

Exploring the Rationale for Prescribing Ankle-Foot Orthoses and Supra-Malleolar
Orthoses for Children with Cerebral Palsy

Submitted by

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Abstract

Cerebral palsy (CP) is a neurological condition that can cause functional and physical impairments such as abnormal muscle tone, poor motor control, and joint deformities. To help improve outcomes for children with CP, both ankle-foot orthoses (AFOs) and supra-malleolar orthoses (SMOs) are prescribed. However, it is unclear when one orthotic intervention should be prescribed over the other.

The aim of this thesis was to explore the orthotists' rationale for prescribing AFOs and SMOs for children with CP.

To help answer the thesis aim, we conducted two sequential studies: a narrative review and a qualitative study.

For the narrative review, we systematically searched a comprehensive range of journal articles, and extracted statements describing the rationale for the prescription of AFOs and SMOs for children with CP. Based on this review, we learned that AFOs were commonly prescribed to affect some aspect of gait, affect energy expenditure and metabolic cost, provide protection or correction to musculoskeletal structures, and to improve balance and coordination. By contrast, there was not a well evidenced rationale for the prescription of SMOs for children with CP. It is important to note that the literature did not describe that AFOs and SMOs were provided to affect outcomes, such as participation, which are also likely important for children with CP. Therefore, we subsequently conducted a qualitative study to better understand the orthotists' rationale for prescribing AFOs or SMOs for children with CP.

The findings of the qualitative study highlighted that there were many complex factors that influenced the orthotic prescription such as gait abnormalities present, child

and family treatment goals, issues with previous orthotic prescription, requirements from medical or other allied health professionals, skin integrity, and the cosmesis of a device. To help guide prescription, it may be helpful to identify primary factors, such as the presence of crouch gait, that might drive the initial prescription (e.g., for an AFO). Other influencing factors (e.g., body weight) that might nuance the prescription could be considered as secondary factors. In these cases, the secondary factors might change the choice of materials or trim lines of the AFO, however, not alter the primary prescription.

In conclusion, there were many factors that influenced the prescription of an AFO or SMO for children with CP. Considering these factors in a framework of primary and secondary influences may improve the rationale for the prescription of these orthotic interventions.

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Statement of Authorship

“Except where reference is made in the text of the thesis, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis accepted for the award of any other degree or diploma. No other person’s work has been used without due acknowledgement in the main text of the thesis. This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution. As referenced in the text of the thesis, I am one of several authors of the two journal-ready manuscripts to make up Chapters 2 and 3 of the thesis.”

Asumi Holly Dailey, 9 July 2023

Author contribution table

Chapter 2: Narrative review

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Chapter 3: Qualitative study

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Chapter 1: Introduction

Cerebral palsy (CP) is a non-progressive, neurological condition that affects approximately 2 per 1000 live births [1]. It is caused by a malformation or injury during brain development [2]. Children with CP often live with functional and physical impairments such as abnormal muscle tone, poor motor control, and joint deformities [3]. The severity of the child's functional impairment can be classified using the Gross Motor Function Classification Scale (GMFCS). The GMFCS is a five-level classification system that describes the gross motor functional level of a child with CP [4]. Children classified within the higher GMFCS levels of IV and V are primarily non-ambulant and use wheelchairs to help them mobilise. By comparison, children classified in the lower GMFCS levels of I-III are ambulant and may (or may not) use gait aids such as crutches or walking frames to aid independent mobility. Irrespective of the GMFCS level, the functional and physical impairments experienced by a child living with CP can limit their ability to participate in activities at the same level as their peers [5,6].

To help improve outcomes for children with CP, both ankle-foot orthoses (AFOs) and supra-malleolar orthoses (SMOs) are often prescribed [7]. By way of definition, AFOs are lower limb orthoses that encapsulate part of the foot and leg segment (Figure 1a). They are designed to provide tri-planar control at the ankle and knee joint [8]. SMOs are orthoses that encompass part of the foot and may extend just superior to the ankle joint (Figure 1b). SMOs primarily provide coronal and transverse plane control of the intrinsic foot joints with limited influence at the ankle joint given the device trim lines remain close to the malleoli [8]. Both types of orthoses are usually custom-made and fabricated using polypropylene.

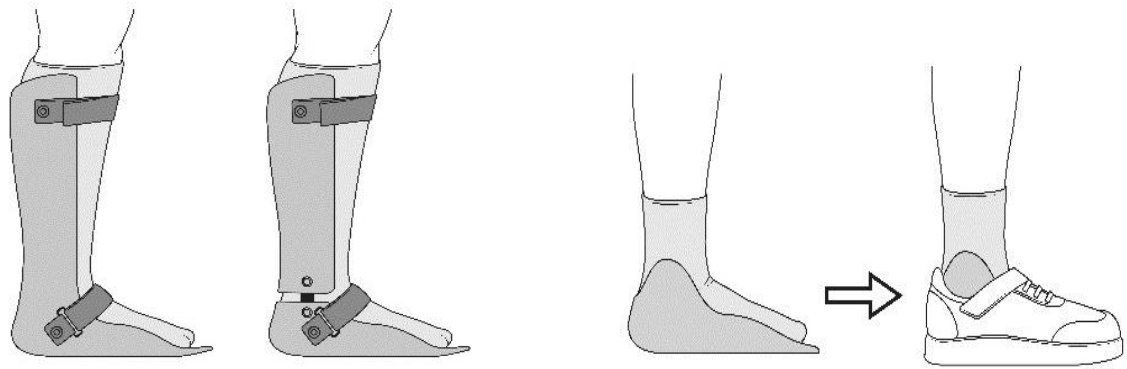


Figure 1a (left): An example of a non-articulated and articulated ankle-foot orthoses. Figure 1b (right): An example of a supra-malleolar orthosis without a shoe and with a shoe. Both sets of figures are used with permission, Royal Children's Hospital, Melbourne, Australia.

Given that AFOs and SMOs are designed to affect different joints and limb segments, it seems reasonable to infer that the rationale for their prescription would be clear. For example, if the goal of orthotic treatment was to normalise motion of the leg segment and knee joint during stance phase, then an AFO would be an appropriate prescription. However, this does not seem to be the case. Based on clinical experience, there are a complex range of factors that seem to influence the prescription of either AFOs or SMOs such as the presence of gait abnormalities, issues with previous orthotic prescription/s, cosmesis preferences, goals of medical or other allied health professionals, problems with skin integrity, family expectations, and the child's desire for less intrusive looking interventions. Similar reflections have been reported in other prescribing professions such as prosthetics [9,10], occupational therapy [11], and podiatry [12]. Collectively, these studies highlight the variety of influences including patient specific factors (e.g., psychosocial, patient goals, past experience of device use), prosthetic or orthotic specific factors (e.g., activity level, funding, aesthetics), as well as the preferences of other health care providers such as physiotherapists and surgeons. Of

these studies [9,10,11], some highlight just how challenging it can be to balance these influences when prescribing a device. Others highlight a disconnect between the clinician's rationale for prescription, and the patient's reason/s for wanting a device [9].

These challenges will likely resonate with the day-to-day experience of many paediatric orthotists, and inevitably leads to ethical and practical questions about prescription. For example, if a child refuses to wear an AFO as it looks too bulky, how much should the clinician compromise on the 'ideal' orthotic design? Is it ethical for the clinician to prescribe an orthotic intervention that will have a high degree of acceptance and wear, even if it is not as effective as the 'ideal'?

Given the many factors that can influence the prescription of an AFO or SMO for children with CP, and the complexity of weighing these factors, it can be challenging for clinicians to develop a clear rationale for orthotic prescription [13]; particularly given the paucity of evidence about the effect of these different interventions. At this point in time, much of the orthotic research is in its infancy, where researchers are conducting observational studies or early-phase experiments to understand the effect of orthotic interventions in small and heterogeneous population groups [14]. As orthotic research matures, studies will evolve to include randomised controlled trials focused on very specific orthotic interventions in discrete groups of children with homogeneous characteristics. Given much of the orthotic research describing the rationale for the prescription of AFOs and SMOs in children with CP is in its early stages of research, this has made it difficult to develop an orthotic prescription framework that is fit-for-purpose [14].

There are some well-established orthotic prescription frameworks and clinical algorithms [15,16,17,18] available for children with CP. While these frameworks are

suitable for ambulant children with CP, they are focused on the impact of gait-related outcomes for the prescription of AFOs [15,16,17,18] or AFOs and SMOs [17].

Although these frameworks are well suited to guide prescription decisions focused on gait-related outcomes, there are a much wider variety of factors that influence orthotic prescription that should be considered for a prescription framework to be truly useful for clinicians. A more holistic framework might: identify the child/family goals, link the goal to a physical presentation/issue, identify an orthotic intervention, and an outcome measure to evaluate the effect of the orthotic intervention given the treatment goal. For example, a child may present with the goal to reduce falls, we could then identify the underlying cause of the falls (e.g., spasticity of the gastrocnemius muscle causing the foot to be in a plantarflexed position throughout swing phase), then identify an orthotic intervention to improve foot position to help prevent falls (e.g., a solid ankle AFO), then identify an outcome measure to evaluate the effectiveness of the orthotic intervention (e.g., the Humpty Dumpty Fall Assessment Scale).

In the absence of a fit-for-purpose prescription framework specific to decisions about AFO and SMO prescription for children with CP, clinicians typically rely on past clinical experience, historical practices of a clinical service, or patient and family preferences, to inform their prescription choices [13]. As such, there are likely inconsistent orthotic prescription practices which can lead to some children being provided ineffective orthotic treatment resulting in poor clinical outcomes [19]. Similar reflections have been observed within occupational therapy practice in the context of upper limb orthotic interventions for children with CP [20].

In summary, children with CP often live with functional and physical impairments such as abnormal muscle tone, poor motor control, and joint deformities that limit their ability to participate. To help improve outcomes for children with CP, both AFOs and

SMOs are often prescribed [7]. There are a complex range of factors that seem to influence the prescription of these orthoses (e.g., gait abnormalities, cosmetic preferences, child/family preferences, past experiences) that are not well reflected in current orthotic prescription frameworks. As such, clinicians tend to rely on past experience and historic practices to inform their prescription choice which inevitably means some children will likely receive interventions that may not be ideal to achieve their treatment goals.

Given this background, the aim of this thesis was to explore the rationale for prescribing AFOs and SMOs for children with CP.

To help answer the research question, we conducted two sequential studies: a narrative review and a qualitative study.

In the narrative review, we systematically searched for a comprehensive range of journal articles, and extracted statements describing the rationale for the prescription of AFOs and SMOs in children with CP. These rationale statements were synthesised to provide us with a better understanding of the rationale for the prescription of AFOs and SMOs for children with CP. Unfortunately, the existing peer reviewed literature did not make it clear when one orthotic intervention should be prescribed over the other. While there was a substantial body of evidence describing the rationale for prescribing AFOs, this evidence overwhelmingly focused on normalising aspects of gait with little evidence about the broader range of outcomes that may be important to children or their families. By contrast, there was little evidence describing the orthotists' rationale for prescribing SMOs for children with CP.

Given that the literature did not provide a clear answer to the research question, we conducted a qualitative study to better understand the orthotists' rationale for

prescribing AFOs or SMOs for children with CP. In designing the semi-structured interview, we were deliberate in probing the orthotists' rationale for prescribing AFOs and SMOs for children with CP from different perspectives; recognising the myriad of factors that may influence the prescription. For example, early in the interview, we asked orthotists to describe their rationale for the orthotic prescription. Later in the interview we asked about how they evaluate the effect of the orthotic prescription given that the rationale and outcome measures used should align. In this way, we hoped to gain a deeper understanding of why clinicians prescribe these orthotic interventions to children with CP.

This thesis is presented in a series of four sequenced chapters. Following this introduction (Chapter 1), the narrative review (Chapter 2), and qualitative study (Chapter 3) have been presented in a format for a journal-ready manuscript. The final chapter (Chapter 4) discusses the findings of these studies and makes a number of recommendations for clinical practice and further research.

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Chapter 2: Narrative review

The contents of this chapter are presented in the form of a journal ready manuscript.

This manuscript has been accepted for publication.

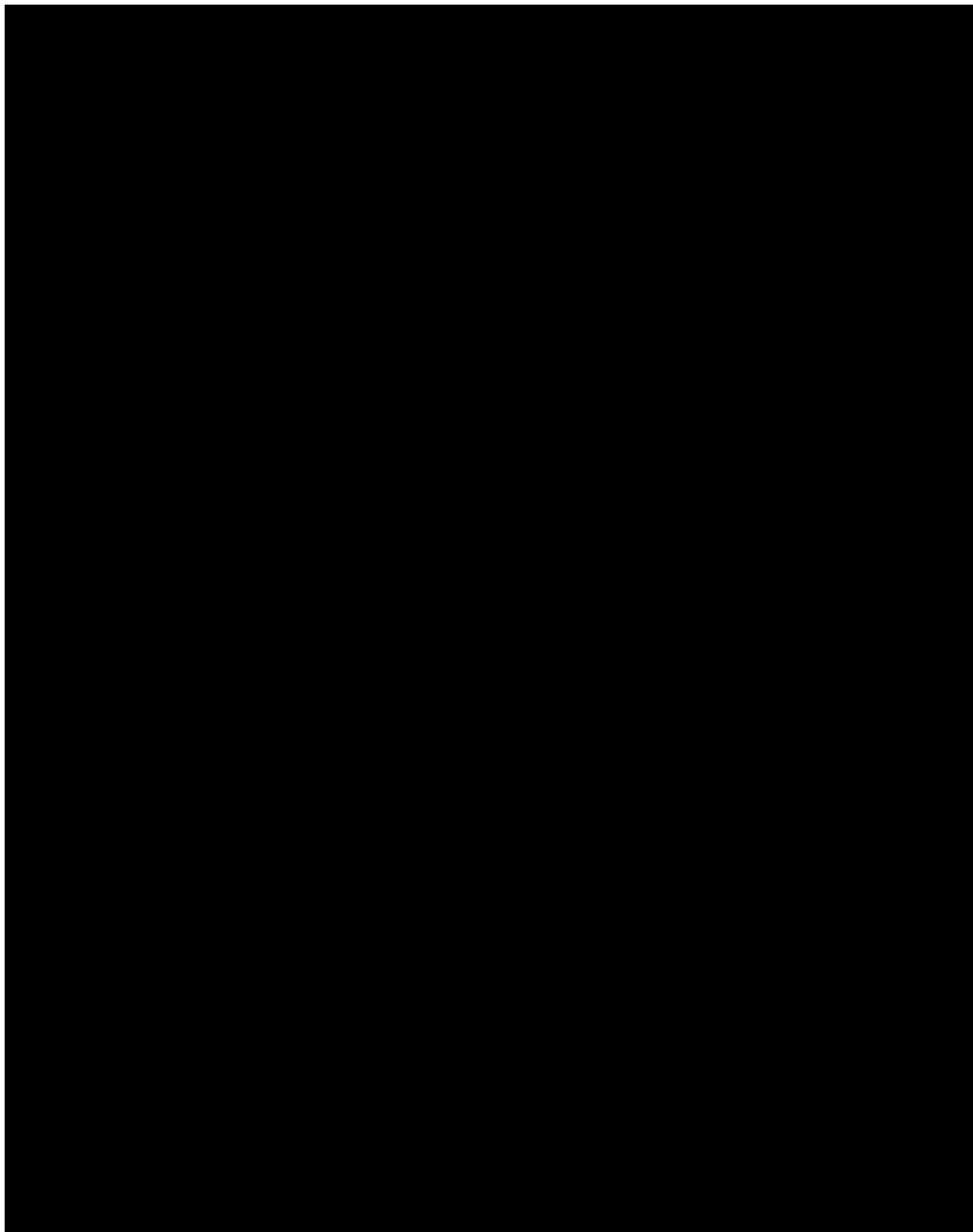
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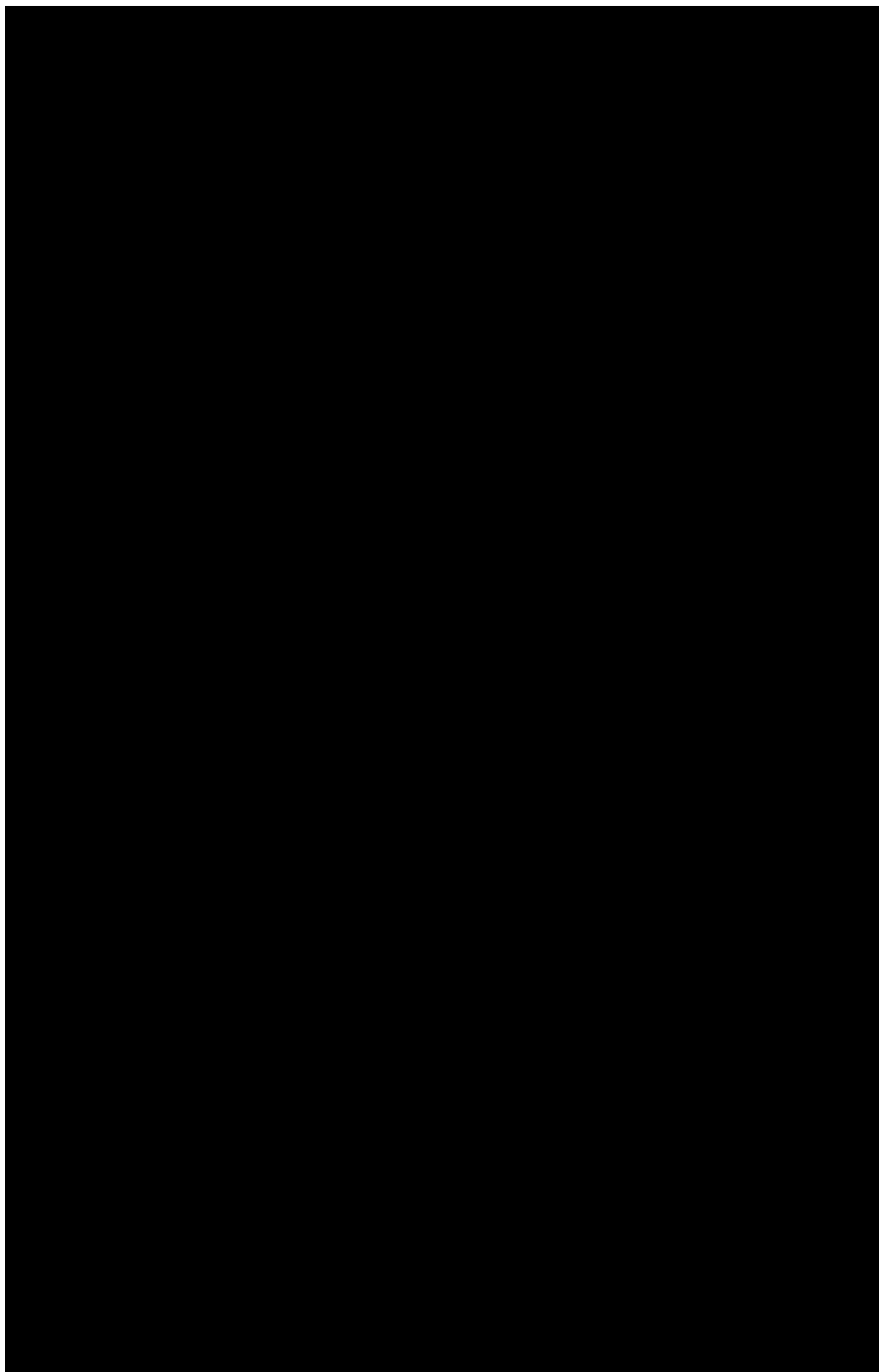
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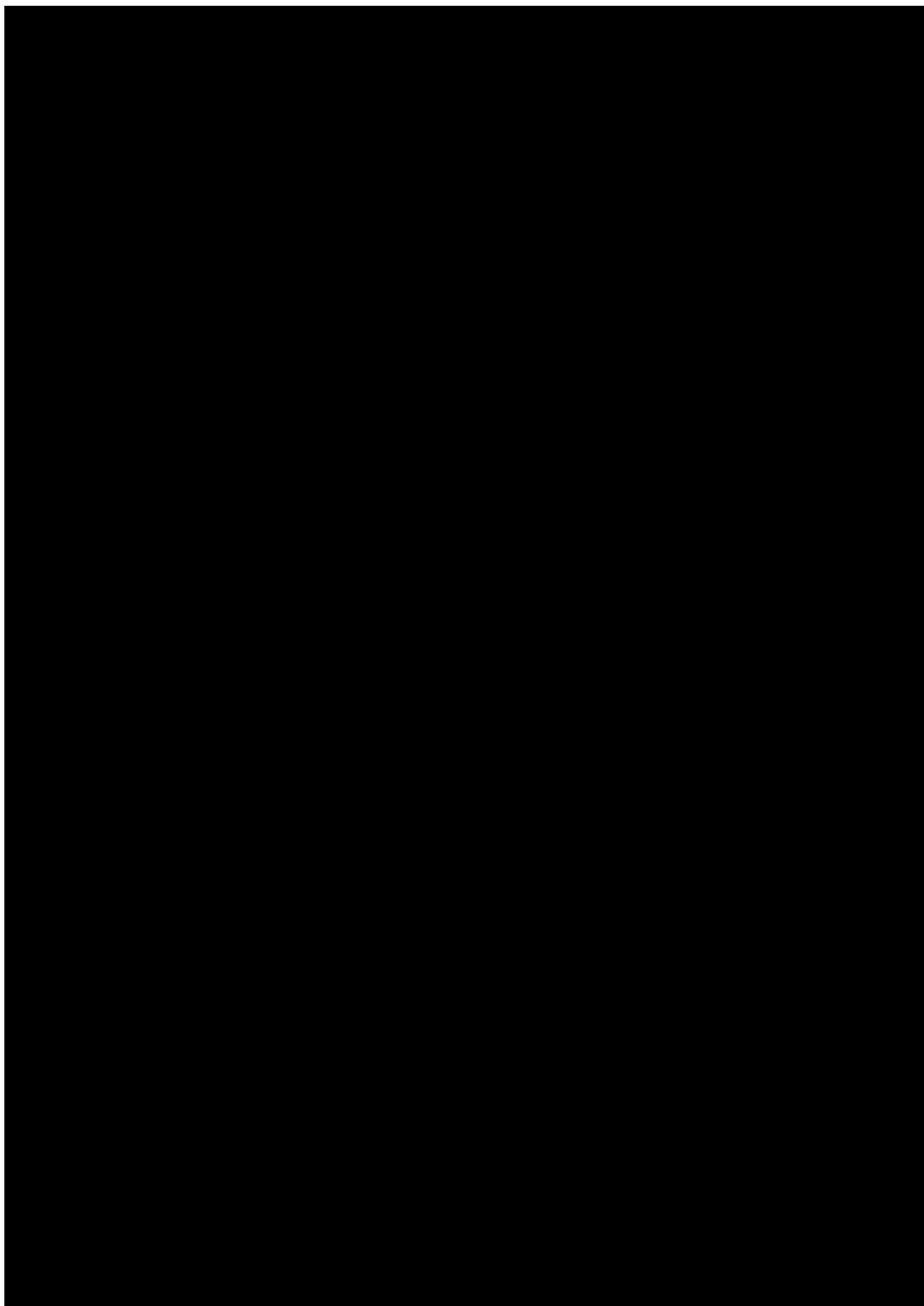
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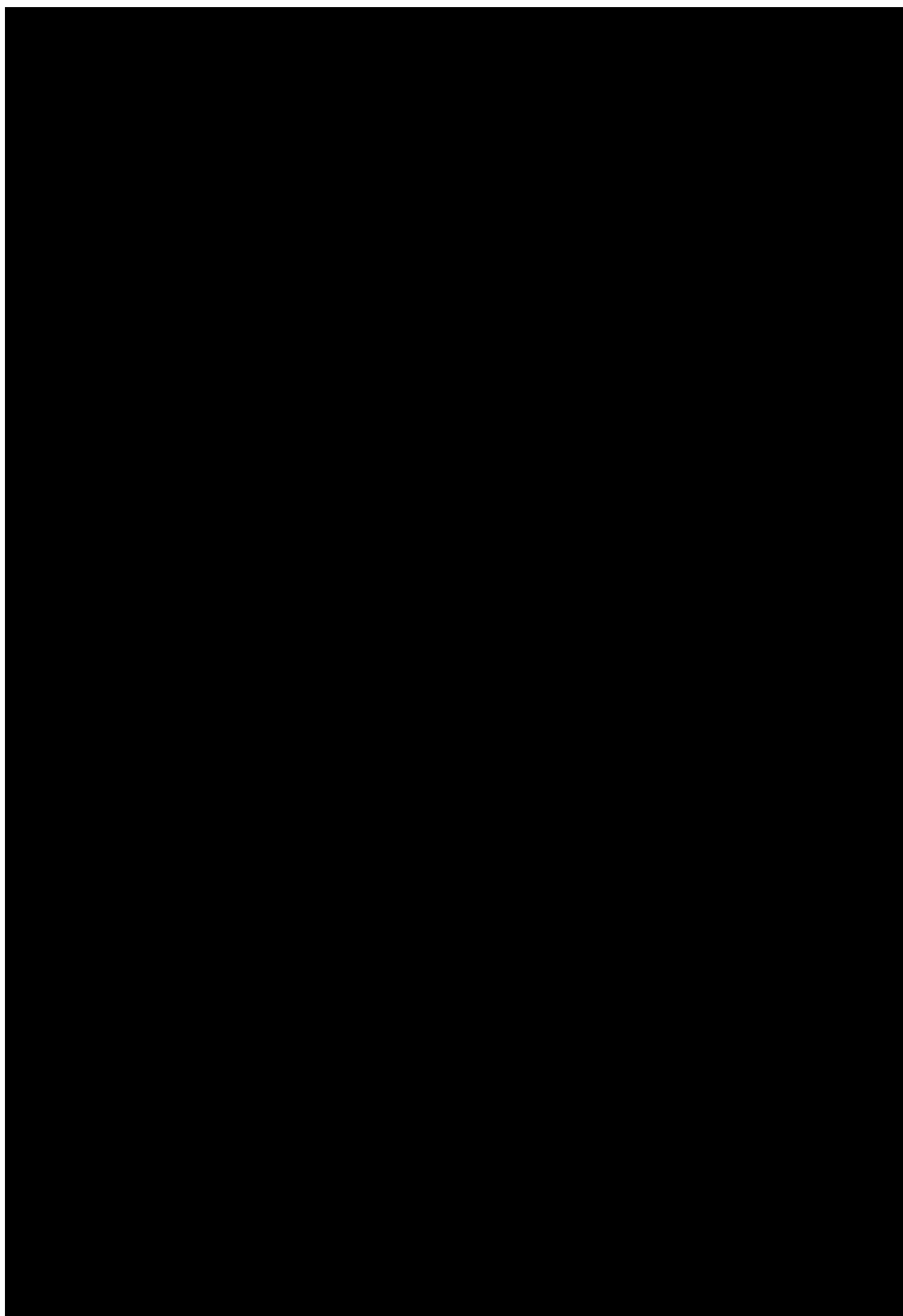
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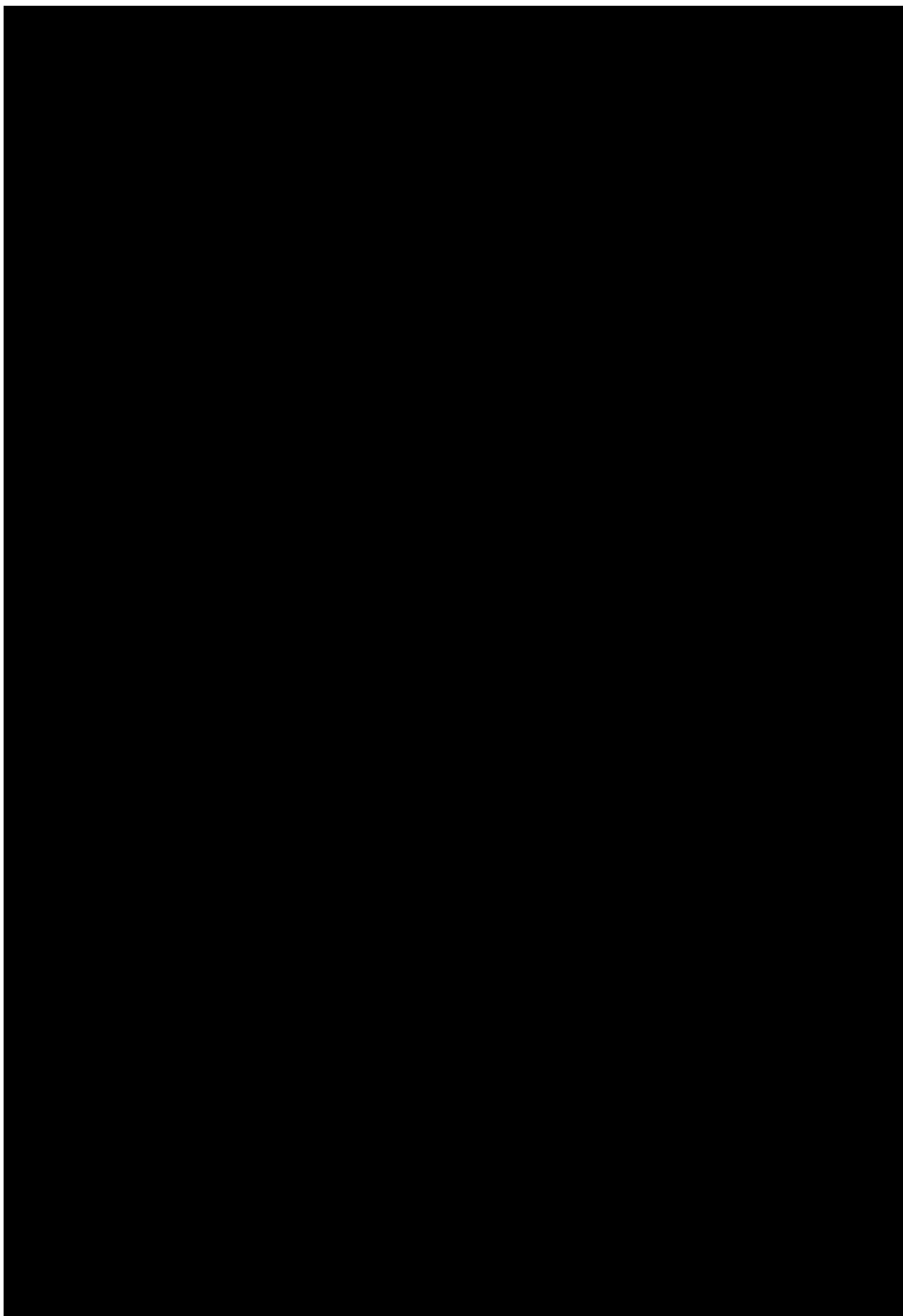
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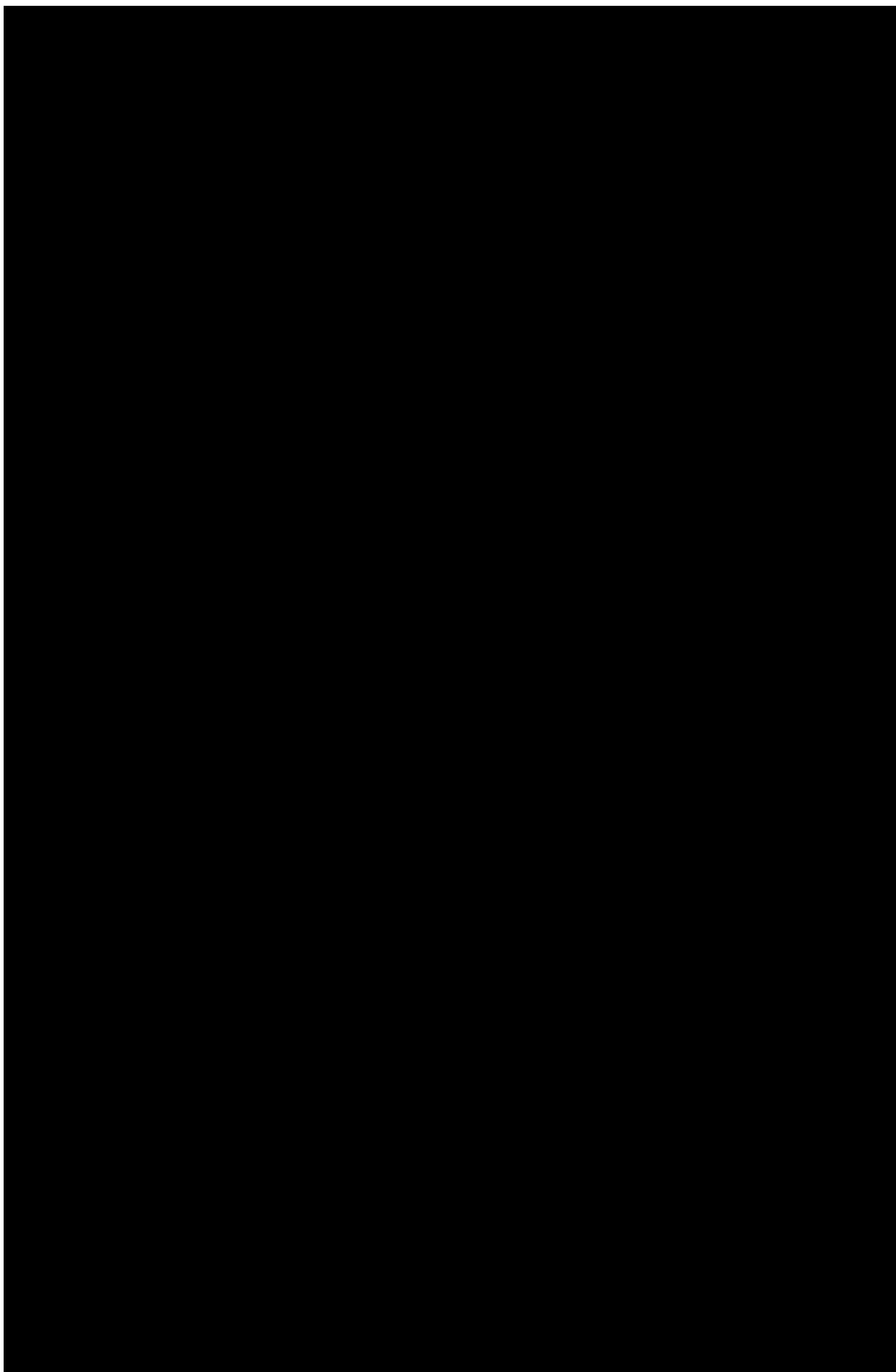


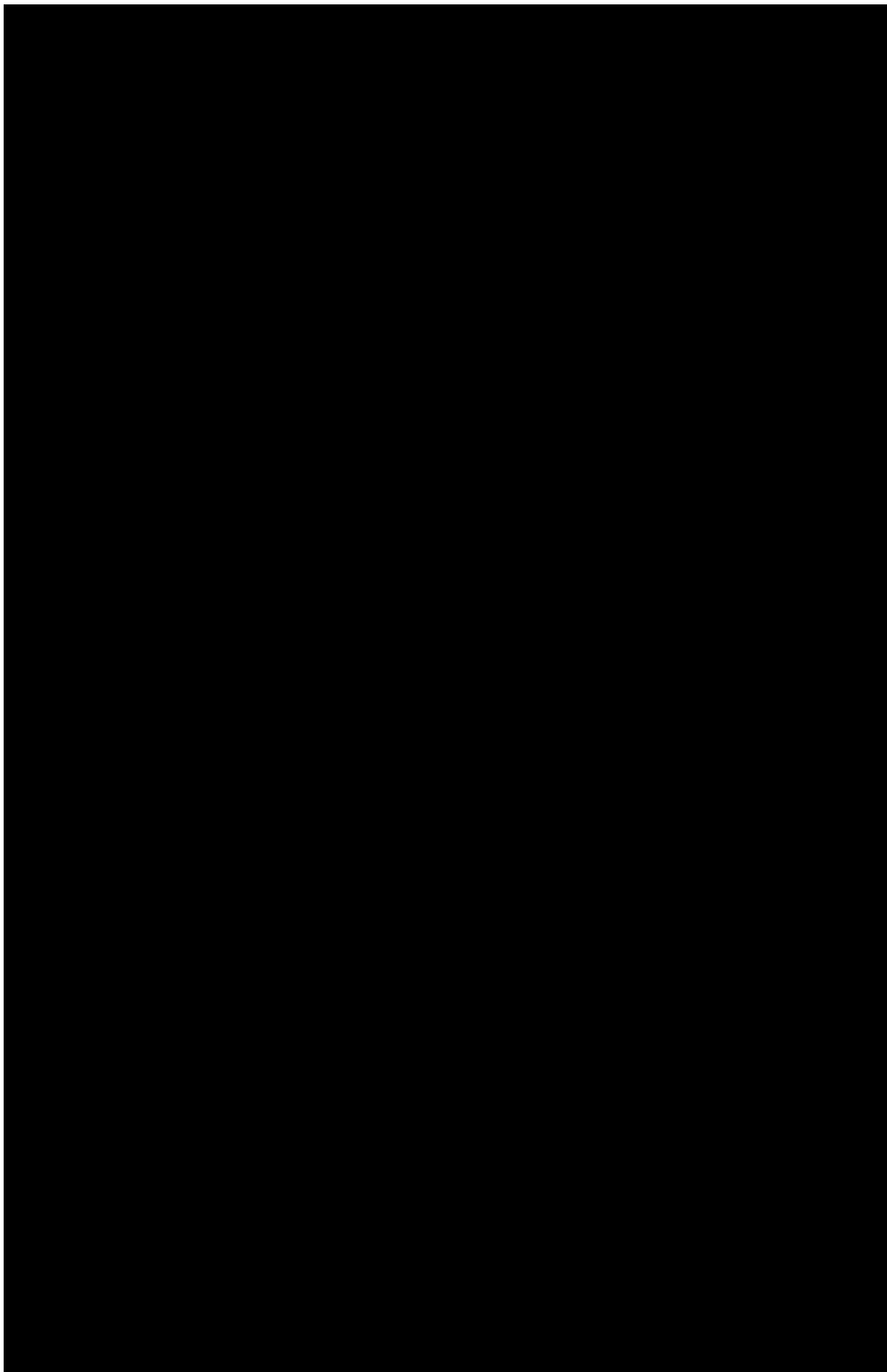


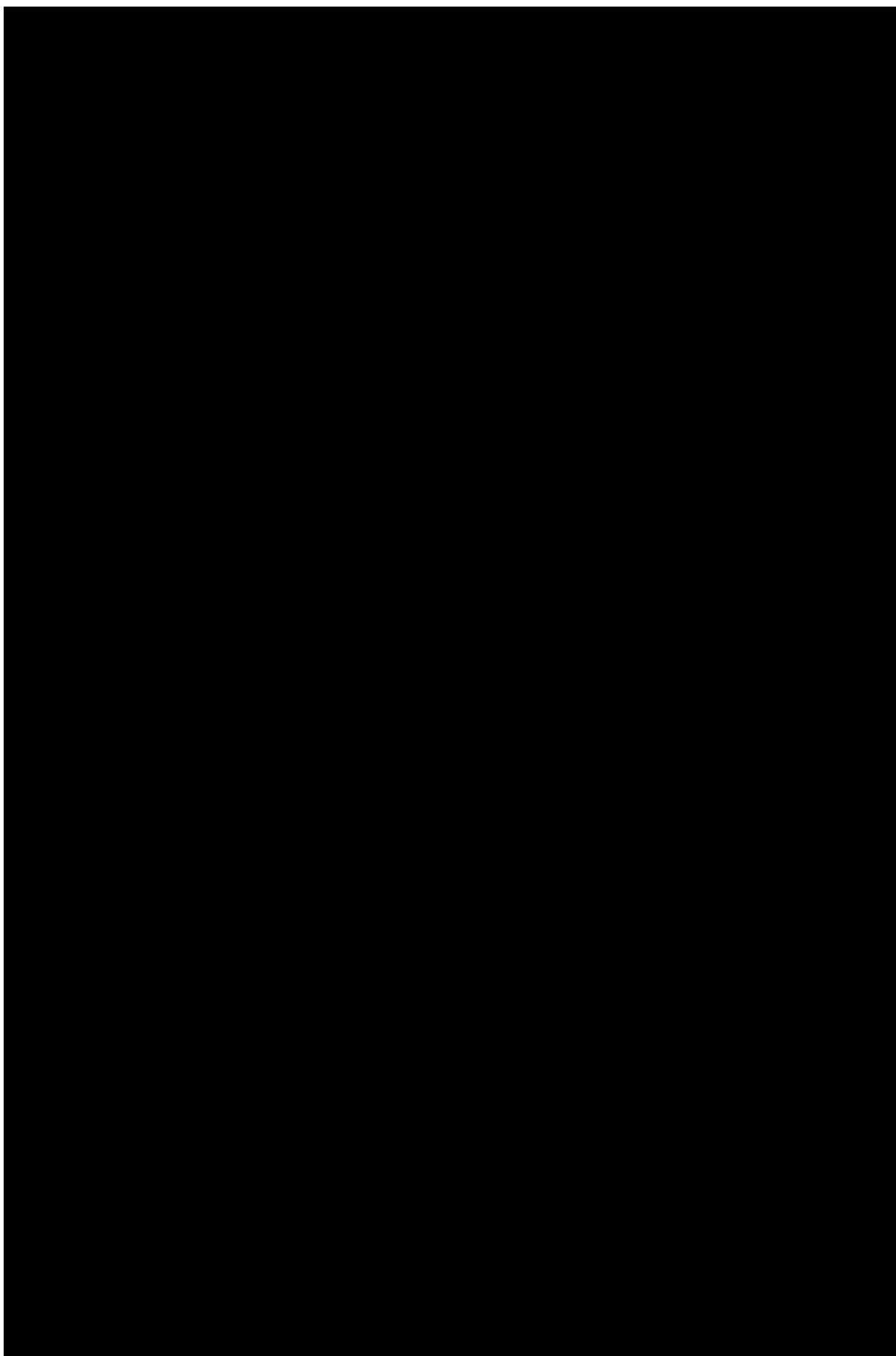


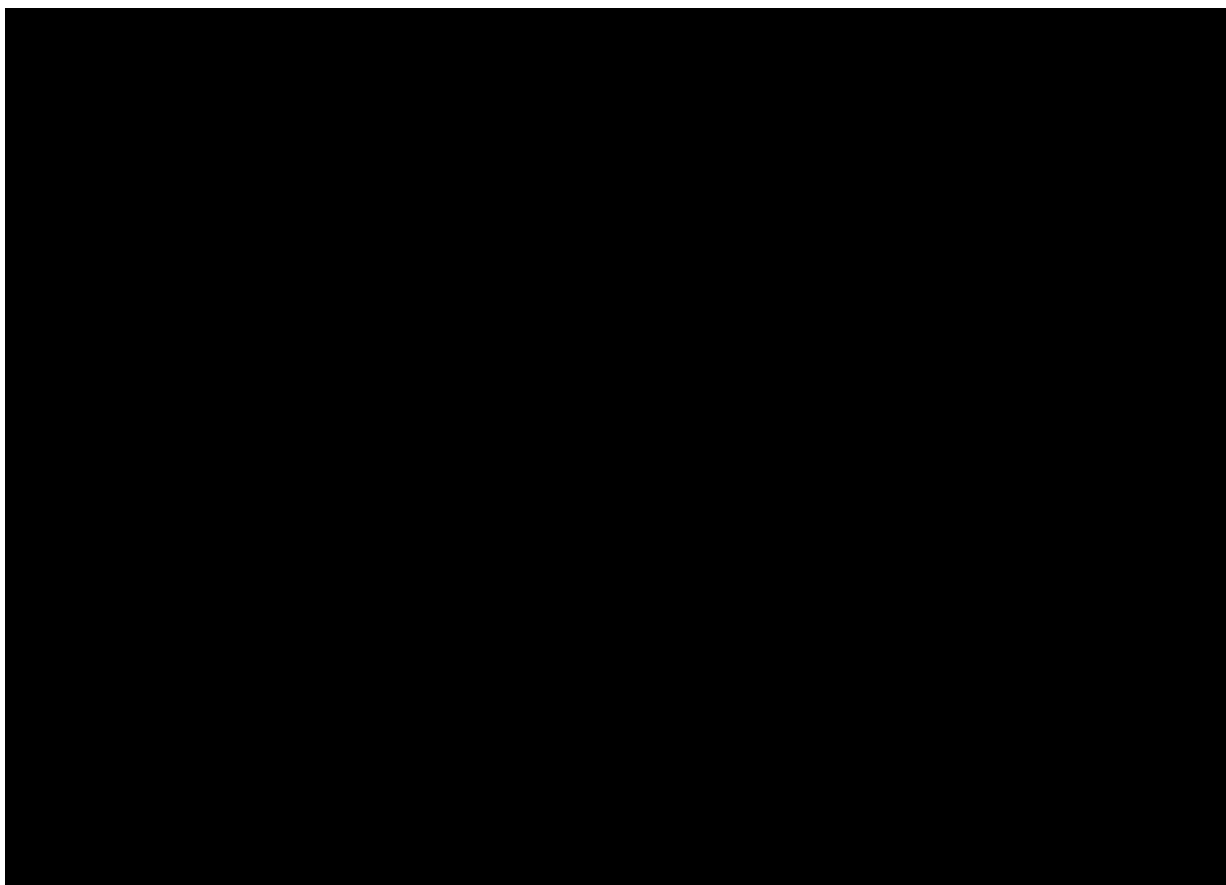


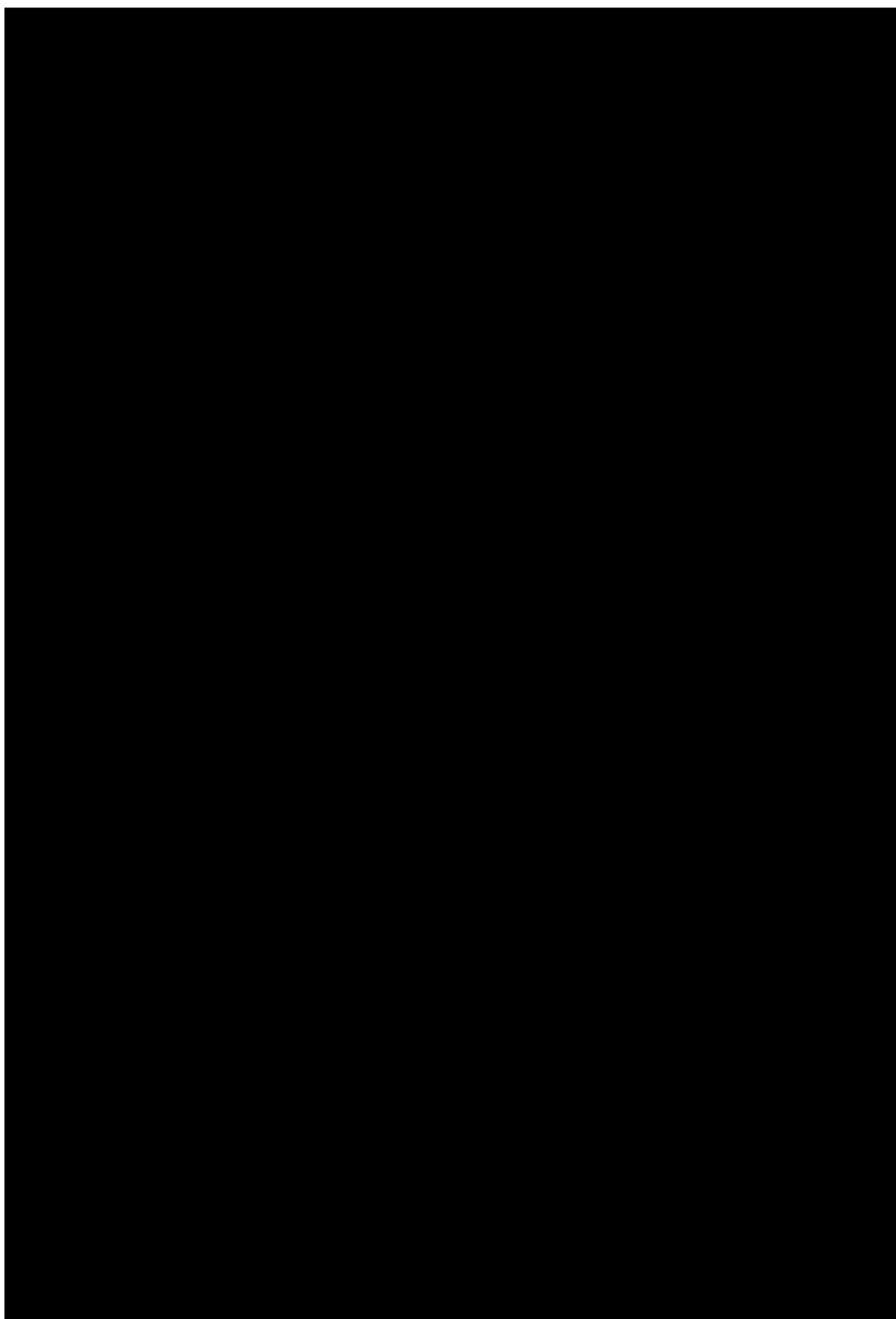


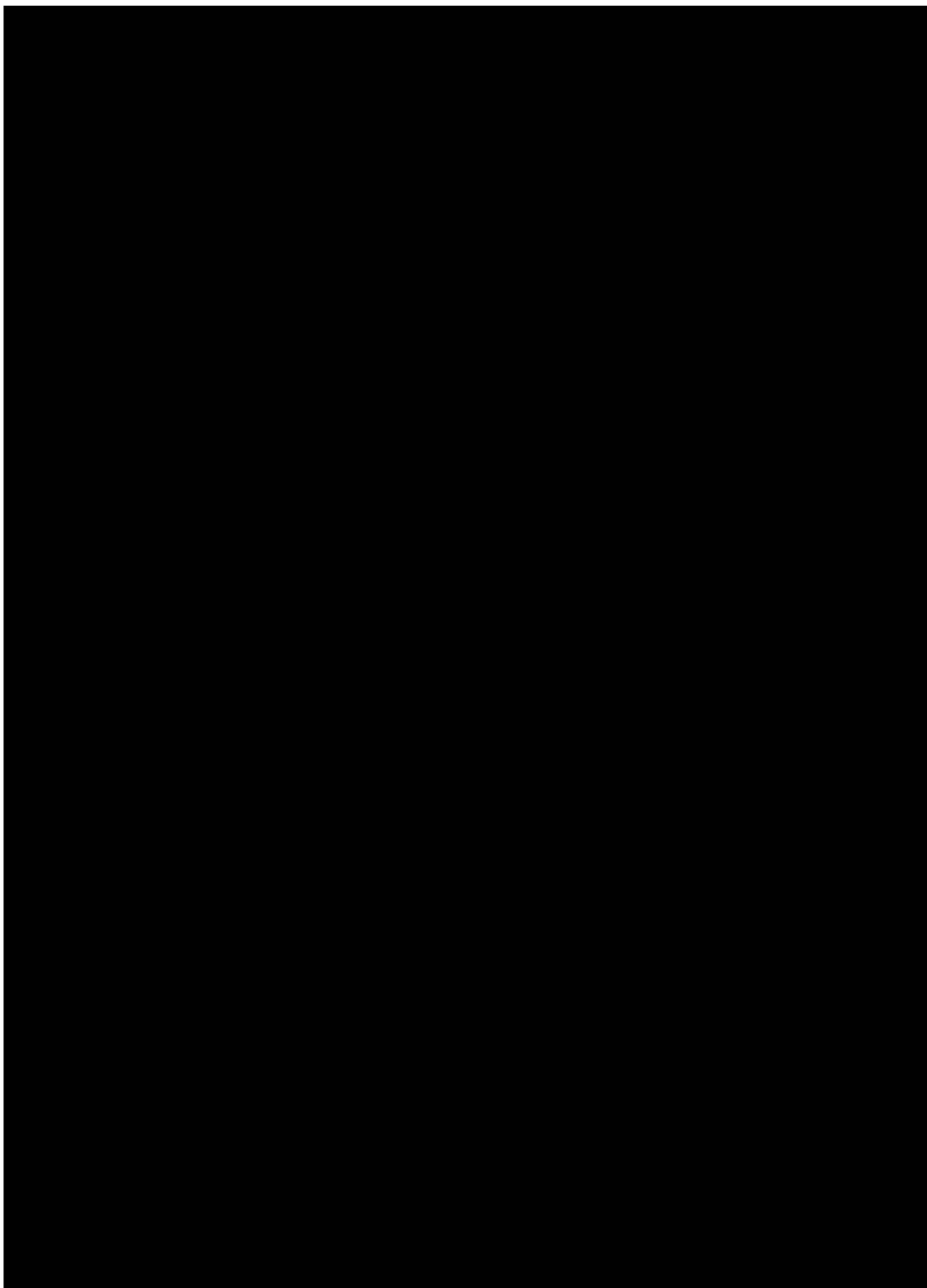












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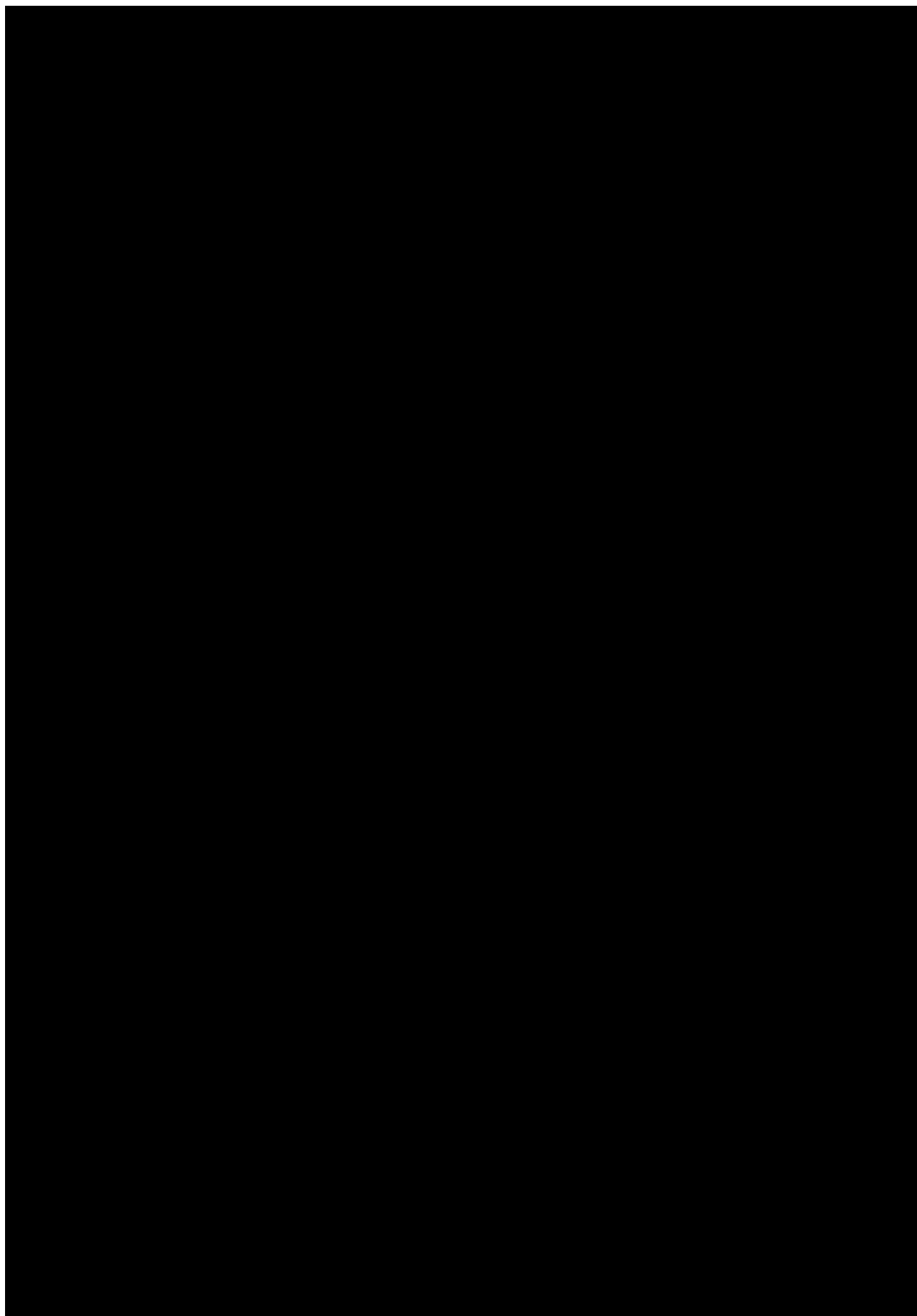
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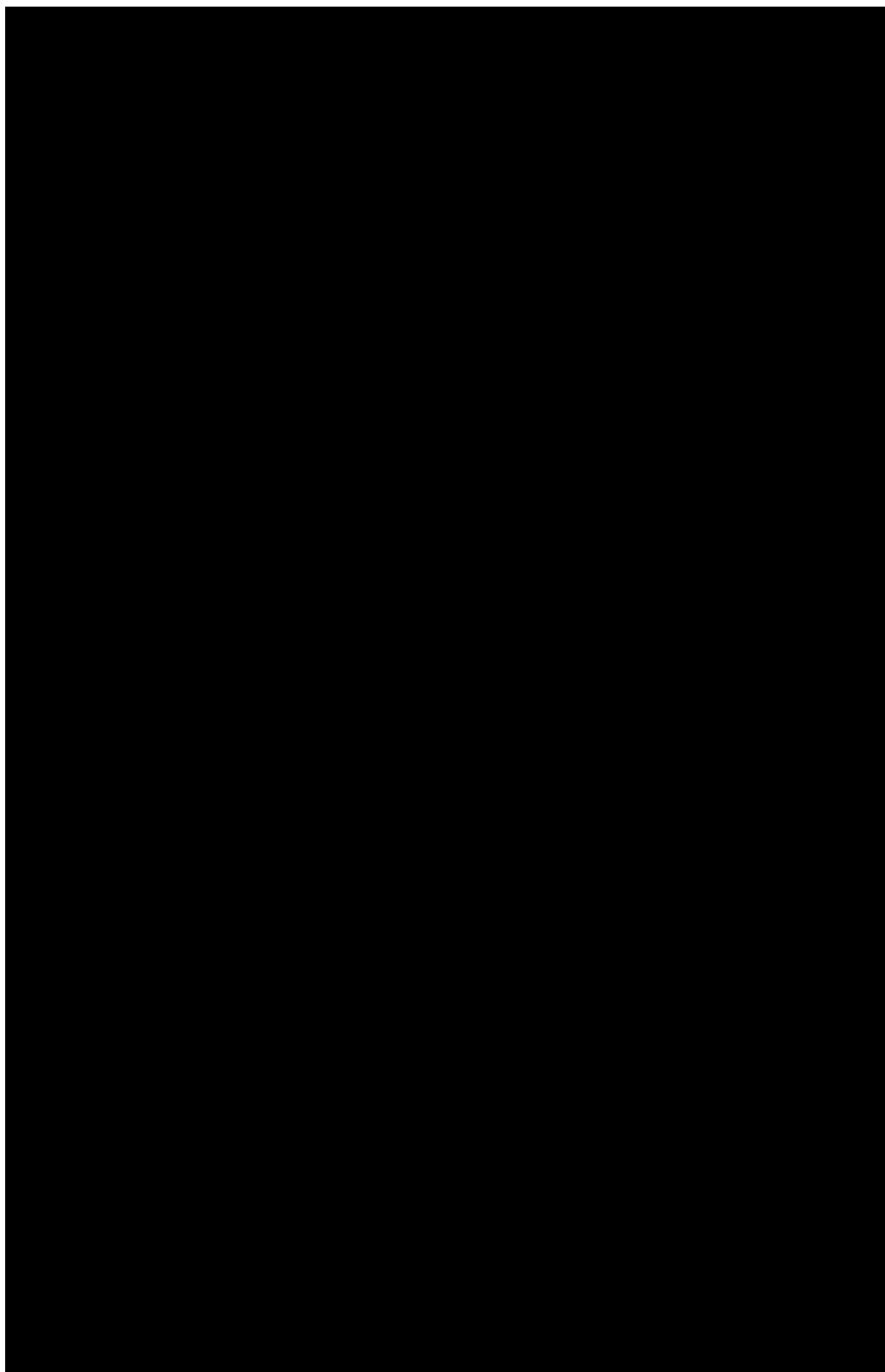
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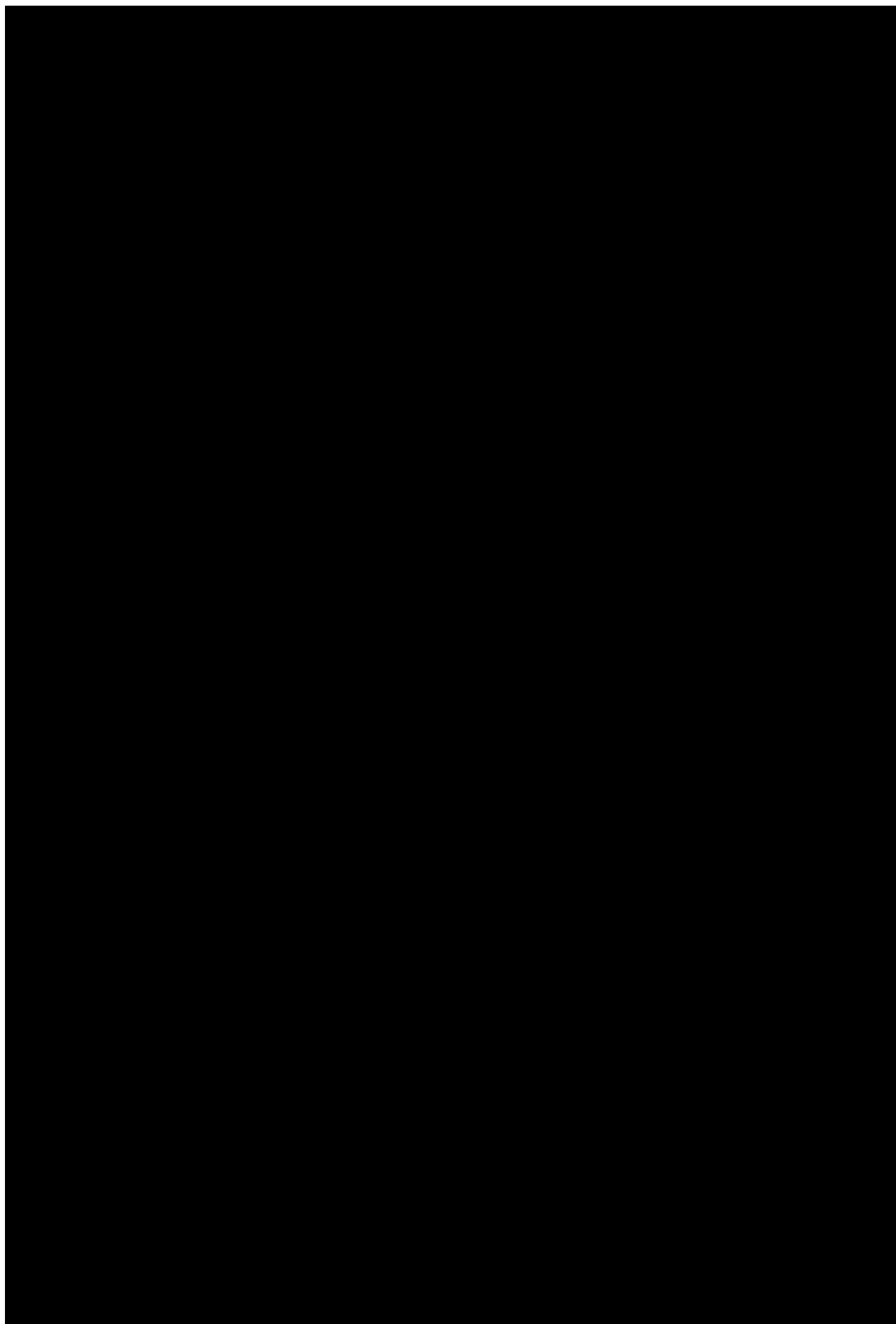
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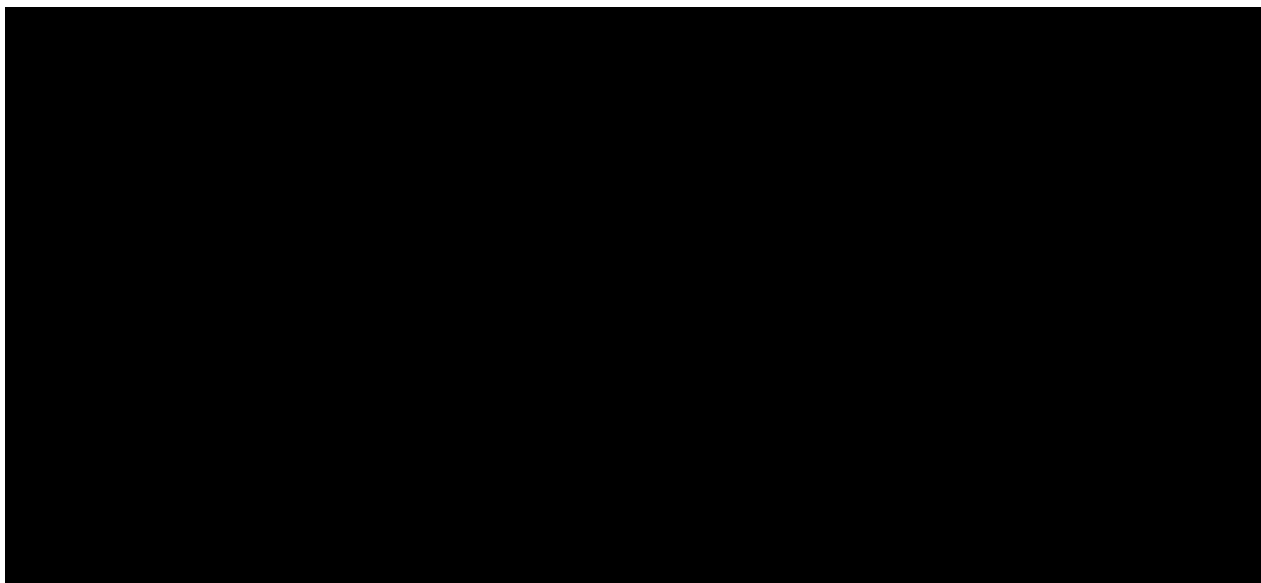
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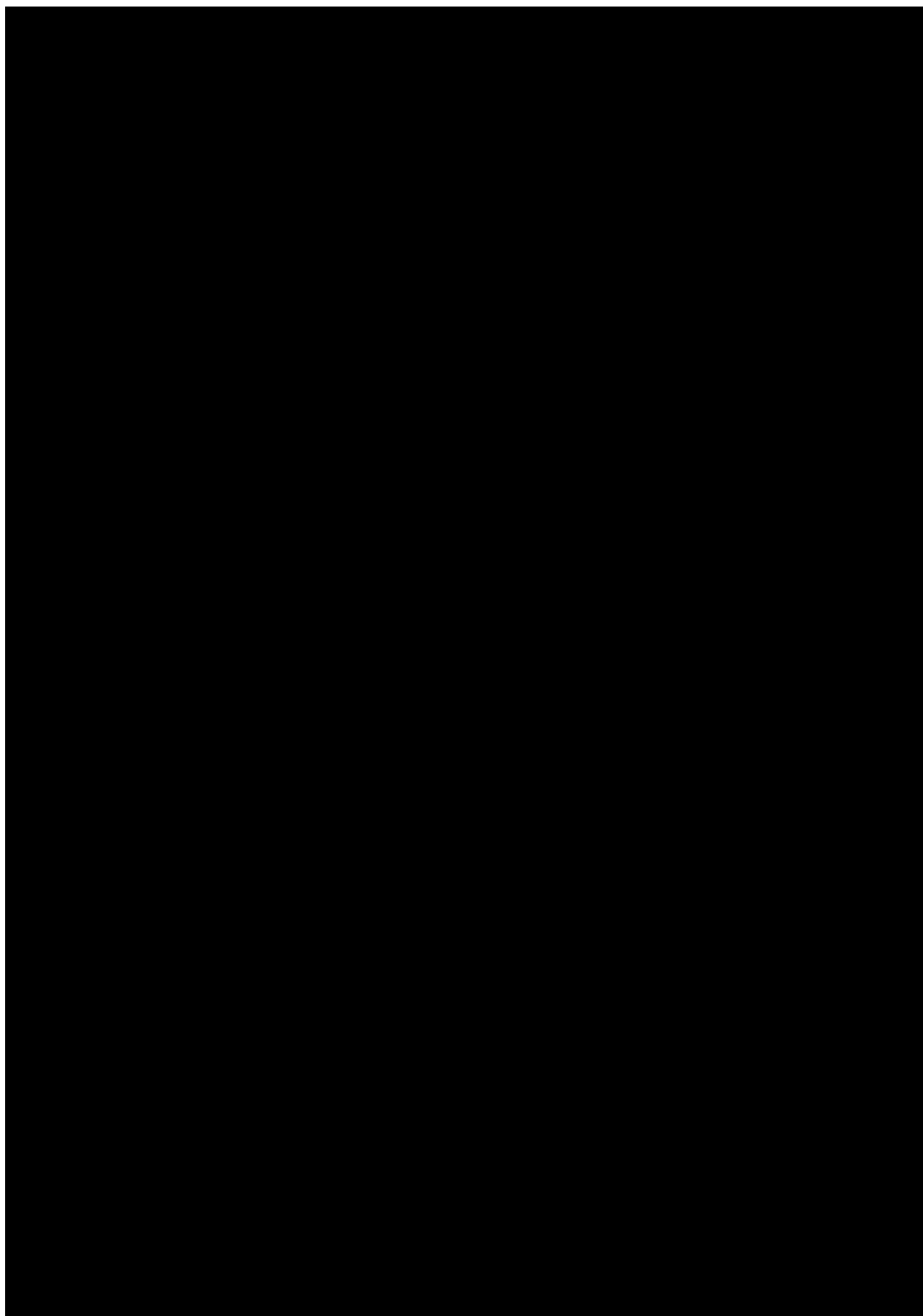
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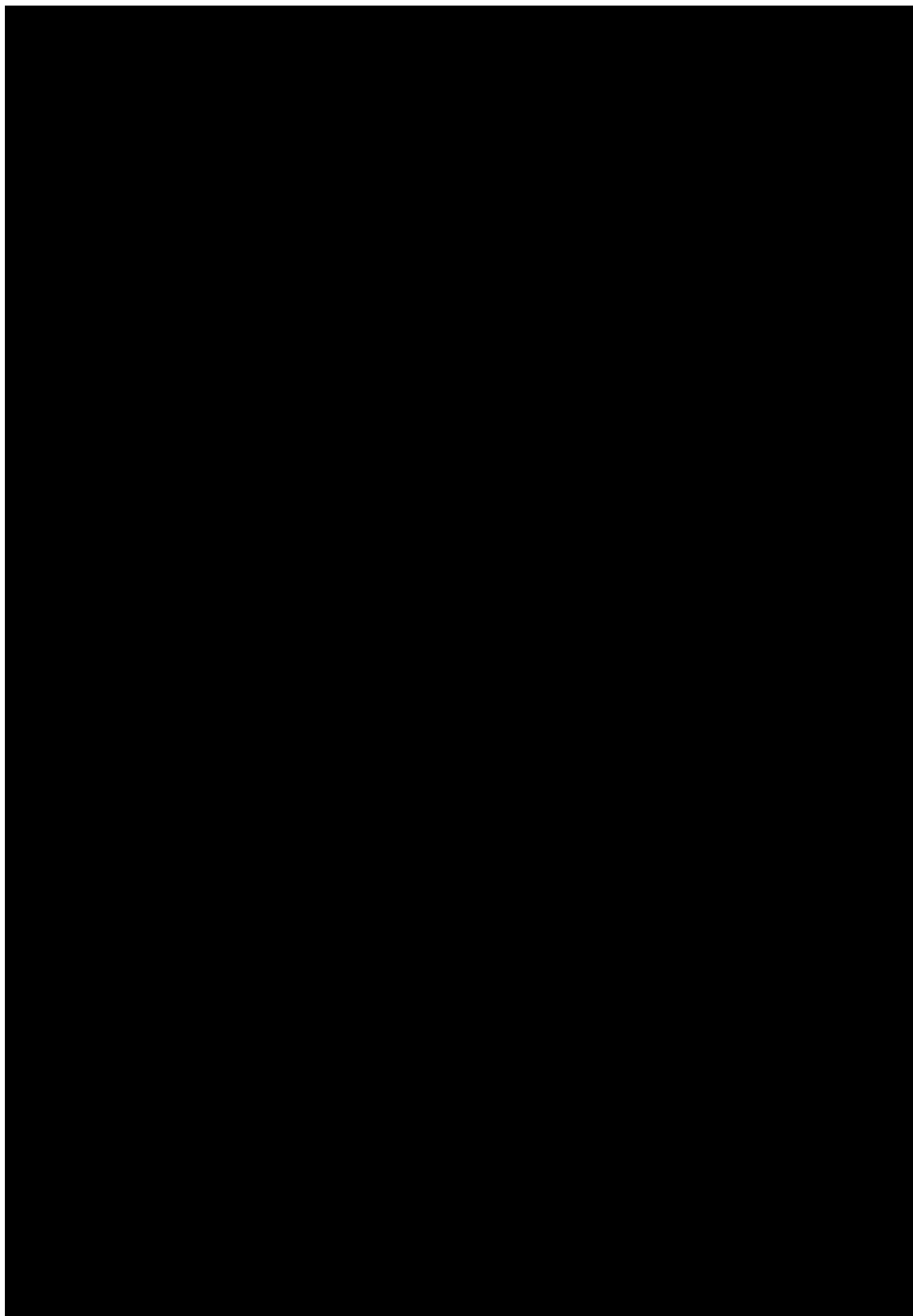


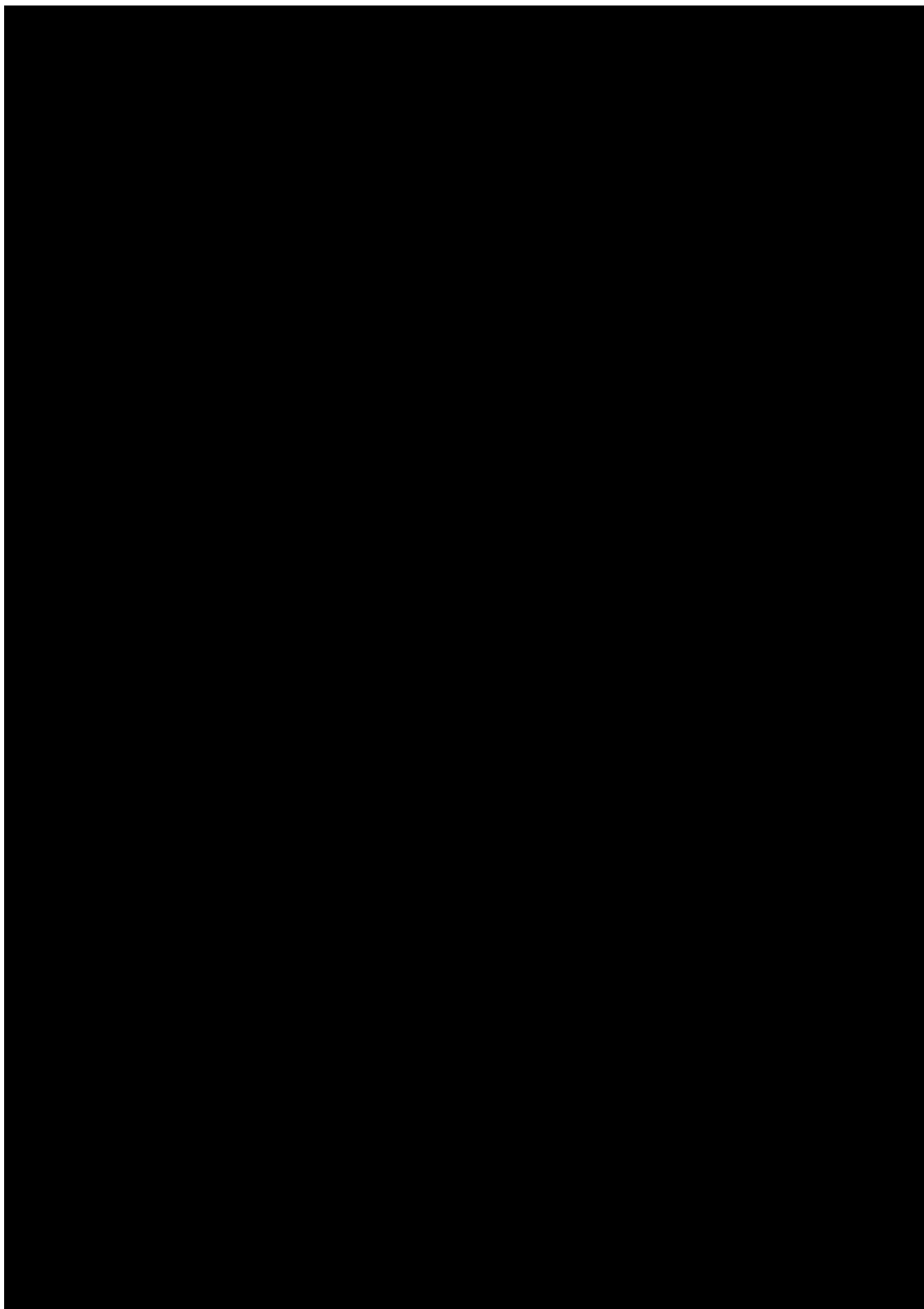




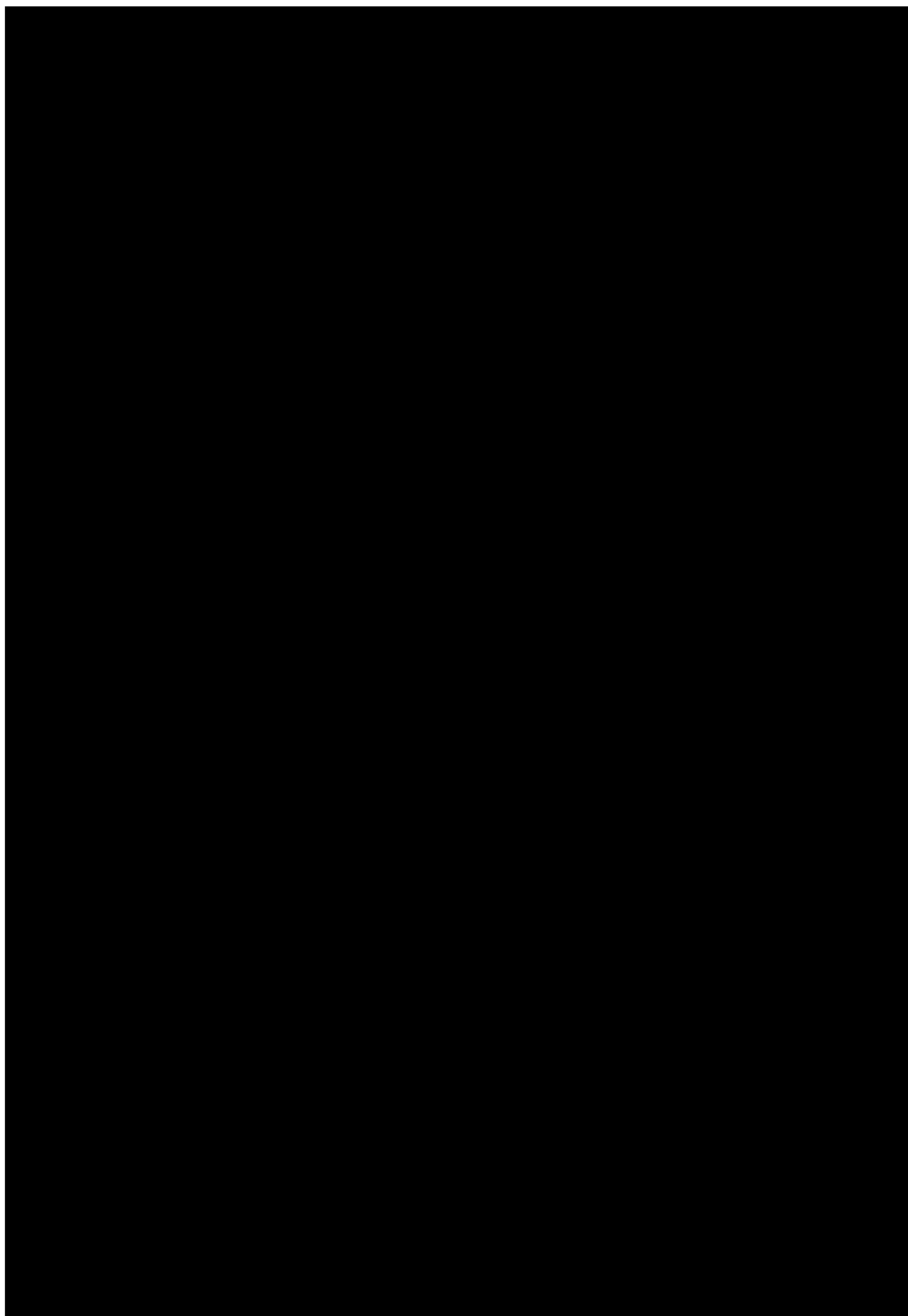


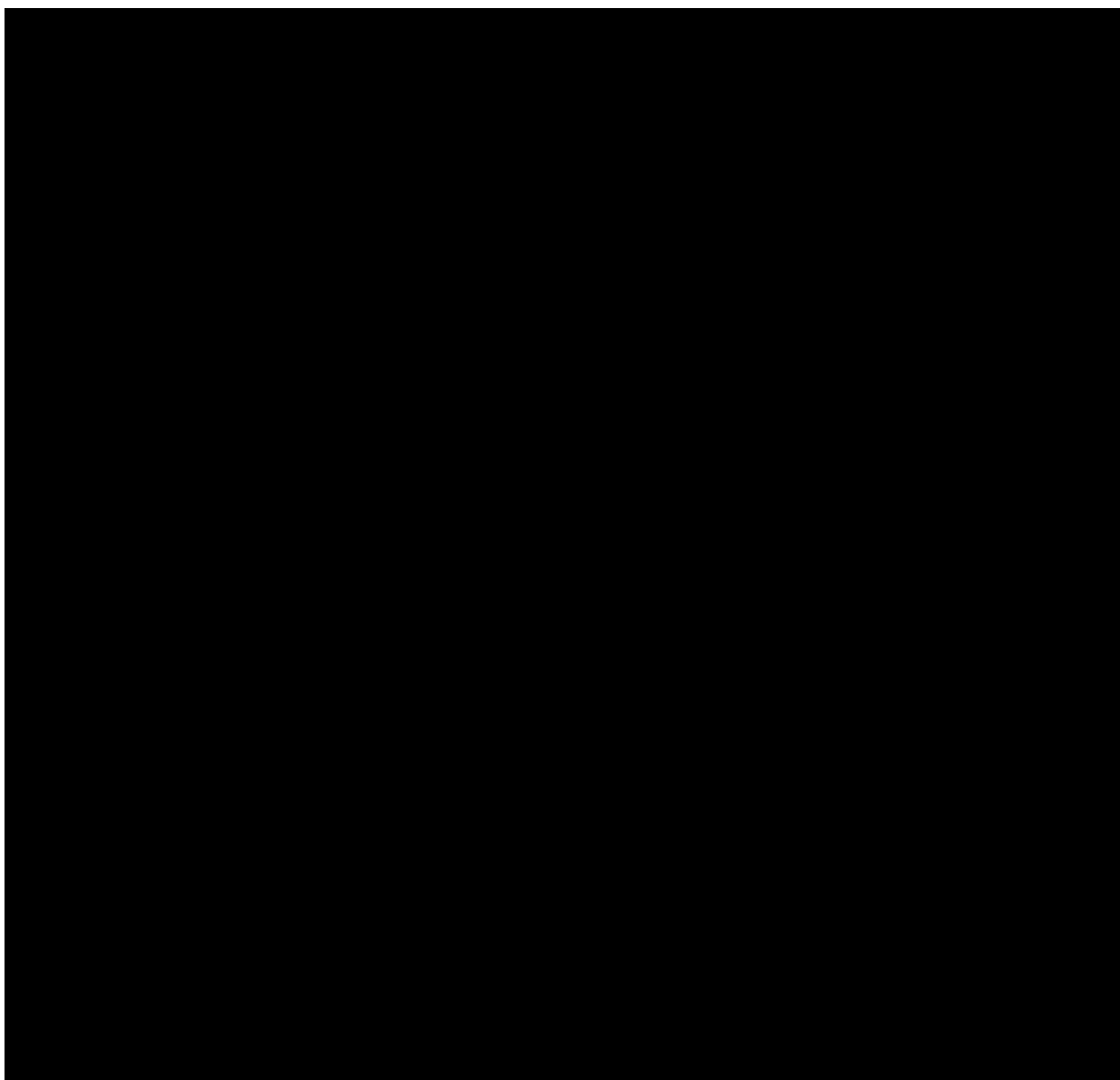


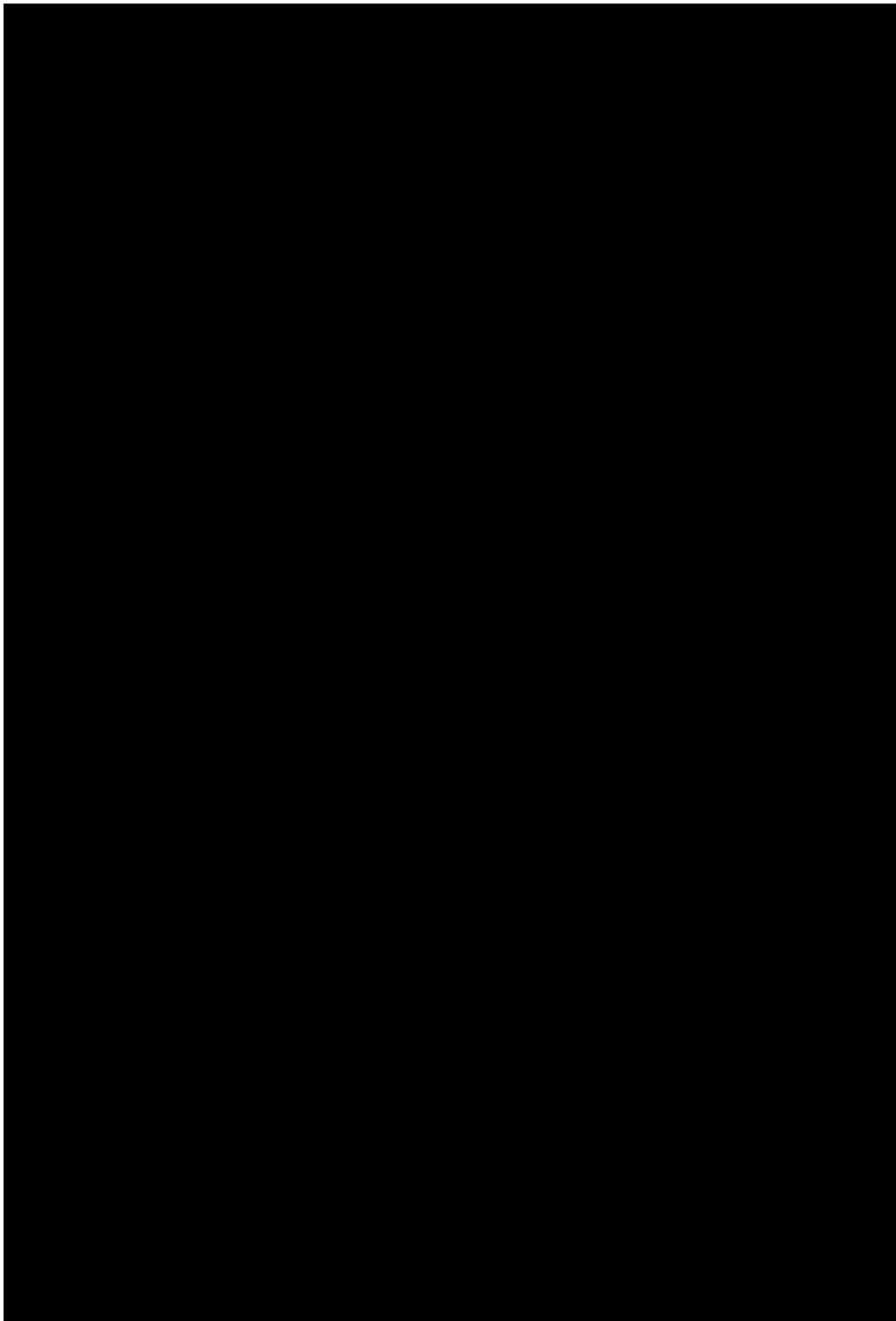


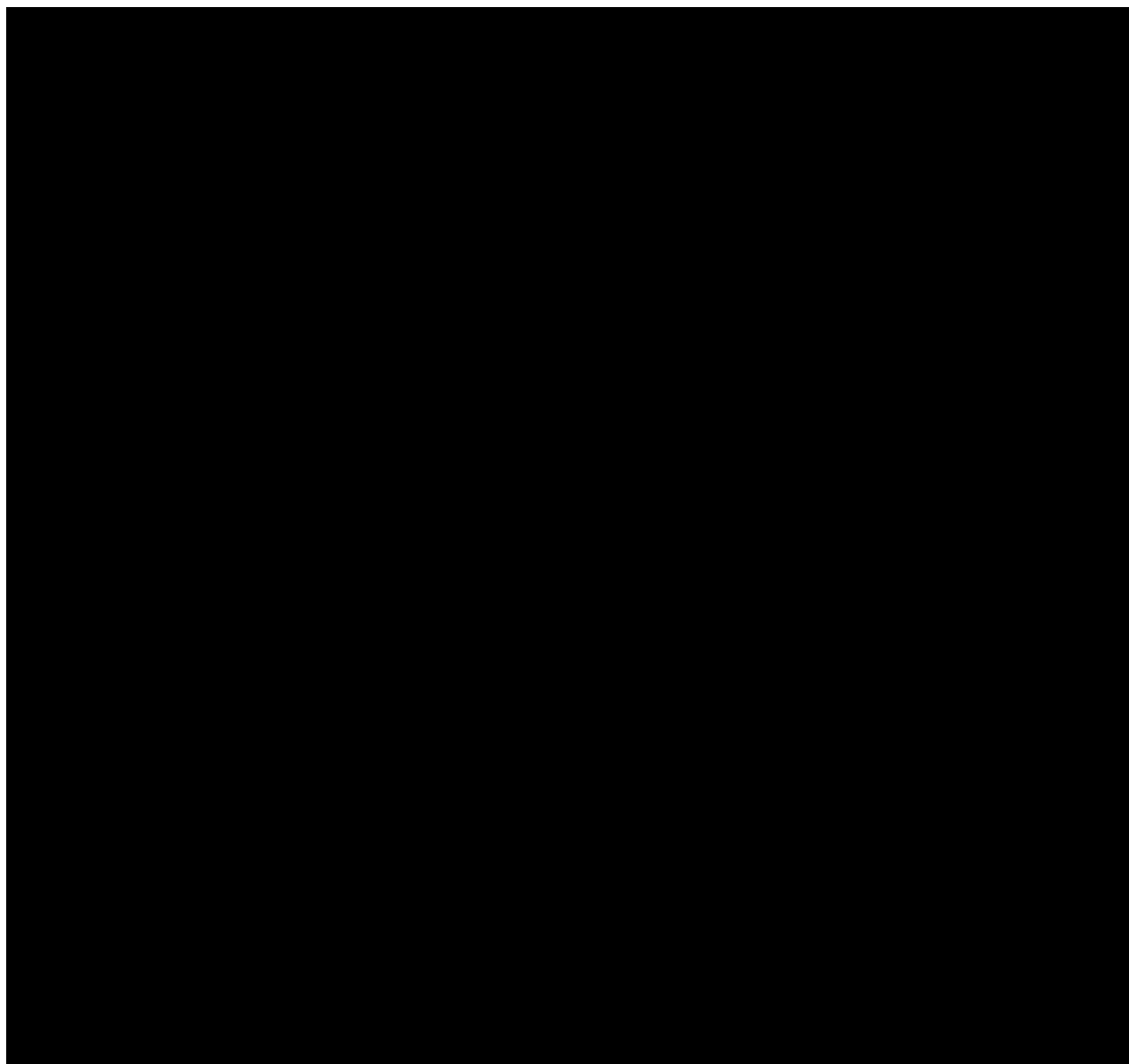


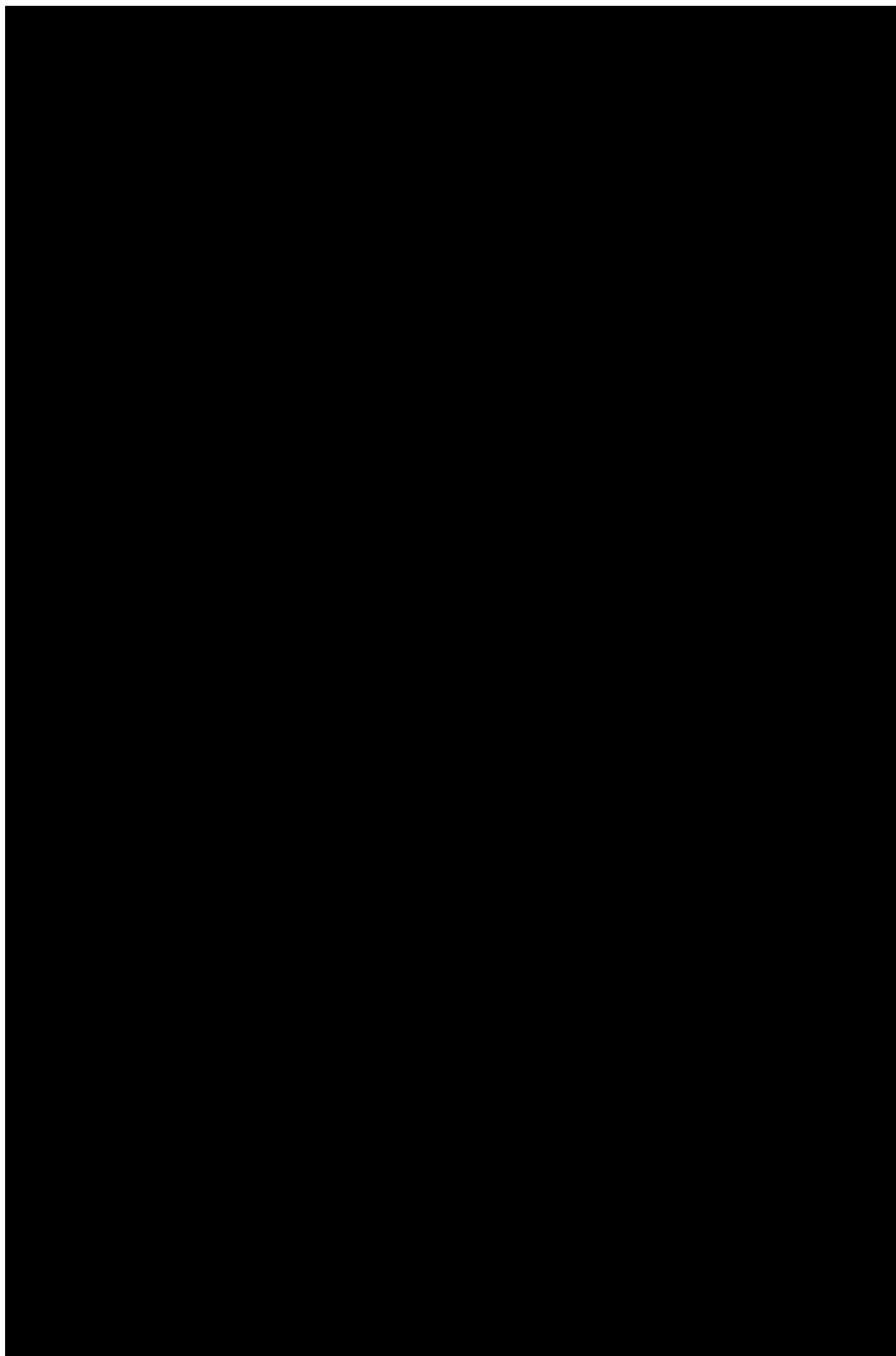


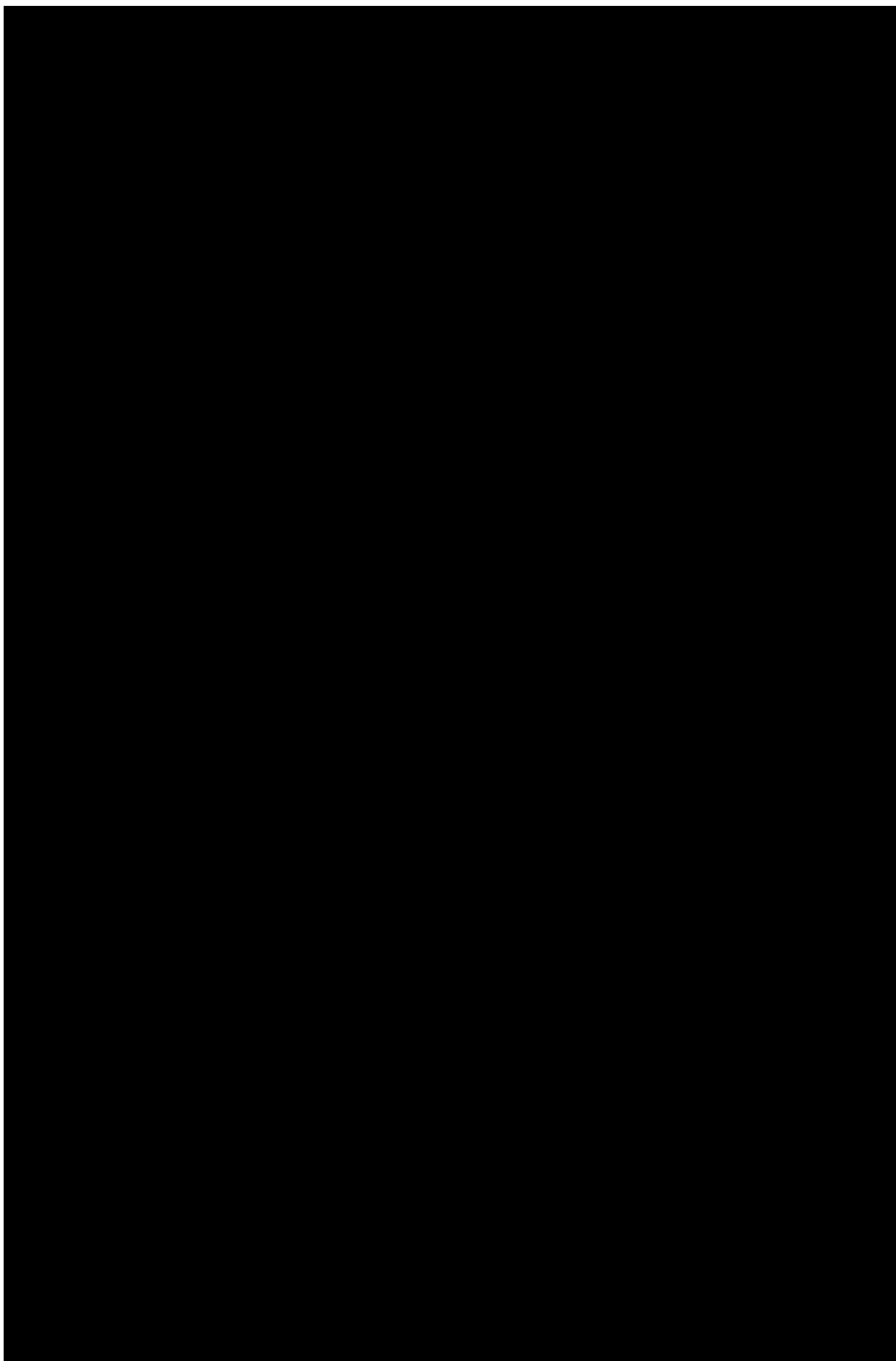


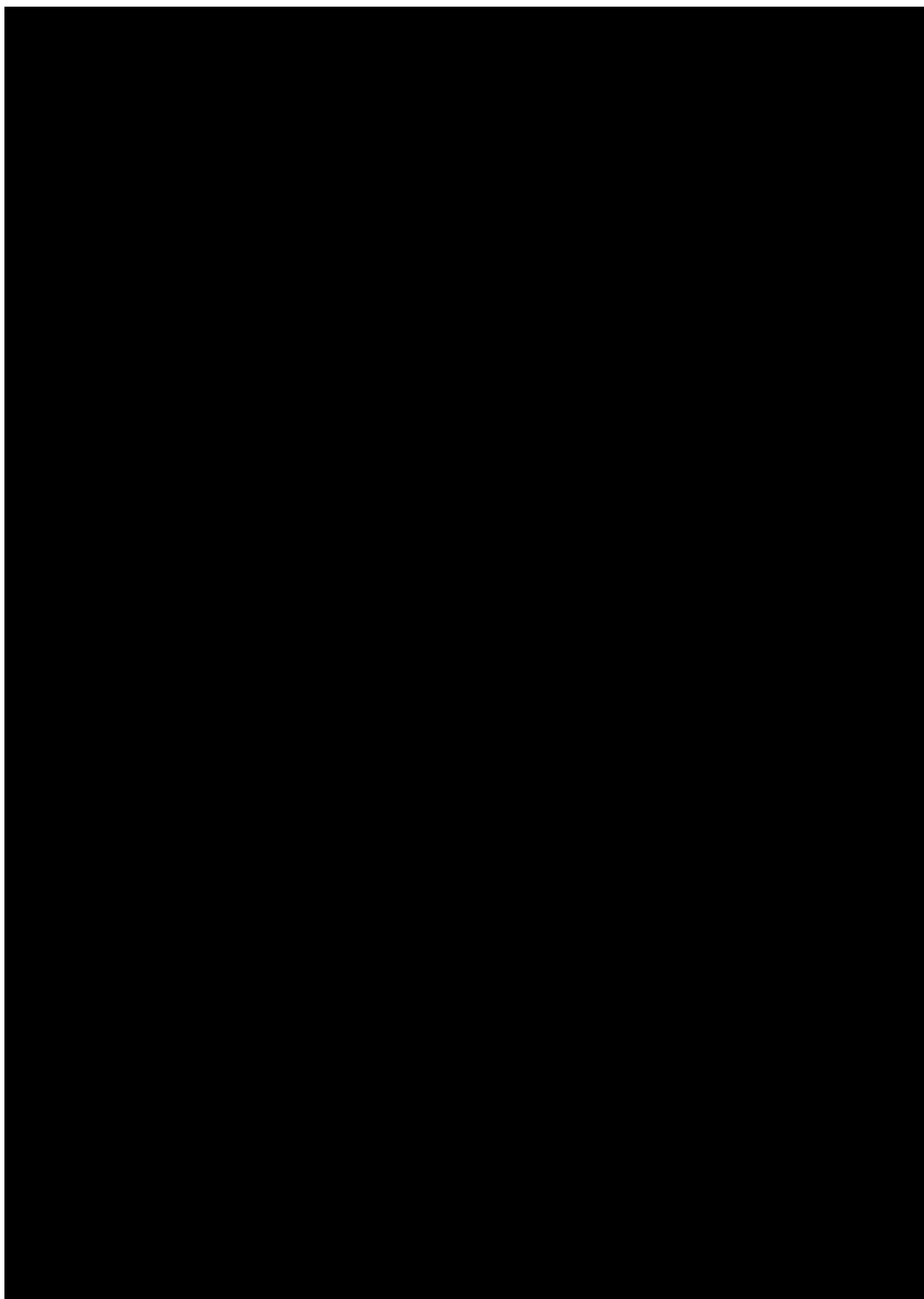


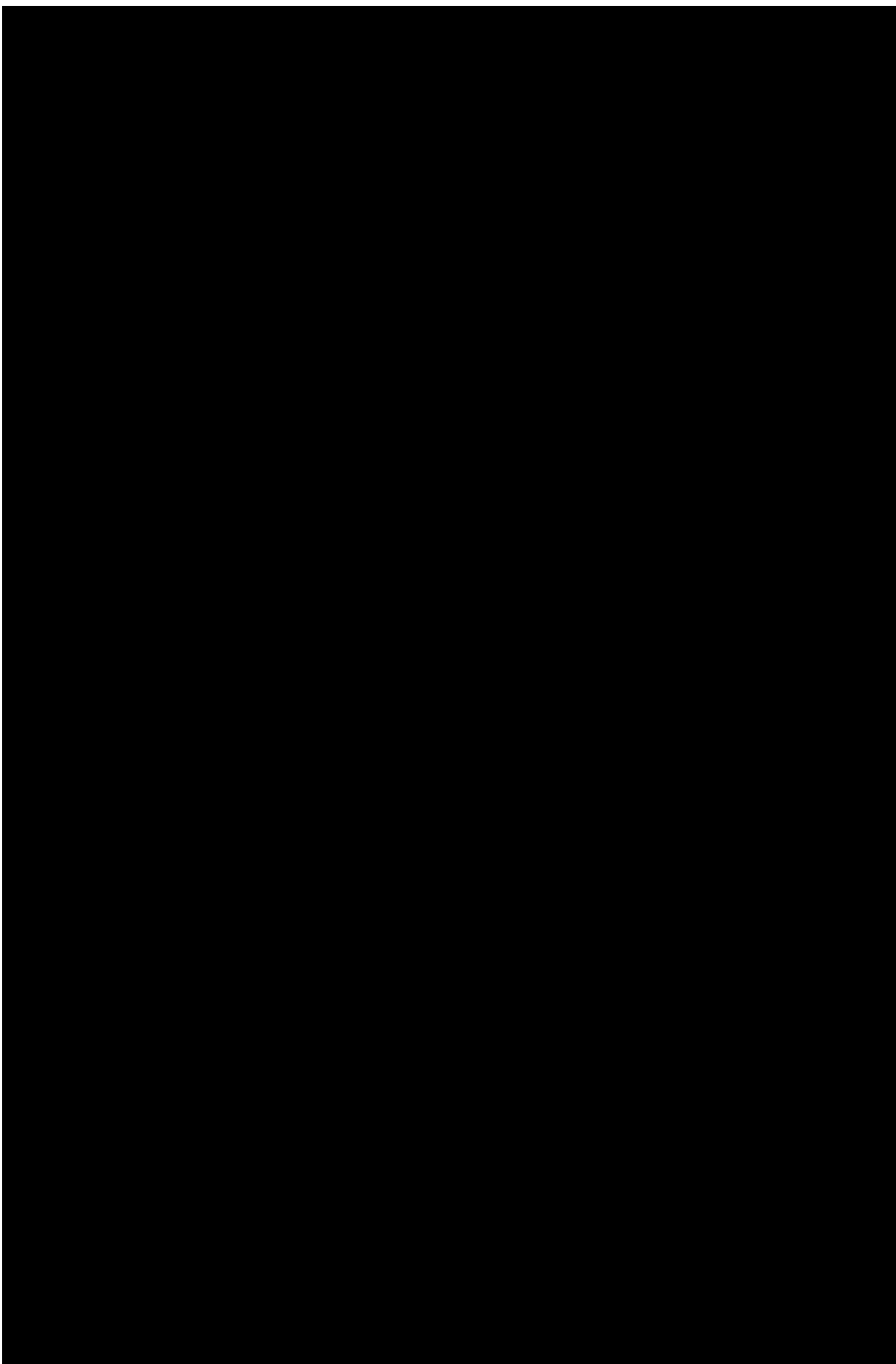


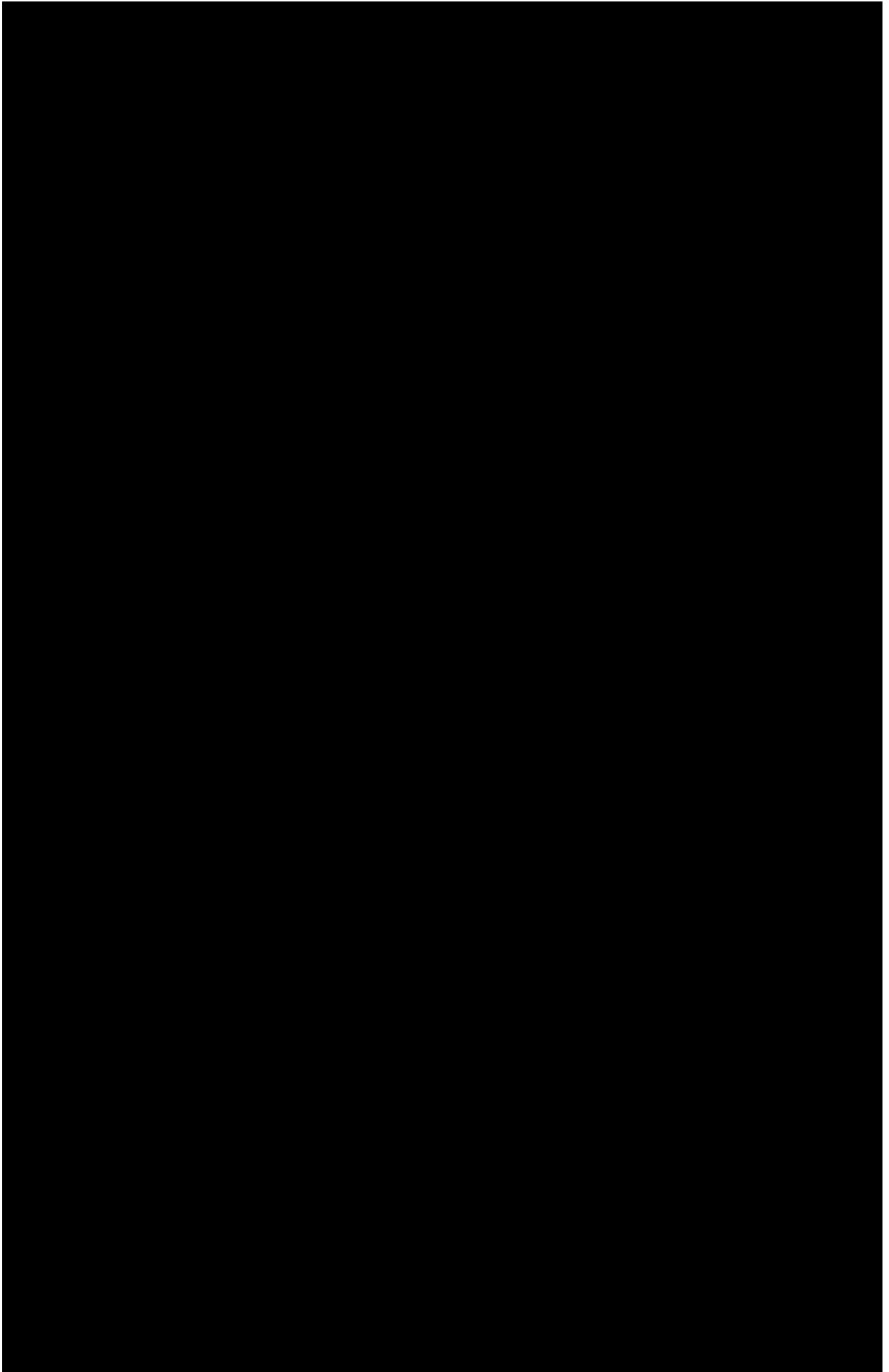


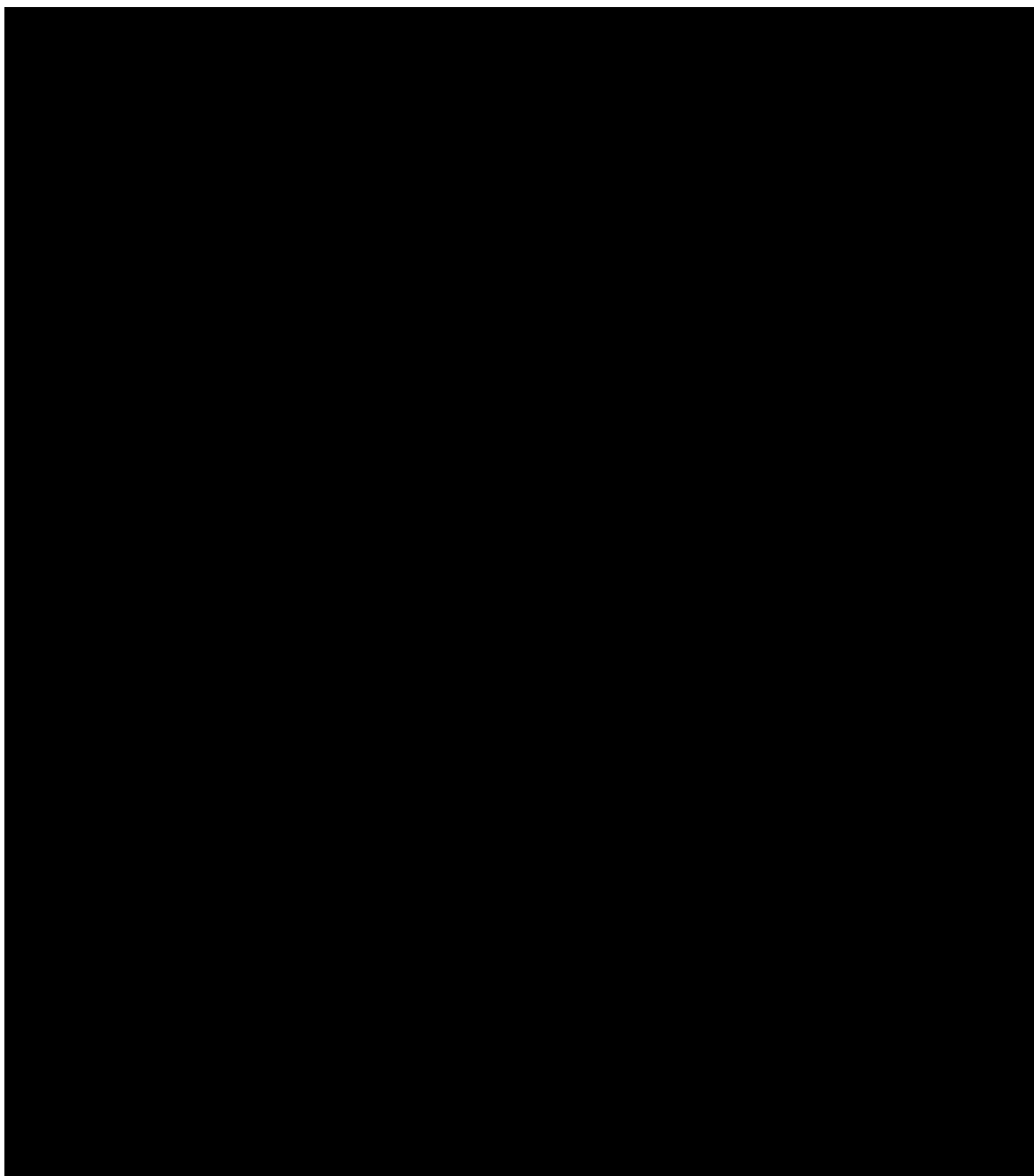


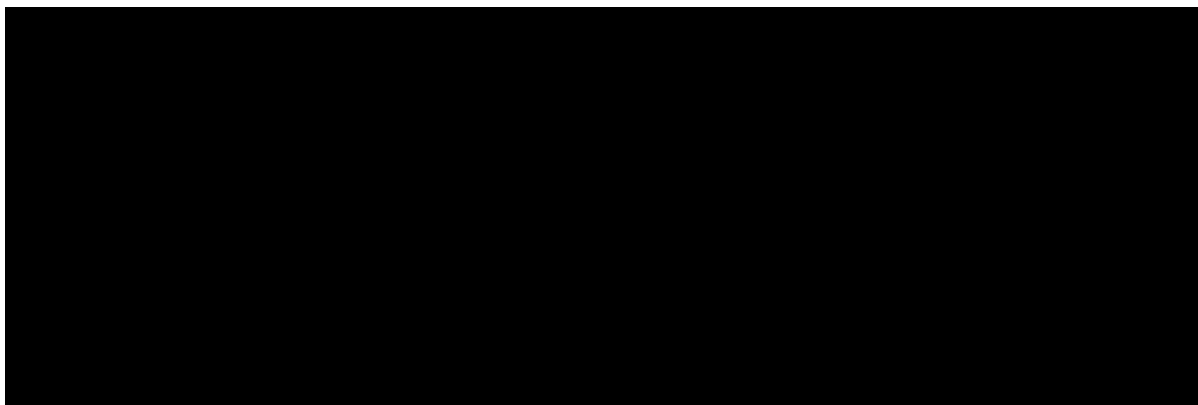


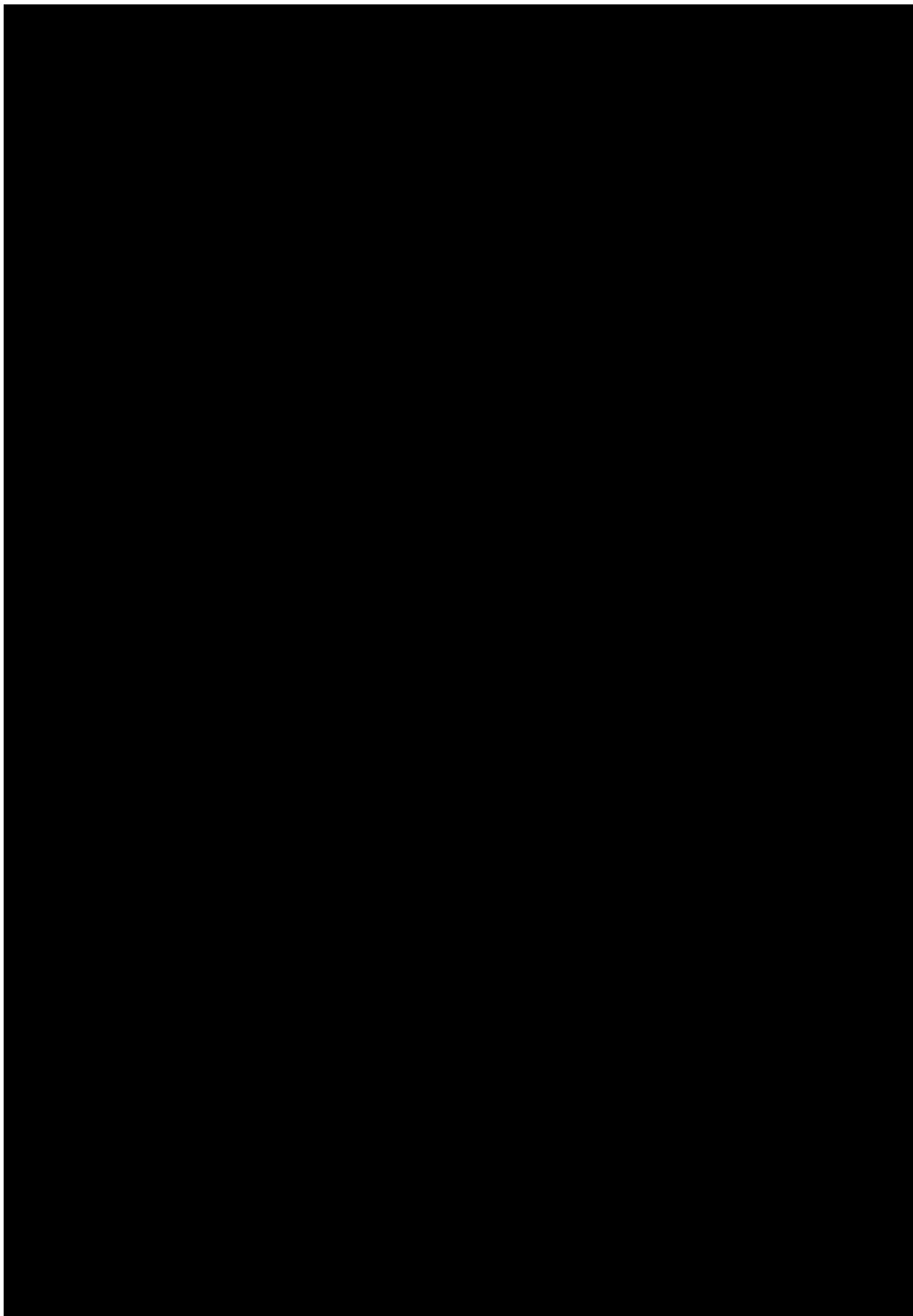


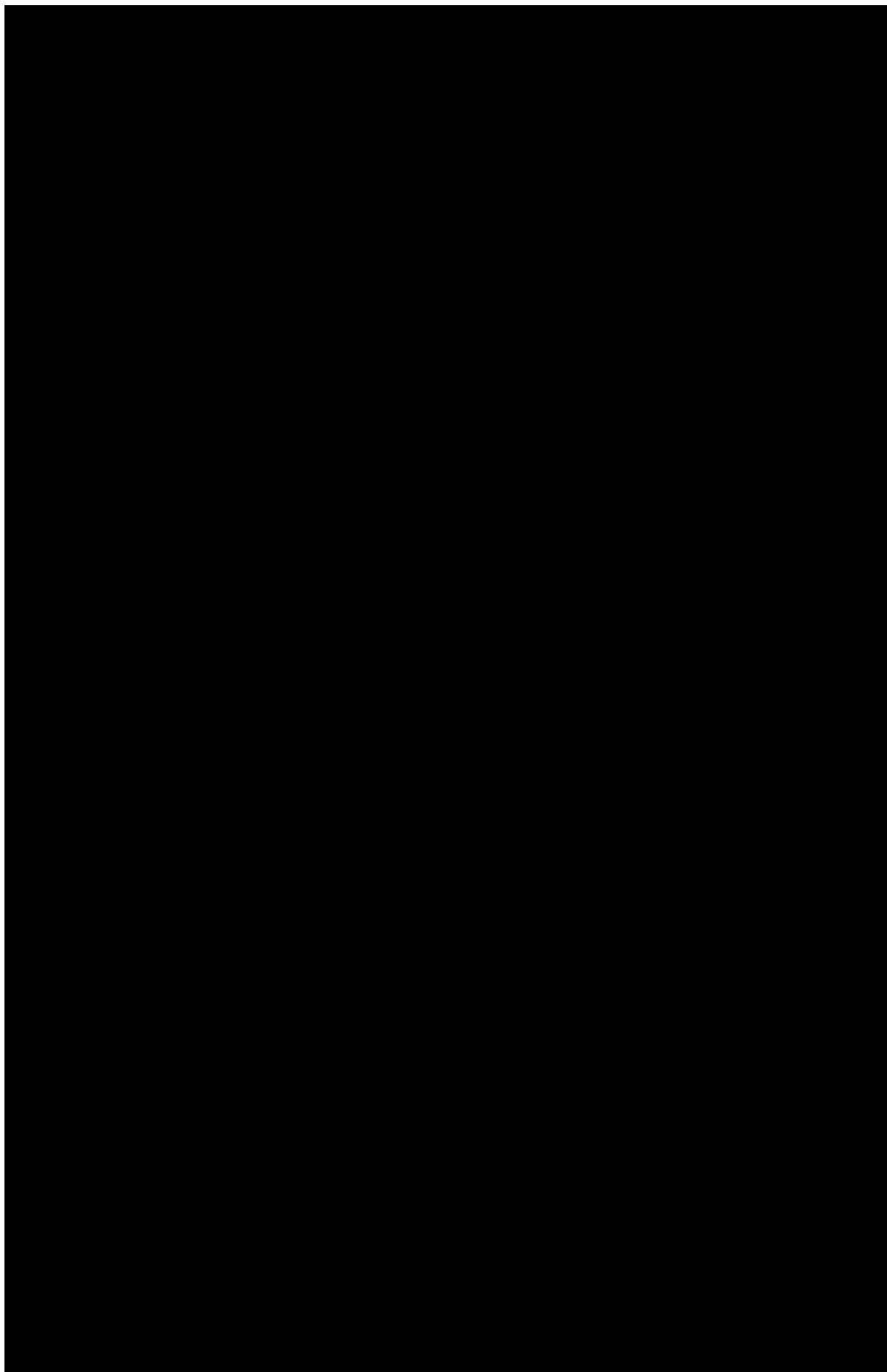


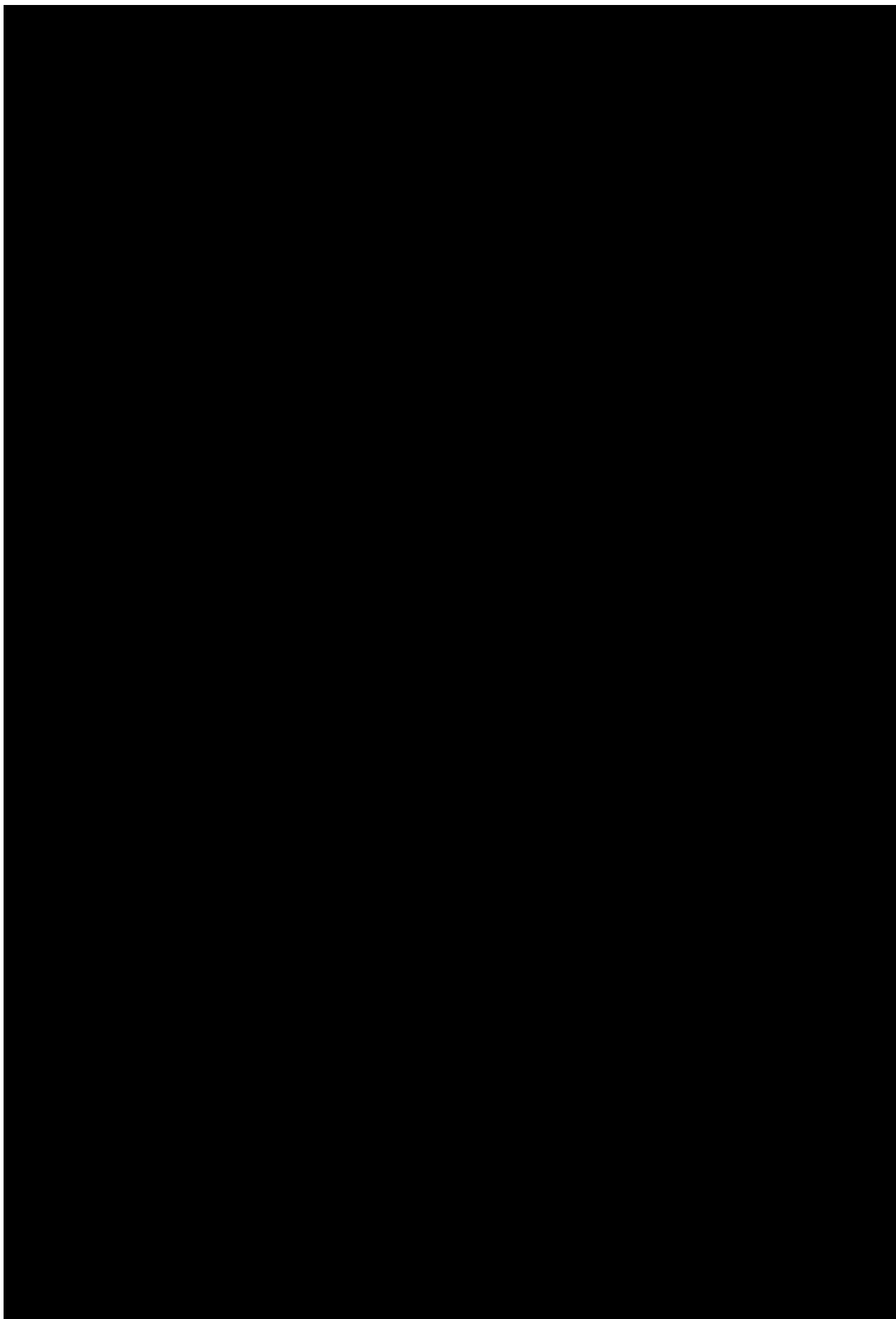


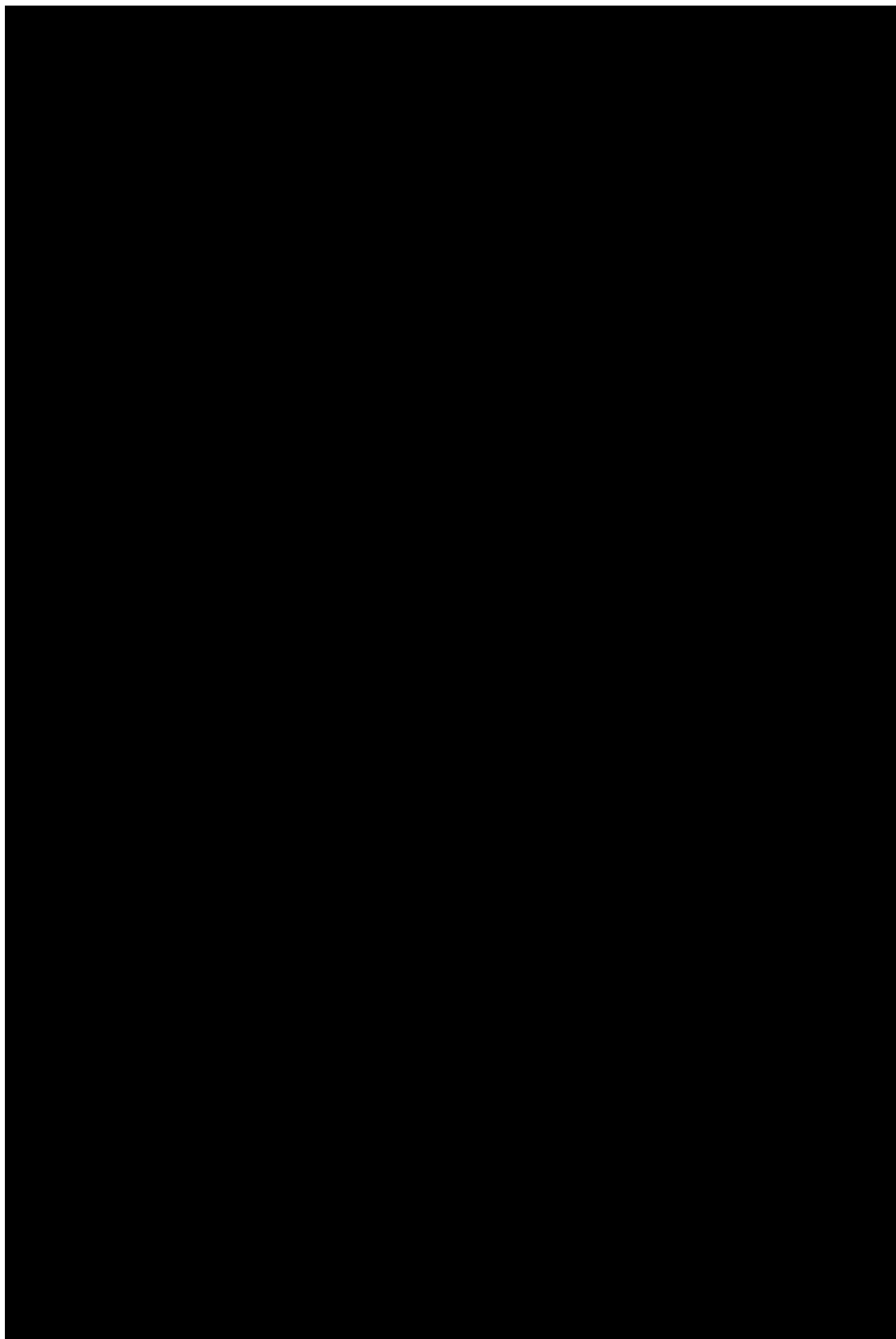




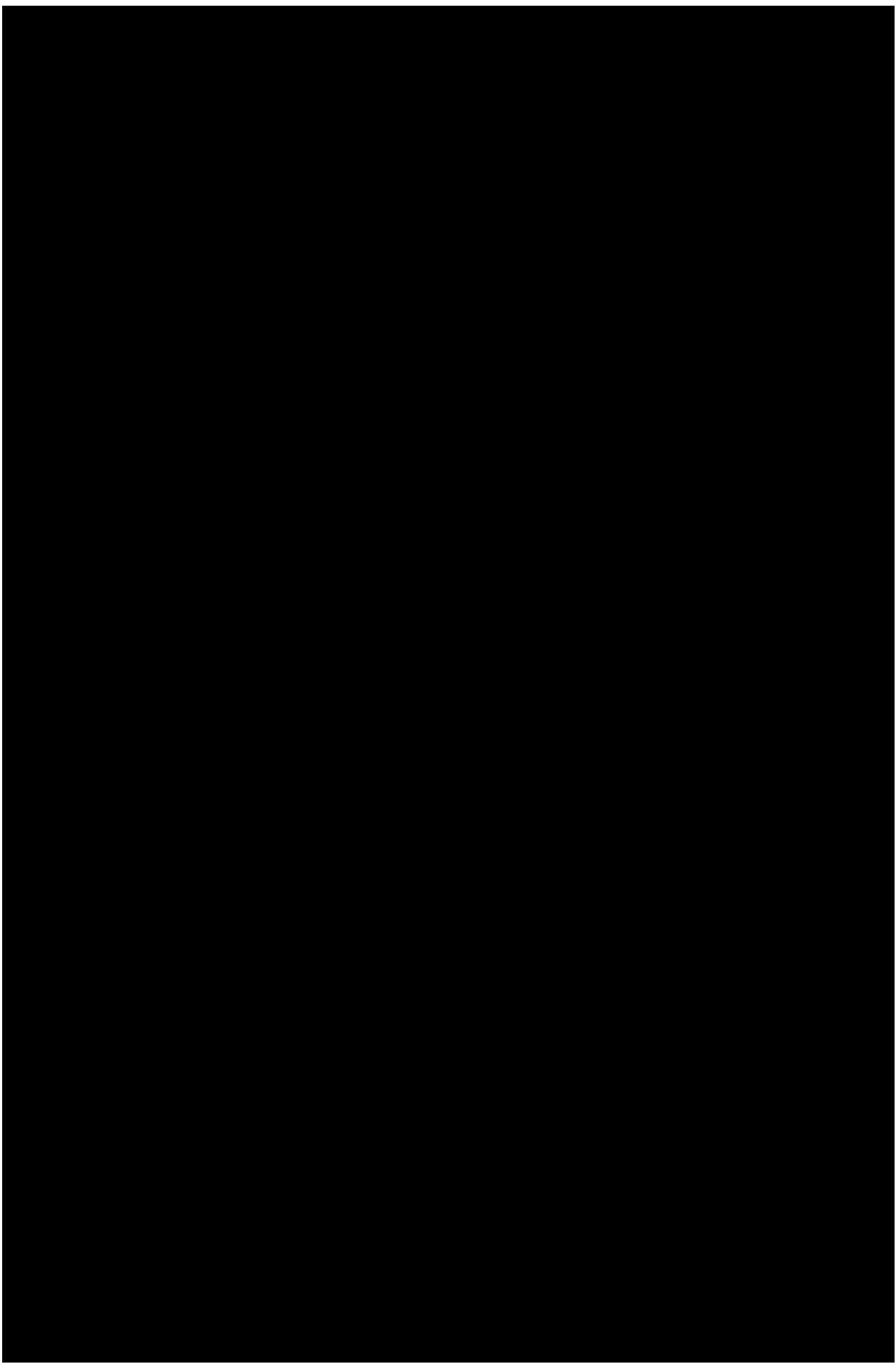


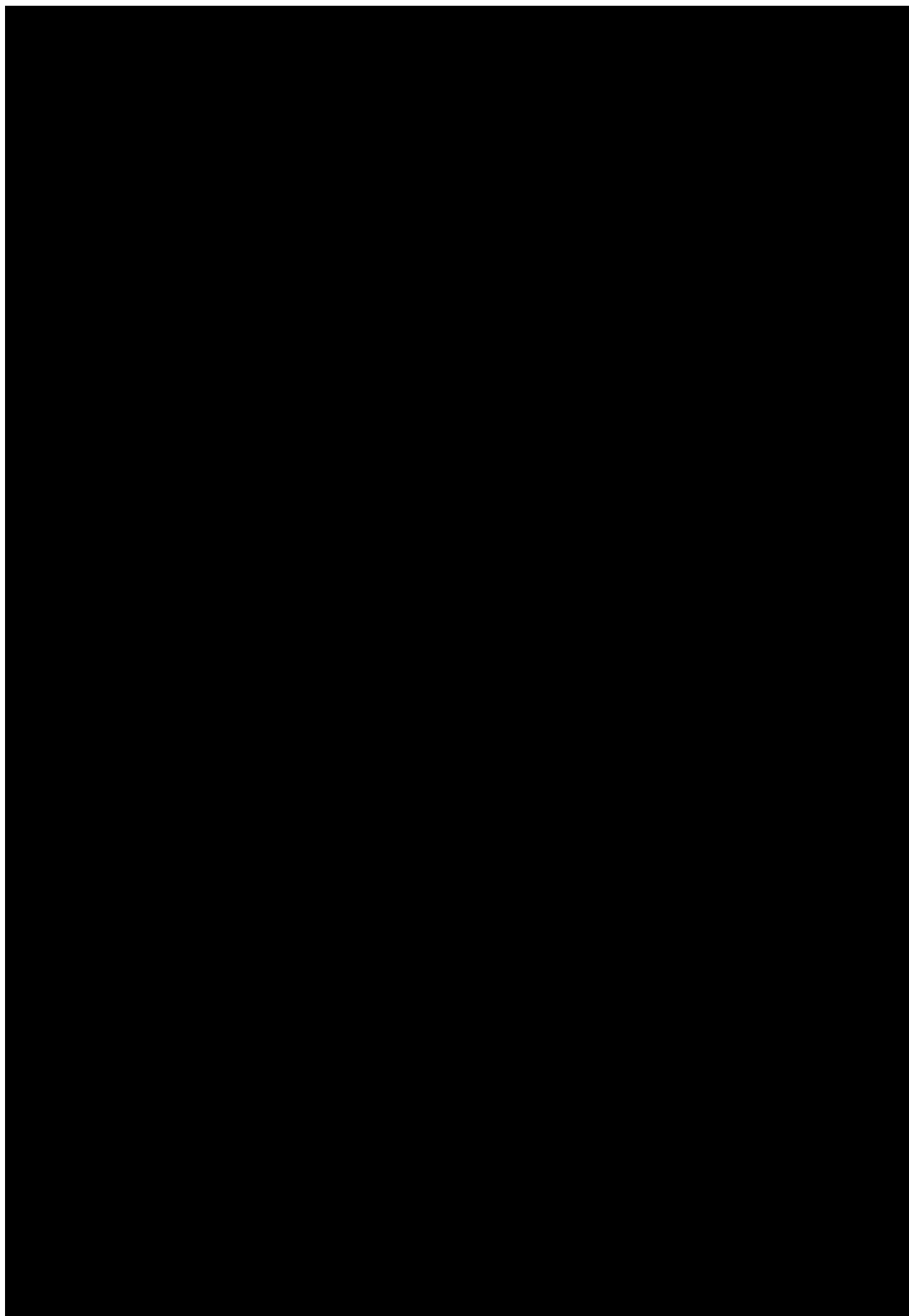


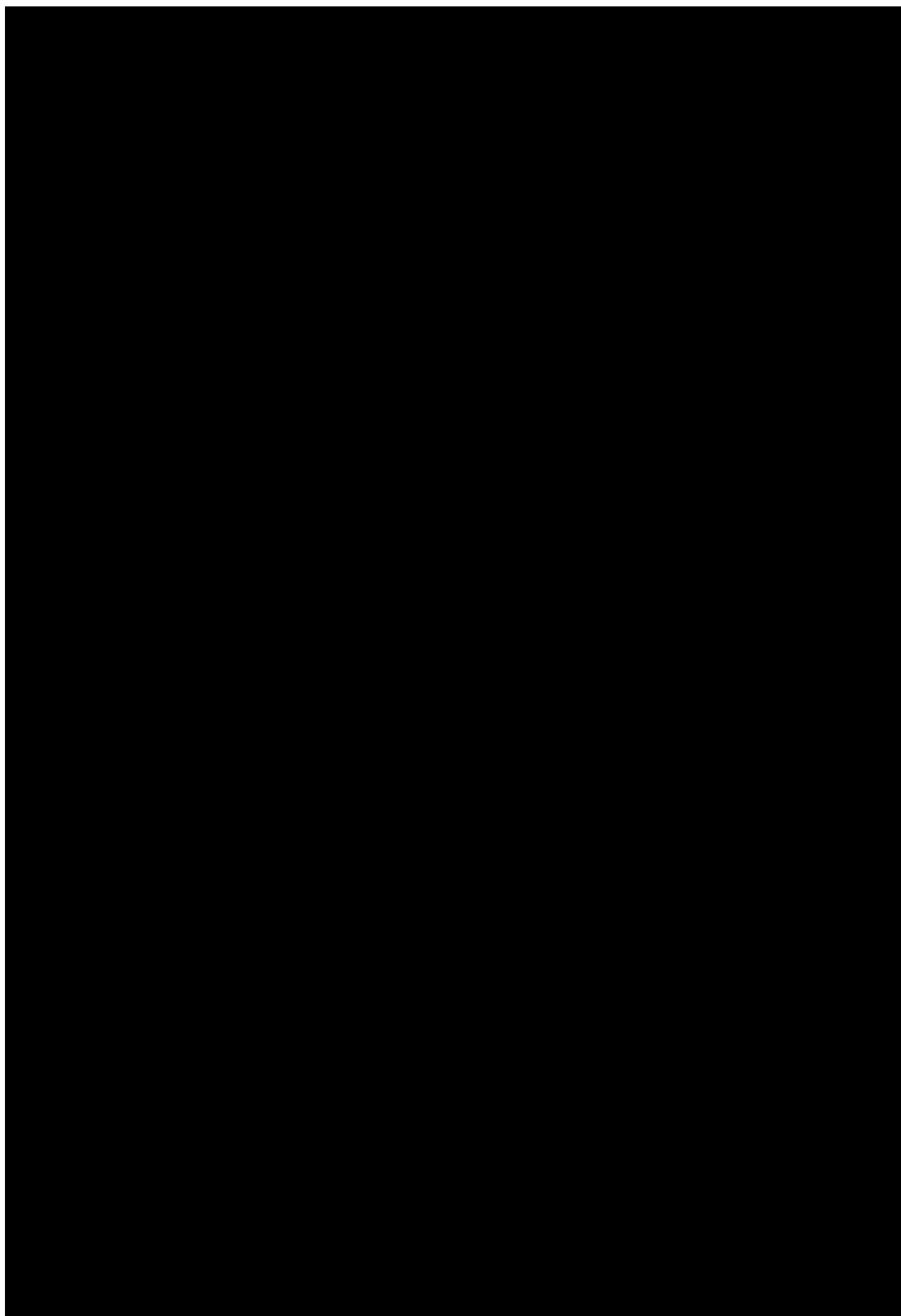


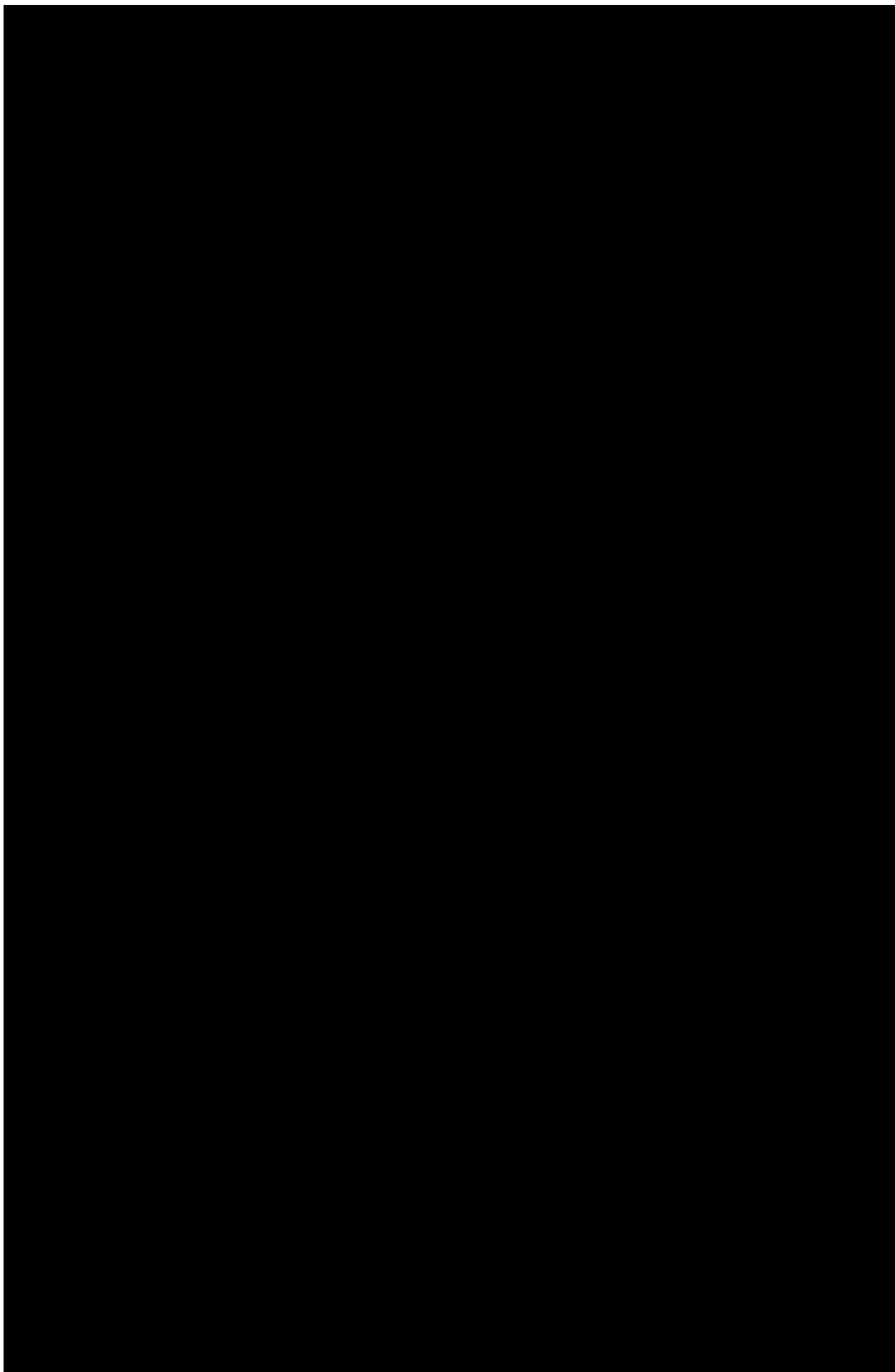


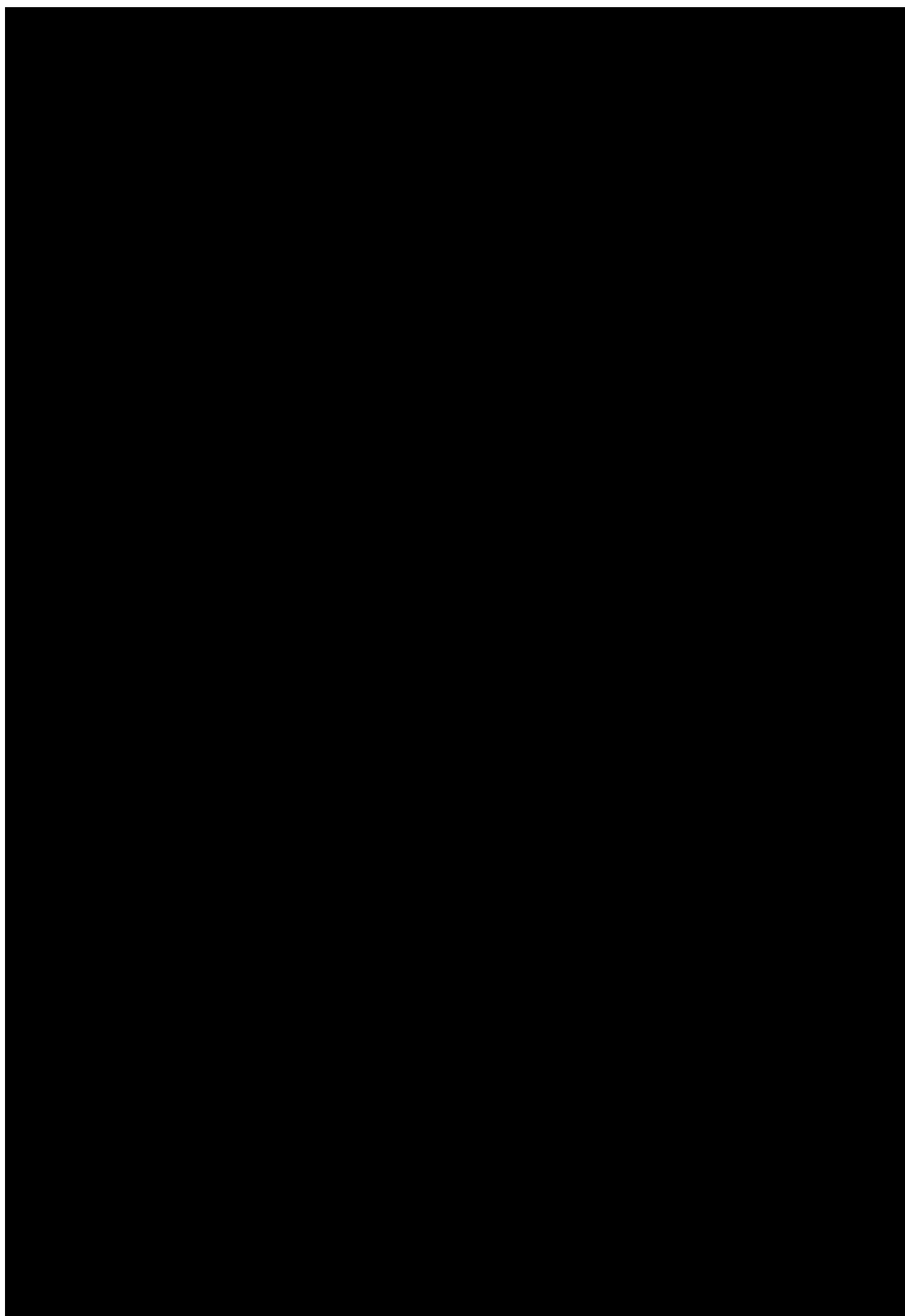


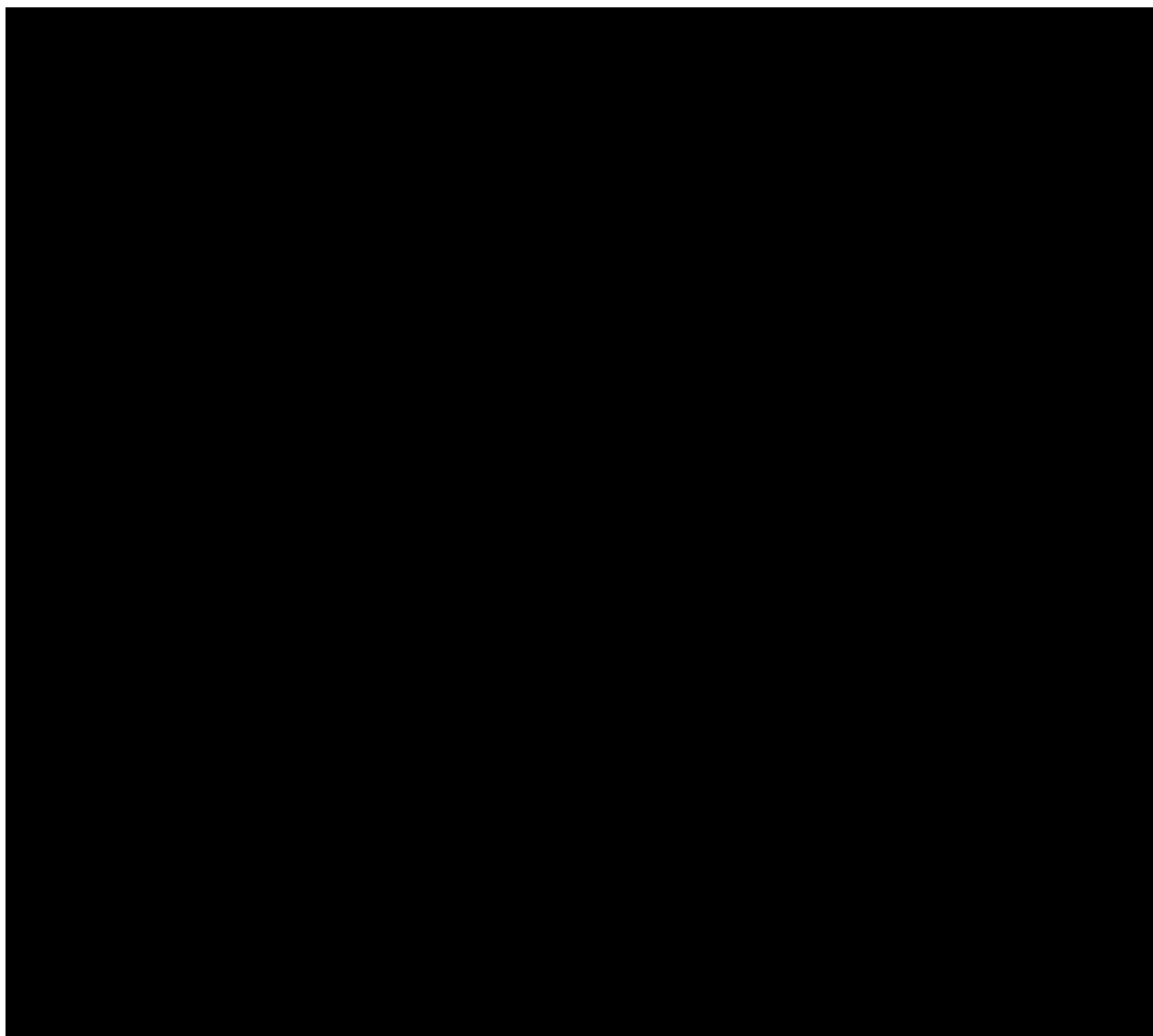












Chapter 3: Qualitative study

The contents of this chapter are presented in the form of a journal ready manuscript.

This manuscript is currently under peer-review.

Exploring the rationale for prescribing ankle-foot orthoses and supra-malleolar orthoses to children with cerebral palsy amongst paediatric orthotists in Australia

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Abstract

Purpose: To explore the rationale for prescribing ankle-foot orthoses and supra-malleolar orthoses in children with cerebral palsy amongst paediatric orthotists in Australia.

Materials and Methods: Purposive, convenience, and snowballing sampling were used to recruit paediatric orthotists across Australia. Semi-structured interviews were recorded and transcribed. The data were independently coded to derive themes and subthemes with illustrative first-person quotes.

Results: Of the 16 participants, most were in the 20-29-year age group, female, and had many years of clinical experience. Two themes were generated: *rationale for*

orthotic prescription, and alignment of prescription rationale with child/family goals.

Experienced clinicians could clearly articulate the key factors that influence their orthotic prescription aligned to the reasons why children/families sought orthotic intervention. Early to mid-career clinicians found this challenging. All clinicians could provide clear and consistent rationale for their prescription when presented with simple rationale statements.

Conclusion: The rationale for prescription should be aligned with the problem/s that drove the child/family to present for orthotic care. With a clear focus on treatment goals that address these problems, the rationale for prescribing either AFOs or SMOs could be clearer if clinicians focused on a few primary factors, and then optimise that prescription using a wider range of secondary factors.

Keywords

ankle-foot orthoses, supra-malleolar orthoses, cerebral palsy, prescription, children

3.1 Introduction

Cerebral palsy (CP) is a non-progressive, neurological condition that affects approximately 2.5 per 1000 live births [1]. It is caused by a malformation or injury during brain development [2]. As a result, children with CP often live with abnormal muscle tone, poor motor control, and joint deformities [3] that limits their activity and participation [4,5]. To help improve outcomes for children with CP, both ankle-foot orthoses (AFOs) and supra-malleolar orthoses (SMOs) are often prescribed [6].

AFOs are lower limb orthoses that encapsulate part of the foot and leg segment. They are designed to provide tri-planar control at the ankle and knee joint [7]. SMOs are orthoses that encompass part of the foot and may extend just superior to the ankle joint. They primarily provide coronal and transverse plane control of the intrinsic foot joints with limited influence at the ankle joint [7].

Given these definitions, AFOs and SMOs are designed to affect different joints and limb segments. As such, it seems reasonable to conclude that the rationale for their prescription would also be clear. However, based on a recent narrative review [8] the rationale for prescribing AFOs was clearer than that for SMO. For example, most studies reported that the rationale for prescribing AFOs for children with CP was to normalise some aspect of gait, such as reducing crouch gait. This view was reflected in the rationale, aims, and outcome measure(s) reported in most studies [8]. By contrast, the rationale for prescribing SMO was not clear given the rationale was often vague, and not aligned with the aim, nor outcome measure(s) used.

There are likely to be a complex range of factors that influence the prescription of either AFOs or SMOs beyond the mechanical effect they may have on gait. For example,

some studies have suggested that SMOs may provide an alternative for children/families wanting a less invasive orthotic intervention [9,10].

If we are to understand the myriad of factors that influence the prescription of AFOs and SMOs for children living with CP, and how orthotists weigh these different factors when deciding on the prescription of either an AFO or SMO, it is important that we learn first-hand about the prescription rationale directly from practising paediatric orthotists.

Therefore, the aim of this study was to explore the rationale for prescribing AFOs and SMOs for children with CP amongst paediatric orthotists in Australia.

3.2 Materials and Methods

Design

This qualitative study was approved by the La Trobe University Human Research Ethics Committee (Reference number: HEC22183).

Participants

Purposive, convenience, and snowballing sampling were used to identify paediatric orthotists providing orthotic care to children in both hospital- and community-based facilities across Australia.

For context, in the Australian hospital-based public system, orthoses are generally government or publicly funded, and the patient (or their family) has no out-of-pocket expenses. By contrast, the community-based private system consists of privately run orthotic facilities, and the child has their orthoses either funded privately (by their

family) or under an insurance scheme; most commonly, the National Disability Insurance Scheme (NDIS).

Purposive sampling: details of paediatric orthotists were collected from a publicly available database (The Australian Orthotic Prosthetic Association Inc. practitioner search database, 2023), as well as through Google (Google Inc., U.S.A.). An email was sent out to prospective participants inviting their participation with a follow-up one-week later.

Convenience sampling: advertisements were made available through the Australian Orthotic Prosthetic Association Inc., including on the association's website and social media platforms (i.e., Facebook, Instagram, LinkedIn, and Twitter). Interested paediatric orthotists could contact one of the researchers (AD) for further information.

Snowball sampling: participants who completed the interview were asked to email other paediatric orthotists within their networks using a template email provided by the research team.

These strategies were adopted to ensure that we recruited a diverse sample of paediatric orthotists working across Australia.

The inclusion criteria were:

1. 18 years of age or over
2. Qualified orthotist/prosthetist
3. Regularly provided either AFOs or SMOs to children with CP
4. Able to interview in English

Data collection

Those who agreed to participate received a follow up email with further information about the study, a downloadable *Participant Information Statement*, and a date and time for the semi-structured interview.

Semi-structured interviews were conducted between September and November 2022. The researcher who conducted the interviews (AD) was a female prosthetist/orthotist, with nine years of clinical experience who worked at a tertiary, specialist paediatric hospital in a large metropolitan city in Australia.

Prior to the semi-structured interviews, the researcher (AD) received training including reading about qualitative interview techniques [11], several practice interviews followed by debriefing with one of two experienced researchers (MD or SA), as well as an undergraduate class on coding and thematic analysis of interview data. One-on-one supervision was provided following each interview where one of the experienced researchers (MD) would have also listened to and coded the interview.

At the commencement of each interview, participants were asked to paraphrase the purpose of the study and describe what would happen during the interview. In this way, the researcher (AD) could be confident that participants had a detailed understanding of what was involved and were able to provide verbal consent.

All interviews were conducted virtually using the teleconferencing platform Zoom (Zoom video communications Inc., 2016), given the intent to interview clinicians from all over Australia.

A semi-structured interview guide ([Chapter 3: Appendix 1](#)) was developed in accordance with principles described by LaForest [12] and Kallio et al. [13]. The interview guide included open-ended, non-leading questions with prompts to

facilitate a rich conversation without questions that would bias the response. The interview guide incorporated four sections: participant demographics, factors that influence the rationale for the type of orthosis provided, the outcome measures used to evaluate the effect of the orthotic intervention, and the reason why children and their families seek orthotic care. The intent of these different topics was to probe the participant's rationale for the prescription of AFOs and SMOs in different ways. For example, by asking the clinician what outcome measure(s) they used to evaluate the effect of an orthosis they provided, it was possible to glean why they provided that device. If the outcome measure was appropriate to quantify some aspect of gait, then we would expect that rationale for the orthotic prescription was gait related. This interview guide was pilot tested with three retired paediatric orthotists with a research background.

Interviews were audio recorded using the Zoom teleconferencing software (Zoom video communications Inc., 2016). The researcher (AD) wrote *field notes* by hand during the interview including prompts for follow-up questions, and impressions.

Data analysis

Interviews were professionally transcribed (Pacific Transcription, Milton QLD). One researcher (AD) read through each transcript and listened to the associated audio recording to ensure that the transcripts were an accurate reflection of the interview. The transcripts were then uploaded to NVivo 12+ (QSR International, Chadstone VIC) for coding and analysis. Two researchers (AD and MD) independently read and coded each interview transcript. Both these researchers were experienced and qualified orthotists/prosthetists. One researcher (AD) had a master's degree in prosthetics and orthotics, with nine years of clinical experience as a paediatric orthotist. The other researchers had undergraduate degrees in prosthetics and orthotics, with post-graduate

training at the doctoral level, with more than 20 years' academic experience. Reconciliation meetings between the two researchers were conducted following the independent coding of each interview, and any differences in the interpretation reconciled. Following each reconciliation meeting, a summary of the themes and illustrative first-person quotes were sent to participants via email for member checking. Participants then had an opportunity to give feedback to ensure the researchers' interpretation was accurate. Adaptations were made based on the feedback received to ensure the interpretation accurately reflected the participant's views. This data analysis process was repeated until no new themes emerged, and data saturation was reached. Once data saturation was achieved, and the participants had provided confirmation that the interpretations of their views were accurate, the data synthesis began. Individual codes that had similar interpretations were grouped into minor themes. Then once the minor themes were developed, they were grouped into major themes. These themes were then developed into narratives with illustrative first-person quotes. A third researcher (SA) who was independent of the interview, coding, and theme development process, reviewed the interview transcripts to ensure the narrative was an accurate representation of the interviews.

3.3 Results

Participants

Of the 16 participants (Table 1) who responded to the invitation, none dropped out during the study. Most participants were from the states of Victoria and New South Wales (62%). All participants (100%) worked in metropolitan cities, and just over half (56%) worked at private orthotic facilities in the community (Table 1).

Participant number	Gender	Age category (years)	Years of experience	State/territory	Public/Private facility	Estimated number children with CP seen per week
1	Female	20-29	6-10	Queensland	Private	6-10
2	Female	40-60	20+	New South Wales	Public	1-5
3	Female	20-29	0-5	South Australia	Private	6-10
4	Female	20-29	0-5	New South Wales	Public	6-10
5	Female	20-29	6-10	Victoria	Public	11-15
6	Female	20-29	0-5	South Australia	Private	6-10
7	Male	20-29	6-10	Victoria	Public	11-15
8	Female	20-29	0-5	Western Australia	Private	6-10
9	Male	40-60	20+	Victoria	Public	11-15
10	Male	20-29	0-5	South Australia	Private	6-10
11	Female	30-39	11-20	Western Australia	Private	1-5
12	Male	20-29	0-5	Victoria	Public	11-15
13	Female	50+	11-20	Victoria	Public	11-15
14	Female	20-29	0-5	South Australia	Private	6-10
15	Female	40-60	20+	South Australia	Private	1-5
16	Female	20-29	6-10	South Australia	Private	6-10

Table 1: Participant demographics

Note: Years of experience was defined as the number of years since the participant had received their orthotic/prosthetic qualification. Public/private facility was defined as the type of orthotic funding model.

69% of the participants were in the 20–29-year-old age group, and 75% identified as female. On average, participants had almost 10 years of clinical experience (9.5 ± 8.6 years); acknowledging that there was considerable variability (range 1.5–26.0 years). On average, participants treated 10–15 children with CP per week. While most of these

appointments were for some form of review, participants reported fitting about three children with AFO(s) per week, and one child per month with SMO(s).

Themes

Two main themes arose from the interviews: *rationale for orthotic prescription*, and *alignment of prescription rationale with child/family goals*. Both themes were rich in detail and included several sub themes (Figure 1).

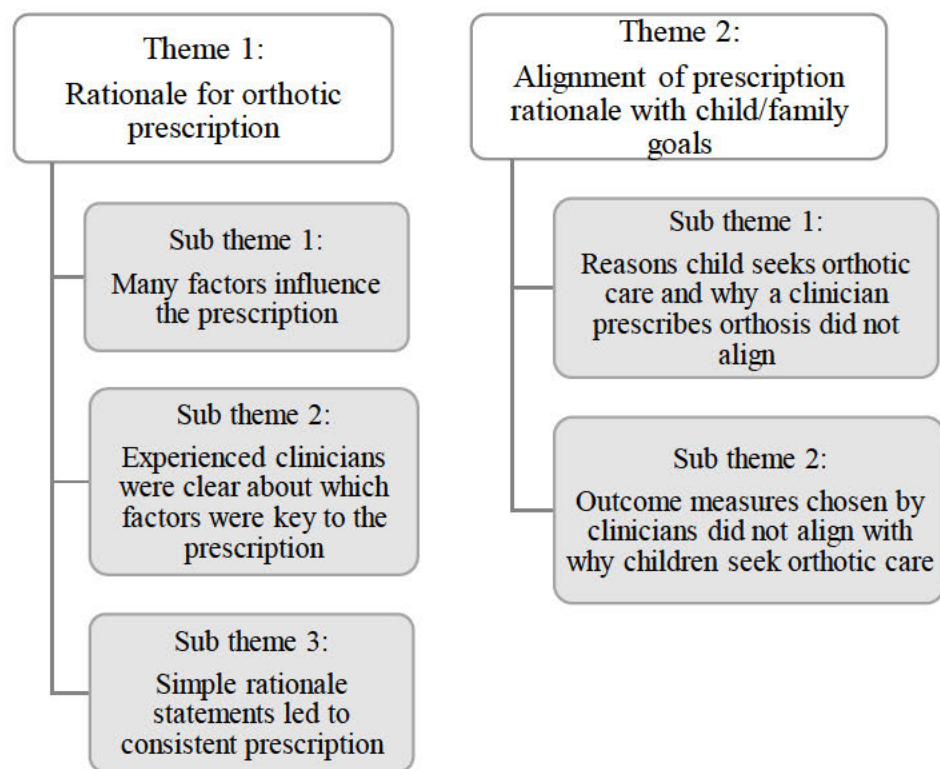


Figure 1: Schematic diagram on summary of themes and sub themes generated.

Theme 1 – Rationale for orthotic prescription

As an overview of this theme, clinicians described many factors that influenced the rationale for why they prescribed AFOs or SMOs for children living with CP. A few clinicians with many years of clinical experience, were able to identify which of these

factors were key to informing their prescription and articulate a logical structure to their decision making. Whilst this skill was not common among clinicians with fewer years of experience, there was agreement about which orthotic prescription was most appropriate when clinicians were provided with simple rationale statements from the literature. In the subsections that follow, each of these sub themes will be unpacked in detail.

Many factors influence prescription: Participants described many factors that influenced the prescription of an AFO or SMO for a child with CP. These factors could be summarised into four categories describing: physical presentation (e.g., strength, spasticity, and joint range of motion), gait pattern (e.g., crouch gait), goals of treatment (e.g., patient and family goals), and compliance (e.g., what the child is willing to use). Examples for each of these categories can be seen in the illustrative first-person quotes below.

“So, what their [ankle and knee joint] ranges are, what their foot posture looks like, spasticity, tone, contracture, all of those sorts of things will influence prescription.” Participant #12

“The shank kinematics...., whether the knee is hyperextended or encroached, stability, falls, patient safety.” Participant #16

“It would be the client’s goals, and a lot of the time the parents and the carers have input for the paediatric cases. The NDIS [National Disability Insurance Scheme] goals, as well, what they are trying to work towards in that plan. Then any other allied health professional goals that we are trying to support, so physio[therapy] goals, things like that. Then orthotic goals, in terms of alignment goals, or if we are trying to increase [joint] range. So, everyone’s goals.” Participant #6

“Well look, I guess there’s a level of compliance from the family. If I think they’re really going to not bother, then I will sort of counsel towards not making something. But then I would then also discuss with the referrer and what my concerns are.” Participant #13

Experienced clinicians were clear about which factors were key to the prescription: While all participants were able to describe a myriad of factors that influenced the prescription for an AFO or SMO for children living with CP, only a couple of very experienced clinicians were able to clearly and logically describe which factors were key to determining whether an AFO or SMO should be prescribed.

“[When considering the prescription, I consider an] observational gait analysis to identify gait deviations, physical assessments to look at muscle restrictions and joint range of motion, chatting to the family to find out where they come from.... then developmental goals.... that needs tri-planar control... you're going to need an AFO. If you don't require the control usually in the sagittal plane, then you can fit an SMO.” Participant #9

“She is actually a 16-year-old girl, and she is a GMFCS [Gross Motor Function Classification Scale] level V and she has one foot that inverts and one foot the everts and a significant spasticity. And the rationale for prescribing AFOs for her is primarily to try and prevent the deformity in her feet becoming fixed to allow her feet to sit on the foot plates of the wheelchair and to keep them in a position which she can stand on, which is in standing frame.” Participant #2

Simple rationale statements led to consistent prescription: Given that only a few experienced clinicians, could clearly describe their rationale for prescribing an AFO or SMO, it was remarkable how consistent all participants were about their prescription for AFOs or SMOs when presented with simple rationale statements from the peer reviewed literature. For example, in response to this statement, “*Supra-malleolar orthoses (SMOs) are commonly prescribed to improve crouch gait*”, all participants agreed that SMOs should not be prescribed for children who walk in crouch gait.

“I think from my experience, I probably disagree with this one. If I had someone with crouch gait, I would more be looking towards an AFO, something with a bit more proximal control. Not that I don't think SMOs could yield some improvement in crouch gait, I just don't think it's optimal for most people. So, disagree.”

Participant #8

“I would disagree with that [statement] simply because they [SMOs] don't provide any control on... Or even with straps and things, the lever arms are not sufficient enough to provide adequate control of restricting dorsiflexion. And if you permit dorsiflexion to occur, you're going to allow knee flexion to occur and therefore that's crouch gait.” Participant #9

Likewise, in response to this statement, “*The supra-malleolar orthosis (SMO) is prescribed primarily to control hind foot and mid foot varus/valgus*”, there was also consistent agreement that SMOs should be prescribed when the problems were limited to the foot.

“Yes. Again, mostly agree. So, we do prescribe them [SMOs] for that mediolateral instability when you have the hindfoot valgus, hindfoot varus and valgus, controlling that and the midfoot as well. So yeah, I agree with that one.”

Participant #4

“The supra-malleolar orthosis, because it crosses the ankle joint, but it doesn't provide control to either plantarflexion or dorsiflexion. It only provides control in the coronal and the transverse plane. So therefore, it will control or attempt to control hind foot varus, valgus or midfoot varus, valgus. So yeah, I'd agree with that.” Participant #9

In cases where spasticity was involved, there was strong agreement from participants that AFOs should be prescribed. For example, in response to this statement, *“Ankle-foot orthoses (AFOs) are frequently prescribed to correct skeletal misalignments in spastic CP”*, there were nuanced responses depending on whether children were primarily wheelchair users or ambulant.

“Yeah, I mostly agree with one, but a lot of the kids we see here [at a public hospital] are GMFCS [Gross Motor Function Classification System] IV and V, so they're not necessarily walking. We also prescribe them for comfortability in wheelchairs and prevent contractures, which can be painful, and help control spasticity. As well as the few that do have a standing frame, they can stand in the standing frame comfortably as well.” Participant #4.

“Yes. I would agree. AFOs definitely do correct skeletal misalignments like their foot posture, their hindfoot varus. And, yes, in spastic CP, I would say they

provide a support by giving them that rigidity, to not have to rely so much on their muscles, use the AFO support. So, they would help improving their efficiency of their gait because they wouldn't be in misalignment or wouldn't be in an incorrect position or an unstable position." Participant #3

"I'd say true. Often, kids with CP can present with high tone which then the stronger muscles pull the alignment of their foot, ankle, knee into different areas. Different alignment of what you'd typically call a normal alignment. And so AFOs are trying to realign, support, which improves stability, having everything stacked on top of each other, and then obviously provides a more efficient gait by combating the overpowering muscles and realign." Participant #5

The consistency of the participants responses to these rationale statements, suggests there is likely a clear rationale for the orthotic prescription, even if only the most experienced clinicians were able to logically describe which of the many factors were key to their decision making. These responses suggest that there may be key factors that influence the orthotic prescription such as: presence of crouch gait, presence of spasticity, and whether deformity was mild and limited to the foot. For example, the AFO was the prescription of choice for children with crouch gait or spasticity. By contrast, for a child with isolated mild foot deformity, an SMO was considered a more appropriate prescription. While these factors may be key to the orthotic prescription, our results highlight the myriad of factors that come into play such as the influence of other healthcare professionals, or a child/family refusing a particular orthosis prescription due to cosmesis, making the prescription process complex.

Most of the clinicians we interviewed reflected on times when they felt unable to provide their preferred prescription of an AFO or SMO. In many cases, these were often junior clinicians (or experience clinicians reflecting on their work history) working under the direction of another allied health or medical professional or given the wishes of a child/family.

“There have been times where we’ve prescribed an SMO when we would’ve preferred to prescribe an AFO. Majority of the time, it’s because a physio’s [physiotherapist] insisted on an SMO for their goals and also patients come with a prescription in mind, and we’ve discussed, and it comes down to that patient choice as well. We’ve got to present the evidence as best we can, but at the end of the day, they make that decision. So yeah, we try and help them make an informed decision, but sometimes it’s not quite what we want. But usually, we’ll try and encourage... We’ll always try and have a conversation with the physio [physiotherapist] and see if we can get on the same page.” Participant #14

“Most of the time, I guess, outside prescribers are pretty good [at listening to an orthotist’s feedback and advise on orthotic prescription]. Sometimes they’re not that willing to, I guess, take on your feedback and your expertise, so there’s definitely been some under-prescribed and over-prescribed AFOs where it’s pretty awful that you kind of have to wait for the child to fail in that device and then re-prescribe.” Participant #5

Some clinicians we interviewed also reflected on times when a child refused to wear their orthosis, particularly AFOs, due to cosmesis. Interestingly, these clinicians then resorted to SMOs when these children did not want to wear their AFOs.

“So again, with age, some of the teenagers they don't want to wear an AFO.

Obviously, cosmetics comes into a big part of it. So again, we've had a few who've negotiated and compromised by doing SMOs over AFOs, because again, wearing something is better than nothing.” Participant #4

“Sometimes, I've had clients who maybe had either previous experience of AFOs and have gotten to an age where their cosmesis is more important than their function or just their bulk over an AFO is no longer suited to their need. It's no longer being worth it, in comparison to the functional gains that they're getting. But, if they still need that foot posture protection, then we would try and get them into a SMO because, obviously, it can be hidden a bit better in a shoe.”

Participant #3

Theme 2 – Alignment of prescription rationale with child/family goals

As an overview of this theme, we sought to understand the clinician's rationale for the prescription of AFOs or SMOs for children with CP by asking participants about why children and their families seek orthotic care, the type of orthotic intervention provided, and the choice of outcome measure(s) used to evaluate the effect. Given there should be alignment between the answers to these questions, the clinicians' responses provided insight into the rationale for the orthotic prescription. In the sub themes that follow, we have explored the rationale for orthotic prescription through this lens.

Reasons child seeks orthotic care and why a clinician prescribes orthosis did not align: In our interviews, there was a notable disconnect between the reasons clinicians believed children and their families seek orthotic care, and how clinicians described the factors that most influence the prescription of AFOs or SMOs for children with CP. Early

in the interview, we asked participants to talk about the factors that influence their rationale for the prescription of AFOs and SMOs for children with CP. Near the end of the interview, long after the initial questions about the factors that influence orthotic prescription were asked, we probed participants to reflect on the reasons why children and their families seek orthotic care. Most participants reported that children and their families seek orthotic care to reduce trips and falls, to keep up with their peers, or to improve their participation.

“In my clinical caseload, I would say big motivators for the children [to seek orthotic care] are often their goals and their activity levels. A frequent goal our clients come to us with is the ability, and very casually put, to keep up with their peers, and how their disability is impacting their ability to participate in the community, or participate at school, or with their friends.” Participant #6

“Orthotic care... I think if they... if their child has regularly fallen, I think that’s probably the first one. They need it for stability. It also depends on the severity of the child. I think if they’ve been recommended by a physio or orthopaedic consultant, or someone else, then that would be a reason.... To allow the child to, developmentally, keep up with their peers and things like that. Whether there’s developmental delays there. If there’s any pain. Reduce balance, reduce stability.” Participant #16

“For some it will be the promised of increased independence of the child and social interaction it comes from being able to independently mobilise and play.” Participant #11

“I would say if they’re at risk of forming contractures or if they’re having any kind of pain, if they’re having issues with their fatigue, if they’re having a lot of

falls or issues with their balance or stability. If there's a gait deviation that's affecting, either their energy or their fatigue or just ability to function in everyday life. Also, if maybe, they have a functional goal they're trying to meet."

Participant #3

Given the orthotists' perspective about why children and their families seek orthotic care, it is noteworthy that most clinicians reported that they prescribed AFOs or SMOs to effect physical function; in particular, to normalise specific aspects of gait.

"Typically, it's through [observational] gait analysis. So, we obviously see them [the child] beforehand. When we do the assessment, we watch how they walk without any device and how they go then. We then obviously make the device, fit the device, and again, watch them have a walk around, see what they can do. And either tune the device after that, after the fitting, see how they go.... So, getting mom or dad or whoever's with them to tell me whether their gait is significantly improved or if it's a normal gait for them or an improved gait. And then sometimes I get them to do a sneaky video at home and send it through once they've had the device a couple of days, and just see how they're going and check through that." Participant #4

".... gait observation as well would be the main way of assessing the outcome of the AFOs and also muscle length." Participant #2

"At the beginning, at the clinical appointment, I will fit it [orthosis], watch them walk from a sagittal and a coronal view, watch them walk in their shoes, check

and make sure that they're comfortable verbally, ask if they're comfortable."

Participant #13

There were a small number of clinicians who were able to align their orthotic prescription with the reasons why families seek orthotic care.

"Orthotic care.... if their child has regularly fallen, I think that is probably the first one [reason for seeking orthotic care]. They need it [an AFO or SMO] for stability." Participant #16

"....it really comes down to what goals that family has stipulated and also what goals we've seen as safety goals and then using those [goals] consistently so that we've got that knowledge back [using an outcome measure to evaluate effect] as to 'has this intervention help them with that goal?'" Participant #15

Outcome measures chosen by clinicians did not align with why children/families seek orthotic care: When asked about the outcome measures used to evaluate the effect of an orthotic intervention, most participants observed a child's gait in a controlled environment (e.g., a treatment room), regardless of the child/family reason for seeking orthotic care.

"Objectively, I use a lot of observational gait analysis." Participant #6

"Generally, from gait observation." Participant #5

"A gait analysis in clinical setting.... like an observed gait." Participant #7

A small proportion of the clinicians we interviewed had access to gait laboratories or used established outcome measures (e.g., 6-minute walk test).

“At the place that I work, we're lucky enough that a lot of kids go through gait analysis as part of their clinical care. So, looking at those reports and seeing AFO versus without an AFO, looking at some of those temporal, spatial aspects of their gait and how we're improving step length and all of those sorts of things.”

Participant #12

“If we [clinician] engage with them [child], they might run a six-minute walk test, for example for us, and then let me know the results.” Participant #8

“Then I'll take video footage of them walking, and we use a Bloorview gait analysis tool so we can analyse each section of gait and work out if there is actually a difference between the previous orthotics, barefoot and the new orthotics.” Participant #10

Interestingly, none of the participants reported using real-world outcome measures, such as measures of participation or falls, that mirrored the reasons why children/families sought orthotic care.

3.4 Discussion

Given the aim of the study, we asked paediatric orthotists why they prescribed AFOs or SMOs for children living with CP. Their responses led to the creation of two themes: *rationale for orthotic prescription*, and the *alignment of prescription rationale with child/family goals*.

When we explored the first theme, *rationale for orthotic prescription*, we observed there was a myriad of factors that influenced whether a clinician prescribed either an AFO or SMO to a child with CP. A few experience clinicians articulated which key factors influenced their prescription and present these in a logical and structured manner. These participants had decades of clinical experience and held senior roles that required teaching and mentoring of orthotic/prosthetic students, junior clinicians, as well as presenting at conferences and workshops. These experiences may have provided them with opportunities to reflect on their clinical practice and find ways of articulating and refining their rationale for orthotic prescription. By comparison, the early- to mid-career clinicians we interviewed may not have had as many of these opportunities and as such, were less able to explain the rationale clearly and logically for their orthotic prescription.

While literature from other prescribing professions has shown a link between clinician experience and an aptitude for clearly articulating their rationale for prescription [14,15,16], there may be other factors involved. Given the design of the study, we do not know whether experience determined whether a clinician can clearly articulate their rationale for orthotic prescription, or whether this is a reflection of their personality, natural ability, education or training, or other experiences such as mentoring new graduates [17,18].

While clinicians with many years of experience could articulate which of the myriad of factors most influenced their prescription, it is interesting to observe that

clinicians consistently agreed on whether AFOs or SMOs would be the most appropriate prescription when presented with simple rationale statements from the literature. These rationale statements often contained one or two sentences that focused on one aspect of the child's presentation (e.g., crouch gait). While this may suggest there are a few key or primary factors that drive the rationale for orthotic prescription, there are likely to be a much wider range of secondary factors that influence the final prescription [19] such as the child's weight, child and family preference, or likely compliance. For example, in the case of a child who presents with a crouch gait, the presence of crouch gait might be considered the primary factor influencing the decision that an AFO is required. The child's weight might be considered a secondary factor given this would influence the exact type of AFO prescribed (e.g., a ground reaction AFO), as well as the type of material used (e.g., carbon fibre).

Our observation that simple case examples lead to consistent orthotic prescriptions is not a new finding and lends weight to the hypothesis that a few key factors likely drive the rationale of orthotic prescription. Eddison [20] reported that clinicians with varying experience were able to consistently agree on the AFO prescription characteristics such as thickness of material, foot plate design and strapping system.

To help guide clinicians on which primary and secondary factors may influence their prescription of AFOs and SMOs for children with CP, a prescription decision framework or clinical algorithm may be valuable [20,21]. While a number of prescription frameworks have already been developed for similar orthotic prescription decisions [22,23], a specific prescription guideline for AFOs and SMOs could help clinicians, with various experience levels, make well-reasoned decisions like the very experienced clinicians in our study.

While a prescription framework that incorporates primary and secondary factors may aid decision making, our interviews highlight other complex factors (e.g., such as when a child and/or their family refuse the prescription of an AFO) that should be considered in the prescription process. These experiences may be analogous to the patient who refuses antibiotic treatment for their bacterial infection, and this related literature may provide some guidance for orthotists. For example, in situations where a patient refuses the prescribed treatment, clinicians should first attempt to understand the reason behind the refusal, and then provide education and counselling, explaining why the recommended treatment is most appropriate whilst addressing the patient's concerns [24]. For patients who continue to refuse the recommended prescription, the clinician should advise the patient that they will not provide an ineffective intervention which would be unethical and in breach of a clinician's code of conduct. The same process could be considered for the patient who refuses an orthotic prescription, such as a child who refuses an AFO intervention for crouch gait and might choose to have an SMO intervention instead.

We acknowledge that the orthotic prescription is often complex, multi-faceted and personal. As such, differences in opinion are common and have been well documented in other allied health professions. For example, in podiatric practice, specifically in foot orthotic prescription theory (e.g., the foot morphology theory, the sagittal plane facilitation theory, and tissue stress theory), there are well documented differences in opinion amongst clinicians and researchers about foot orthotic prescription; specifically, the appropriateness of the foot morphology theory, the sagittal plane facilitation theory, and tissue stress theory [25]. Likewise, in the occupational therapy profession, there are differences in clinical opinion when it comes to prescribing upper limb orthoses to children with CP [26,27]. Given there are currently no clear prescription guidelines,

occupational therapists rely on past clinical experience and training, which then leads to variation in care [26,27], much like the variations in care observed in podiatry practice [28].

When we explored the second theme, *alignment of prescription rationale with child/family goals*, we observed that there was a disconnect between the clinicians' views of why children with CP and their families seek orthotic care and the prescription rationale. We observed that clinicians often focused on normalising the mechanics of gait with their orthotic intervention, and choose outcome measures; accordingly, even though children and their families were more concerned about outcomes related to participation, fatigue, or falls, as illustrative examples. Few orthotists used outcomes to quantify or make standardised observations about the effect of the orthotic intervention aligned with the reasons that drove children and their families to seek orthotic care.

Although outcome measures do not directly influence the orthotic prescription, measuring the effectiveness of a prescribed orthotic intervention should reflect the goals that are most important to the child and/or family. Previous studies [26,27,29,30] have reflected our observations, and also reported on the disconnect between the rationale for orthotic prescription, the outcome measures used to evaluate the effectiveness of the intervention, and why children with CP and their families seek orthotic care. The alignment of these considerations is key to helping ensure that the rationale for the orthotic prescription is appropriate to the reasons why a child and their family have sought orthotic care, and our efforts to evaluate the effectiveness of the interventions provided.

Clinical implications and recommendations

This study highlights that:

- Clinicians should be clear about the reasons children/families come asking for orthotic care (e.g., to reduce fatigue), and deliberately align the rationale for orthotic prescription accordingly (e.g., fatigue can be reduced by normalising a child's crouch gait).
- When determining the rationale for prescribing AFOs and SMOs for children with CP, it may be helpful to identify what are the primary factors that will drive the prescription (e.g., normalising crouch gait), and what are the secondary factors (e.g., child's weight) that will determine the exact type of orthotic intervention.
- Observations and outcome measures should be thoughtfully chosen to reflect the rationale for orthotic intervention (e.g., observing knee kinematics), as well as to align with the reason/s why children with CP and their families seek orthotic care (e.g., quantifying fatigue in the real-world using outcome measures such as the Patient-Reported Outcomes Measurement Information System (PROMIS) Pediatric-Fatigue).
- The development of an AFO and SMO specific prescription decision framework for children with CP that is sectioned into primary and secondary factors.
- When children and their families refuse an orthotic prescription, the clinician should initially seek to understand the reasons for the refusal and provide education and counselling. If the child and their family continue

to refuse the prescribed intervention, then the clinician should be confident to not provide an inappropriate prescription.

- Given the insights from our interviews, less experienced clinicians may benefit from support to align the reasons why the child/family present with the rationale of the orthotic intervention. Similarly, clinicians may benefit from support to navigate complex conversations with other health professionals or children/families about the most appropriate orthotic intervention.

Study limitations

There are number of limitations to the study, that are worthy of note. We acknowledge that about two thirds of the participants in the study had less than 10 years of clinical experience. Had our study included a larger proportion of very experienced clinicians, we may have found that more clinicians could clearly articulate which key factors drove the rationale for their orthotic prescription. Although most of these clinicians had less than 10 years' experience, their experience reflects the current orthotist workforce responsible for prescribing AFOs and SMOs to children with CP in Australia. From a recent Australian orthotist/prosthetist workforce snapshot in 2019 [31], participants in this investigation were similar to the workforce as a whole given the average age of an orthotist is 38 years old; most (46%) were based in Victoria and 86% of clinicians work at a metropolitan facility. There is currently no data available that is specific to the paediatric orthotist workforce.

Given the size of the sample, some may be concerned about whether we achieved data saturation. By the tenth interview, we observed a lot of repetition in the factors that

influenced orthotic prescription, outcome measures used to evaluate the effect, responses to the rationale statements, and the reporting of why children and their family sort orthotic care amongst the participants. We then interviewed a further six participants to engender confidence that there were no new codes or themes would be generated.

We acknowledge that some readers may be concerned that the results may not be generalisable across Australia given the small number of participants, and the variations in the population across public- and private- orthotic services. We estimate that the 16 participants reflect about 65% of the paediatric orthotist workforce in Australia given there is generally one specialist paediatric hospital and one private paediatric orthotic facility per state or territory: typically, with fewer than 10 paediatric orthotists at each. Some participants noted that orthotic services affiliated with a public hospital, tend to see more complex presentations given their access to specialist medical and multidisciplinary teams. Similarly, private orthotic facilities in the community typically do not have access to these extra services, and generally see fewer complex children at the higher GMFCS levels.

We acknowledge that the study was conducted in one country with clinicians who trained in similar education settings, worked in similar healthcare settings, and therefore likely have similar views about orthotic prescription. We encourage readers to be thoughtful in applying the findings of our research to very different healthcare settings, where practice norms may be different.

3.5 Conclusion

CP is a complex condition, making the prescription rationale process challenging. There were a myriad of factors that influenced the prescription of AFOs and SMOs in

children with CP. Clinicians with many years of experience were better able to articulate the key factors that influence their prescription, as well as align their orthotic prescription with the reasons children and with families sought orthotic care. While this capability was not common among the early to mid-career clinicians we interviewed, it is important to note that all clinicians were able to consistently agree on an orthotic prescription when presented with simple rationale statements from the literature. This may suggest that there are some primary factors (e.g., crouch gait) that influence the prescription of AFO or SMOs, and that when considered in isolation of the myriad of complicating factors that influence prescription in the real world, clinicians can make consistent decisions. Clinicians may find the concept of primary and secondary factors helpful in reflecting on their orthotic prescription practice given their use in other areas of healthcare. There are opportunities to develop an AFO and SMO prescription framework to assist clinicians with orthotic prescription for children with CP.

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Declaration

The authors report there are no competing interests to declare.

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Chapter 4: Discussion

This thesis explored the orthotists' rationale for prescribing AFOs and SMOs for children with CP. In response to this aim, we completed two studies- a narrative review and a qualitative study, to help us to better understand the clinician's rationale for prescribing these orthotic interventions.

Based on the narrative review (Chapter 2), numerous studies described that AFOs were prescribed for children with CP to normalise aspects of gait, such as to reduce crouch [1-23]. We also learnt that AFOs were sometimes prescribed to help reduce energy expenditure and metabolic cost [6,9,20,24-26], provide protection or correction to musculoskeletal structures [14,15,17,21,27,28], and improve balance and coordination [27,29-32]. By comparison, there was little literature reporting on the use of SMOs for children with CP [8,10,14,33,34], and as such there is less confidence that SMOs were provided to control hind foot and mid foot varus or valgus.

Based on these reflections it seems reasonable to infer that orthotics research has focused on the use of AFOs for children with CP and reported on a narrow range of outcomes related to walking and physical function. Unfortunately, the literature does not seem to reflect the broader range of outcomes that are important to children with CP and their families (e.g., the ability to participate in activities alongside their peers) nor the many factors we see clinicians consider when prescribing an orthotic intervention (e.g., treatment goals of the child/family, cosmetic appearance, likely compliance). Given this gap in the literature, it was important that we conducted a qualitative study to ask paediatric orthotists why they prescribe AFOs and SMOs for children with CP so as to understand their prescription rationale.

As reported in Chapter 3, the findings of the qualitative study highlighted that there were many factors that influence the orthotic prescription including: gait abnormalities present, child/family treatment goals, issues with previous orthotic prescription, cosmesis of a device, requirements from medical or other allied health professionals, skin integrity, family expectations, and the child's desire for less intrusive looking interventions.

Given the myriad of factors that influenced orthotic prescription, a few clinicians described a structured process to weigh the different considerations and arrive at the prescription of either an AFO or SMO. Similar observations have been reported by Kane et al. [35] who looked at physiotherapists prescribing AFOs to children with CP. Kane and colleagues [35], highlighted that it was challenging for physiotherapists to weigh the influence of a variety of factors that influence the orthotic prescription, such as the parent and child's perception of AFOs and funding.

Given the challenges that clinicians seemed to face in weighing the myriad of factors that influence the prescription, it was interesting that clinicians were able to consistently provide an appropriate rationale for their orthotic prescription when presented with simple rationale statements. As an example, clinicians consistently agreed that AFOs should be prescribed for children presenting with a crouch gait, to help promote knee joint extension or a complex physical presentation such as gastrocnemius/soleus muscle spasticity, to help mitigate a spastic response in these muscles by maintaining a neutral ankle joint position [36,37]. Clinicians consistently agreed that SMOs should be prescribed for children with mild isolated foot deformities. Given this observation, we hypothesise that there are likely some key considerations, such as the presence (or absence) of crouch gait or spasticity within the gastrocnemius/soleus muscle, that might drive the initial orthotic prescription. These

might be considered as primary factors. Other factors, such as body weight, might nuance the initial orthotic prescription. These could be considered secondary factors. In these cases, the secondary factors might change the choice of materials or trim lines, however they do not alter the initial orthotic prescription of either an AFO or SMO.

The concept of using primary and secondary factors to help guide prescription is not new. Prescribing professions such as medicine, use this concept also. As an example, Maxwell and colleagues [38] described the relationship between how primary and secondary factors can influence the final prescription of antibiotics. The primary diagnosis or factor, such as a bacterial infection, drives the initial prescription (e.g., antibiotics), however the secondary diagnosis or factor, such as an allergy to penicillin, may influence the final prescription decision (e.g., type of antibiotic prescribed).

There was one final insight from this study that was key to understanding the prescription rationale, and the clinical recommendations that follow. When we probed clinicians about their rationale for AFO and SMO prescription, there was a disconnect between why clinicians prescribe AFOs and SMOs, the reasons clinicians gave for why children and their families sort orthotic care, and the outcome measures they described using to evaluate the effect of the orthotic intervention. Whilst many clinicians reported that they prescribe AFOs and SMOs to improve some aspect of gait, and occasionally used observed gait analysis to evaluate the effect, this did not align with why clinicians thought children and their families sought orthotic care, which was often to reduce trips/falls or to improve participation.

This reflection well aligned with the ‘Treatment and Enablement Theory’, that is used in clinical research [39]. By a way of background, the treatment theory is the active ingredient or intervention that creates change. For example, an AFO designed to reduce

the amount of knee flexion (i.e., crouch) during stance phase. The enablement theory describes the level of improvement due to the intervention, and how it effects an outcome. For example, if the AFO normalises knee flexion during stance, what effect does it have on reducing the number of falls or improving participation. In this study, orthotists were focused on the treatment theory, not the enablement theory, as evidenced by the disconnect observed between why clinicians prescribe AFOs and SMOs, the reasons clinicians believed children and their families presented for orthotic care, and the outcome measures they used to evaluate the effect of the orthotic intervention.

The findings from this research have a number of implications for clinical practice.

Clinicians should deliberately align the reason for the orthosis, with the orthotic prescription, and choose appropriate outcomes to evaluate the effect. For example, if the reason for the child presenting for orthotic care is to help improve participation, then the rationale for the orthotic prescription should align with this. Then an outcome measure should be chosen to measure the effectiveness of the orthosis in improving participation. Numerous authors [40-43] have previously advocated for orthotists to be explicit about the goal of the orthotic intervention and to routinely use outcome measures aligned with that goal. Given the best practice recommendations already in place [41], we encourage clinicians to adapt their clinical practice accordingly.

Based on the findings of our studies, there are a number of implications for future research.

Firstly, we encourage researchers to include a more representative range of children in research; particularly children from GMFCS levels IV-V. Most studies included in the literature review included a narrow range of children with CP;

specifically, children aged between 8-10 years with GMFCS levels I, II or III. This focus on ambulant children may explain the reason for the focus on gait related outcomes in the existing research. Without the representation of children with higher GMFCS levels (IV-V), many of whom are non-ambulant, we cannot fully appreciate the rationale for orthotic prescription across all GMFCS levels, given that the rationale for AFO prescription will vary across the GMFCS spectrum. During the interviews, many clinicians reported that for non-ambulant children with CP who are wheelchair users, they prescribe AFOs for positioning and contracture management, rather than to improve gait. There are opportunities to conduct in-depth orthotics research focused on the orthotic needs of non-ambulant children with CP.

Secondly, there are opportunities to develop an AFO- and SMO-specific prescription decision framework for children with CP. That decision framework might consider the model of primary and secondary factors which perhaps best characterises the expert behaviour observed by a handful of very experienced clinicians in our research. Currently there are a range of orthotic prescription frameworks and algorithms available for children with CP [44-47]. Most of these frameworks are designed for AFO intervention only [44,45,47] and all are gait focused. Given the wide variety of factors that influence orthotic prescription beyond gait (e.g., prior orthotic experience, cosmesis of a device), we wish to reaffirm the need for a more holistic prescription framework [40]. In the absence of a fit-for-purpose orthotic prescription framework specifically for AFOs and SMOs, there are opportunities to conduct research to develop and pilot test a prescription framework.

Consistent with recent research [48] we encourage clinicians and researchers to utilise real-world outcomes, such as participation, and shift away from the narrow focus on gait related outcomes. Without including real-world outcome measures, especially if

they are the main reason why a child and their family seek orthotic care, it is difficult to fully understand the effect of the orthotic intervention.

Given there were few studies [7,19,25-27] that described the rationale for prescribing SMOs for children with CP, we recommend further research in this area. Further research may help us to gain a deeper understanding as to why SMOs are prescribed to children with CP and to evaluate the effect that SMOs have on a range of outcomes important to children/families (e.g., gait, mobility, participation, falls).

Finally, we encourage researchers to report the details of both AFO and SMO interventions in keeping with previous calls [49,50]. Ridgewell and colleagues [49] developed a reporting check list and have advocated for the routine use of these reporting guidelines for describing orthotic interventions. Similarly, we encourage journal editors and reviewers to enforce better reporting of orthotic interventions and adopt the current reporting guidelines for orthotic interventions. Improving AFO and SMO reporting can improve the quality of the evidence base and make syntheses of the literature more effective.

We acknowledge that the thesis is based on research conducted in Australia and as such, most clinicians who participated in this research will have been trained in similar education settings, worked in similar healthcare settings, and therefore likely have similar views about orthotic prescription. We encourage readers to be thoughtful when applying the findings of our research to very different healthcare settings, where practice norms may be different.

4.1 Conclusion

In conclusion, CP is a complex condition that makes orthotic prescription challenging and multi-factorial. Given that clinicians were consistent with their orthotic prescription when presented with simple rationale statements, this highlights that there may be a few key factors that influence the primary orthotic prescription. Once these key factors have been identified, clinicians can then consider secondary factors to help optimise their orthotic prescription. Clinically, we recommend that clinicians deliberately align the reason for the orthotic intervention, with the prescription, and choose appropriate outcomes to evaluate the effect. For future research, we encourage researchers to include children with CP with all GMFCS levels as well as to include real-world outcome measures, such as participation.

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