CONFIDENTIAL LEGAL MEMORANDUM ATTORNEY WORK PRODUCT - PRIVILEGED

TO: Litigation Team FROM: Senior Partner, Securities Fraud Division RE: BioGenesis Pharmaceutical Corp. - Executive Replacement Pattern Analysis DATE: December 15, 2024 CASE NO: 2024-SEC-9845

== EXECUTIVE SUMMARY ==

This memorandum analyzes the pattern of executive departures and replacements at BioGenesis Pharmaceutical Corporation between January 2020 and November 2024. Our investigation reveals a systematic replacement of qualified executives with individuals lacking requisite credentials, coinciding with regulatory scrutiny of the company's clinical trial data integrity.

TIMELINE PERIOD: January 1, 2020 - November 30, 2024 (4 years, 11 months) COMPANY: BioGenesis Pharmaceutical Corporation REGULATORY MATTER: SEC Investigation into Securities Fraud, FDA Warning Letters TOTAL EXECUTIVES ANALYZED: 12 individuals SUSPICIOUS APPOINTMENTS: 6 individuals

== PART I: ORIGINAL QUALIFIED EXECUTIVE TEAM (2020-2021) ==

1. DR. SARAH MITCHELL, MD, PhD - CHIEF EXECUTIVE OFFICER Employment Period: January 1, 2020 - March 15, 2021

Background: Dr. Mitchell brought 25 years of pharmaceutical industry experience to BioGenesis. She held an MD from Johns Hopkins School of Medicine and a PhD in Molecular Biology from MIT. Prior to joining BioGenesis, she served as Senior Vice President of Drug Development at Merck for 12 years, where she led 15 successful FDA drug approvals. Her expertise in oncology drug development was internationally recognized.

Departure Circumstances: Dr. Mitchell resigned on March 15, 2021, citing "irreconcilable differences with the Board regarding data integrity standards." Internal emails obtained during discovery show she raised concerns about rushed clinical trial timelines and inadequate safety monitoring protocols.

2. ROBERT CHEN, CPA, MBA - CHIEF FINANCIAL OFFICER Employment Period: January 1, 2020 - April 1, 2021

Background: Chen was a Certified Public Accountant with 18 years of experience in pharmaceutical finance. He held an MBA from Wharton School of Business and previously served as CFO of two mid-sized biotech companies. He was known for implementing rigorous financial controls and transparent reporting practices.

Departure Circumstances: Chen was terminated on April 1, 2021, three weeks after Dr. Mitchell's resignation. His termination letter cited "failure to align with company growth objectives," but internal

documents reveal he questioned accounting practices related to clinical trial cost capitalization.

3. ELIZABETH HARRISON, JD - GENERAL COUNSEL Employment Period: January 1, 2020 - May 10, 2021

Background: Harrison was a licensed attorney with 20 years of experience in healthcare regulatory law. She graduated from Yale Law School and previously worked at the FDA's Office of Chief Counsel for 8 years before entering private practice. Her expertise included FDA regulatory compliance, securities law, and corporate governance.

Departure Circumstances: Harrison resigned on May 10, 2021, stating she could not "ethically continue in her role given the Board's directives." Discovery documents show she drafted multiple memos warning about potential FDA violations that were ignored.

4. DR. JAMES RODRIGUEZ, PhD - CHIEF SCIENTIFIC OFFICER Employment Period: January 1, 2020 - February 28, 2022

Background: Dr. Rodriguez held a PhD in Biochemistry from Stanford University and had 22 years of drug discovery experience. He published over 100 peer-reviewed papers and held 15 patents in cancer therapeutics. He previously led research divisions at Genentech and Bristol Myers Squibb.

Departure Circumstances: Dr. Rodriguez continued longer than other original executives but ultimately resigned on February 28, 2022, after his research team was disbanded and replaced with contractors.

5. PATRICIA WONG, PharmD - VICE PRESIDENT OF REGULATORY AFFAIRS Employment Period: January 1, 2020 - June 15, 2021

Background: Wong held a Doctor of Pharmacy degree from UCSF and had 15 years of regulatory affairs experience. She previously worked at the FDA as a Drug Safety Officer for 6 years and had successfully managed 8 New Drug Applications (NDAs) at previous companies.

Departure Circumstances: Wong was terminated on June 15, 2021, allegedly for "failure to meet submission deadlines." However, internal emails show she repeatedly requested additional time to ensure regulatory filing accuracy.

6. DANIEL THOMPSON, MBA - VICE PRESIDENT OF CLINICAL OPERATIONS Employment Period: January 1, 2020 - July 20, 2021

Background: Thompson held an MBA from Northwestern's Kellogg School and had 14 years of clinical trial management experience. He previously managed Phase III trials at Pfizer and had a track record of ensuring patient safety and data integrity.

Departure Circumstances: Thompson resigned on July 20, 2021, citing "ethical concerns about patient safety protocols" in his resignation letter.

==========
== PART II: REPLACEMENT EXECUTIVES (2021-2023) - QUALIFICATION CONCERNS ========
==========

SUSPICIOUS PATTERN IDENTIFIED: Between March 2021 and September 2023, six executives were replaced with individuals lacking standard industry qualifications. This pattern coincided with increased regulatory scrutiny.

1. KEVIN MORRISON - CHIEF EXECUTIVE OFFICER (REPLACEMENT) Employment Period: April 1, 2021 - November 30, 2024

Background Analysis - RED FLAG: Morrison has NO pharmaceutical industry experience. His background is entirely in real estate development. He holds a Bachelor's degree in Business Administration from a regional state university and spent 15 years as a commercial real estate developer. His LinkedIn profile shows NO healthcare-related roles, training, or certifications.

Relationship Concerns: Morrison is the brother-in-law of Board Chairman Thomas Blackwell. Internal emails show Blackwell personally recruited Morrison, stating "we need someone who won't question our growth strategy."

Post-Appointment Actions: Under Morrison's leadership, clinical trial safety monitoring was reduced by 40%, and data integrity audits were eliminated. He fired three compliance officers who raised safety concerns.

2. ANGELA MARTINEZ - CHIEF FINANCIAL OFFICER (REPLACEMENT) Employment Period: May 1, 2021 - November 30, 2024

Background Analysis - RED FLAG: Martinez holds a CPA license that was SUSPENDED in 2019 by the California Board of Accountancy for "failure to maintain professional competence and ethical standards." Prior to suspension, she worked at a small accounting firm handling individual tax returns. She has ZERO corporate finance experience and NO pharmaceutical industry background.

Qualification Issues: Martinez failed the CPA ethics examination twice and was cited for improper client fund handling. Her license remains suspended, yet she is serving as CFO of a publicly-traded pharmaceutical company.

Post-Appointment Actions: Multiple financial restatements occurred under her tenure. SEC investigation documents show questionable revenue recognition practices and clinical trial cost capitalization that inflated earnings.

3. BRIAN FOSTER, JD - GENERAL COUNSEL (REPLACEMENT) Employment Period: June 1, 2021 - November 30, 2024

Background Analysis - RED FLAG: Foster obtained his law degree from an unaccredited ONLINE law school (California Coastal School of Law, which lost ABA accreditation in 2021). He took the California Bar Exam 4 times before passing on his fifth attempt in 2018. His prior legal experience consists of 2 years doing residential real estate closings.

Competency Concerns: Foster has NO securities law experience, NO regulatory law training, and NO pharmaceutical industry knowledge. He has never handled FDA matters, SEC compliance, or corporate governance issues.

Post-Appointment Actions: Multiple FDA warning letters went unanswered. Securities law disclosures contained material omissions. He advised the Board to ignore whistleblower complaints.

4. MARK STEVENS - CHIEF SCIENTIFIC OFFICER (REPLACEMENT) Employment Period: March 15, 2022 - November 30, 2024

Background Analysis - RED FLAG: Stevens holds a "PhD" from a diploma mill (Pacific Western University, shut down by California authorities in 2006 for selling degrees). His actual educational background is a Bachelor's degree in General Studies. He worked as a pharmaceutical SALES REPRESENTATIVE for 8 years - NOT a scientist.

Credential Fraud: Stevens' resume lists publications in peer-reviewed journals that DO NOT EXIST. His claimed patents cannot be found in USPTO records. Background verification revealed his entire scientific credentials are fabricated.

Post-Appointment Actions: Clinical trial protocols were significantly weakened. Safety endpoints were removed from study designs. Multiple research staff resigned citing "dangerous practices."

5. RACHEL GREEN, PharmD - VP REGULATORY AFFAIRS (REPLACEMENT) Employment Period: July 1, 2021 - November 30, 2024

Background Analysis - RED FLAG: While Green does hold a legitimate PharmD degree, she was hired directly out of pharmacy school with ZERO regulatory affairs experience. Her only work experience is 1 year as a retail pharmacist at CVS. She has never worked at FDA, never submitted regulatory applications, and has no understanding of drug development regulations.

Relationship Concerns: Green is the daughter of Board member Margaret Green. Internal emails show she was hired at her mother's insistence despite recruiters recommending candidates with 10+ years regulatory experience.

Post-Appointment Actions: Multiple FDA submissions were rejected for incompleteness. Warning letters were received for failure to report adverse events. She approved marketing materials that violated FDA promotional guidelines.

6. TYLER JENKINS - VP CLINICAL OPERATIONS (REPLACEMENT) Employment Period: August 1, 2021 - November 30, 2024

Background Analysis - RED FLAG: Jenkins' background is as a FITNESS CENTER MANAGER and PERSONAL TRAINER. He has ZERO healthcare experience, NO clinical research training, and NO medical or scientific education beyond a high school diploma. His resume lists "10 years managing health and wellness programs" at various gyms.

Incompetence Evidence: Jenkins does not understand basic clinical trial terminology, FDA Good Clinical Practice (GCP) guidelines, or patient safety protocols. Multiple deposition transcripts show he cannot explain clinical trial phases, informed consent requirements, or adverse event reporting obligations.

Post-Appointment Actions: Patient safety monitoring was outsourced to unqualified contractors. Clinical trial data showed anomalies consistent with fabrication. Three trial sites were shut down by FDA for protocol violations.

==========
== PART III: CONTINUING QUALIFIED EXECUTIVES (Remained Throughout Period) ==========
==========

7. DR. LINDA FOSTER, PhD - SENIOR VICE PRESIDENT OF RESEARCH Employment Period: January 1, 2020 - November 30, 2024

Background: Dr. Foster holds a PhD in Pharmacology from Columbia University and has 20 years of drug discovery experience. She survived the purge of qualified executives, likely because her department was not directly involved in clinical trial oversight where most fraud occurred.

8. MICHAEL CHANG, MBA - VICE PRESIDENT OF OPERATIONS Employment Period: January 1, 2020 - November 30, 2024

Background: Chang holds an MBA from Duke University and has 16 years of pharmaceutical manufacturing operations experience. His role focused on manufacturing and supply chain, areas not central to the clinical trial fraud investigation.

==========
== PART IV: REGULATORY AND LEGAL MILESTONES ==========
==========

MILESTONE 1: WHISTLEBLOWER COMPLAINT FILED Date: September 1, 2021 Actor: Dr. Sarah Mitchell (Former CEO) Description: Dr. Mitchell filed a confidential whistleblower complaint with the SEC alleging securities fraud, specifically citing the appointment of unqualified executives following her departure and manipulation of clinical trial data.

MILESTONE 2: FDA SITE INSPECTION - DEFICIENCIES IDENTIFIED Date: November 15, 2021 Actor: Food and Drug Administration (FDA) Description: FDA conducted routine inspection of BioGenesis clinical trial sites and identified "significant deficiencies in data integrity, patient safety monitoring, and protocol compliance." The inspection was triggered by adverse event reports that were not properly submitted.

MILESTONE 3: FDA WARNING LETTER ISSUED Date: January 10, 2022 Actor: Food and Drug Administration (FDA) Description: FDA issued Warning Letter citing violations of 21 CFR Part 312 (IND regulations) including failure to ensure qualified investigators, inadequate safety monitoring, and failure to report adverse events within required timeframes. The letter demanded immediate corrective action.

MILESTONE 4: SEC INVESTIGATION OPENED Date: March 1, 2022 Actor: Securities and Exchange Commission (SEC) Description: SEC opened formal investigation into potential securities fraud at BioGenesis, triggered by Dr. Mitchell's whistleblower complaint and subsequent FDA enforcement actions. Investigation focused on materially misleading statements about clinical trial progress and executive qualifications.

MILESTONE 5: CLINICAL TRIAL PLACED ON FDA HOLD Date: June 20, 2022 Actor: Food and Drug Administration (FDA) Description: FDA placed BioGenesis' pivotal Phase III cancer drug trial on clinical hold, halting all patient enrollment and dosing. The hold was based on "unreliable data, inadequate patient safety monitoring, and questions about data integrity." This caused BioGenesis stock to drop 45%.

MILESTONE 6: FINANCIAL RESTATEMENT ANNOUNCED Date: August 15, 2022 Actor: BioGenesis Pharmaceutical Corp. Description: Company announced restatement of financial results for 2021 and Q1-Q2 2022, citing "errors in revenue recognition and clinical trial cost capitalization." The restatement reduced reported revenues by $125 million and increased operating losses by $67 million.

MILESTONE 7: CLASS ACTION LAWSUIT FILED Date: September 12, 2022 Actor: Investor Group / Plaintiff's Attorneys Description: Securities class action lawsuit filed in U.S. District Court for the Southern District of New York, alleging violations of Securities Exchange Act Sections 10(b) and 20(a). Complaint alleged company made materially false statements about clinical trial progress, executive qualifications, and regulatory compliance.

MILESTONE 8: DEPARTMENT OF JUSTICE CRIMINAL REFERRAL Date: February 8, 2023 Actor: Securities and Exchange Commission (SEC) Description: SEC made criminal referral to Department of Justice recommending investigation of potential criminal securities fraud. Referral specifically cited "scheme to defraud investors through appointment of unqualified executives, manipulation of clinical trial data, and false public disclosures."

MILESTONE 9: PRODUCT DEVELOPMENT PROGRAM TERMINATED Date: May 1, 2023 Actor: BioGenesis Pharmaceutical Corp. / FDA Description: BioGenesis announced termination of lead cancer drug development program after FDA determined data integrity issues could not be remediated. The program represented 80% of company's market valuation. Stock dropped 78% on the announcement.

MILESTONE 10: BANKRUPTCY FILING Date: October 15, 2023 Actor: BioGenesis Pharmaceutical Corp. Description: BioGenesis filed Chapter 11 bankruptcy petition in Delaware citing "insurmountable regulatory obstacles, litigation liability, and inability to raise capital." Petition listed $850 million in liabilities against $120 million in assets.

MILESTONE 11: SEC ENFORCEMENT ACTION FILED Date: April 22, 2024 Actor: Securities and Exchange Commission (SEC) Description: SEC filed civil enforcement action against BioGenesis and individual executives (Morrison, Martinez, Foster) alleging securities fraud. Complaint sought disgorgement of ill-gotten gains, civil penalties, and officer/director bars.

MILESTONE 12: CRIMINAL INDICTMENTS UNSEALED Date: September 15, 2024 Actor: U.S. Department of Justice Description: Federal grand jury returned criminal indictments against CEO Kevin Morrison, CFO Angela Martinez, and Board Chairman Thomas Blackwell charging conspiracy to commit securities fraud, wire fraud, and making false statements to federal agencies. Trial scheduled for March 2025.

==
== PART V: LEGAL ANALYSIS AND PATTERN IDENTIFICATION ==========================
==

CENTRAL FRAUD THEORY: Between March 2021 and August 2021, BioGenesis' Board of Directors systematically removed qualified executives who raised concerns about clinical trial integrity and

replaced them with demonstrably unqualified individuals who would not question management directives. This executive replacement pattern enabled securities fraud by:

1. Eliminating internal controls and oversight 2. Suppressing adverse information about clinical trial problems 3. Creating an environment where data manipulation could occur 4. Misleading investors about company's regulatory compliance and prospects

TIMING CORRELATION: The appointment of unqualified executives directly preceded and enabled the fraudulent conduct: - March-August 2021: Qualified executives terminated/resigned - April-August 2021: Unqualified replacements hired - September 2021-June 2022: Period of maximum fraudulent activity (data manipulation, failure to report adverse events, misleading disclosures) - September 2021 onward: Cascade of regulatory enforcement and legal consequences

EXECUTIVE QUALIFICATION DEFICIENCIES: 1. Morrison (CEO): NO pharmaceutical experience, appointed through nepotism 2. Martinez (CFO): SUSPENDED CPA license, NO corporate finance experience 3. Foster (GC): Online law degree from unaccredited school, NO relevant experience 4. Stevens (CSO): FAKE PhD from diploma mill, fraudulent credentials 5. Green (VP Reg): ZERO regulatory affairs experience, hired through nepotism 6. Jenkins (VP Clinical): GYM MANAGER with NO healthcare background

VICTIM IMPACT: - Investors: Lost over $2 billion in market capitalization - Patients: 47 trial participants suffered serious adverse events that were not properly monitored - Employees: 300+ jobs lost due to bankruptcy - Healthcare System: Wasted resources on fraudulent drug development program

COMPARISON TO PRECEDENT: This case bears similarities to Theranos (fraudulent blood testing technology), Insys Therapeutics (bribery and fraud in opioid marketing), and Outcome Health (defrauding pharmaceutical advertisers). All involved: - Systematic deception of investors and regulators - Appointment of unqualified personnel to suppress dissent - Manipulation or fabrication of key operational data - Catastrophic collapse when fraud exposed

==
== PART VI: WITNESSES AND EVIDENCE SOURCES ====================================
==

KEY COOPERATIVE WITNESSES: 1. Dr. Sarah Mitchell (Former CEO) - Whistleblower, star witness 2. Robert Chen (Former CFO) - Forensic accounting testimony 3. Elizabeth Harrison (Former GC) - Legal compliance testimony 4. Dr. James Rodriguez (Former CSO) - Scientific integrity testimony

DOCUMENTARY EVIDENCE: - 125,000+ pages of internal emails and documents - Board meeting minutes showing executive hiring decisions - Clinical trial protocols and data (authentic vs. falsified) - FDA inspection reports and warning letters - SEC investigation files and witness testimony - Financial records showing improper accounting

EXPERT WITNESSES RETAINED: - Pharmaceutical industry executive recruiter (standards for executive qualifications) - Former FDA official (regulatory compliance standards) - Clinical trial integrity expert (GCP violations) - Securities fraud economist (damages calculation) - Forensic accountant (financial statement fraud)

==
== CONCLUSION ==

==========

The BioGenesis case represents a clear pattern of securities fraud enabled by the systematic replacement of qualified executives with unqualified loyalists. The temporal correlation between executive turnover and fraudulent conduct, combined with the egregious qualification deficiencies of replacement executives, supports both civil and criminal liability.

Trial preparation should emphasize the "before and after" narrative: a legitimate pharmaceutical company with qualified leadership transformed into a fraudulent enterprise through deliberate appointment of incompetent executives who would not challenge illegal conduct.

RECOMMENDED TRIAL STRATEGY: 1. Open with timeline showing qualified executive departures 2. Emphasize shocking lack of qualifications of replacements 3. Show direct causation between unqualified executives and fraud 4. Close with consequences: patient harm, investor losses, company destruction

This case should result in significant penalties and prison time for responsible executives and board members.

END OF MEMORANDUM