



**Australian Government**

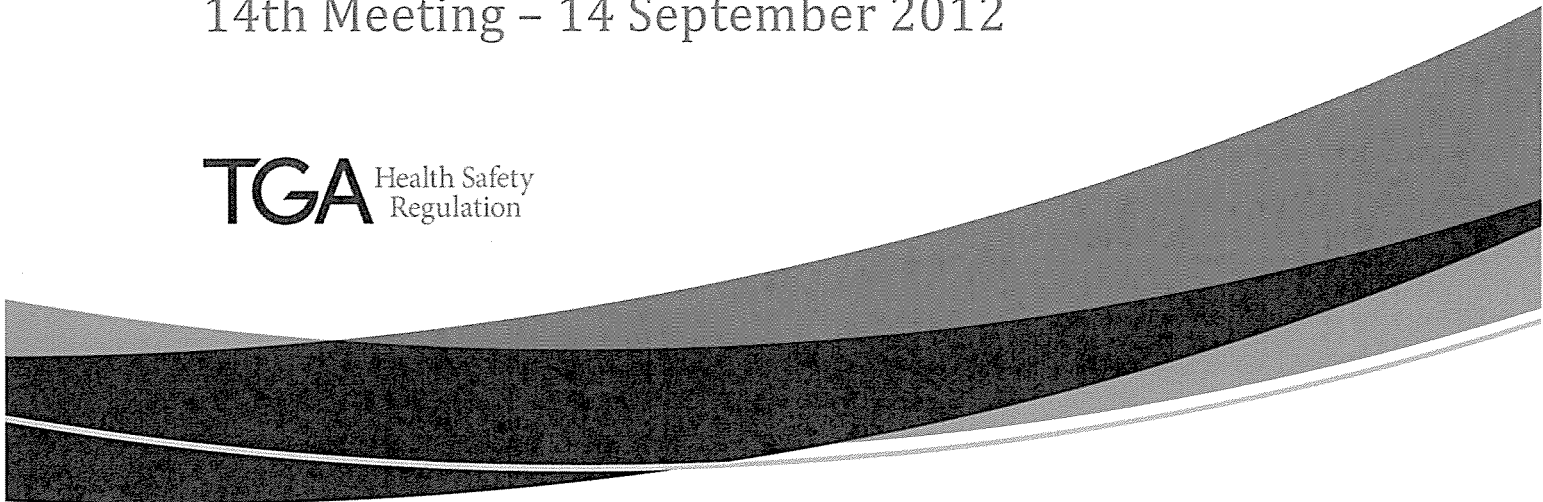
**Department of Health and Ageing**  
Therapeutic Goods Administration

# Advisory Committee on the Safety of Medicines

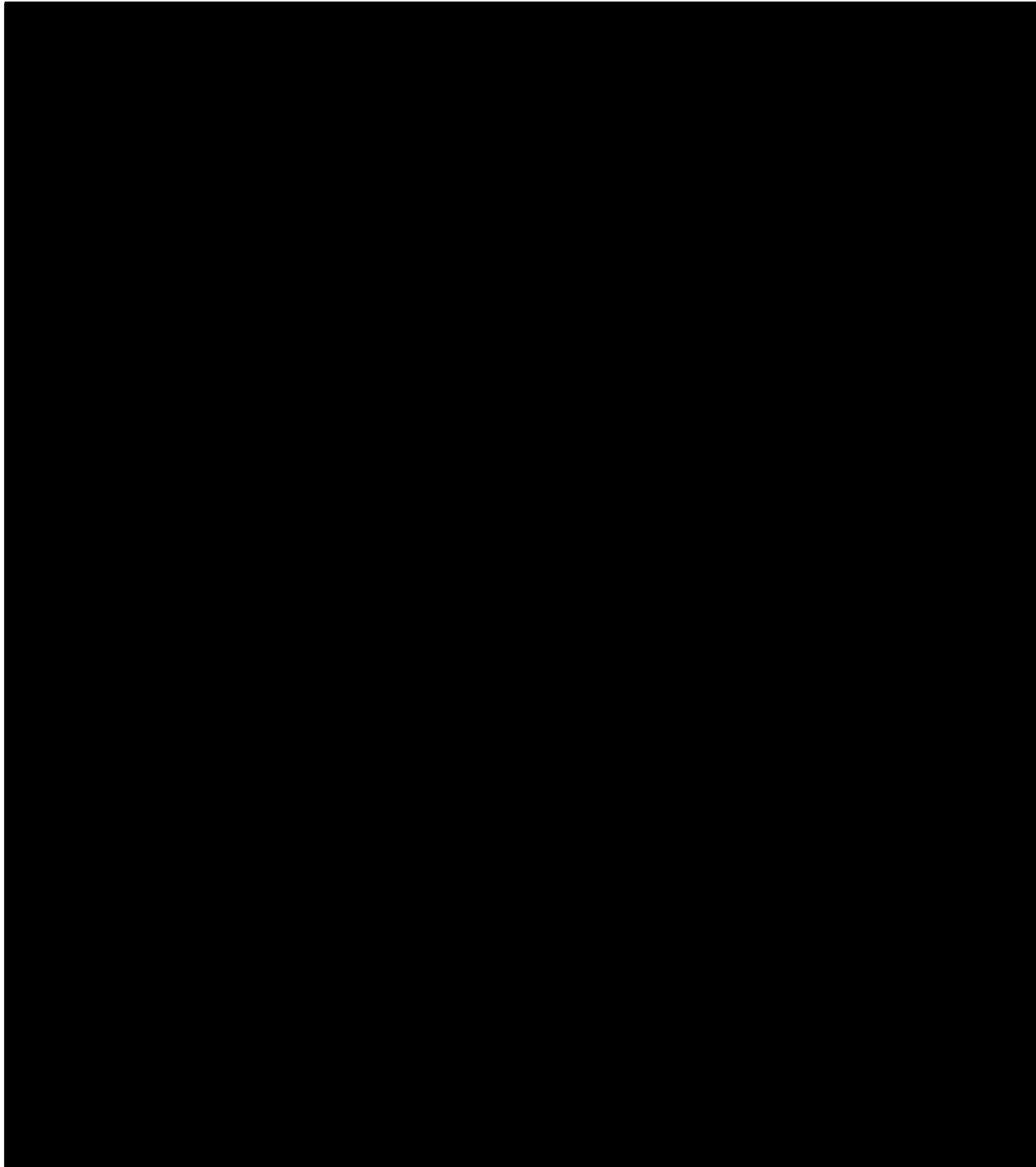
Minutes

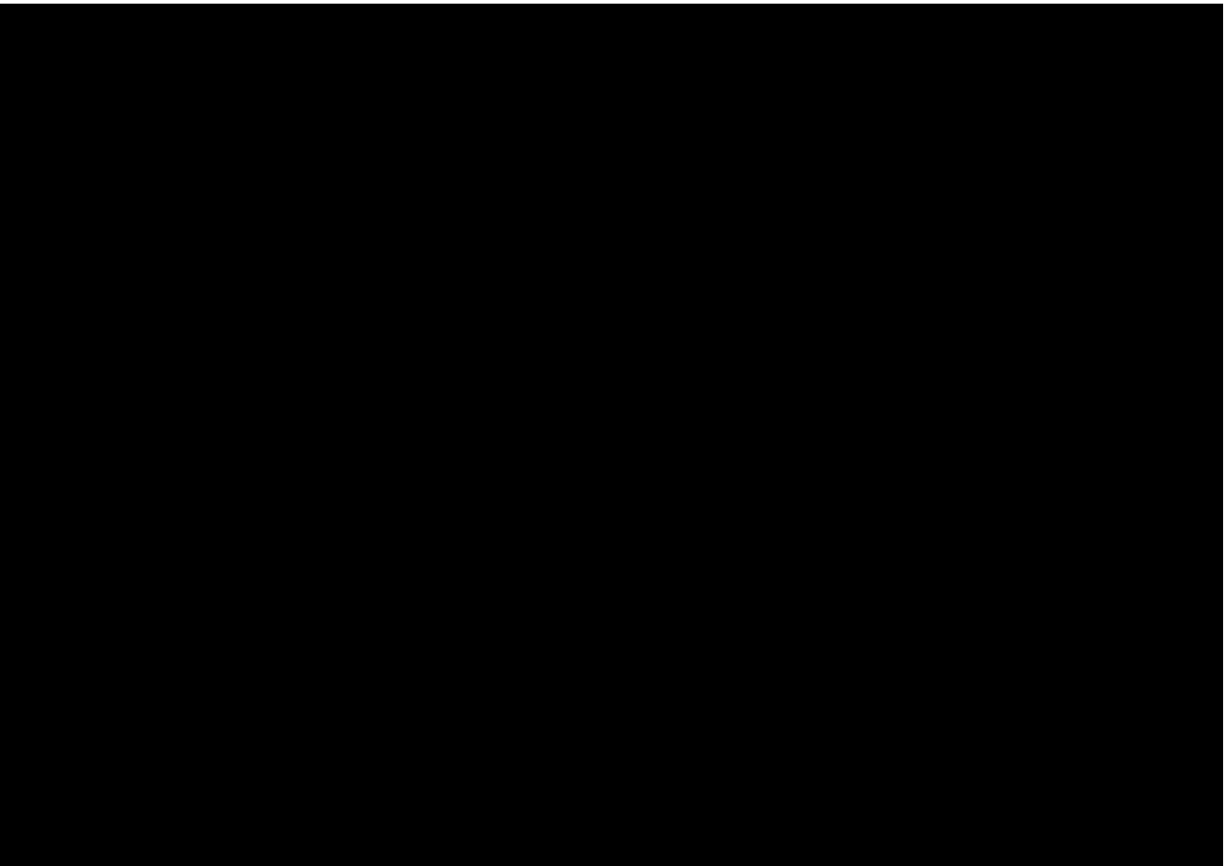
14th Meeting – 14 September 2012

**TGA** Health Safety  
Regulation

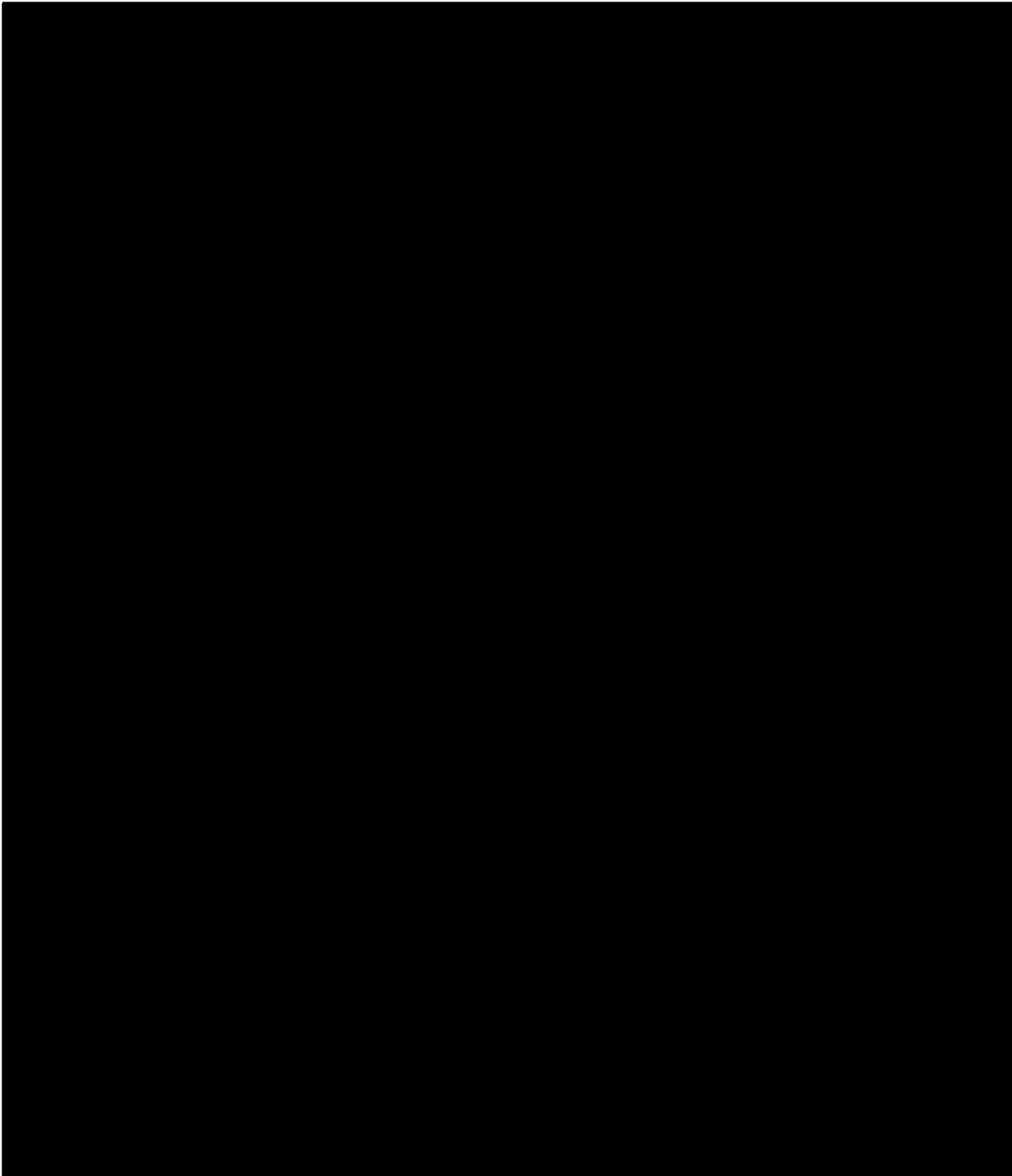




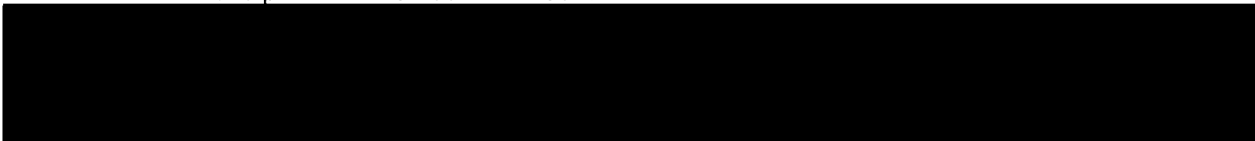


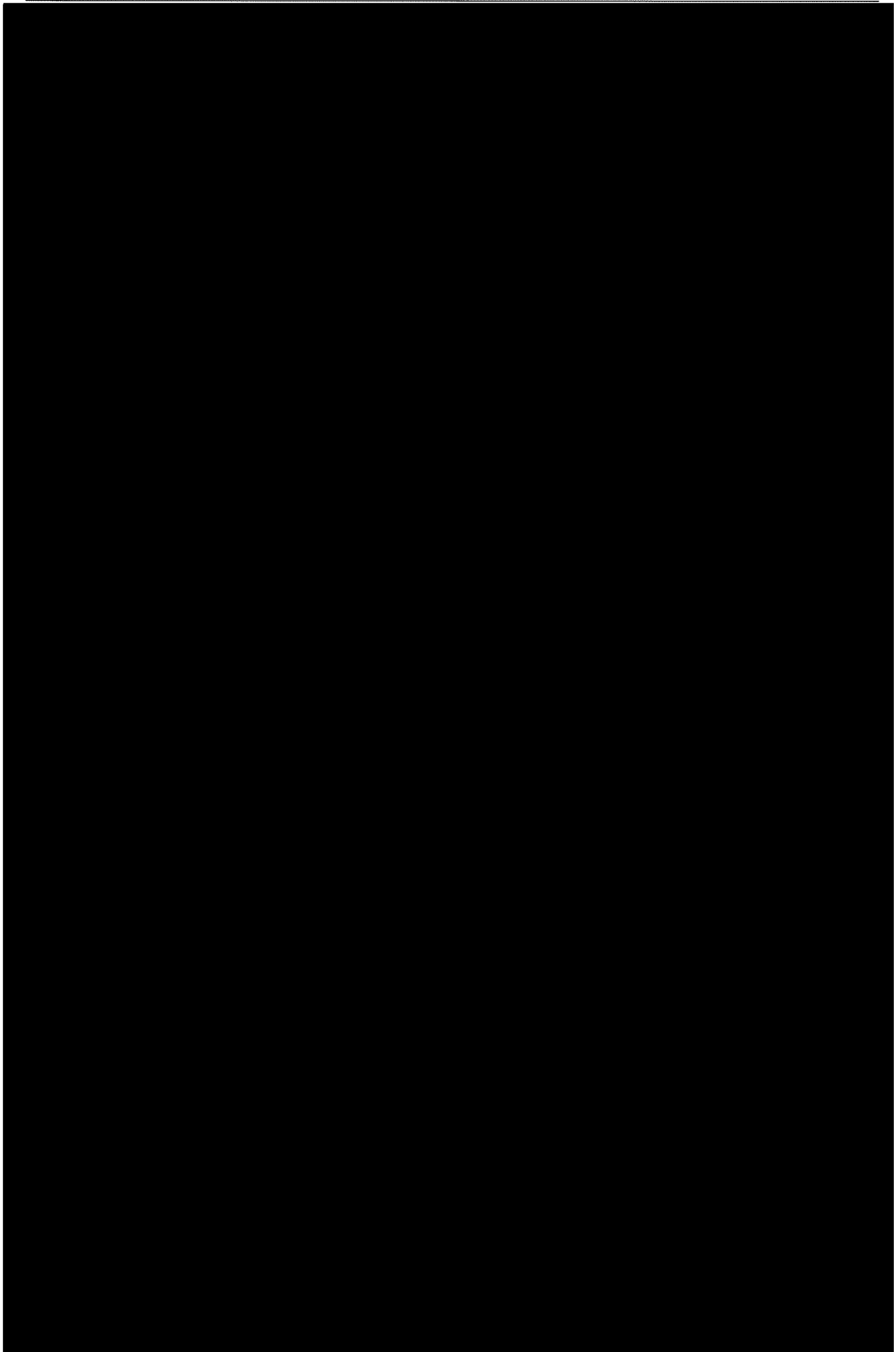


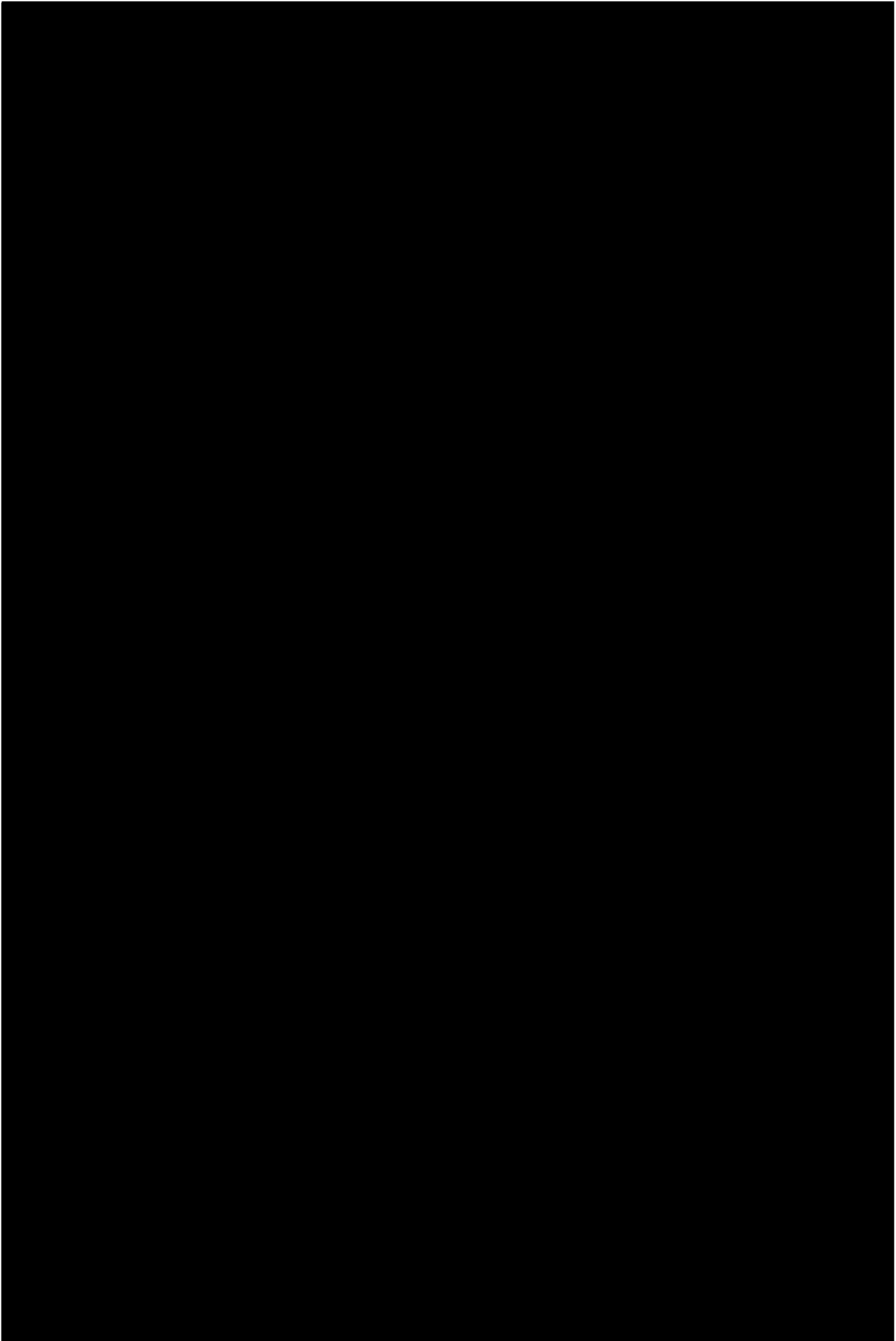
- TGA officers:**
- Dr John Skerritt, TGA National Manager
  - Dr Tony Gill, TGA Principal Medical Advisor (a/g)
  - Dr Jane Cook: Head, Office of Product Review
  - Dr Rona Hiam: Medical Officer, Office of Product Review (Items 4.1 – 4.4)
  - Dr Kaye Robertson: Medical Officer, Office of Product Review (Items 4.1 and 4.2)
  - Dr Shaun Williams: Evaluator, Office of Product Review (Item 4.4)
  - Dr John Donohoe, Senior Advisor, Office of Medicines Authorisation (Item 7.1)
  - Dr Ting Lu: Director (a/g), Clinical Evaluation Unit 2, Office of Medicines Authorisation (Items 4.3 and 4.4)
- DoHA Officers:**
- Mr Paul Creech, Director, Quality Use of Medicines, Pharmaceutical Policy, Pharmaceutical Benefits Division (Item 7.1)
  - Mr David Pearson, Director, Specialised Supply, Pharmaceutical Access, Pharmaceutical Benefits Division (Item 7.1)
- Secretariat:**
- Dr Katherine Gray: Secretary (a/g), Office of Product Review
  - Mrs Kirsten Sharp: Minute Secretary, Office of Product Review

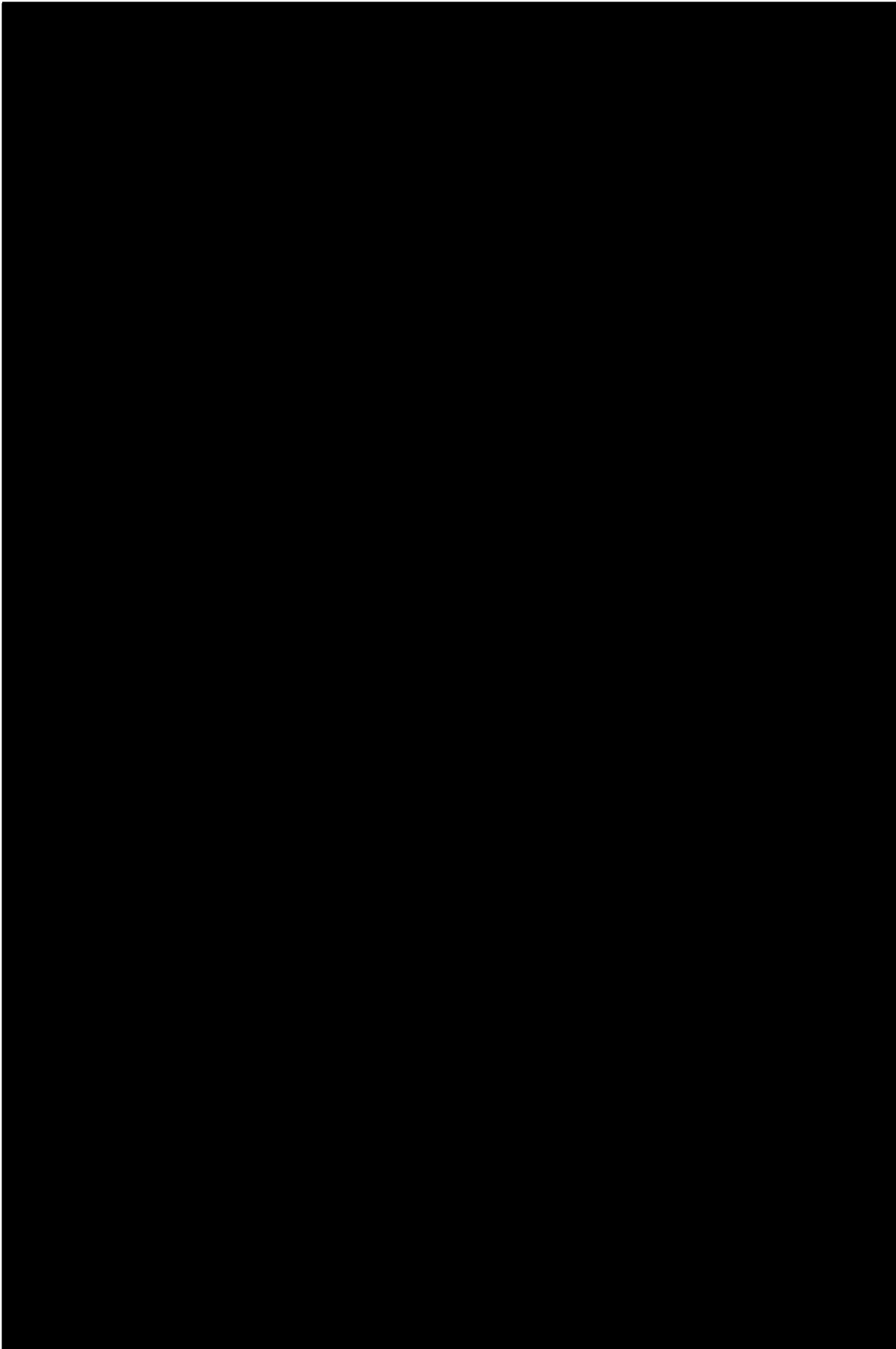


- Meeting 1, 5 March 2010, Item 6.3 Recommendations of the Psychiatric Drug Safety Expert Advisory Panel: *actions from the report from the Expert Panel:*
  - Ongoing – staff in OPR are currently negotiating with the sponsor and finalising the outstanding actions. A summary of all actions taken will be provided once the process has been finalised.

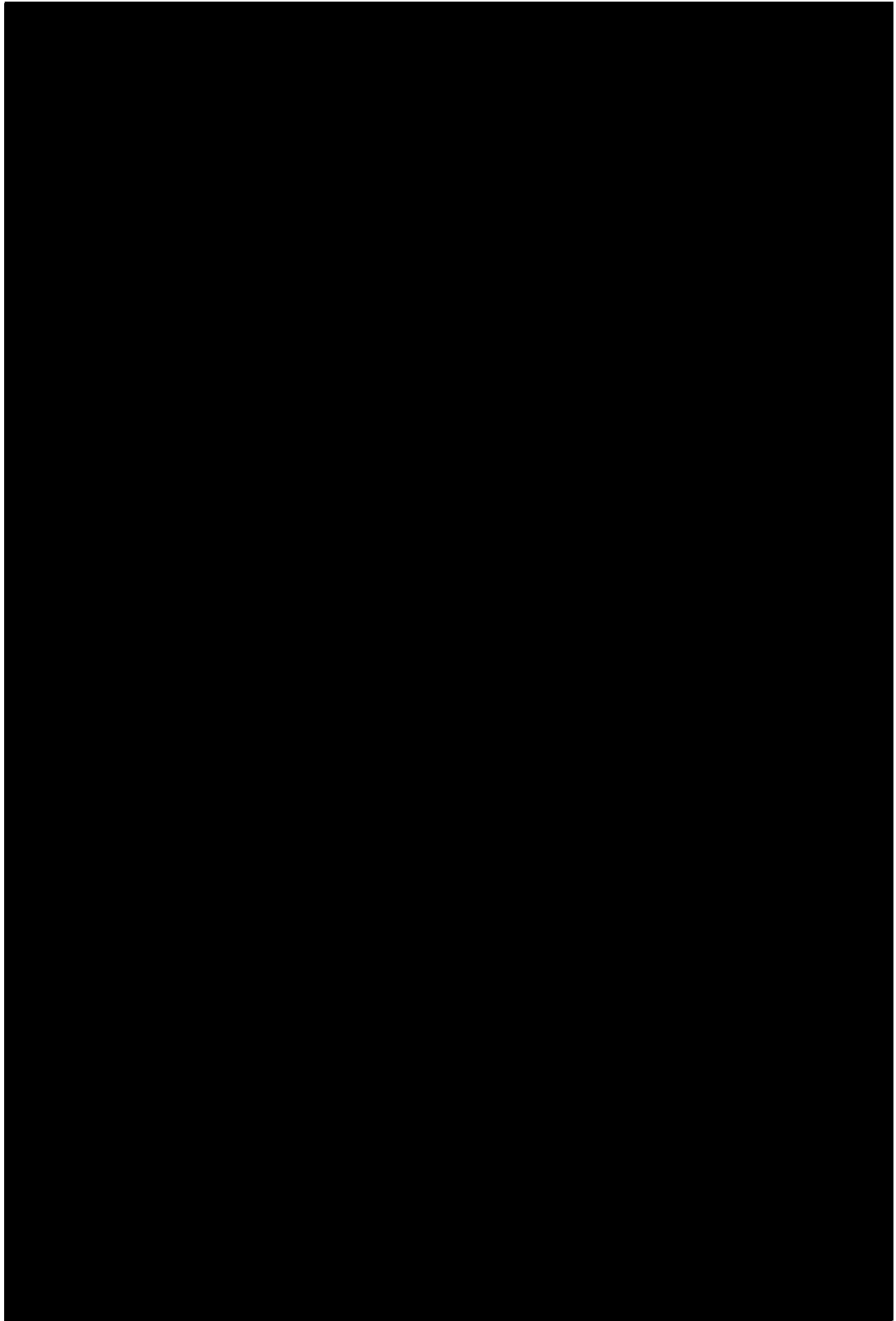


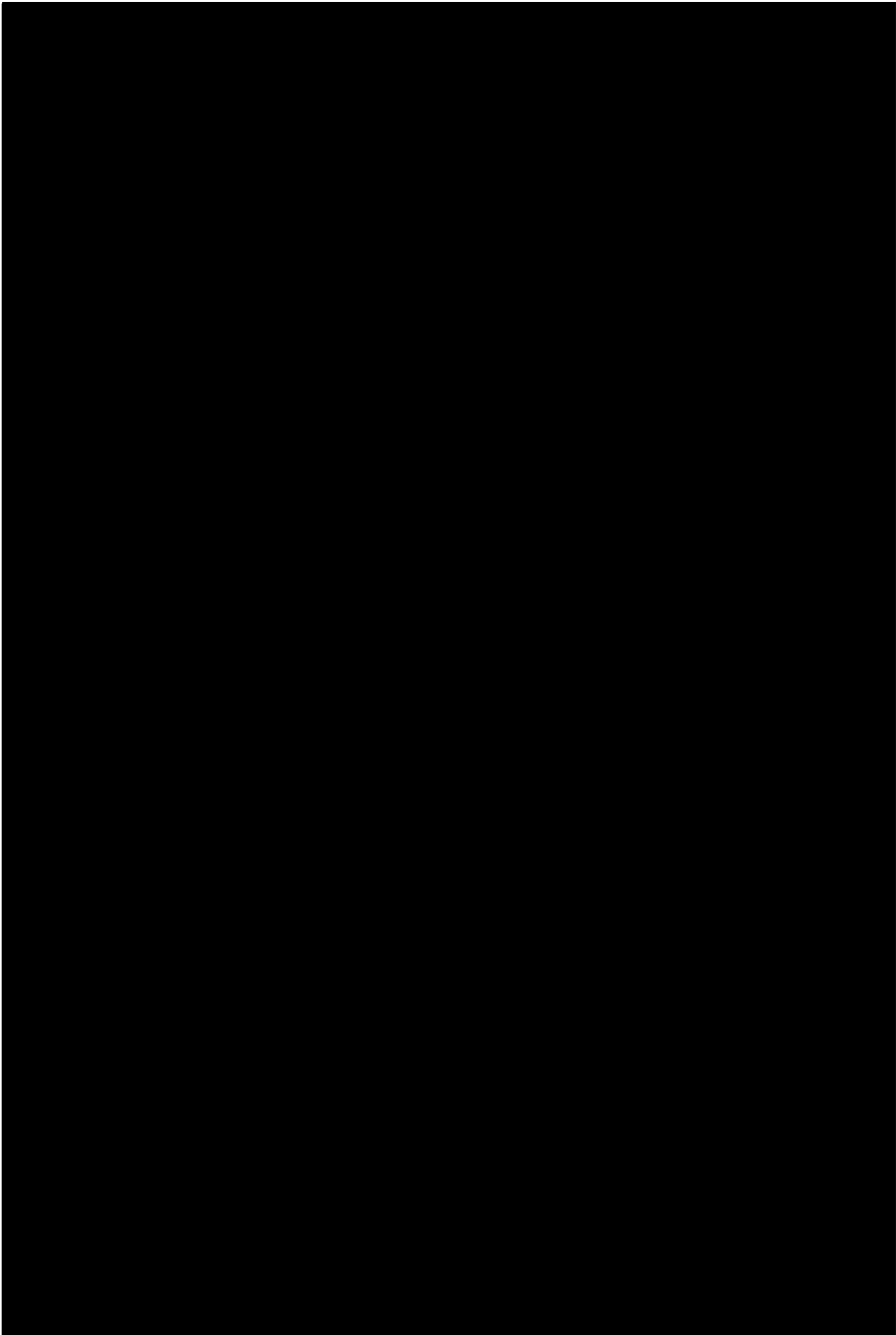


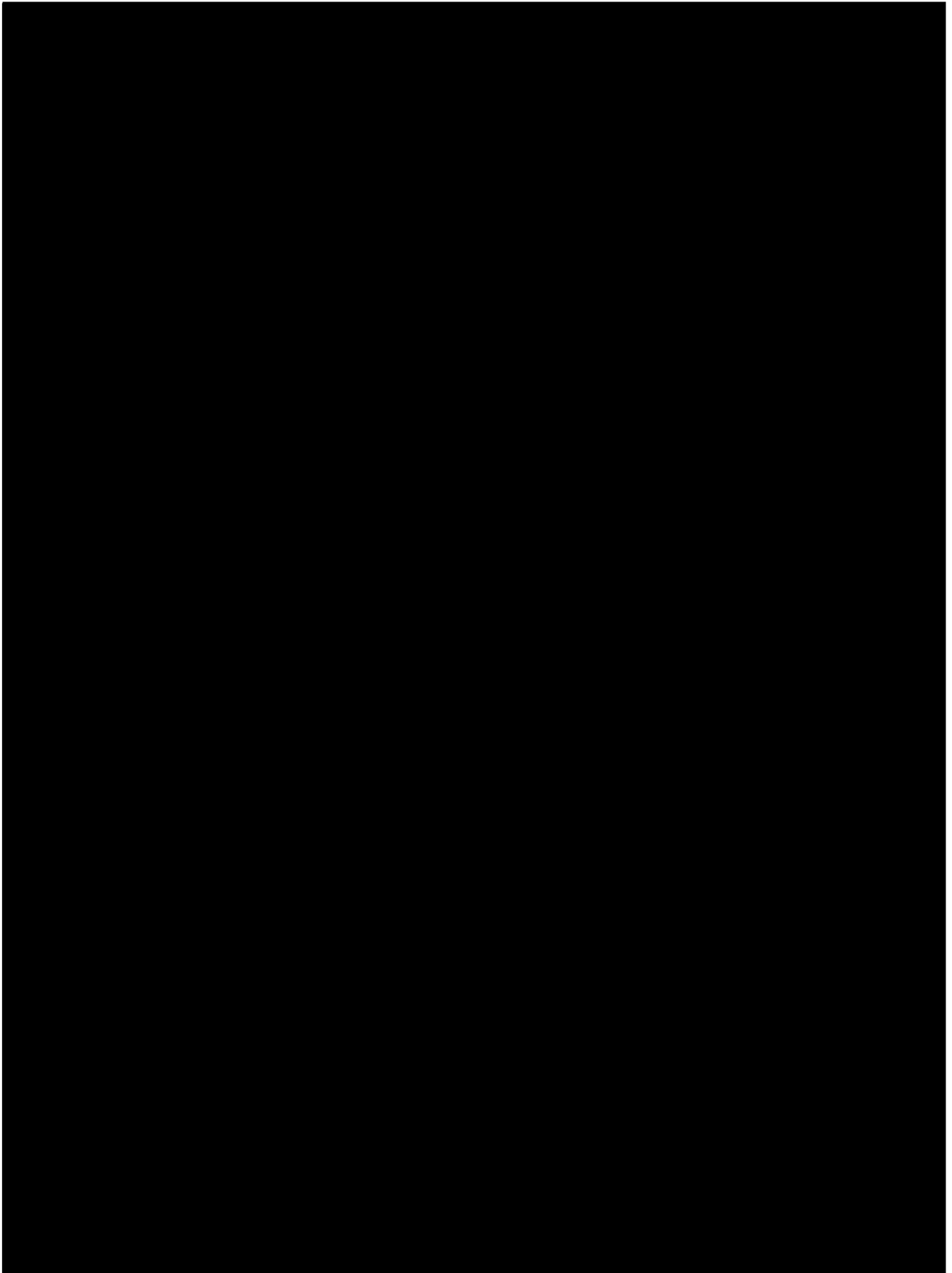


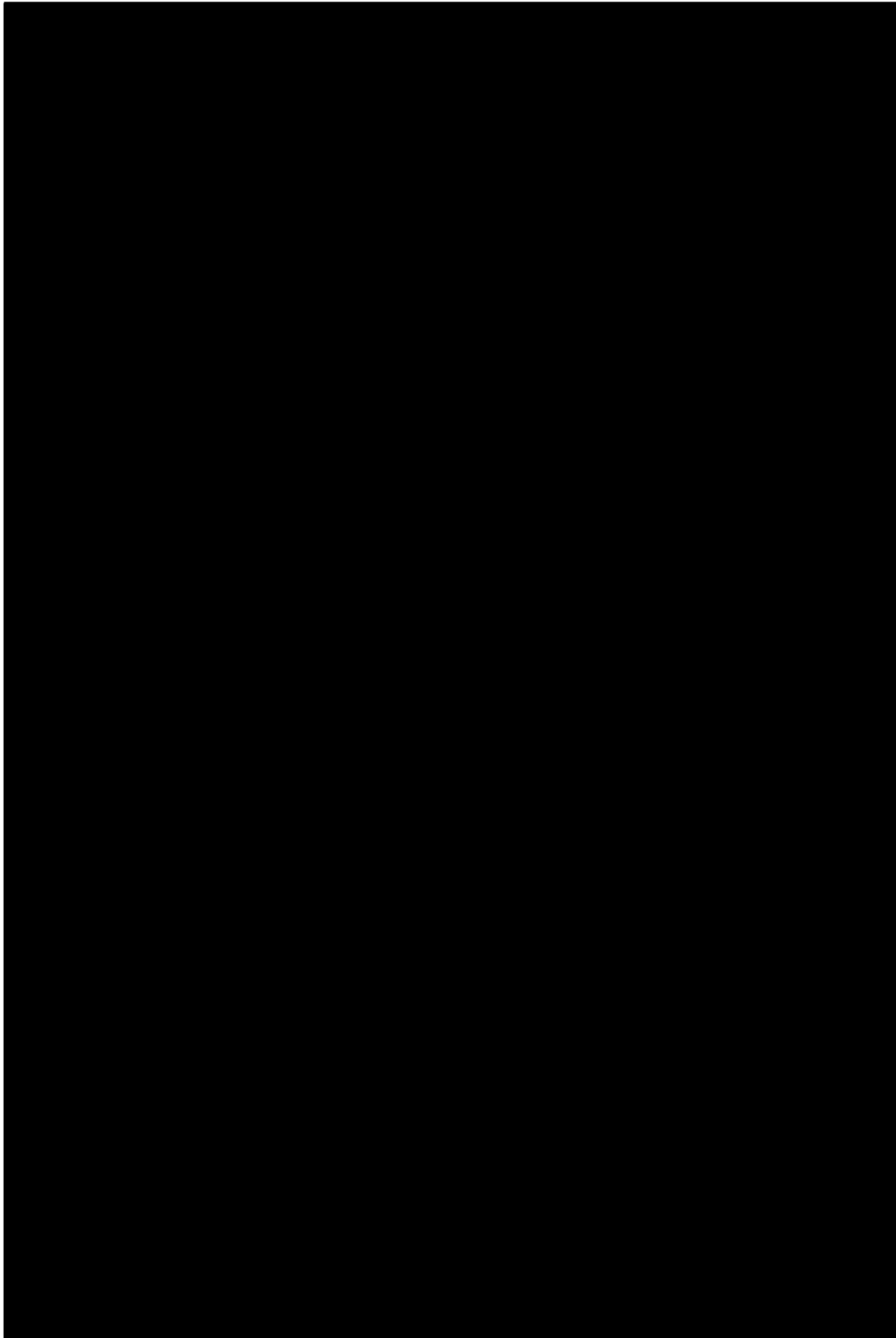


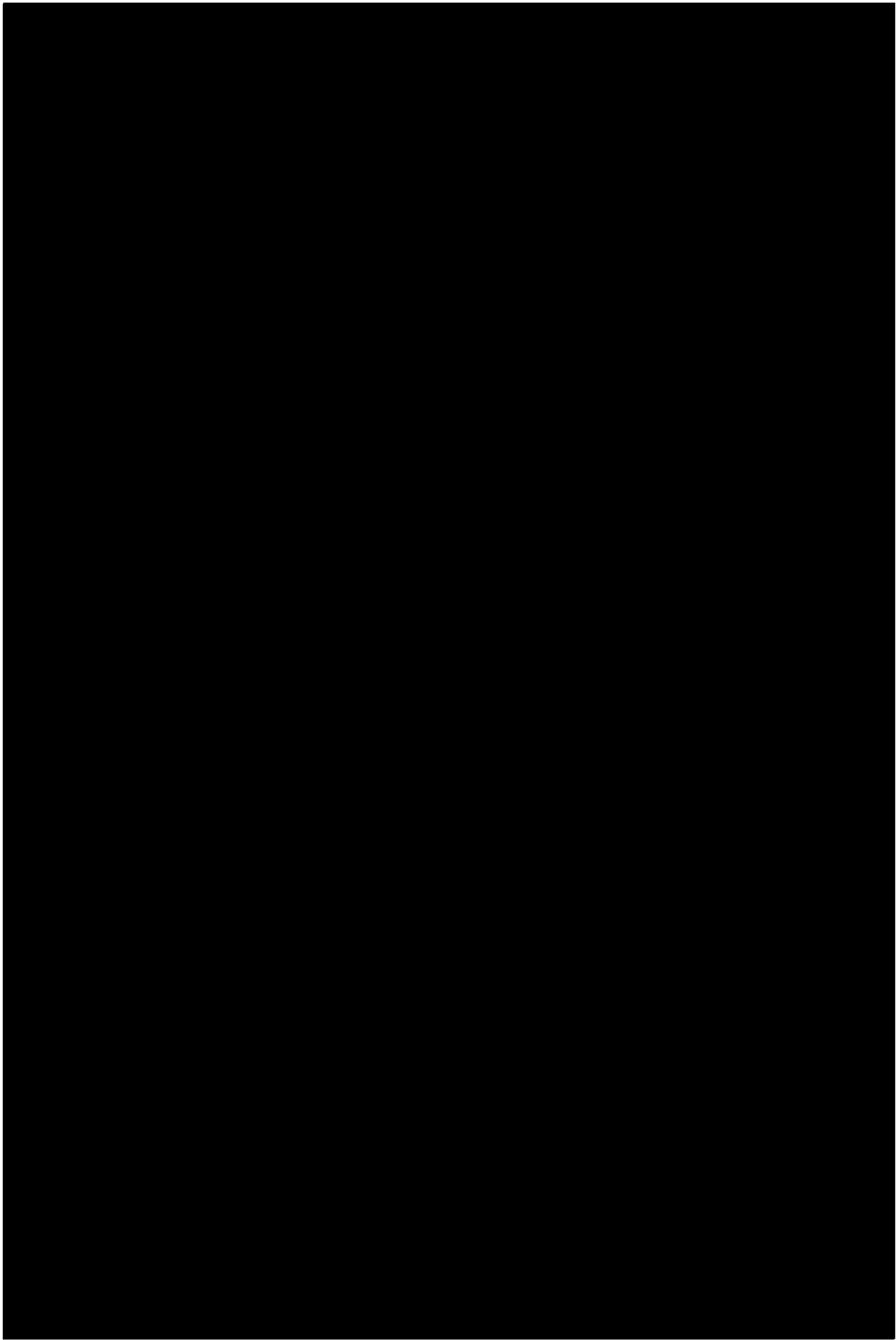


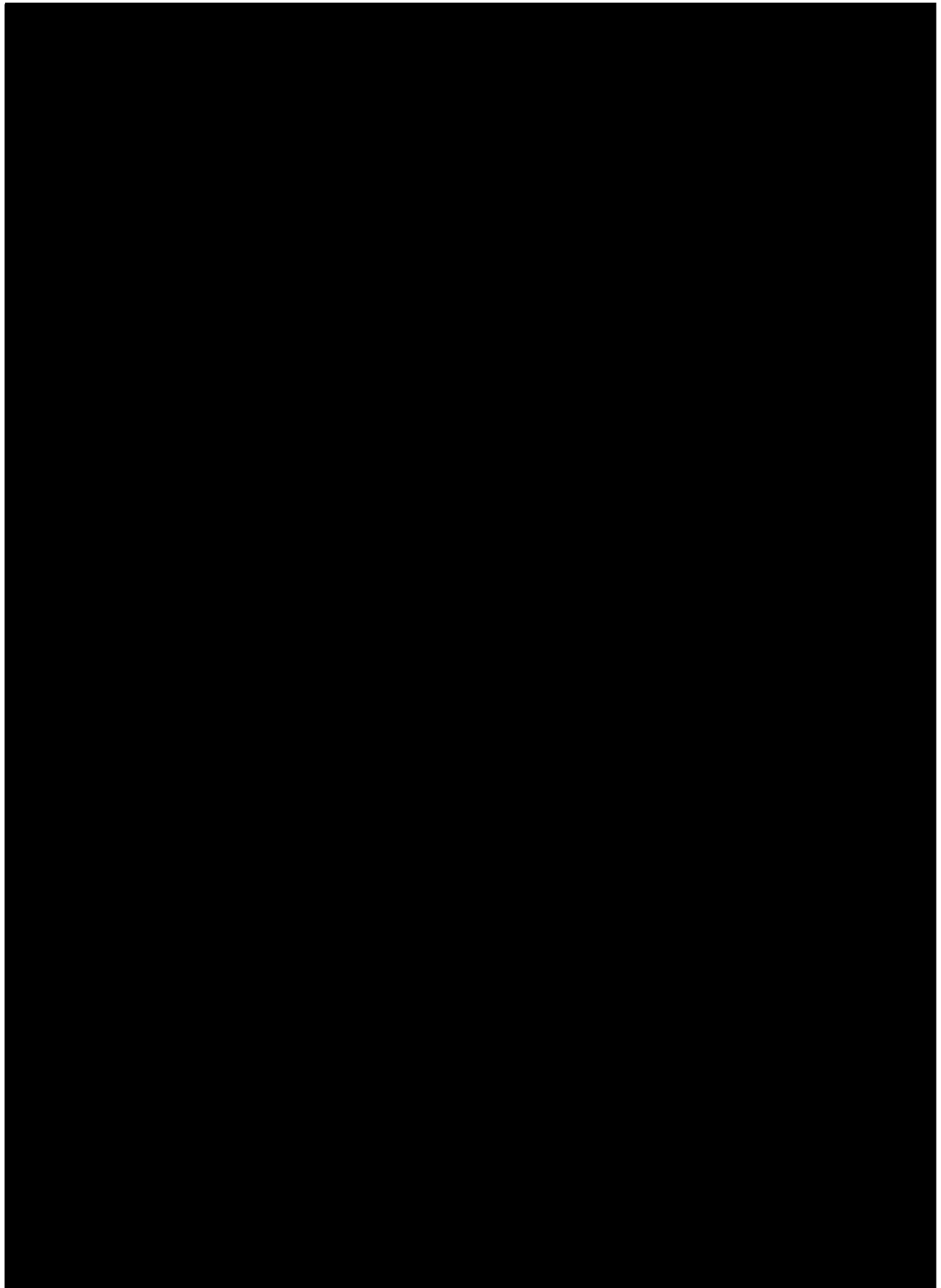


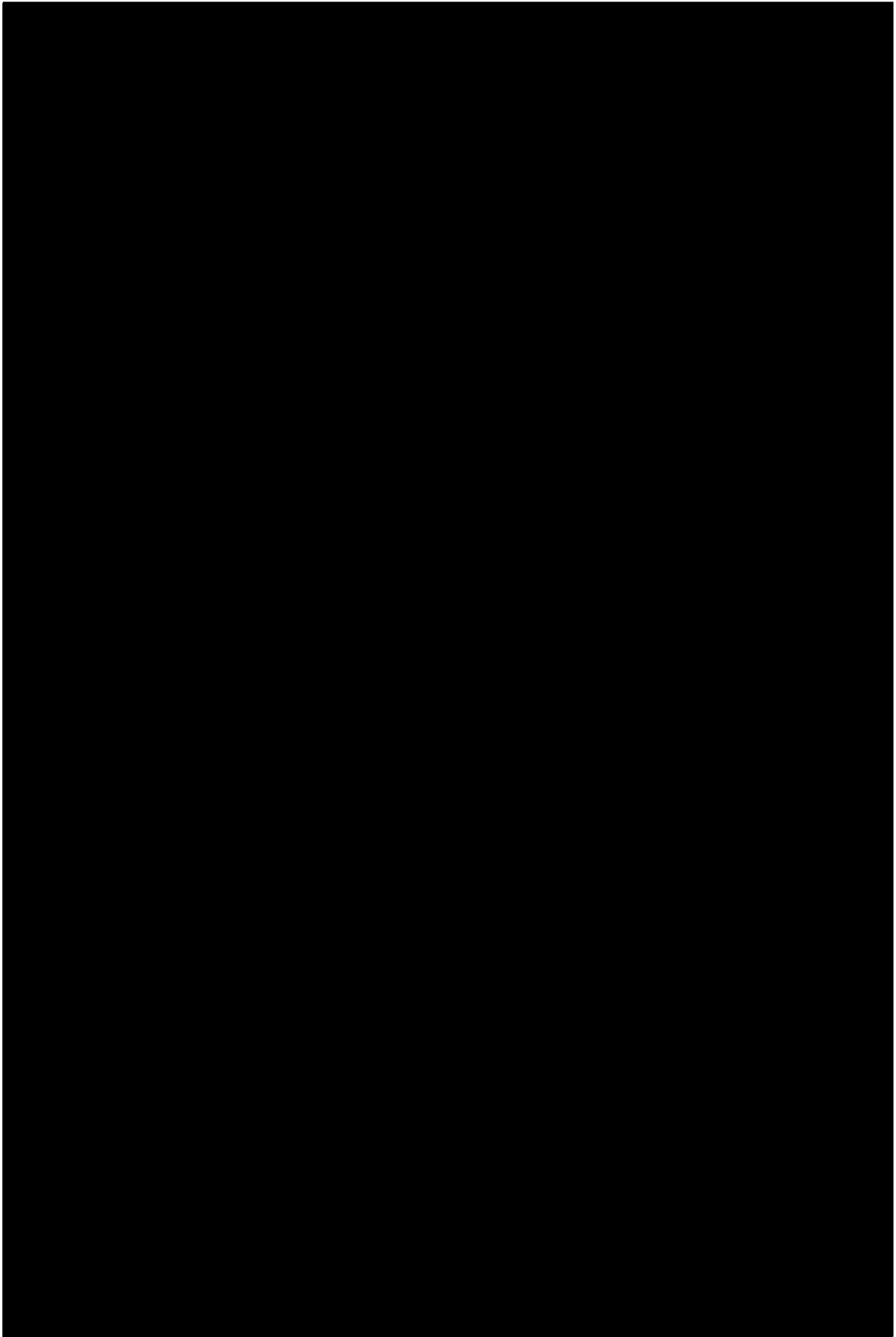


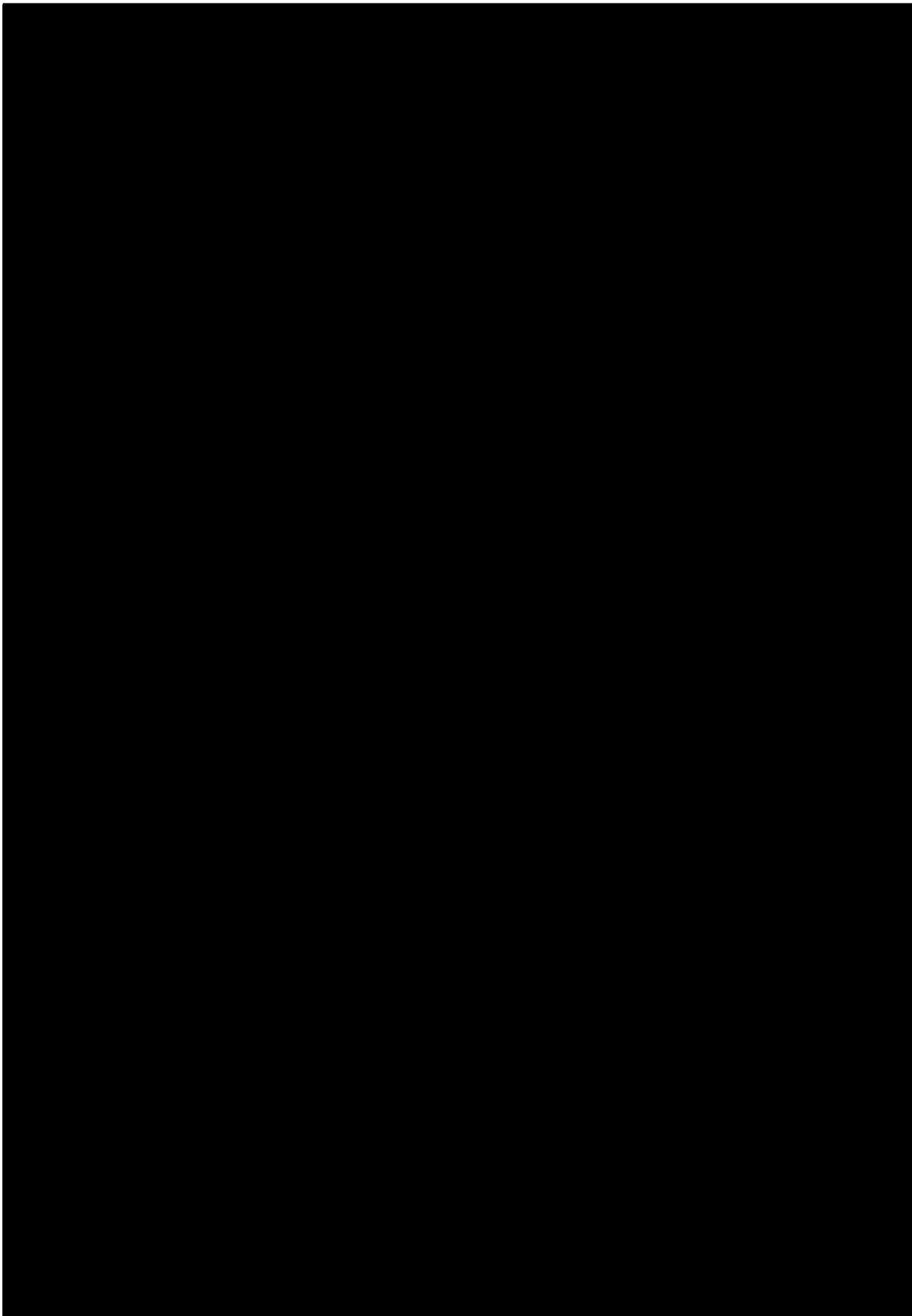




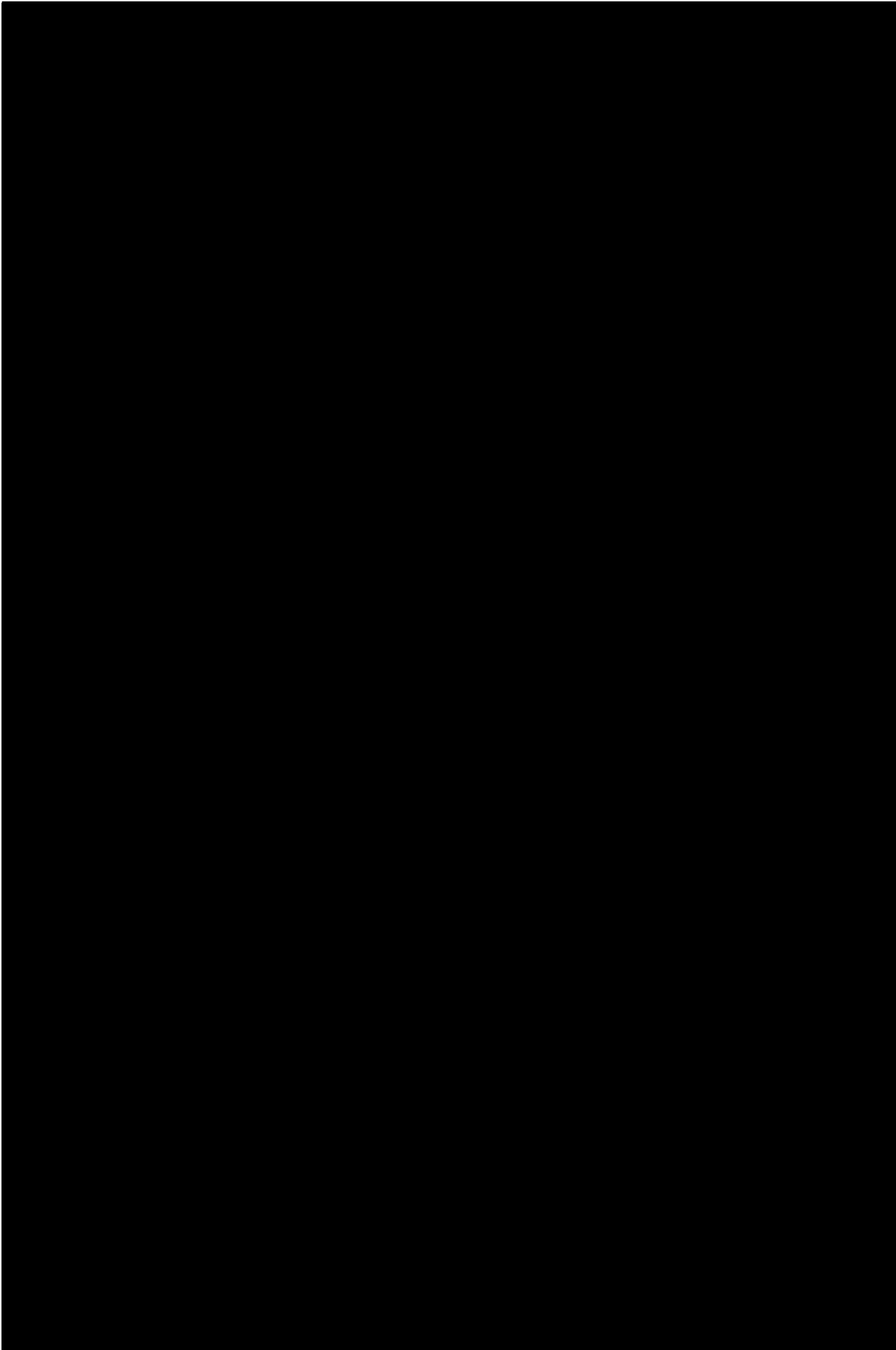


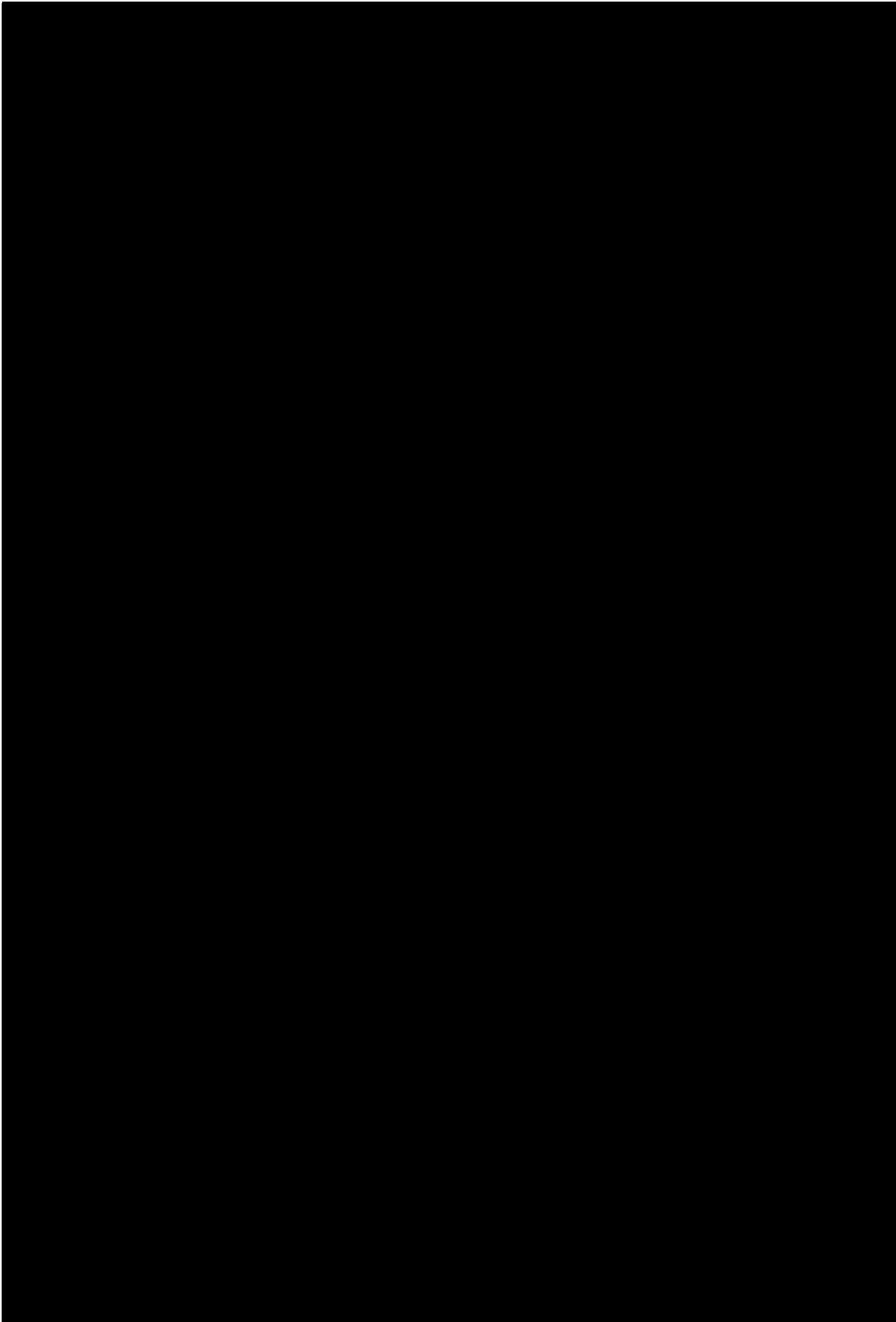


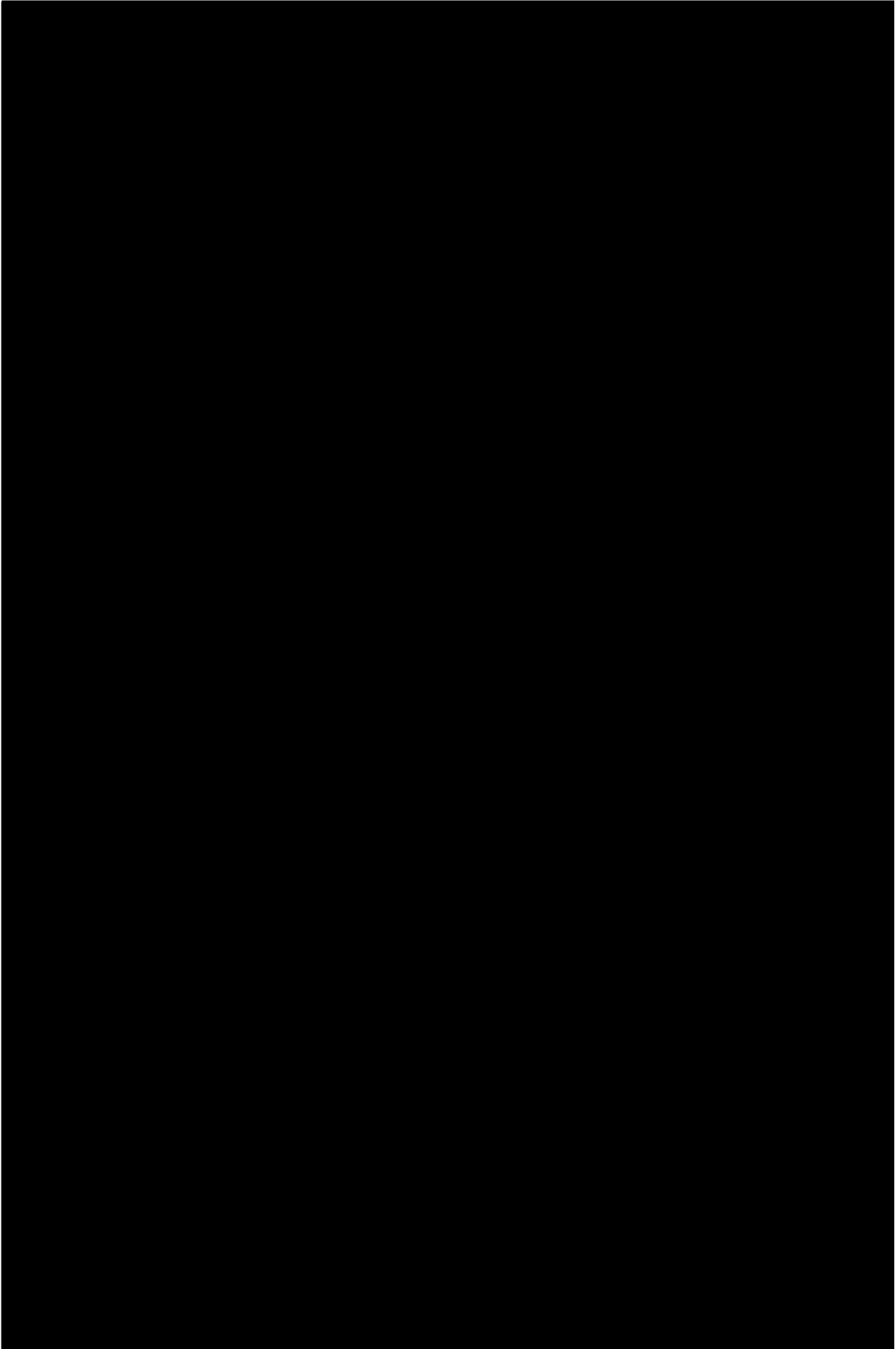


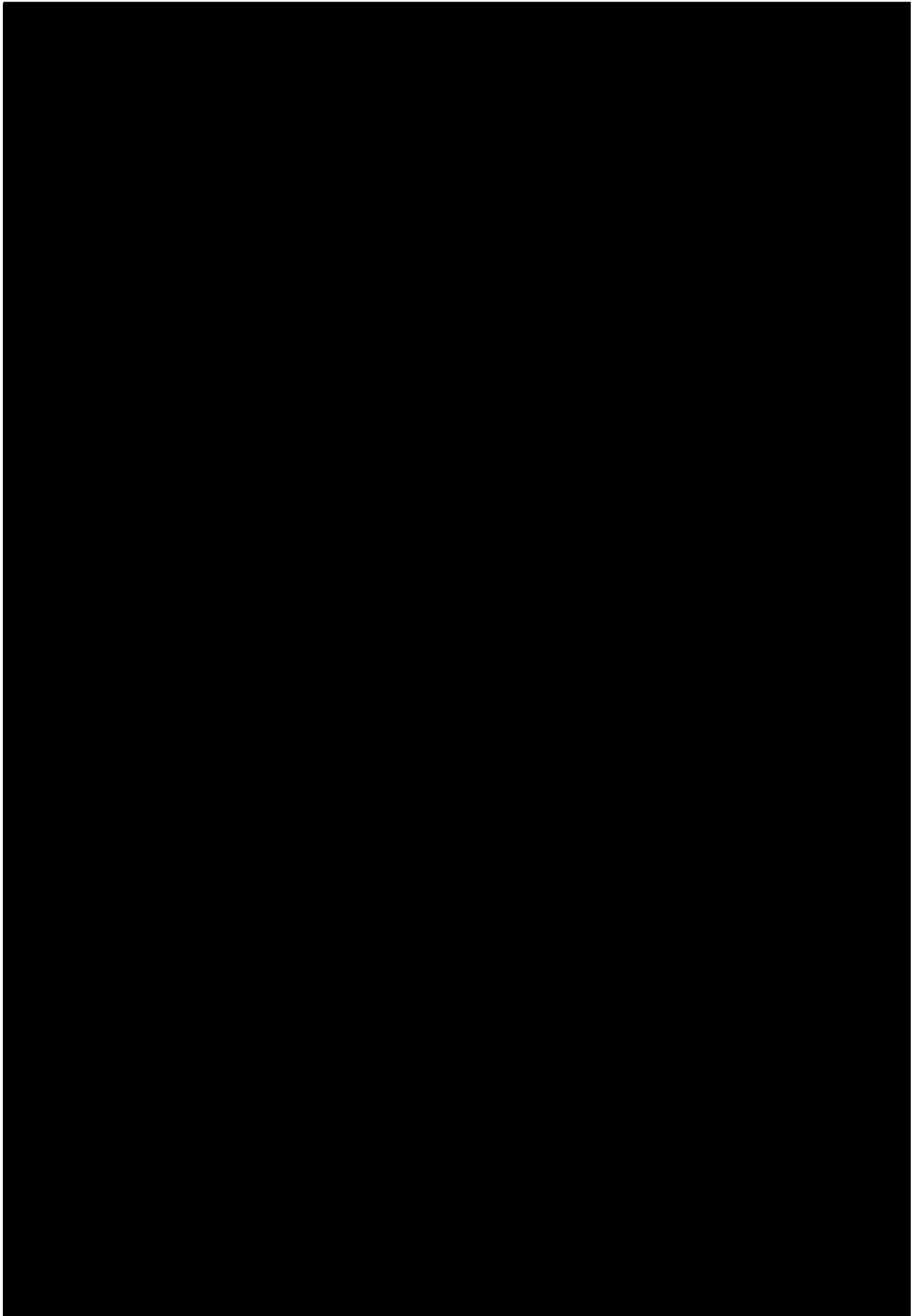


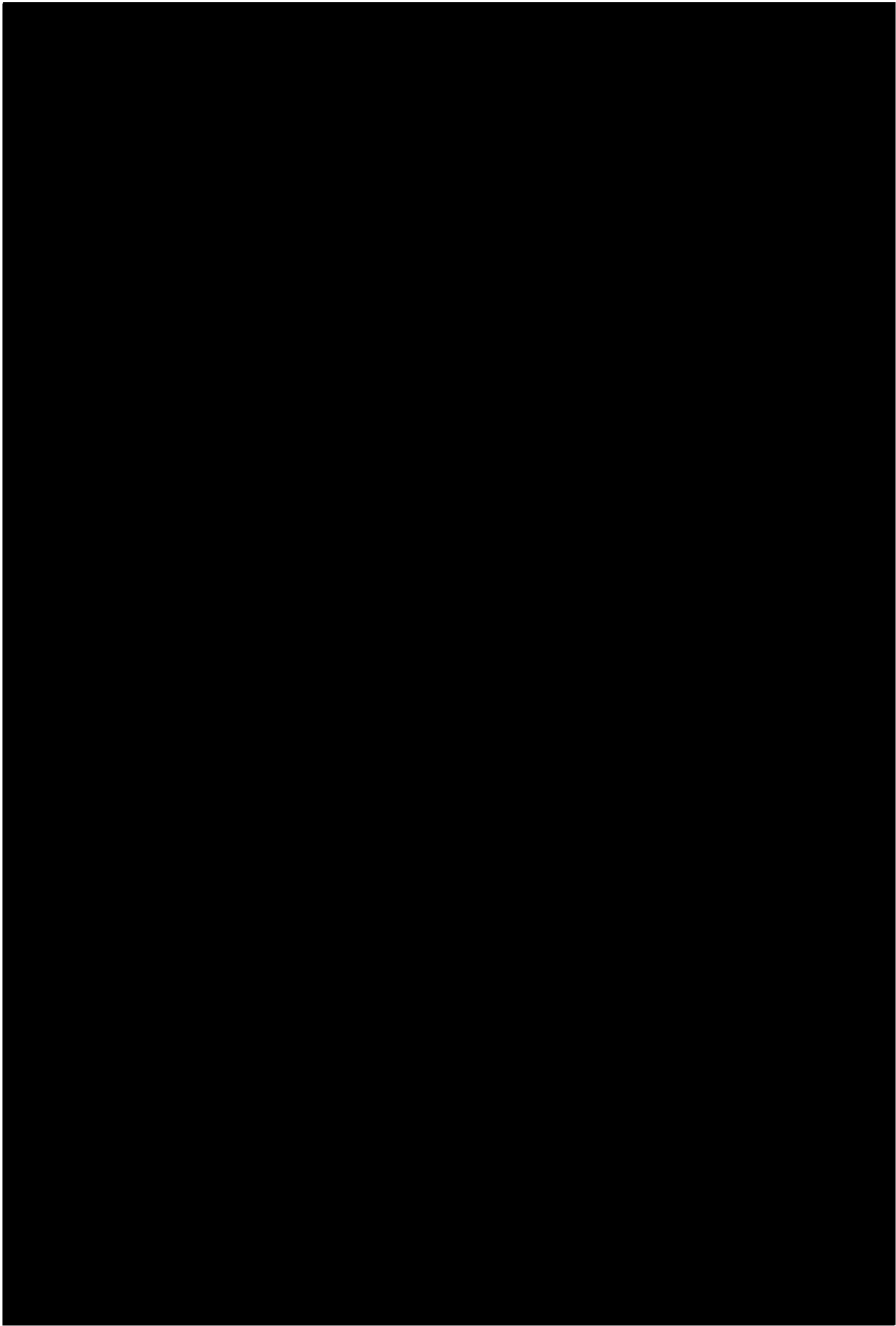


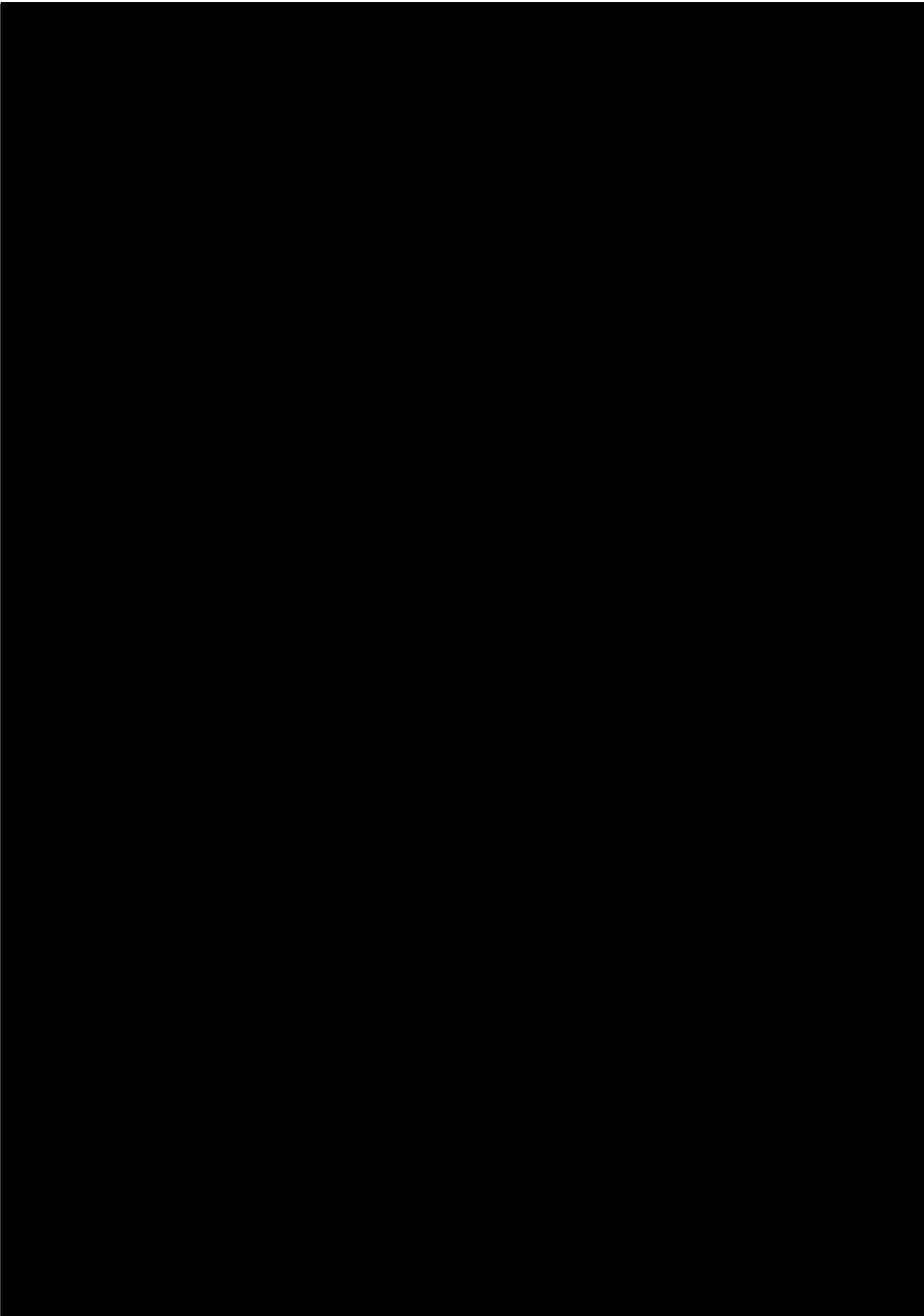


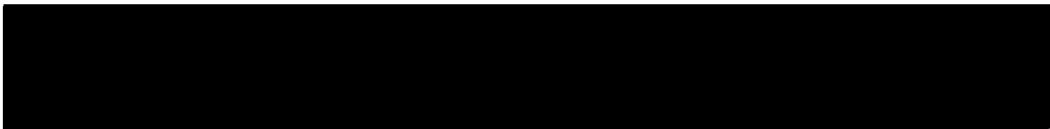
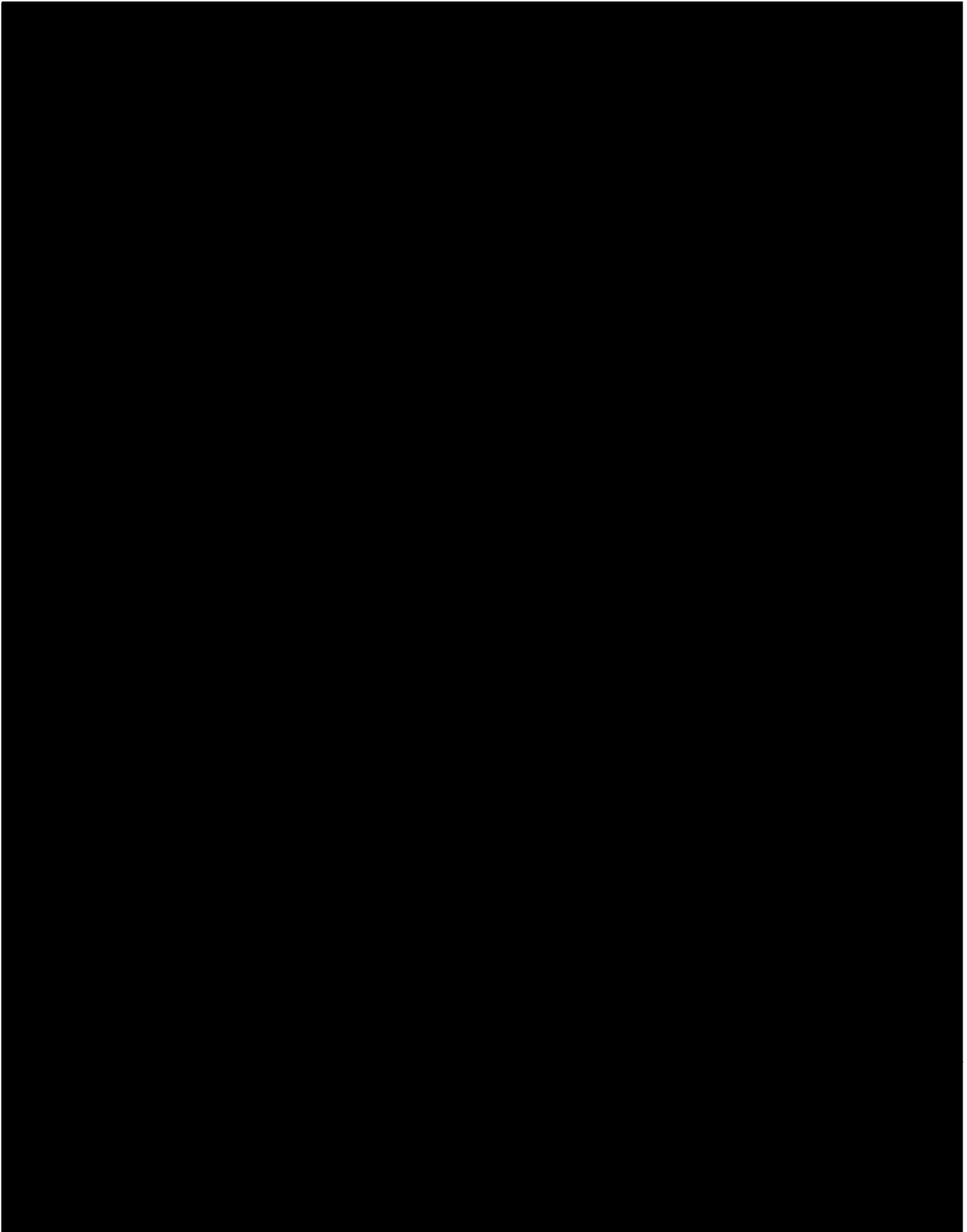


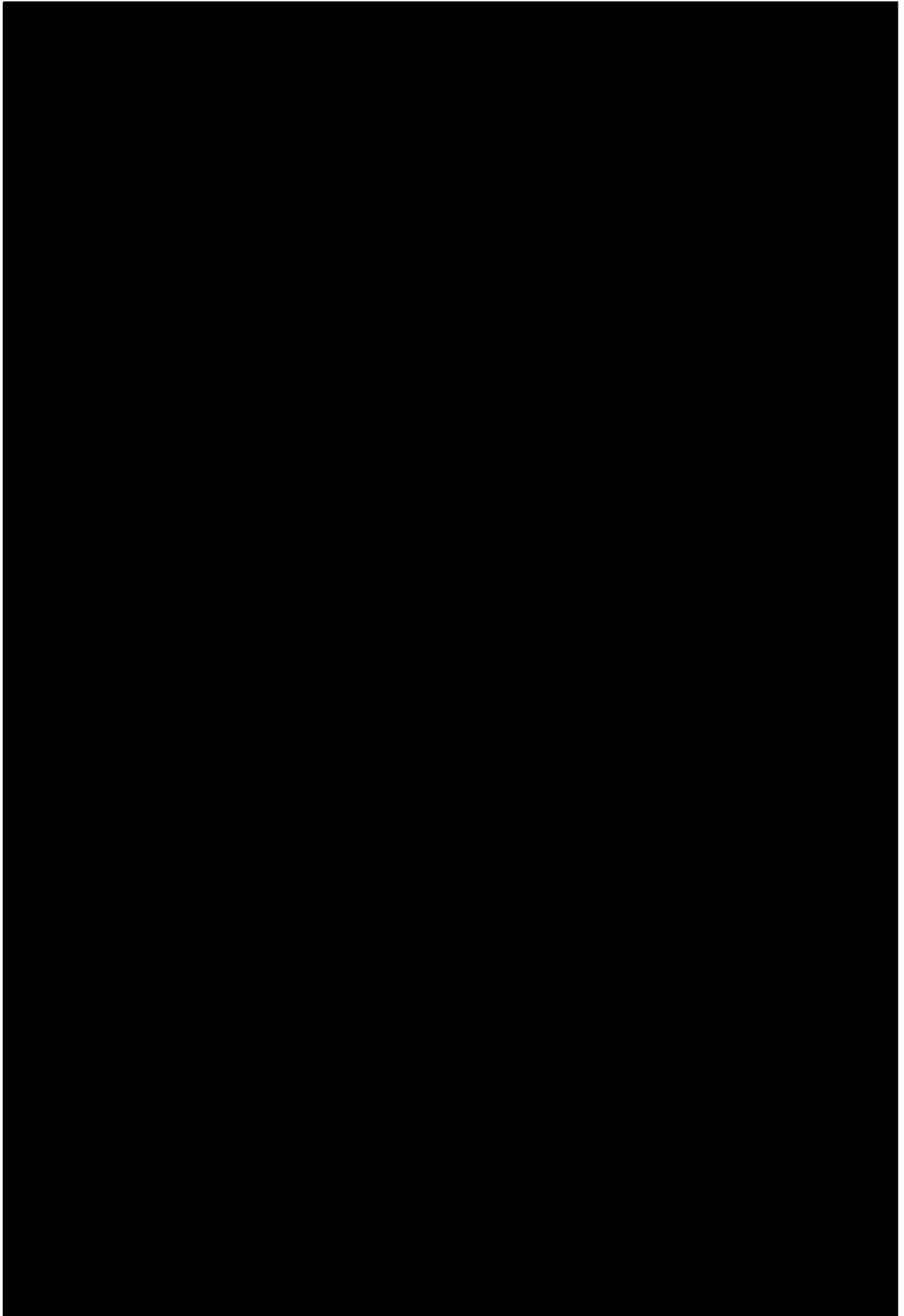




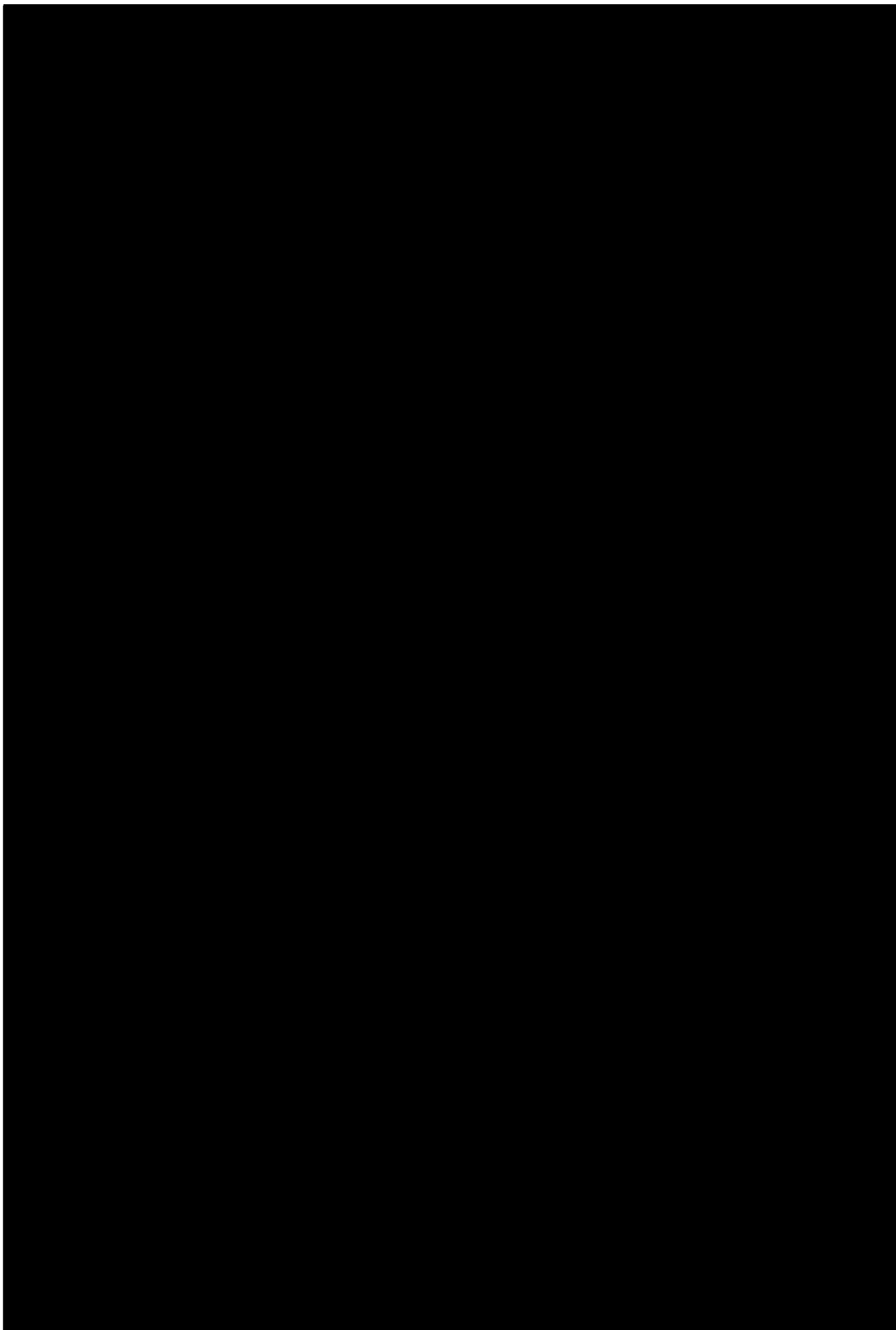


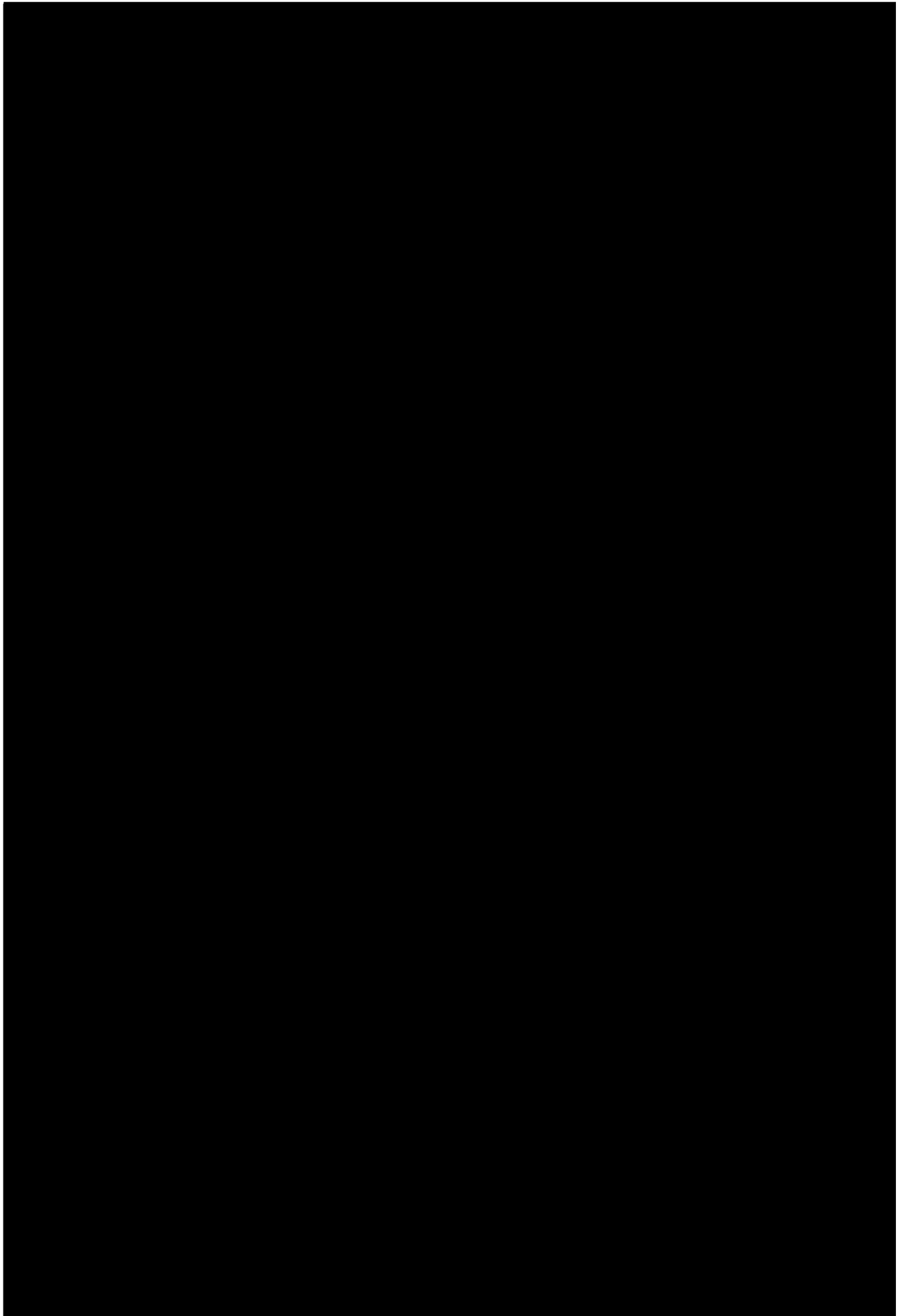


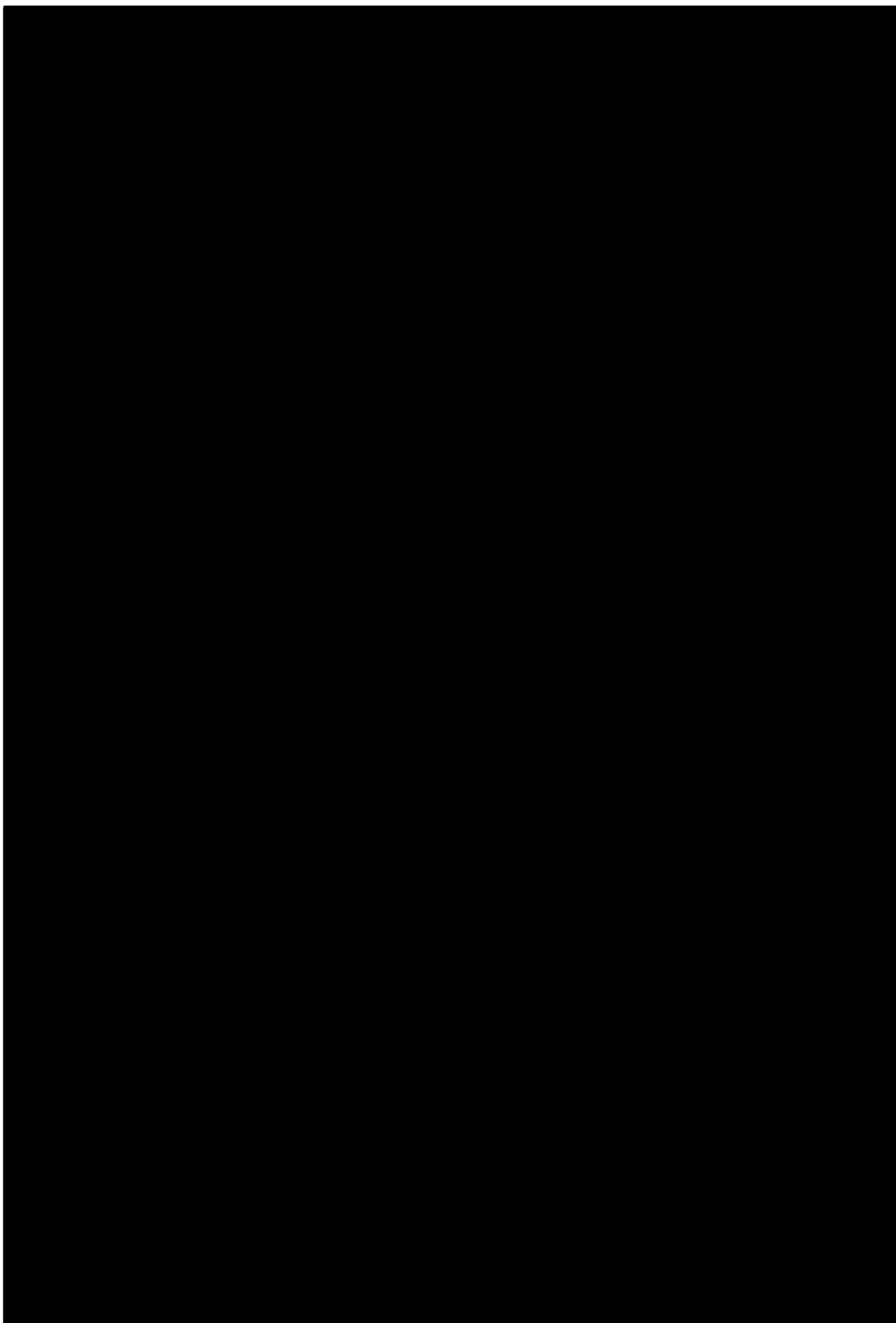












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Reference R12/1124046