



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

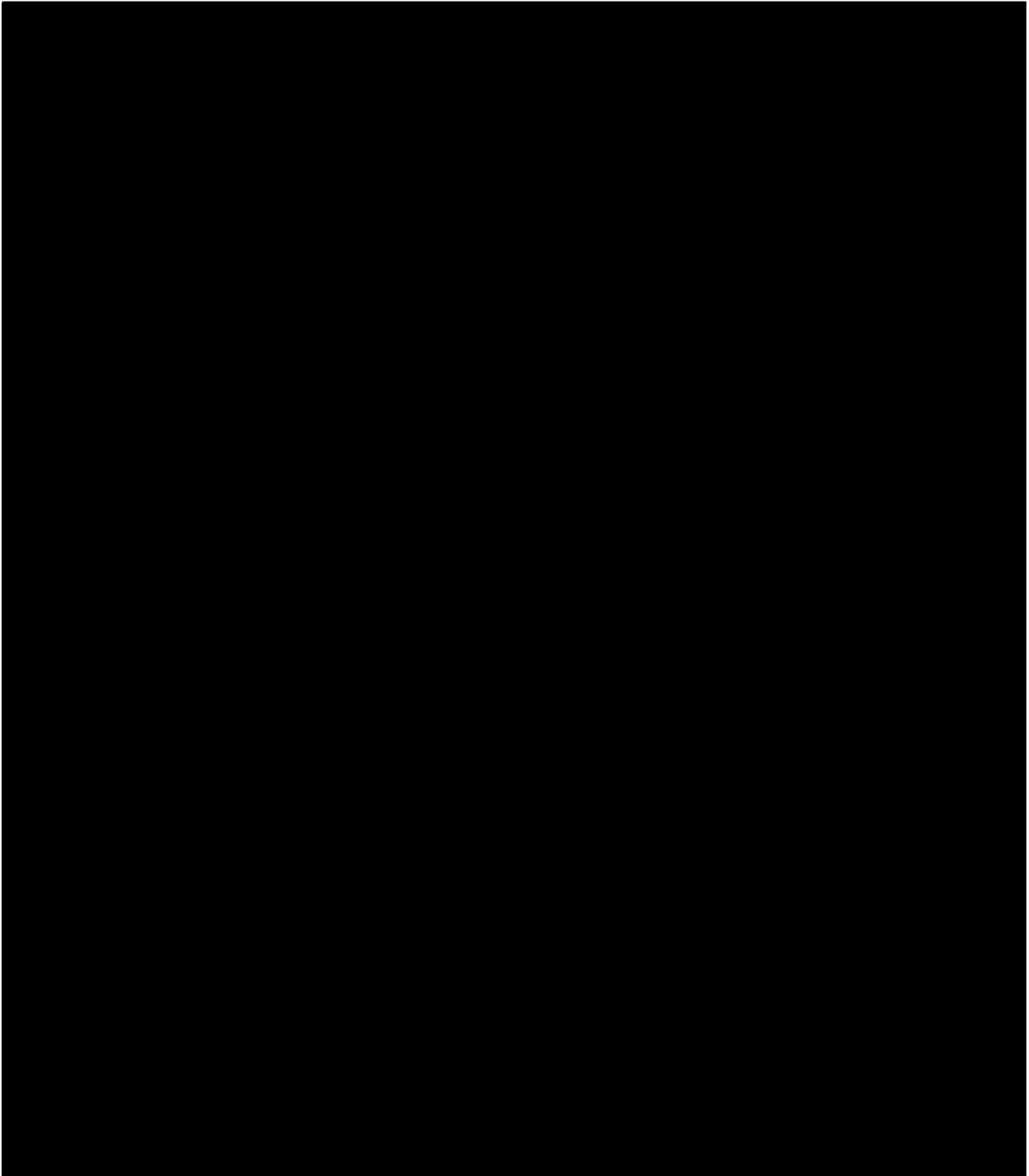
Advisory Committee on the Safety of Medicines

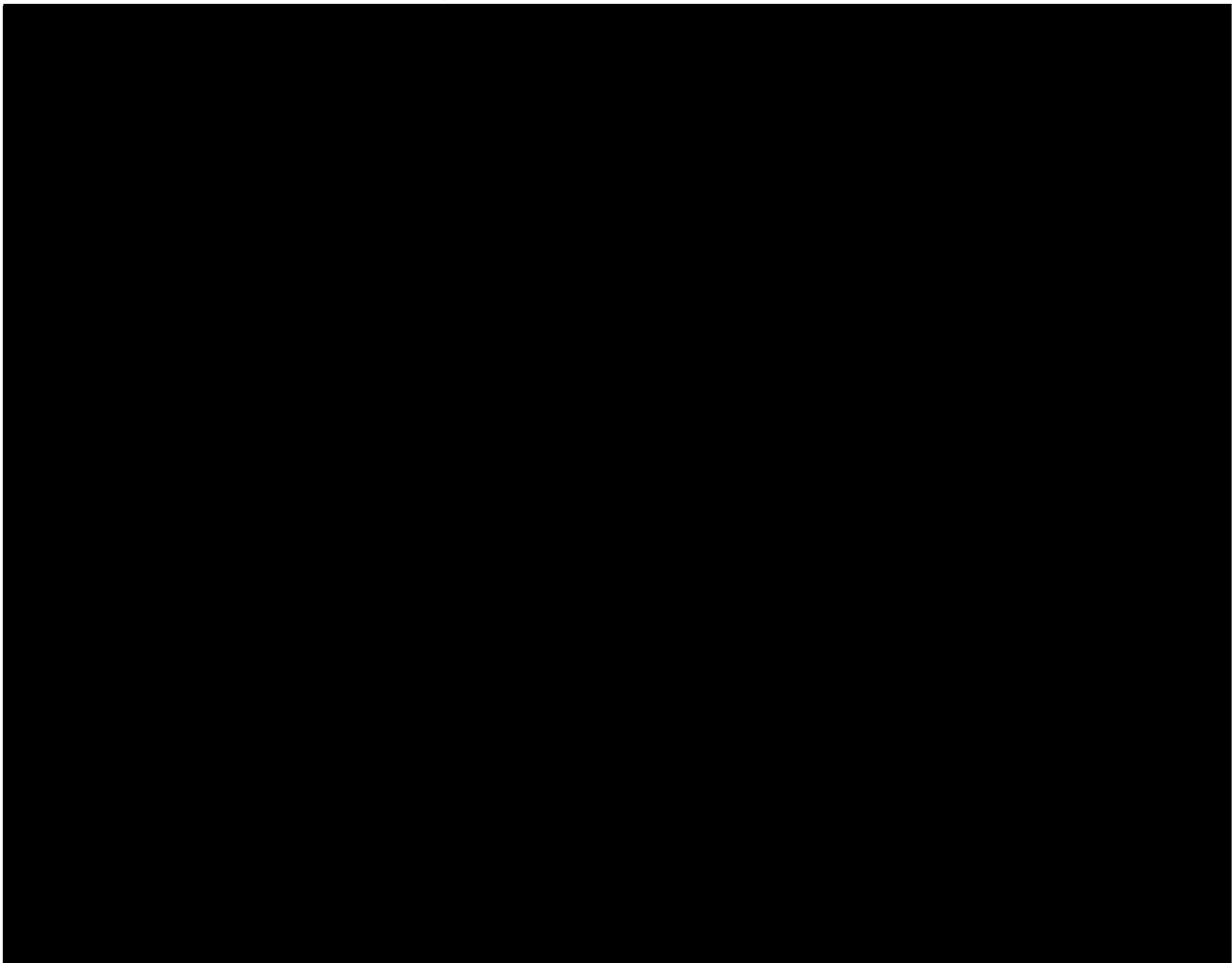
Minutes

13th Meeting - 27 July 2012

TGA Health Safety
Regulation

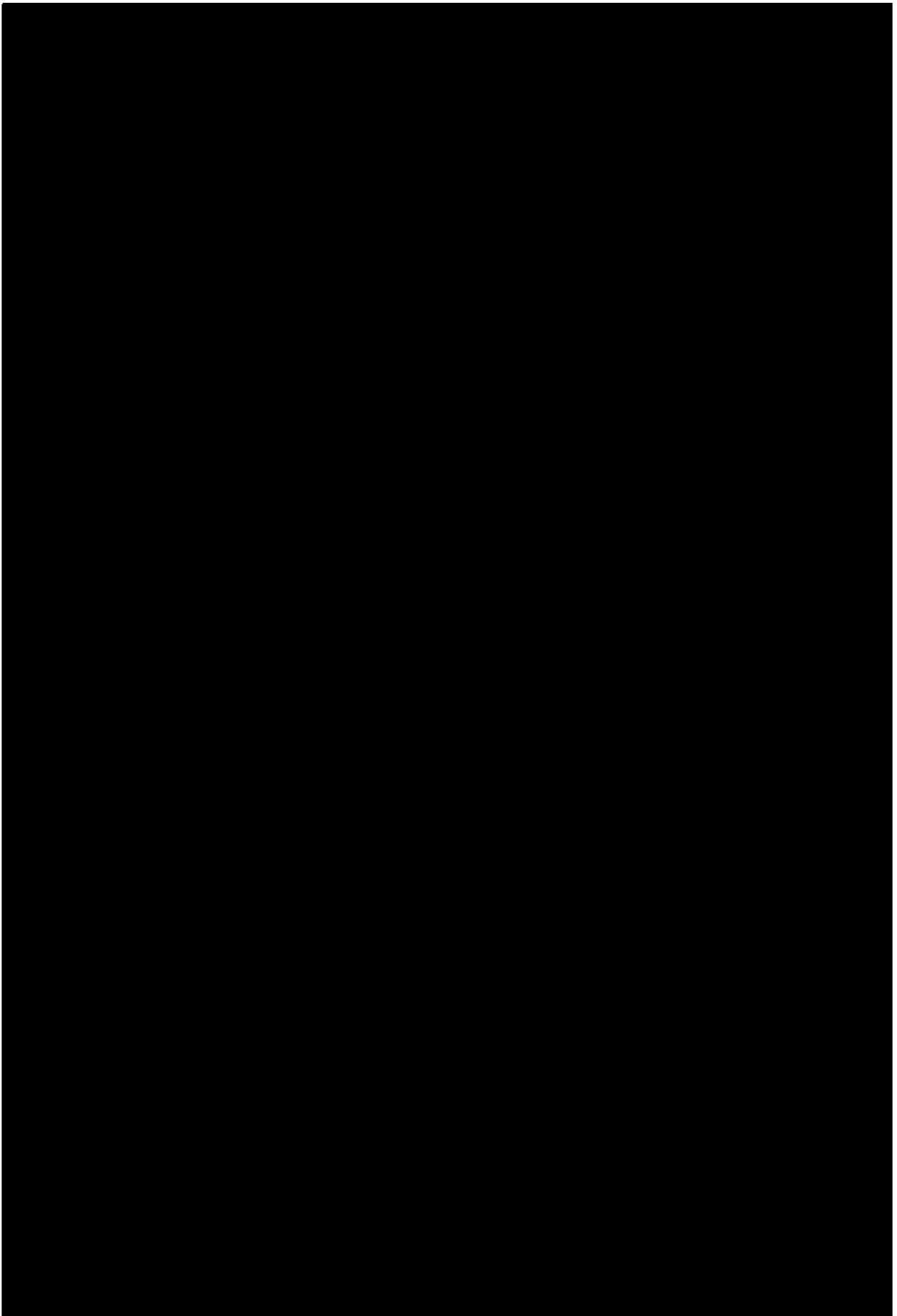
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TGA officers: Dr Jane Cook: Head, Office of Product Review
Dr Kaye Robertson: Medical Officer, Office of Product Review
Dr Richard Hill: Medical Officer, Office of Product Review
Dr Tony Gill: Acting Principal Medical Advisor, TGA Executive
Dr John McEwen: Medical Advisor, TGA Executive (Items 1, 2, 3.1 and 3.3)

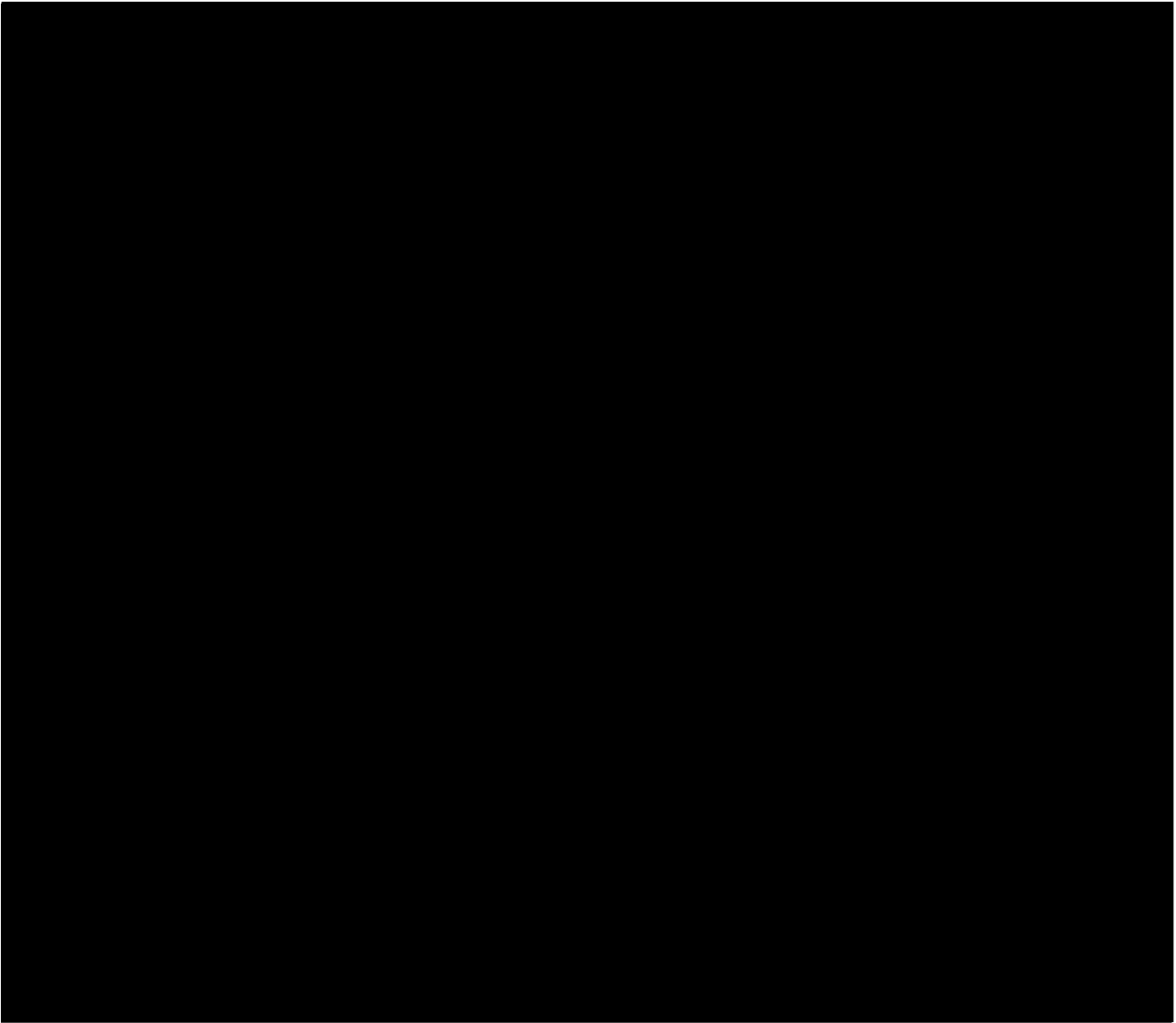
Secretariat: Dr Katherine Gray: Secretary (a/g), Office of Product Review
Mrs Kirsten Sharp: Minute Secretary, Committee Support Unit, Office of Parliamentary & Strategic Support

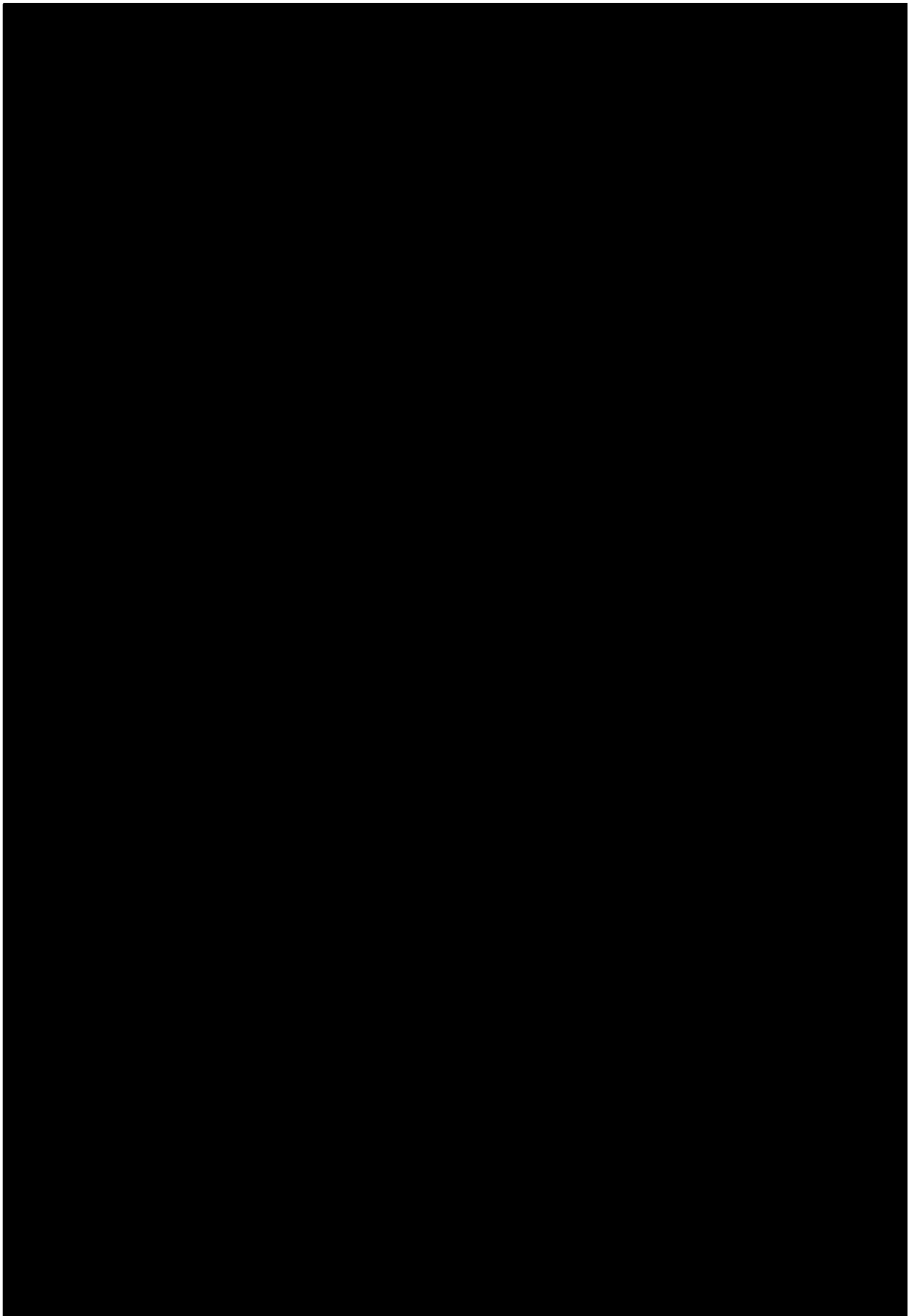


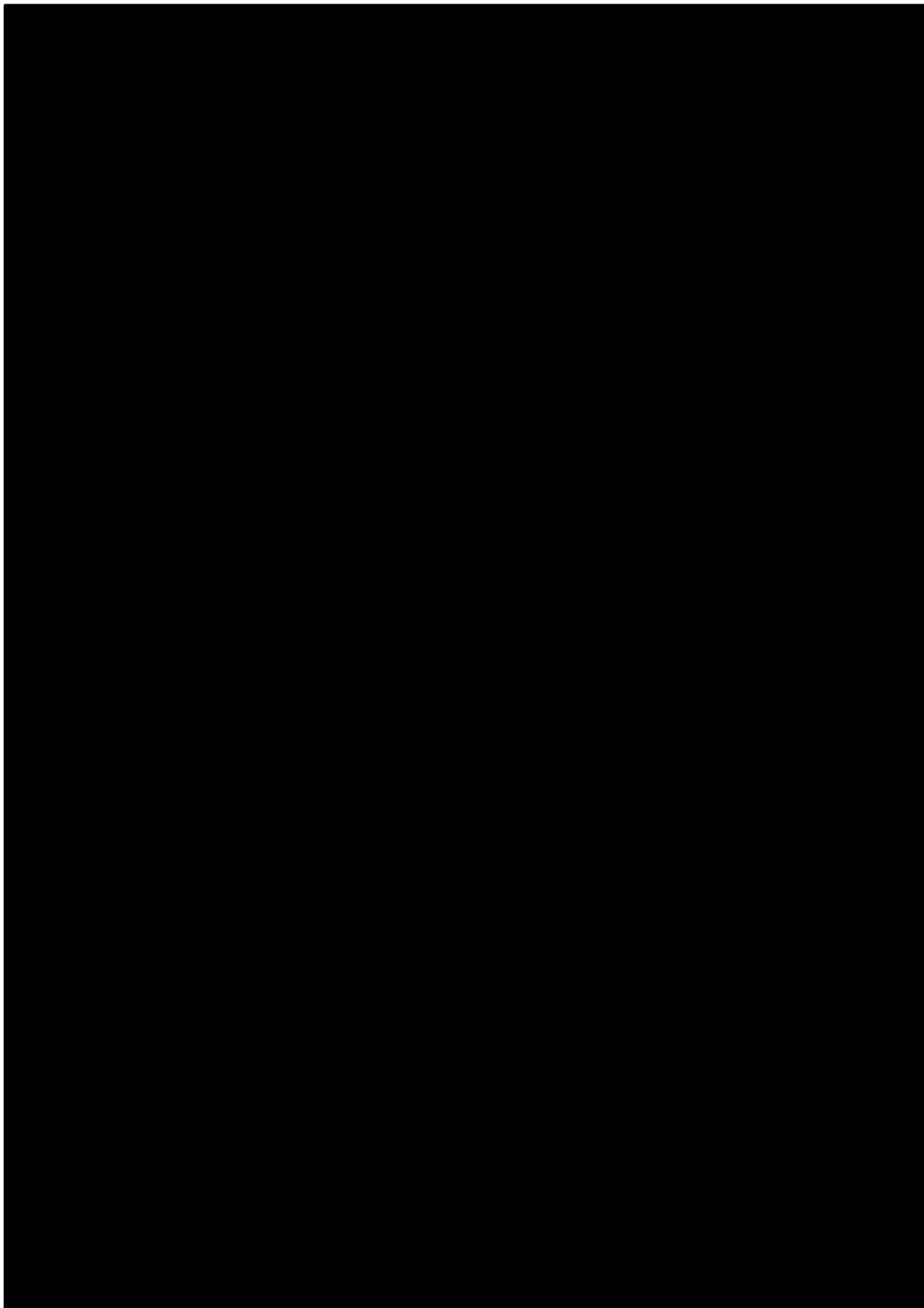
2.2 Action items

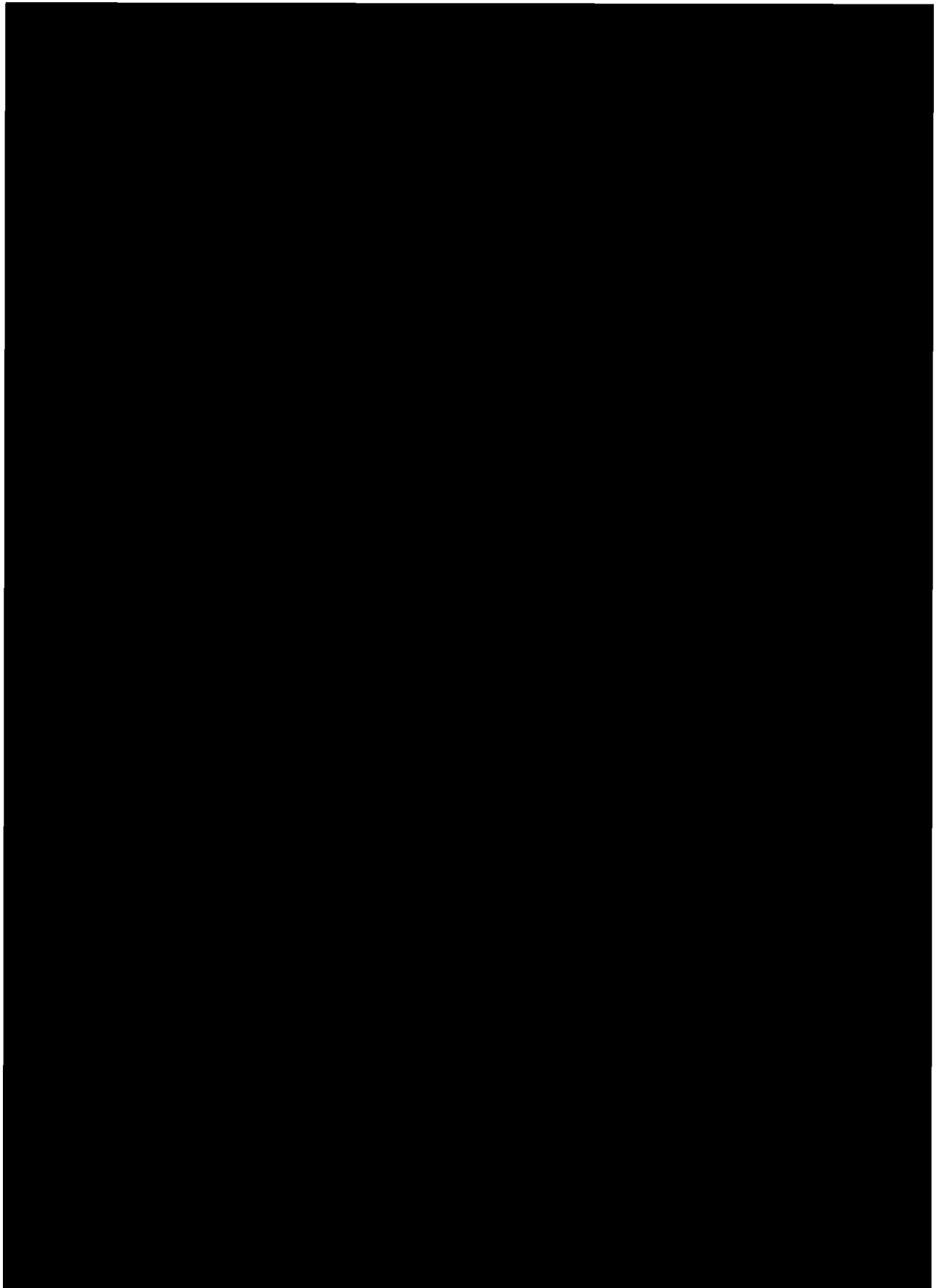
- Meeting 1, 5 March 2010, Item 6.3: *The report from the Psychiatric Drug Safety Expert Advisory Panel is to be discussed at a future meeting. TGA to inform ACSOM of the outcomes of the report and specify any advice required about the contents of the report.*
 - The Secretary advised members that this item was ongoing. Staff in OPR are currently finalising the outstanding actions, and a summary of all actions taken will be provided to ACSOM when final.

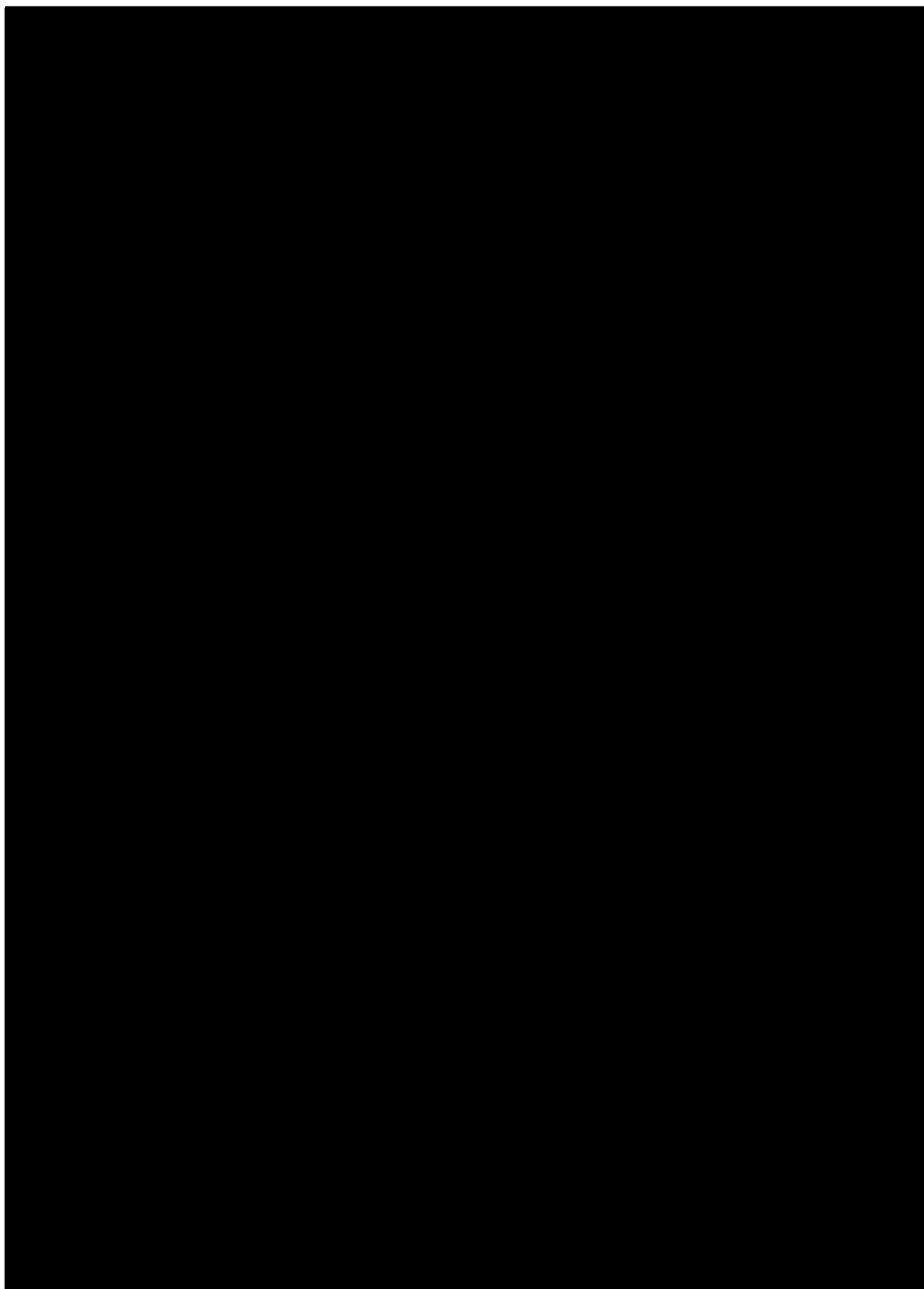
Members stated that there was evidence to suggest that increasing numbers of patients were being prescribed psychiatric drugs such as quetiapine (including off-label) without the appropriate discussions about serious metabolic side effects including weight gain; and without appropriate management of these side effects. Members were concerned that existing guidelines were not being translated into practice. It was noted that a group of experts had been established to discuss these issues. An ACSOM member who was a member of this group advised that he would consult with the group and report back to ACSOM.

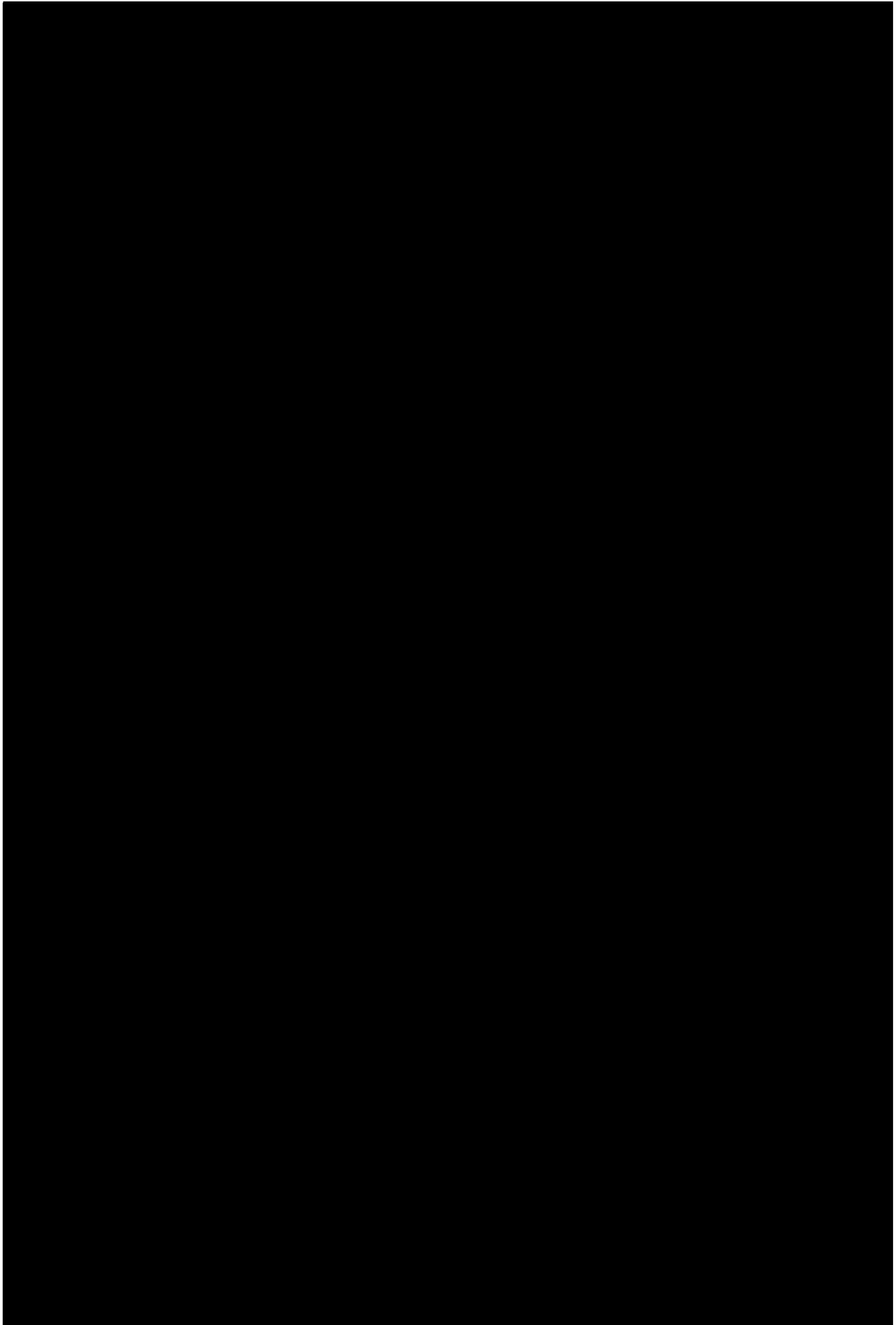


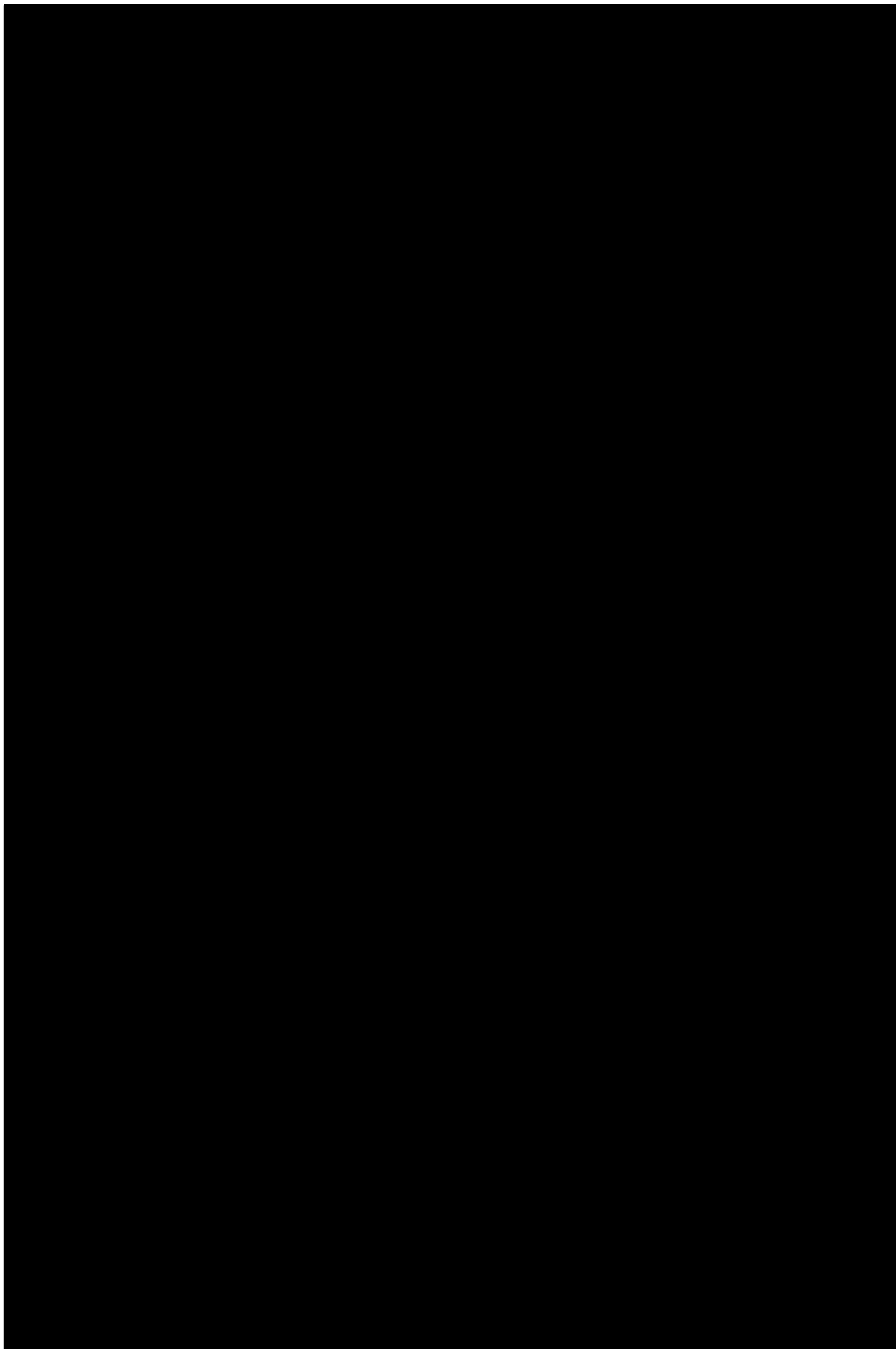


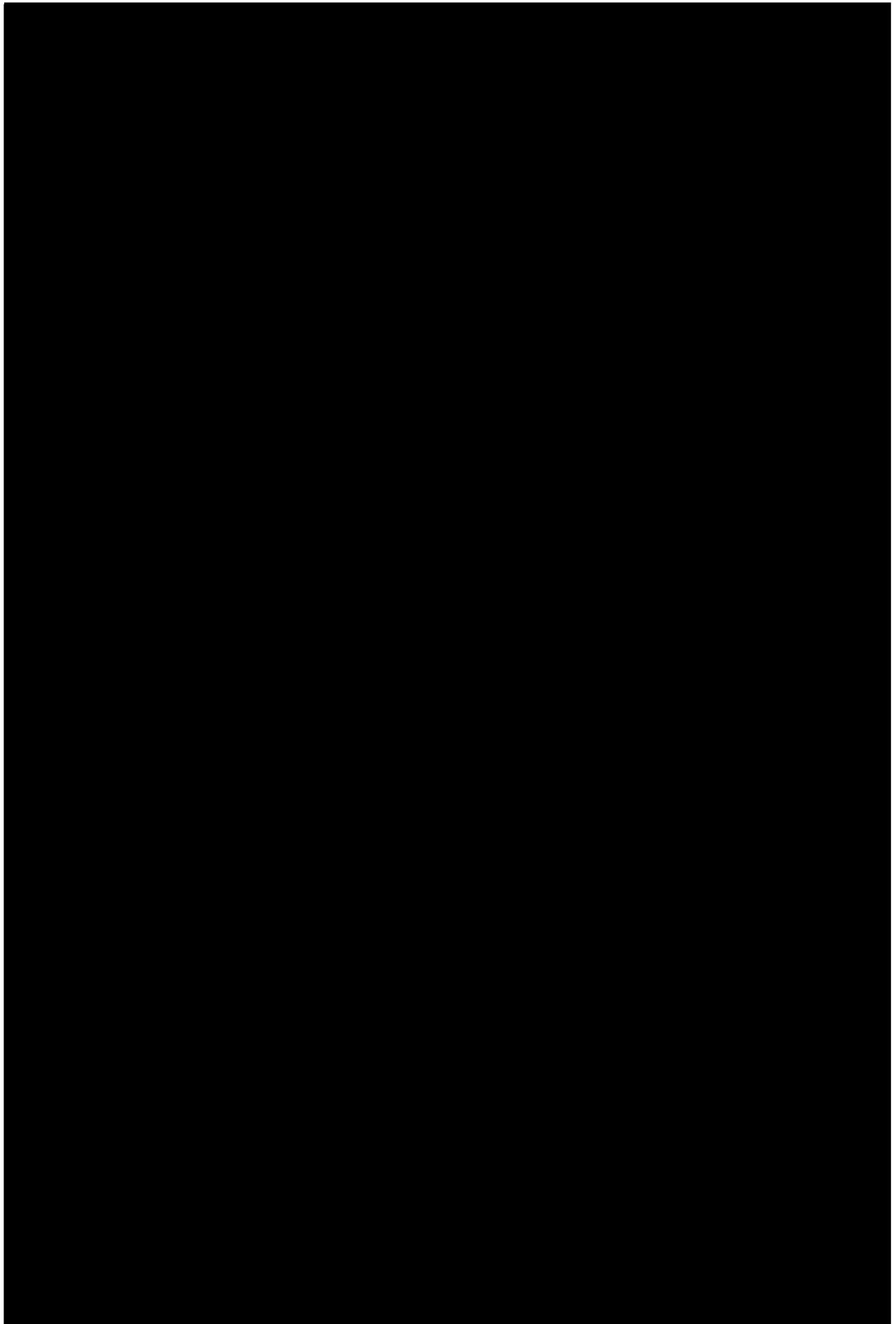


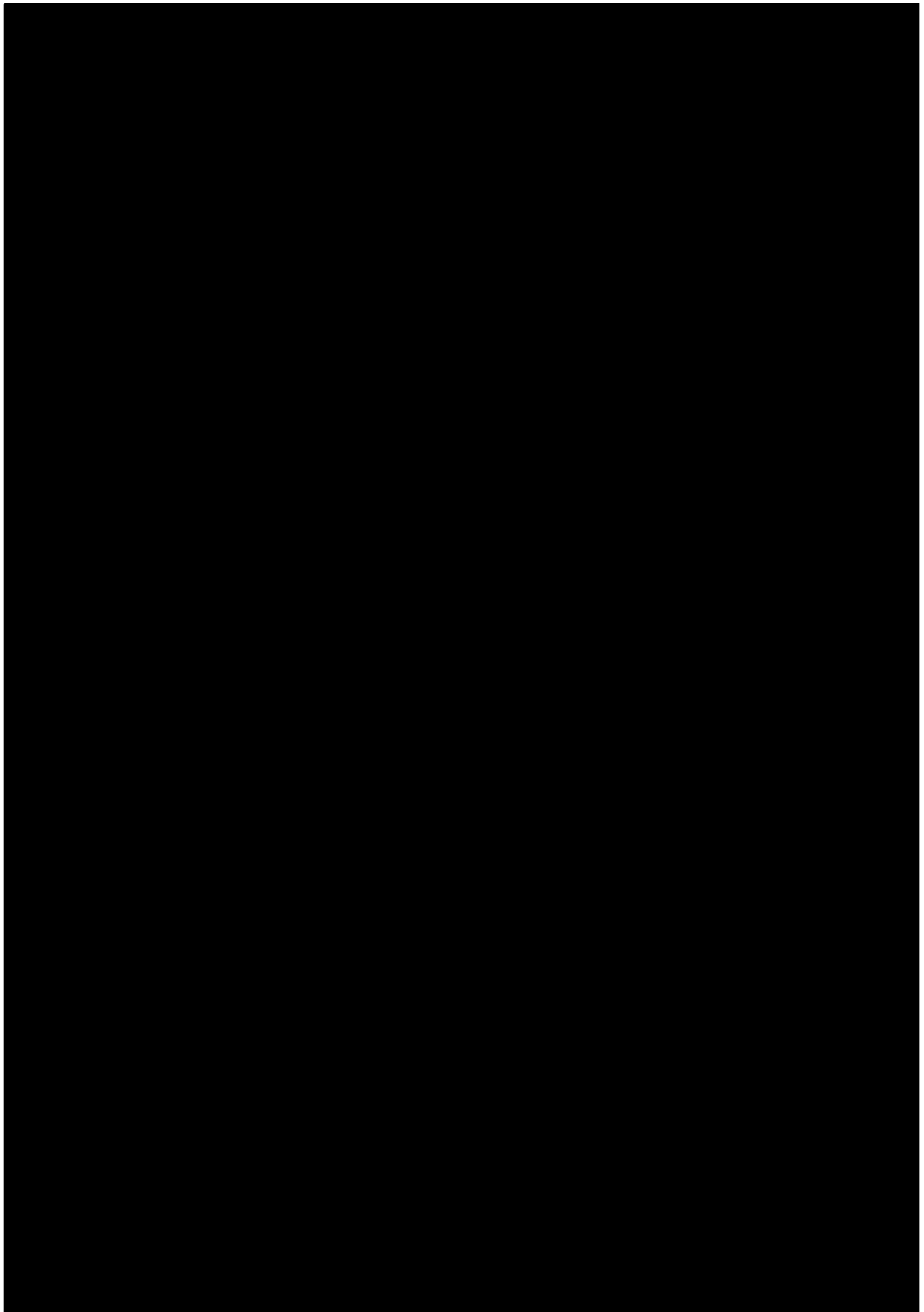


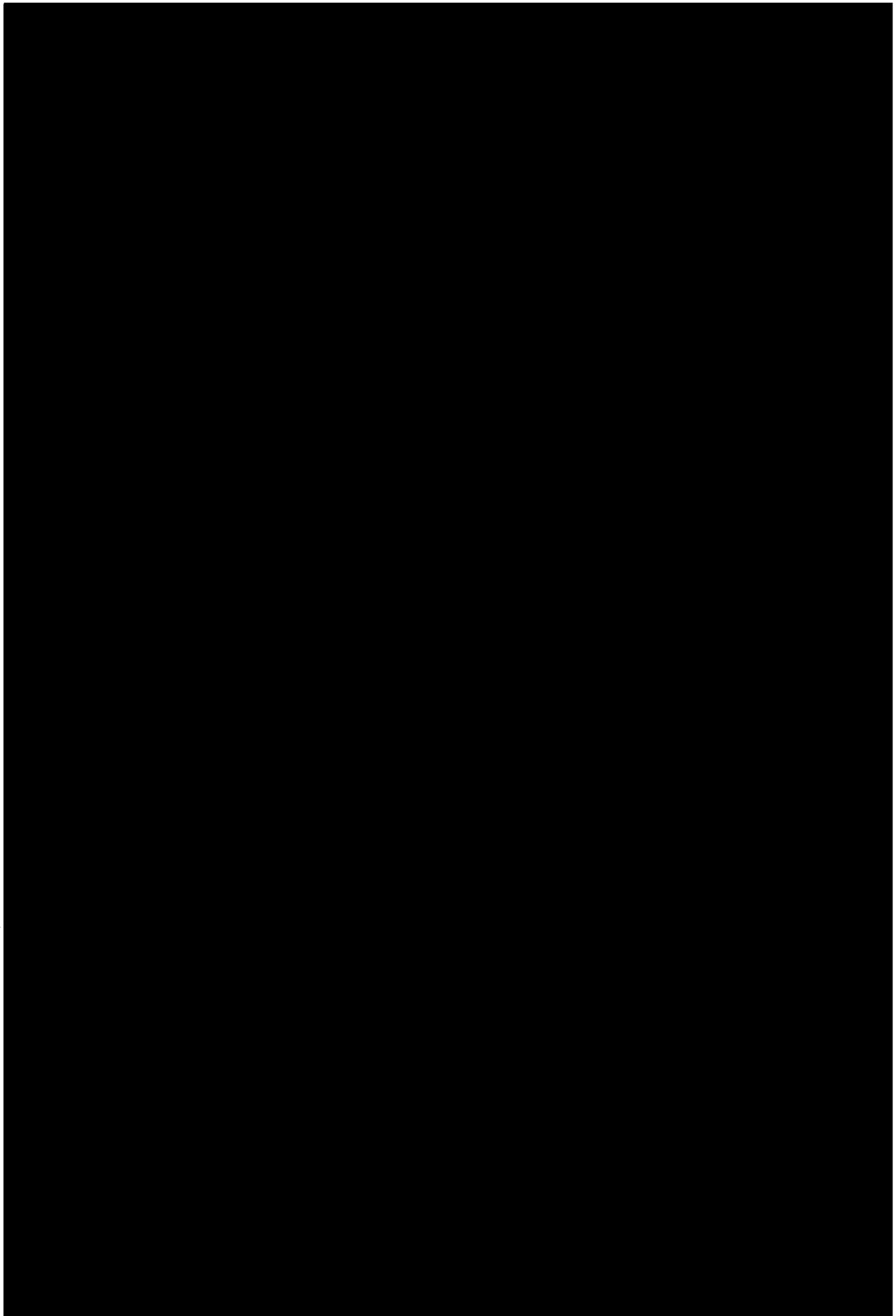


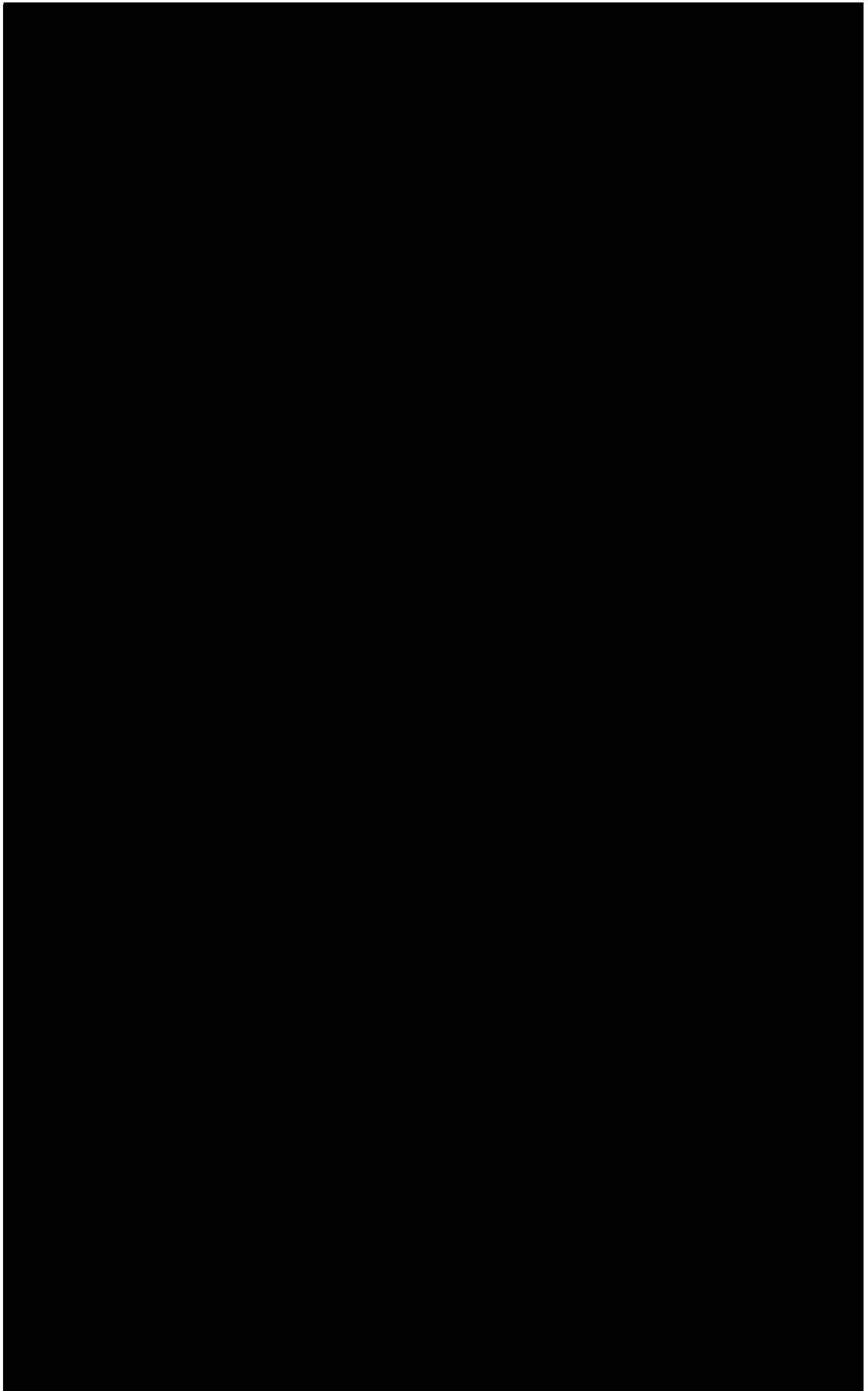


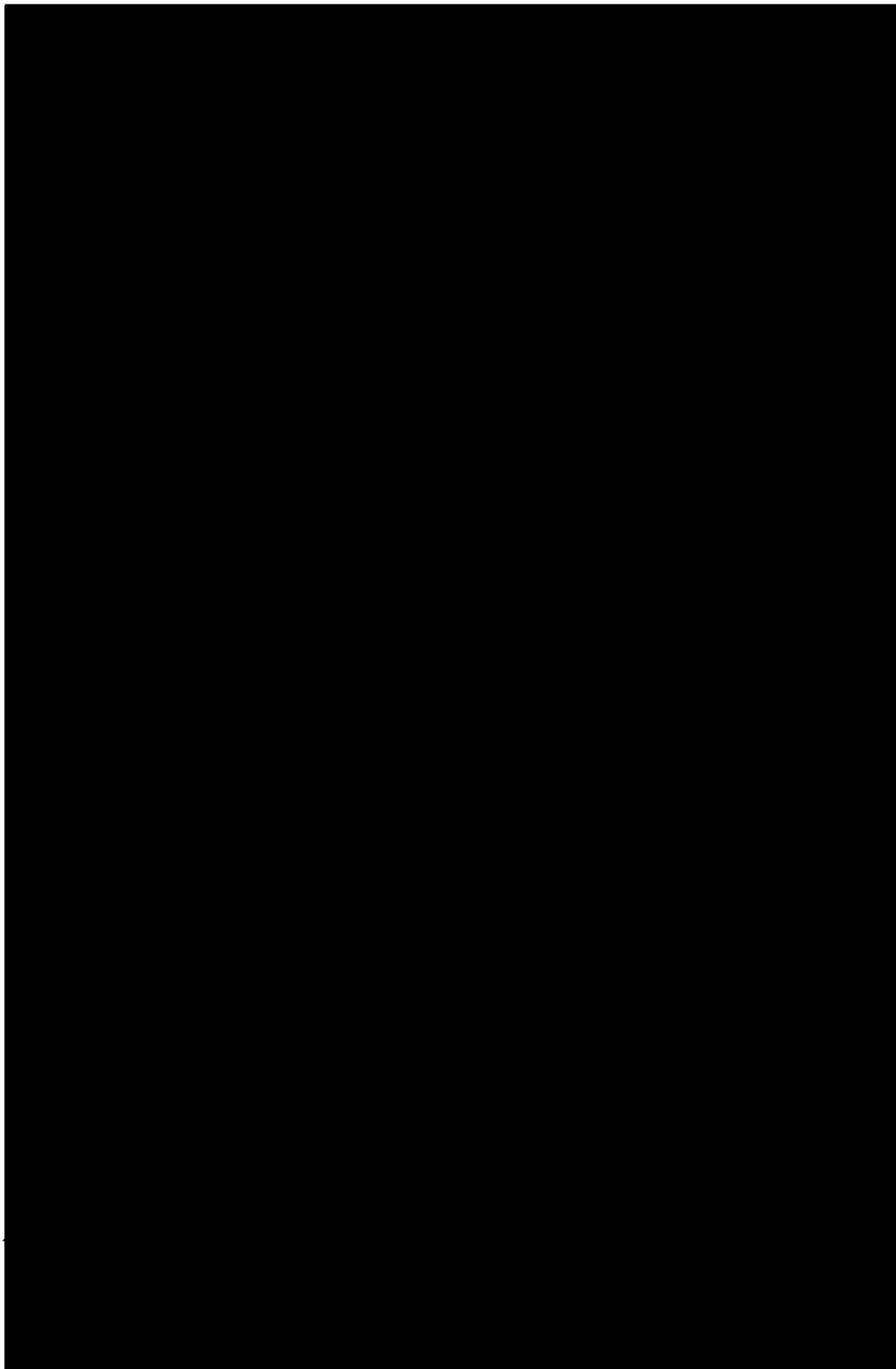


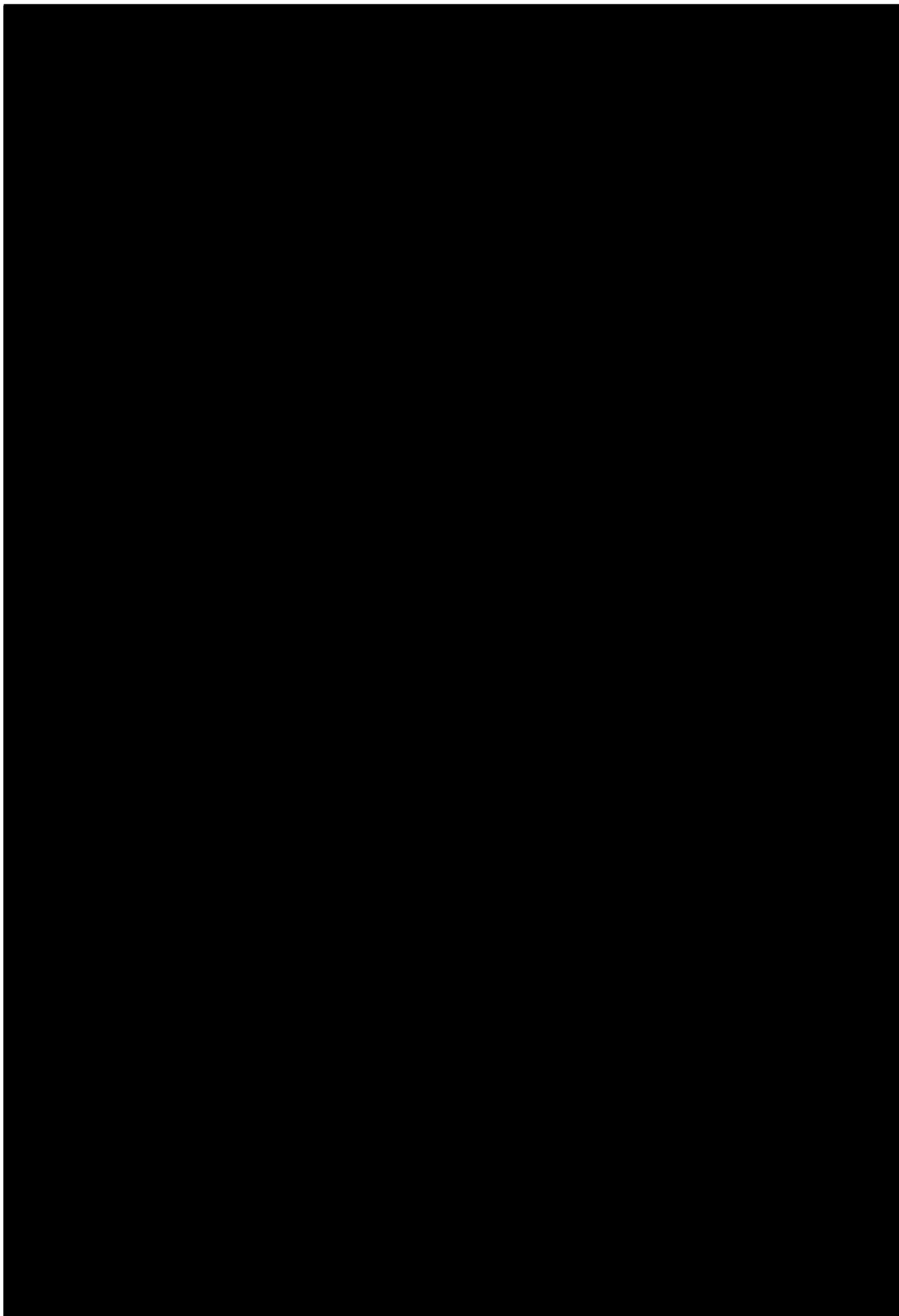


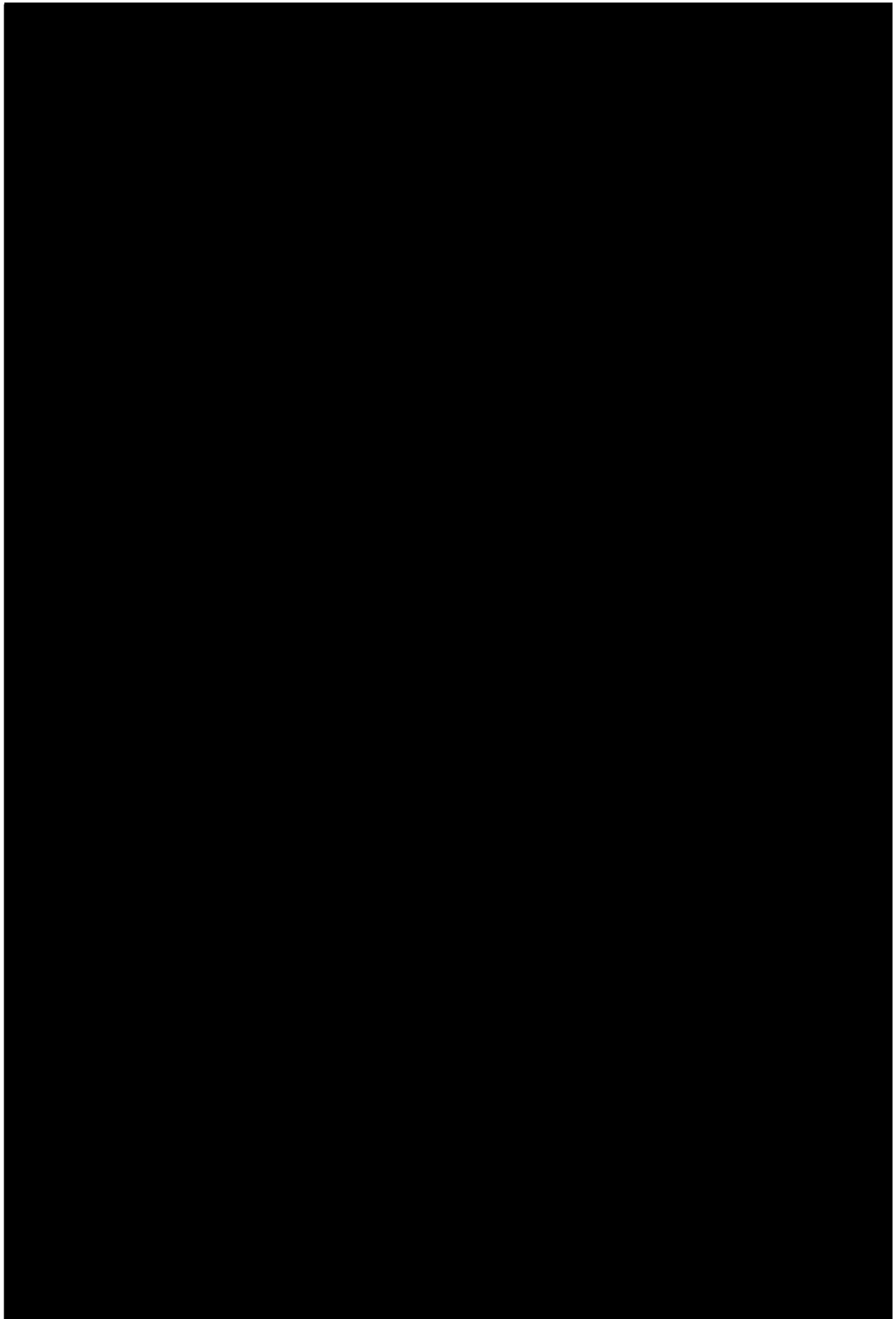


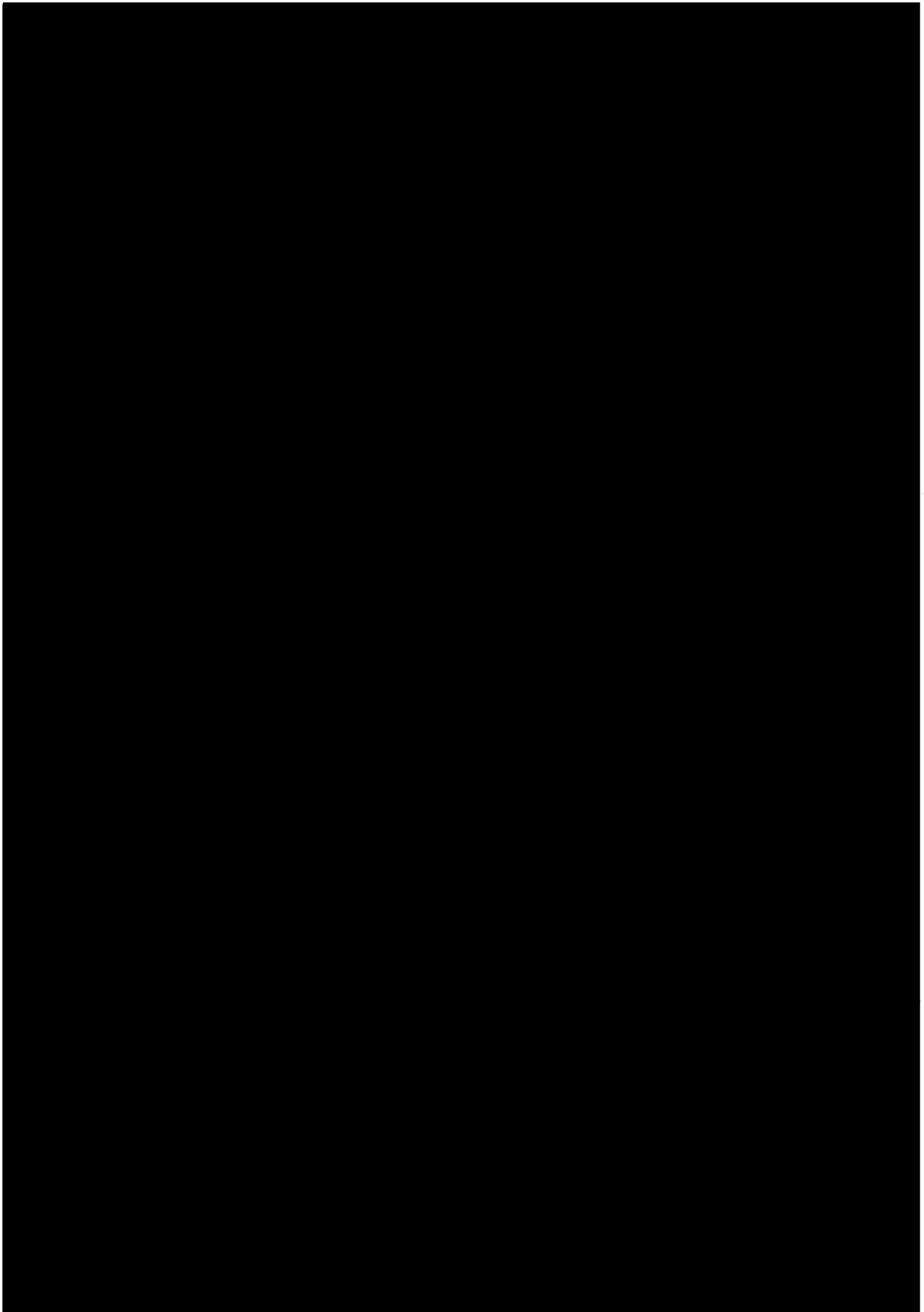


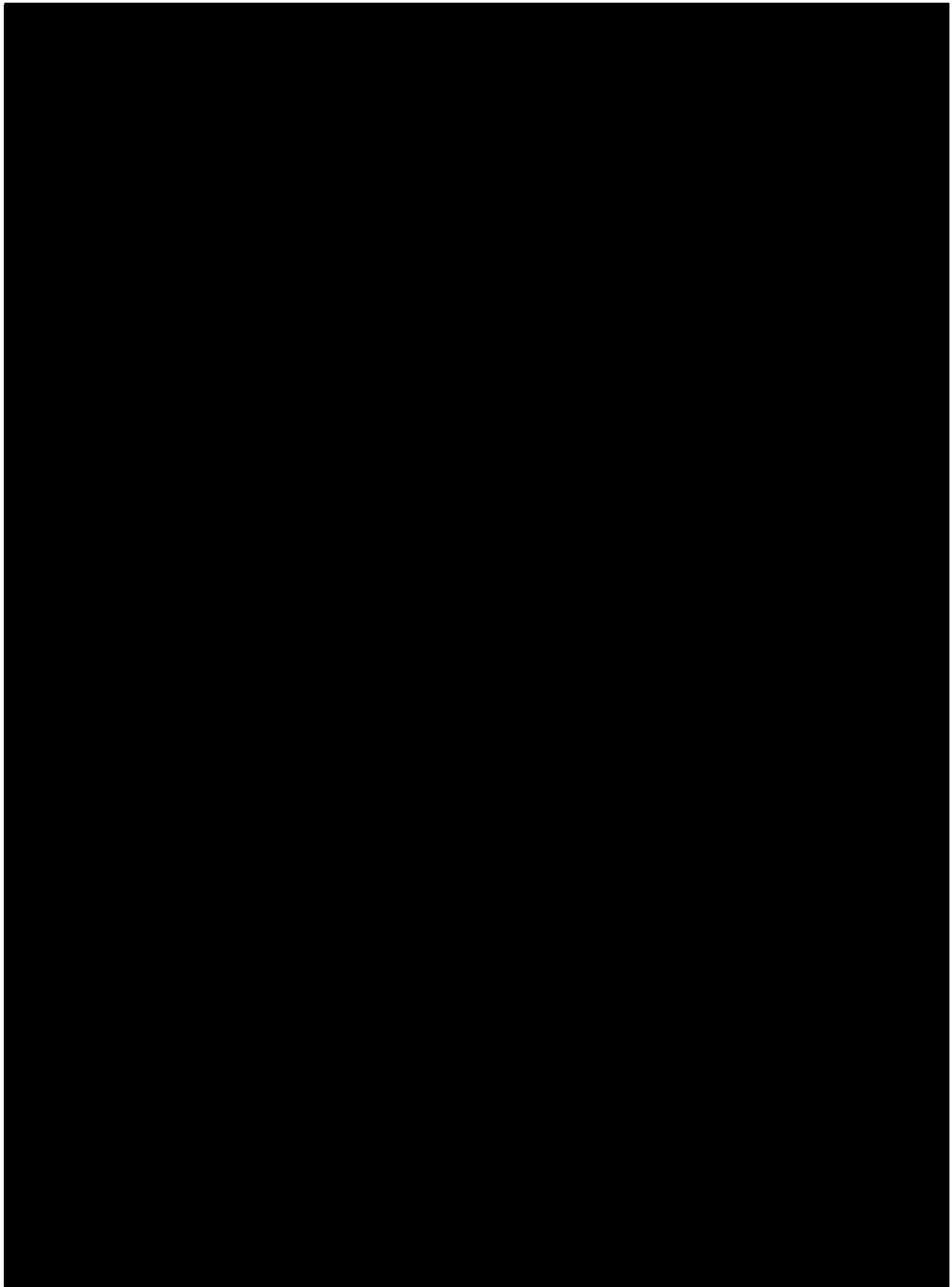




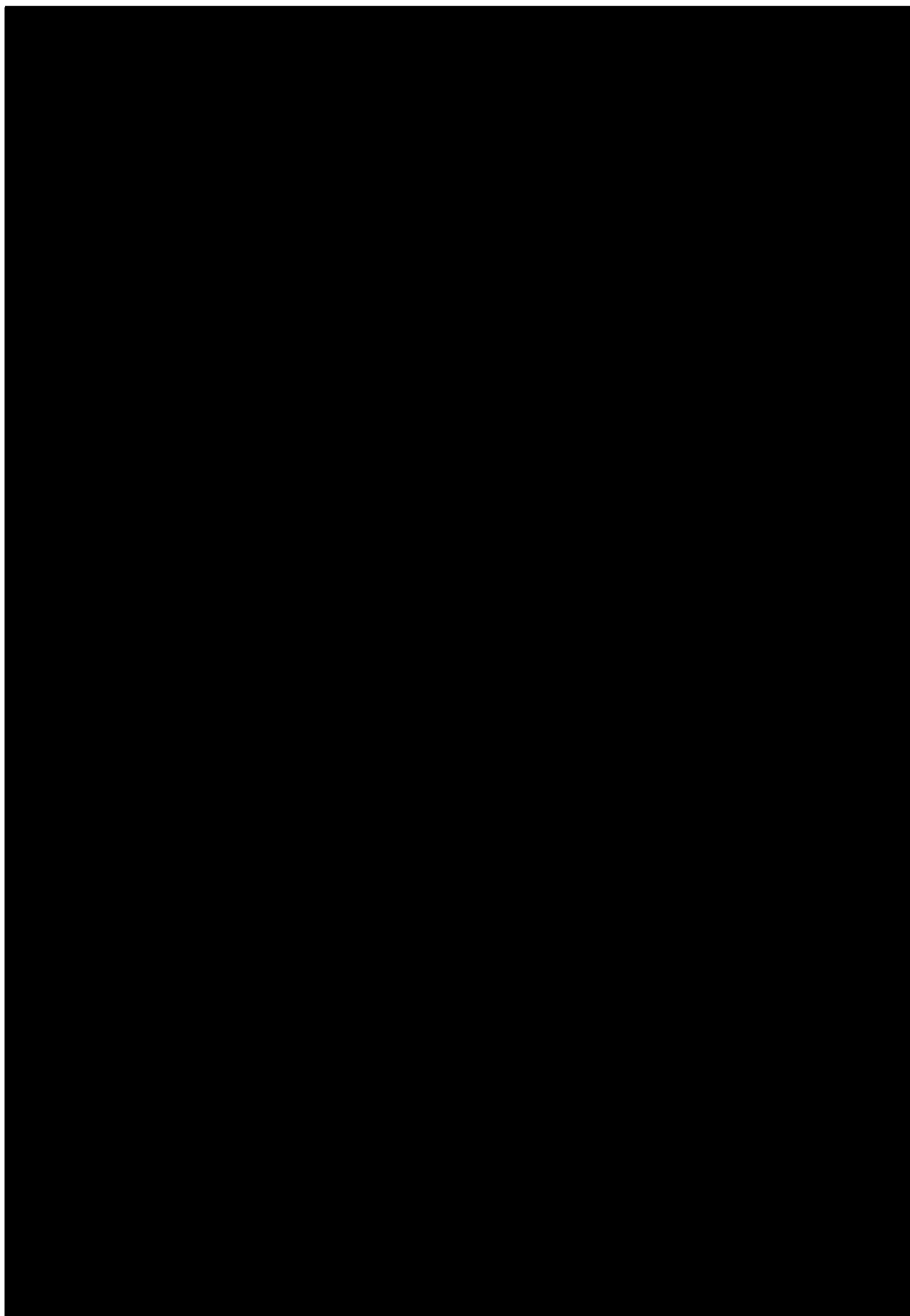


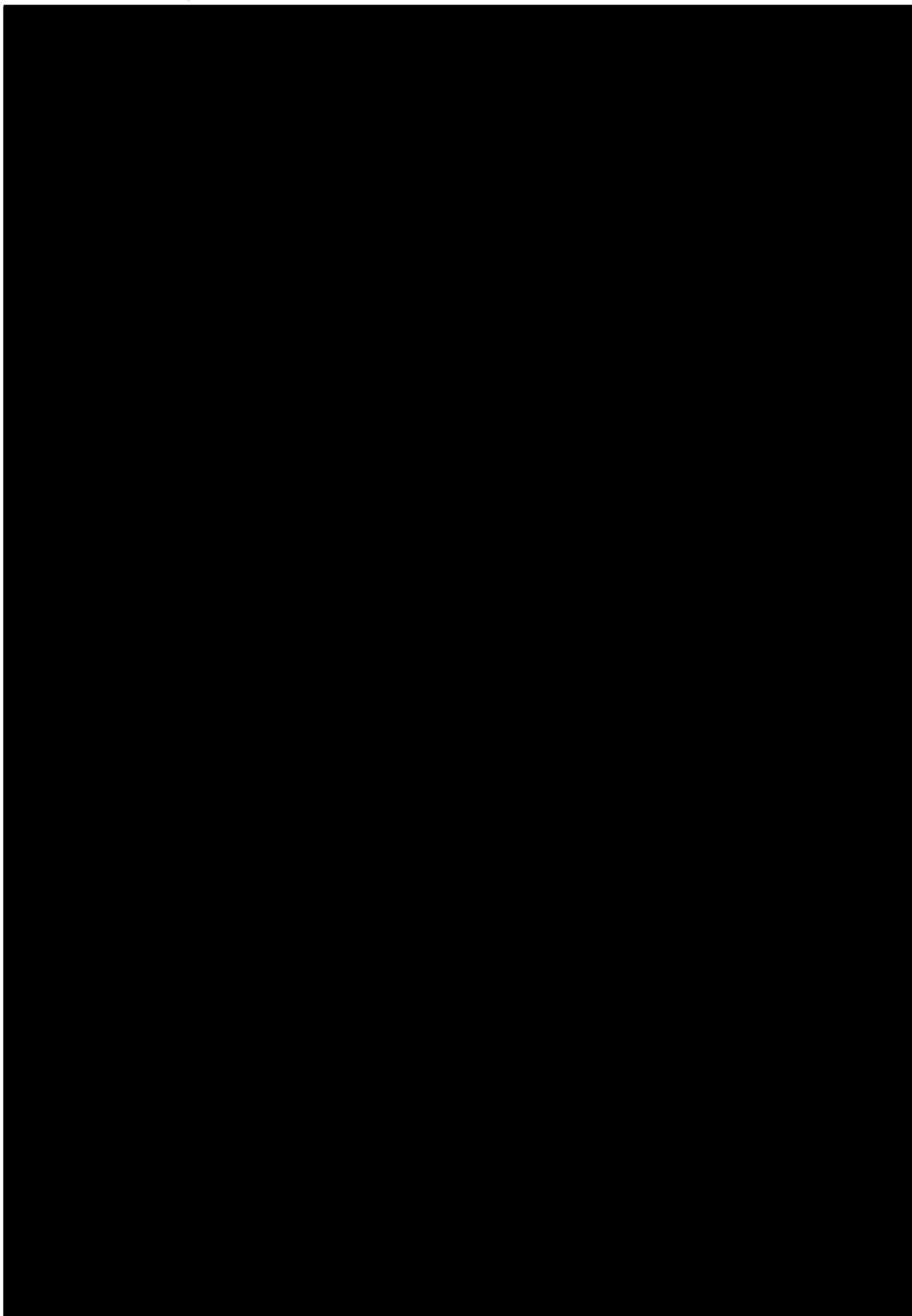


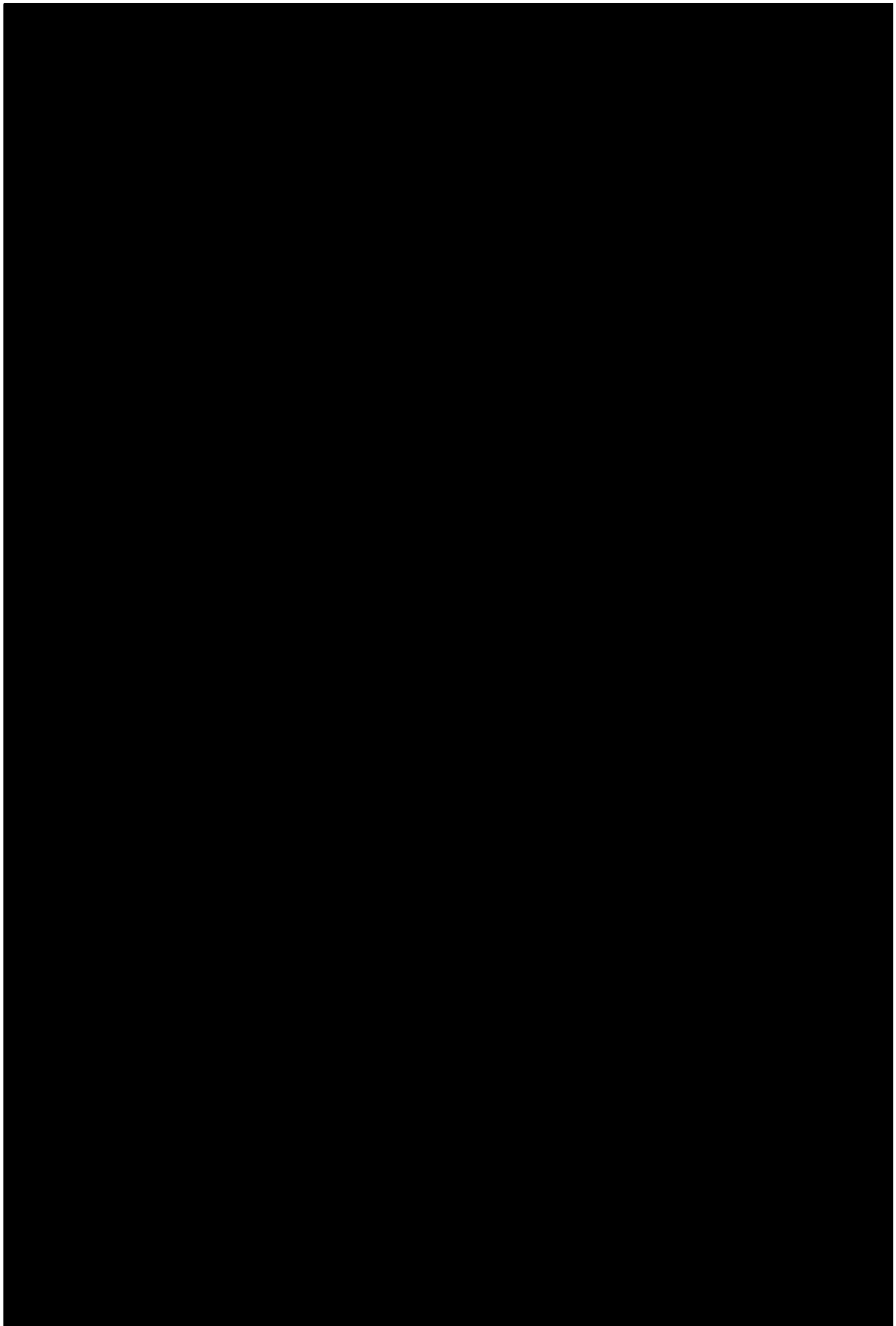


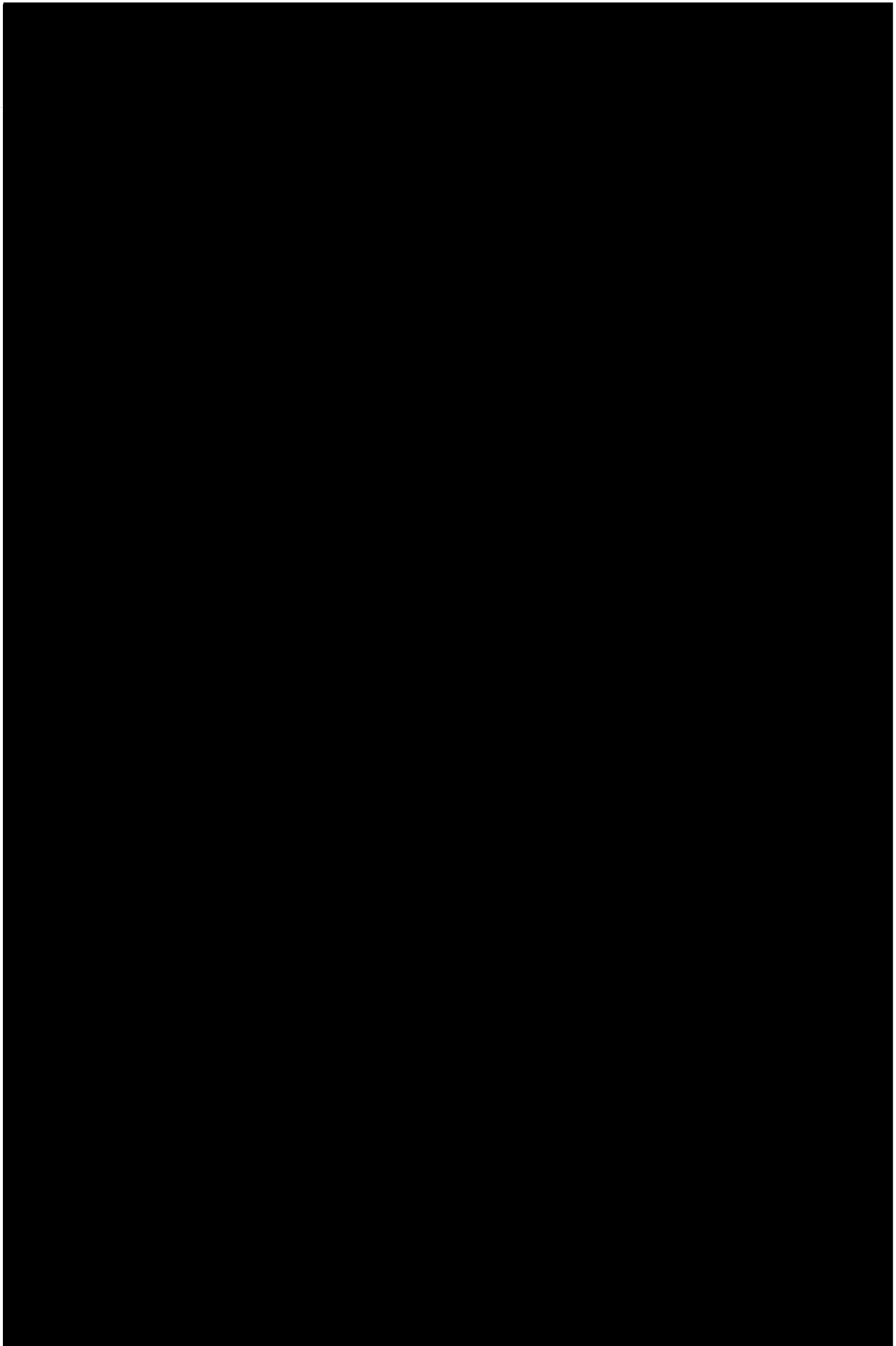


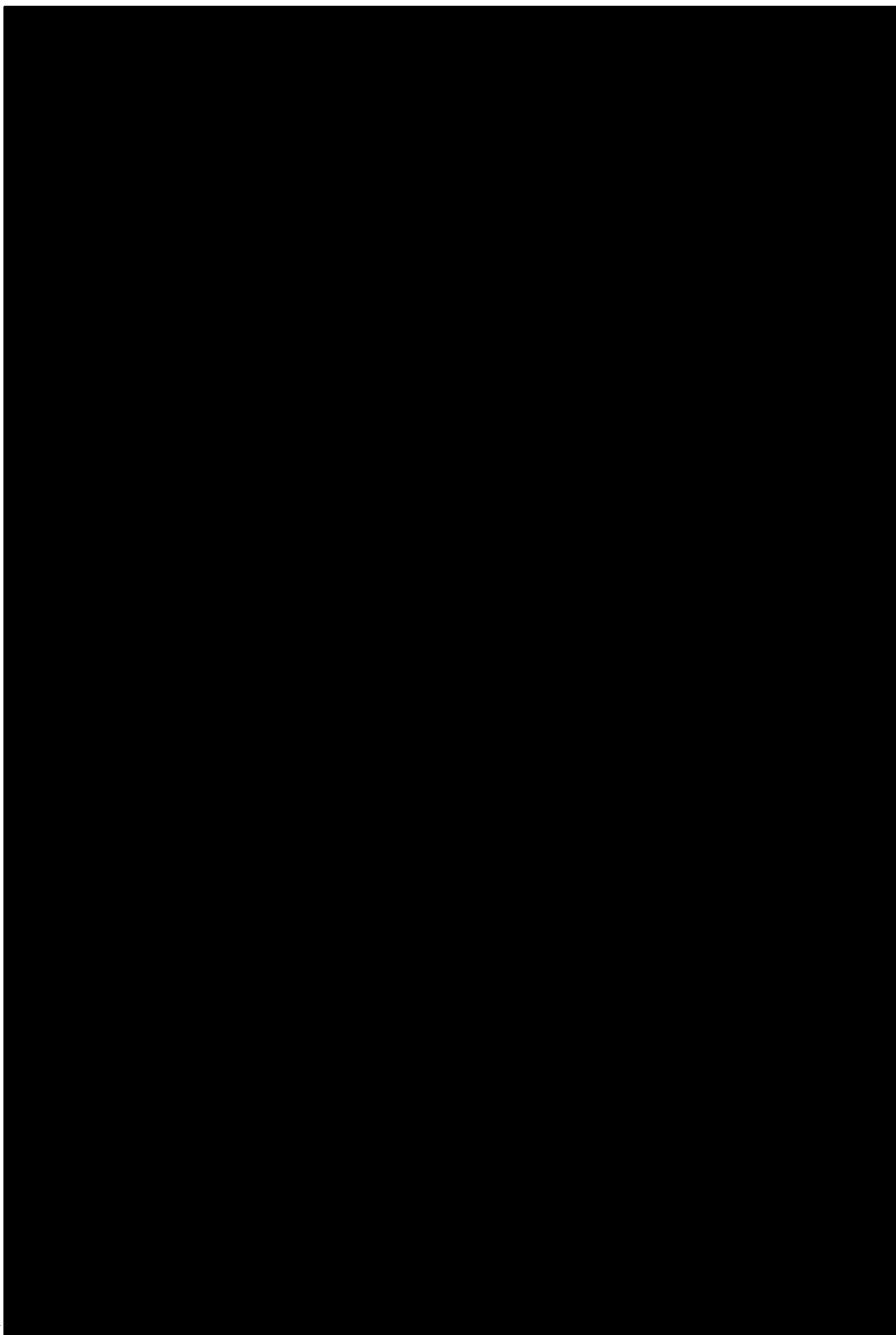


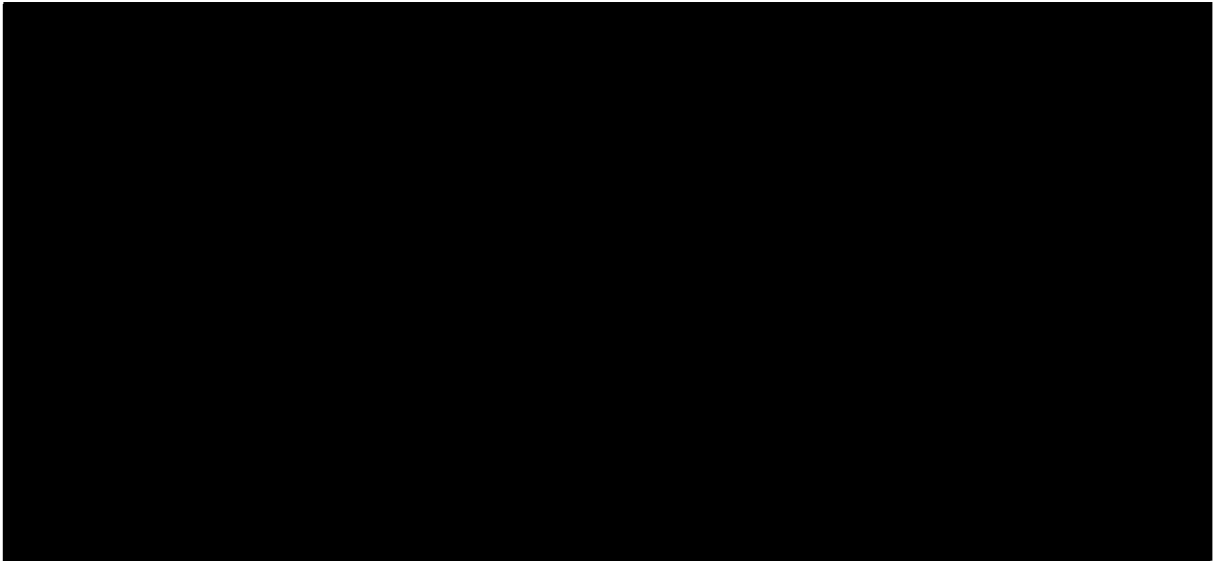












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Reference R12/1033878