



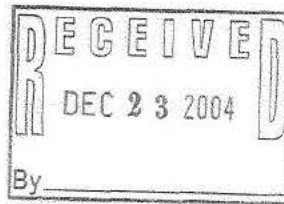
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

PIND 69,852

Biogen Idec
Attention: Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA 02142



[REDACTED]

Please refer to your Pre-Investigational New Drug Application (PIND) file for BG00012 for psoriasis.

We also refer to the meeting between representatives of your firm and the FDA on November 23, 2004. The purpose of the meeting was to discuss the pre-clinical and early clinical plans.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, please contact Frank Cross, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

(See appended electronic signature page)

Jonathan Wilkin, M.D.
Division Director
Division of Dermatologic and Dental Drug
Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

Meeting Date: November 23, 2004
Meeting ID# 14024

Time: 9:30 a.m.

Location: S300

BG00012

Indication: Treatment of psoriasis

Sponsor: Biogen Idec

Pre-IND Meeting

Meeting Chair: Jonathan K. Wilkin, M.D.

Meeting Recorder (CSO/Project Manager): Frank H. Cross, Jr., M.A., CDR

FDA Attendees, titles and offices:

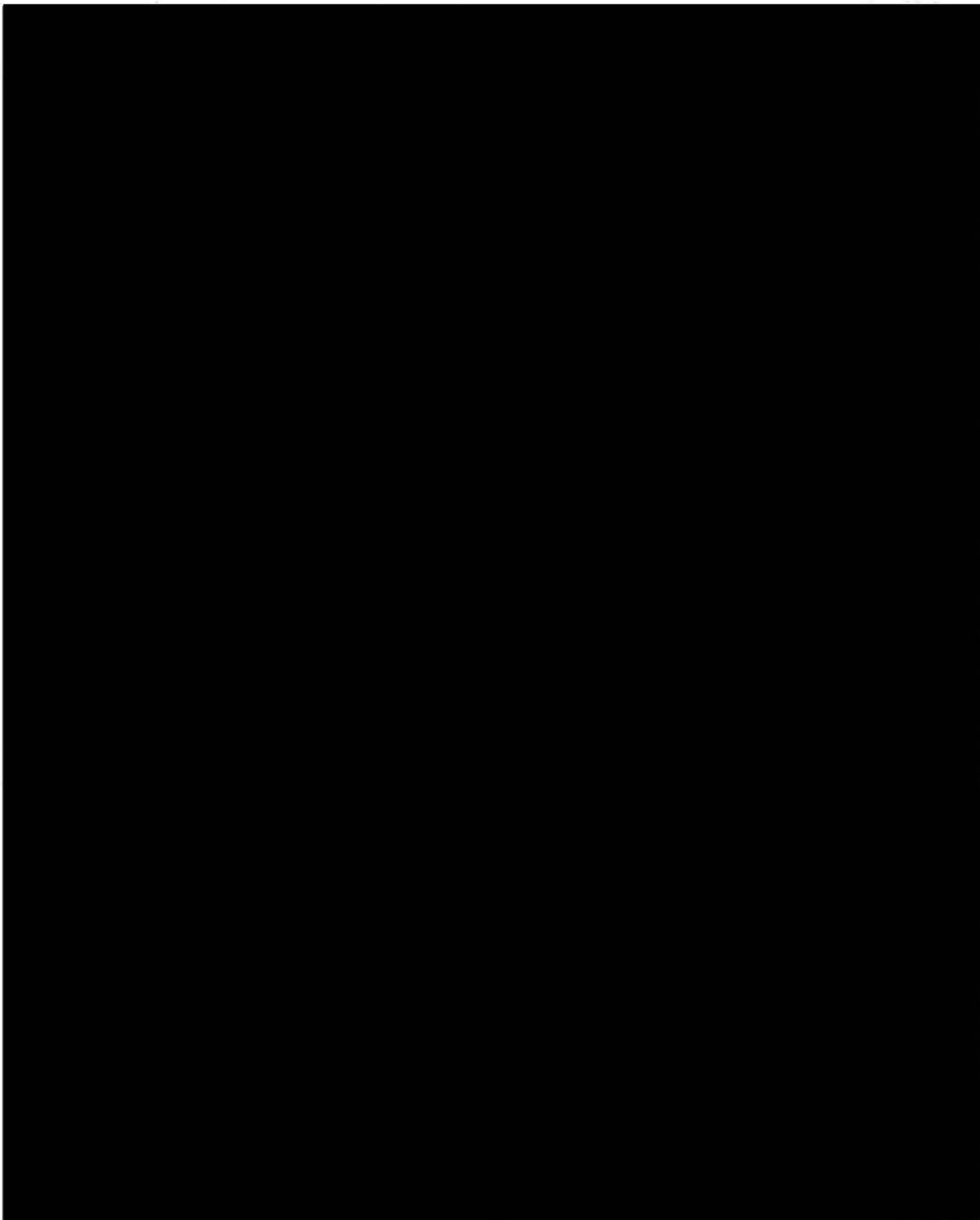
Jonathan K. Wilkin, M.D., Division Director, DDDDP, HFD-540
Jonca Bull, M.D., Office Director, ODEV, HFD-105
Ramesh Sood, Ph.D., Chemistry Team Leader, DNDCHII, HFD-830
Norman See, Ph.D., Pharmacology/Toxicology Reviewer, DDDDP, HFD-540
Raman Baweja, Ph.D., Clinical Pharmacology/Biopharmaceutics Team Leader, DPEIII, HFD-880
Lei Zhang, Ph.D., Clinical Pharmacology/Biopharmaceutics Reviewer, DPEIII, HFD-880
Markham Luke, M.D., Ph.D., Clinical Team Leader, DDDDP, HFD-540
Denise Cook, M.D., Medical Officer, DDDDP, HFD-540
Joseph Porres, M.D., Ph.D., Medical Officer, DDDDP, HFD-540
Mohamed Alesh, Ph.D., Biostatistics Team Leader, DBIII, HFD-725
Matt Soukup, Ph.D., Biostatistics Reviewer, DBIII, HFD-725
Frank H. Cross, M.A., CDR, Senior Regulatory Management Officer, DDDDP, HFD-540

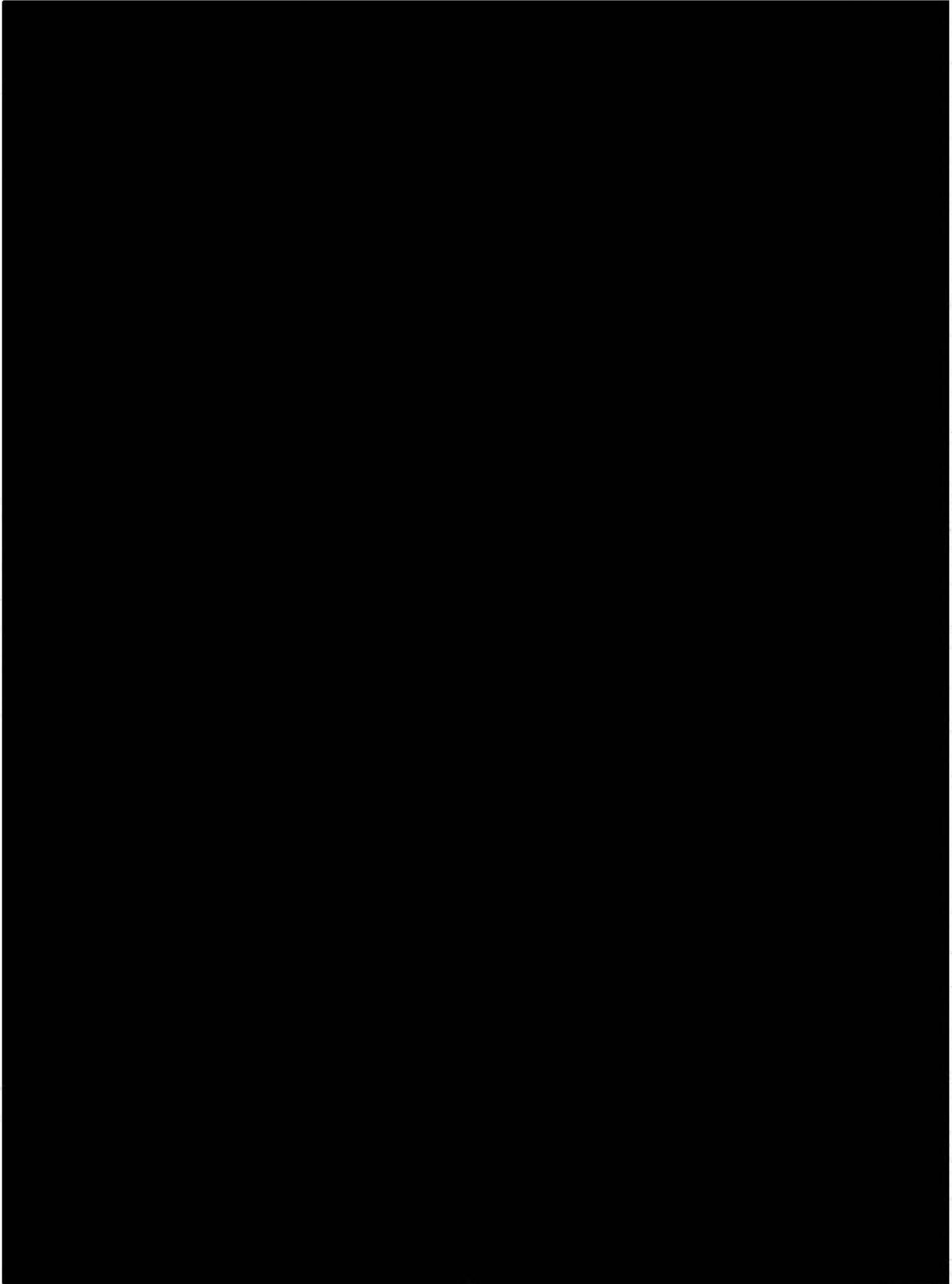
Sponsor Attendees, titles and offices:

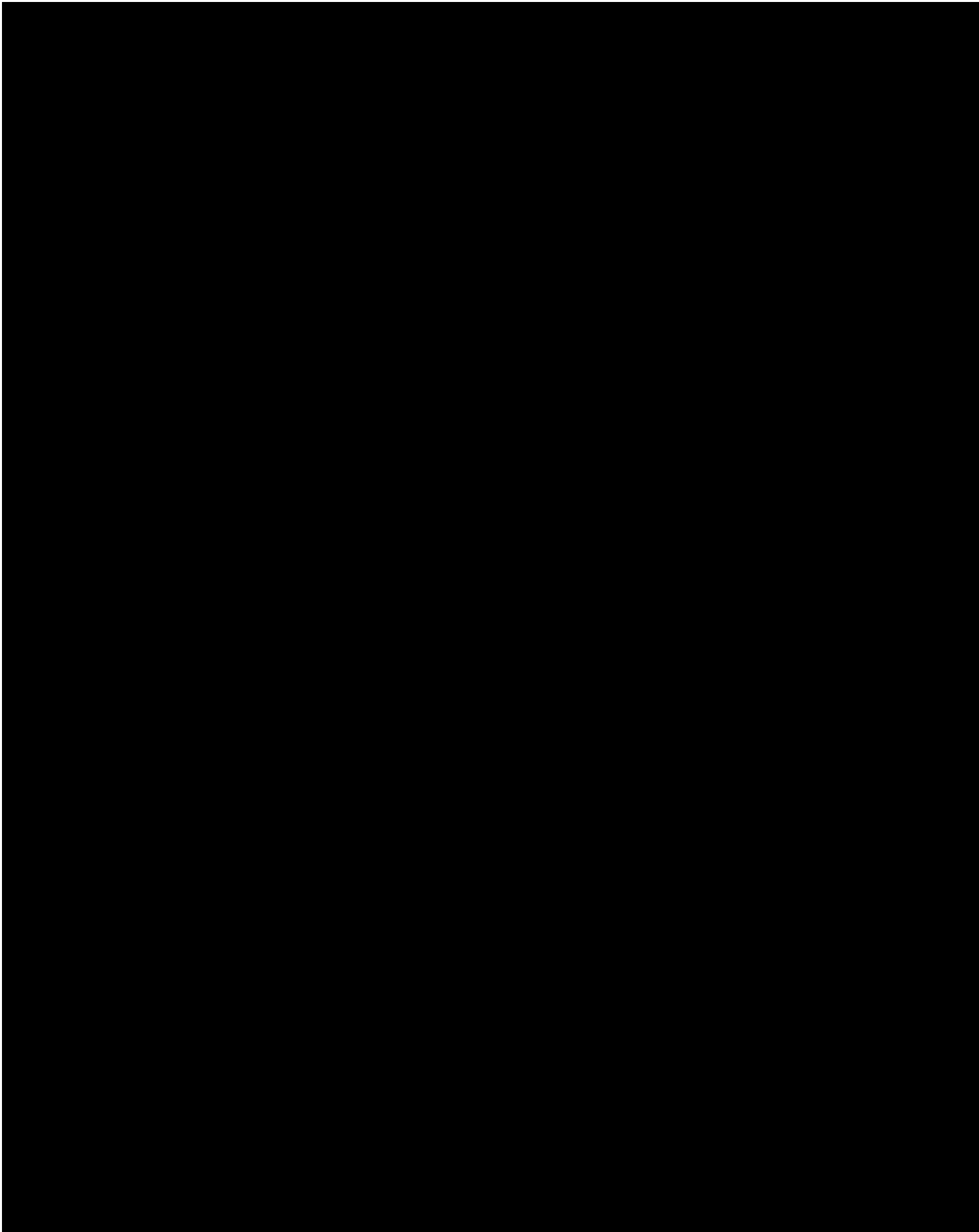
[REDACTED]

Barry Ticho, Director, Medical Research

[REDACTED]







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