

## Exhibit 3 The Food and Drug Administration (FDA) Chart of Clinical Trials

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#### Initial Legislation

The foundation of the modern clinical trial process was enacted in 1938 with the Federal Food, Drug, and Cosmetic Act. This act required that drugs be proven safe prior to marketing. The manufacturers of drugs had to provide scientific proof of safety by submitting an Investigational New Drug (IND) filing prior to human trials, and a New Drug Application (NDA) before marketing new drug products.

#### Pre-clinical Trials

The IND must provide pre-clinical data of sufficient quality to justify the testing of the drug in humans. The drug approval process starts in the laboratory with pre-clinical trials. Studies using the compound in cell cultures, isolated tissues, and laboratory animals are conducted. This gives researchers a pretty good idea of what to expect in human trials. On average, only one compound in a thousand will actually make it to human testing. When the company receives FDA approval, the company moves the drug on to Phase I testing in human subjects. At this point, the compound has a one-in-five chance of eventually reaching the market.

#### Phase I Trials

The human subjects in the study are normally healthy volunteers. The sample is normally not more than 100 patients. The basic goal of Phase I is to determine how the drug is absorbed, distributed in the body, metabolized, and excreted. If the company moves on to begin Phase II trials, the drug's chance of eventually making it to market improves to just under 30%.

#### Phase II Trials

Phase II trials consist of small, well-controlled experiments that continue to evaluate the drug's safety and assess side effects. The drugs are given to volunteers (usually between 100 and 300 patients) who actually suffer from the disease or condition being targeted by the drug. Statistical end points are established for the drug that represent the targeted favorable outcome of the study. The current standard of cure for the medical condition can be used as a benchmark in setting the end point. A drug that moves on to begin Phase III testing has about a 60% chance of being approved by the FDA.

#### Phase III Trials

Phase III is intended to verify the effectiveness of the drug against the condition it targets. The study also continues to build the safety profile of the drug and record possible side effects and adverse reactions resulting from long term use. Phase III studies are tightly controlled, double-blind studies with a sample size of at least 1,000 patients. Normally two pivotal trials are required to ensure the validity of the studies. Assuming the drug reaches the desirable end point in Phase III trials the company will then file a New Drug Application. At this point the drug has better than a 70% chance of being approved by the FDA. Approval of the NDA averages 18-24 months. Upon approval, the company may begin to market and distribute the drug.

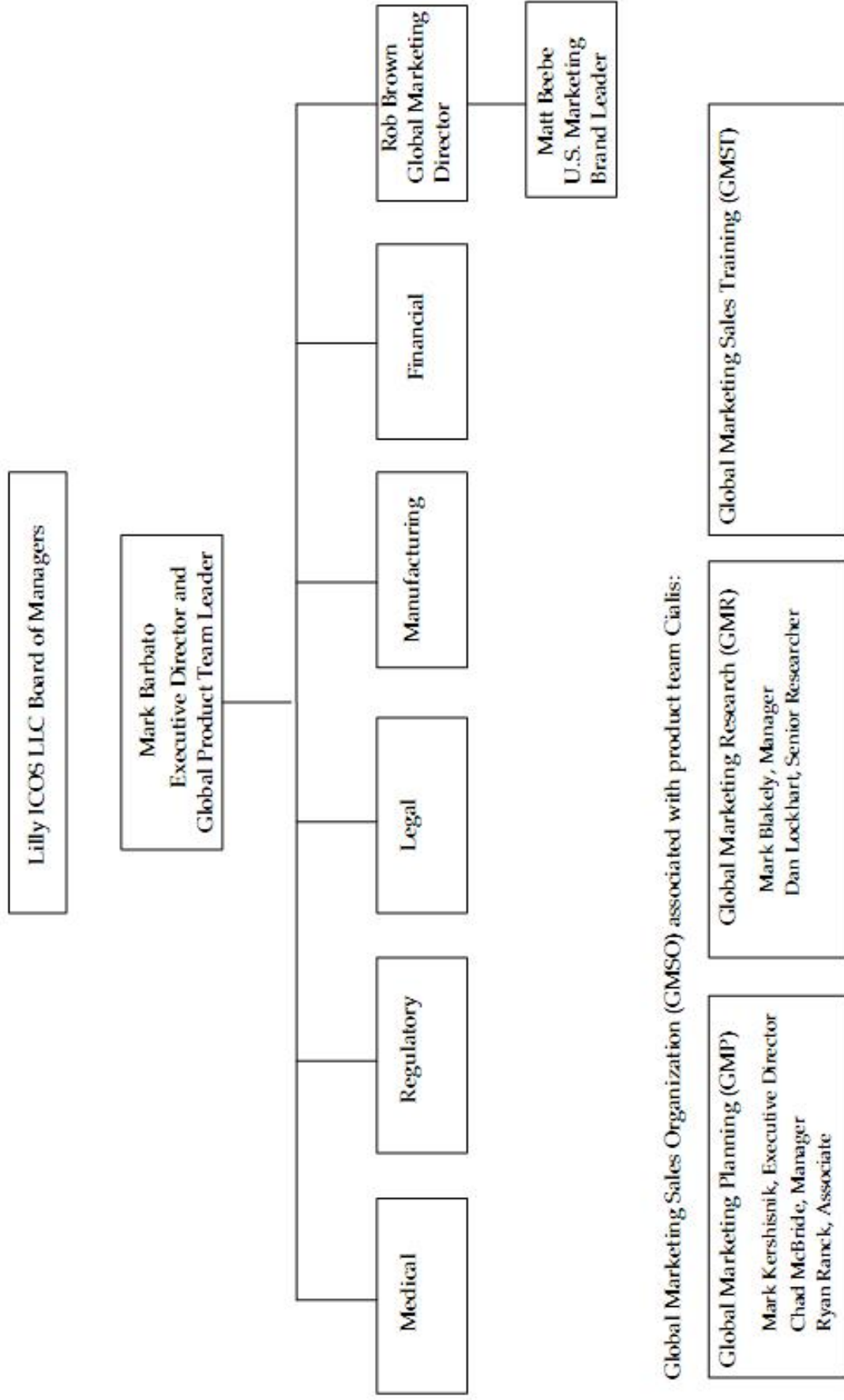
#### Cost of Clinical Trials

Estimates regarding the cost of pushing a drug through clinical trials range from \$350 million to \$500 million.

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Source: Adapted from "Clinical Trials" published by U.S. Food and Drug Administration.

**Exhibit 4** Organizational Chart—Product Team Cialis<sup>a</sup>



Global Marketing Sales Organization (GMSO) associated with product team Cialis:

**Global Marketing Planning (GMP)**  
 Mark Kershnik, Executive Director  
 Chad McBride, Manager  
 Ryan Ranck, Associate

**Global Marketing Research (GMR)**  
 Mark Blakely, Manager  
 Dan Lockhart, Senior Researcher

**Global Marketing Sales Training (GMST)**

Source: Lilly ICOS.

<sup>a</sup>Product team comprises both Lilly and ICOS members. The Lilly ICOS LLC Board of Managers oversees the activities of the product team (the eight-member board also includes Barbato, Clark, and Blum).