture that respects and builds quality into everyday business operations
Conclusions
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• If you work in a mid/large size Pharma company, there is a good chance your company will receive a Warning Letter and even might fall into a Consent Decree.

• Addressing the “causes” proactively vs. dealing with them after a regulatory action, can protect a company from the negative financial, cultural, and social impacts.