

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO. LTD,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00739
Patent No. 10,888,601

EXPERT DECLARATION OF RICHARD MANNING, PH.D.

CONFIDENTIAL MATERIAL - SUBJECT TO PROTECTIVE ORDER

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I, Richard Manning, Ph.D., do hereby declare:

1. Introduction

1.1. Qualifications

- (1) I am a Managing Director at Intensity, a Secretariat Company. I provide data-driven insights to help clients address complex economic questions. Among other things, I have experience conducting economic analyses in matters involving breach of contract, fraud, pricing, economic valuation, intellectual property, antitrust, patent infringement, business strategy, and public policy.
- (2) I earned my B.A. in Economics from Brigham Young University. I received my Ph.D. in Economics from the University of Chicago. After obtaining my Ph.D., I was an economics professor at Brigham Young University and a visiting professor in the Graduate School of Business at the University of Chicago. As an academic, my teaching and research focused on price theory, the economic analysis of law, industrial organization, and the economics of government regulation.
- (3) My career includes 14 years as an executive at multinational pharmaceutical companies. I was Senior Director at Pfizer Inc and Executive Director at Merck & Co., Inc. I led economic analysis and strategy development to shape practices related to emerging business concerns. Examples of my work include:

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- Leading and undertaking economic analysis and strategy relative to challenges affecting pricing, reimbursement, and intellectual property protection in global markets.
 - Collaborating with outside academic economists to analyze critical issues including healthcare benefit design, healthcare system reform proposals, marketing and advertising, intellectual property protection, FDA regulatory reform, including biosimilars approval processes and safety, and new product R&D.
- (4) Previously, I also was Director of Advisory Strategy at PricewaterhouseCoopers where my responsibilities included working on strategic partnerships, merger and acquisitions activity, economic valuation of early-stage companies, and other economic analyses for biopharmaceutical, medical device, financial, and healthcare clients.
- (5) Prior to joining Intensity, I was a Partner at Bates White, an economics consulting firm offering analysis and expert testimony services to law firms, Fortune 500 companies, and government agencies.
- (6) My areas of expertise include:
- Economic Valuation and Damages
 - Breach of Contract, Fraud, and other Commercial Litigation
 - Intellectual Property

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- Securities Litigation
- Tax, Antitrust and Competition
- Public Policy

(7) I have provided expert testimony in the U.S. District Court, the Delaware Court of Chancery, the U.S. Bankruptcy Court for the District of Delaware, the U.S. Patent and Trademark Office Patent Trials and Appeals Board, and the International Chamber of Commerce; served as consulting expert; and prepared reports on various matters in the biopharmaceutical and healthcare industries. A comprehensive list of my qualifications can be found in my CV. See Attachment A-1. My testimony experience over the past four years can be found in Attachment A-2.

1.2. Scope of work

- (8) Intensity has been retained by Morrison & Foerster LLP on behalf of Regeneron Pharmaceuticals, Inc. (Regeneron). Intensity is being compensated at my standard hourly rate of \$1,050 for my work in this matter. Intensity is being compensated for time spent by others on my team at rates lower than my hourly rate. Neither Intensity's nor my compensation depends upon the substance of my testimony or the outcome of this matter.
- (9) I was asked to evaluate and, if called upon, to testify concerning commercial success as an objective indicator of non-obviousness in *Inter Partes* review No. IPR2023-00739 regarding U.S. Patent No. 10,888,601 (the '601 Patent).

- (10) In forming the opinions expressed in this declaration, I relied upon my education, experience, and knowledge of the subjects discussed. Additionally, I relied on the Declaration of Michael W. Stewart, M.D. (Ex. 2027). I held a conversation with Dr. Stewart. I also have considered documents and other materials, which are cited herein.

1.3. Framework for commercial success

- (11) I understand that evidence of commercial success is one of the objective indicators that a patent owner may rely upon to support an argument of non-obviousness of a claimed invention.¹ I understand that the Federal Circuit has stated that “[c]ommercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.”² I understand that, for commercial success to constitute evidence of non-obviousness of a patent, there must be a nexus between the claimed technology and evidence of commercial

¹ *Demaco Corp. v. F. Von-Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391–92 (Fed. Cir. 1988).

² *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005).

success. Moreover, the evidence must demonstrate that the commercial success is due at least in part to the claimed features of the invention and not entirely to factors unrelated to the claimed invention.³ Additionally, I understand that the commercial success must not relate exclusively to a feature that was known in the prior art.⁴ I further understand that Federal Circuit case law holds that “if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant.”⁵

- (12) It is my understanding that the courts commonly accept indicators including significant sales levels, significant sales growth, substitution towards the novel product or method and away from alternative products or methods, persistent price

³ Ex. 2067 (United States Patent and Trademark Office, Manual of Patent Examining Procedure, Ninth Edition, Revision: 2/2023, 716.03 I., at 700–257; and 716.03(b) at 700–278 and 700–259).

Demaco Corp. v. F. Von-Langsdorff Licensing Ltd., 851 F.2d 1387, 1391–92 (Fed. Cir. 1988).

⁴ *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1364–65 (Fed. Cir. 2023).

⁵ *Ormco Corporation, et al. v. Align Technology, Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006).

premiums, or the absence of substantial discounting, and other economic indicators as evidence of commercial success of a novel product.⁶ In the context of pharmaceutical products (and by extension biologic products), sales can be measured in terms of revenues, prescriptions, or daily doses, and sales growth can be measured in terms of sales or share of sales within a product category.⁷

⁶ Ex. 2068 (Guha, Rahul, Jian Li, and Andrea L. Scott (2009), “The Economics of Commercial Success in Pharmaceutical Patent Litigation,” *Landslide* 1(5)).

⁷ Ex. 2068 (Guha, Rahul, Jian Li, and Andrea L. Scott (2009), “The Economics of Commercial Success in Pharmaceutical Patent Litigation,” *Landslide* 1(5)).

2. U.S. Patent No. 10,888,601

- (13) The application for the '601 Patent, entitled Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders, was filed on April 29, 2019 and issued as the '601 Patent on January 12, 2021.⁸ The abstract of the '601 Patent reads as follows:

The present invention provides methods for treating angiogenic eye disorders by sequentially administering multiple doses of a VEGF antagonist to a patient. The methods of the present invention include the administration of multiple doses of a VEGF antagonist to a patient at a frequency of once every 8 or more weeks. The methods of the present invention are useful for the treatment of angiogenic eye disorders such as age related macular degeneration, diabetic retinopathy, diabetic macular edema, central retinal vein occlusion, branch retinal vein occlusion, and corneal neovascularization.⁹

⁸ Ex. 1001 (Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders, U.S. Patent No. 10,888,601 (filed 4/29/2019, issued 1/12/2021)).

According to the patent, the earliest provisional application, No. 61/432,245, was filed on January 13, 2011.

⁹ Ex. 1001 (Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders, U.S. Patent No. 10,888,601 (filed 4/29/2019, issued 1/12/2021)).

- (14) I understand the following claims are under review in this proceeding: claims 10–12, 17–19, 21, 25–28, and 33.¹⁰ Generally, I understand that the '601 Patent is directed to the use of a VEGF antagonist to treat angiogenic eye disorders according to the methods of treatment recited in the claims, which include multiple treatment phases, the last of which includes treatments administered in intervals of approximately every 8 weeks.¹¹ Specifically, I understand that these claims relate to use of a VEGF antagonist to treat DME, DR, and DR in patients with DME according to the methods of treatment recited in the claims.¹²

¹⁰ Decision Granting Institution of *Inter Partes* Review, 10/20/2023, Paper 9, at 2.

¹¹ Ex. 1001 (Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders, U.S. Patent No. 10,888,601 (filed 4/29/2019, issued 1/12/2021), col 2, line 63–col 3, line 2; col 4, lines 1–23).

Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § VII).

¹² Ex. 1001 (Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders, U.S. Patent No. 10,888,601 (filed 4/29/2019, issued 1/12/2021), col 2, line 63–col 3, line 2; col 4, lines 1–23).

- (15) The most recent FDA approved label for Eylea recommends three to five monthly injections in the affected eye, depending on the indication, followed by a fixed dosing interval. See Attachment B-1. This label contains indications DME and DR.¹³ For both DME and DR, the FDA-approved label for Eylea recommends five initial monthly injections followed by an 8-week fixed dosing interval. See Attachment B-1. I will refer to these initial monthly doses (i.e., the single initial dose and the one or more secondary doses administered 4 weeks after the preceding dose) as the “loading doses” or loading period, and tertiary doses as the “fixed dosing interval” phase.

Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at §§ VI.C. and XIV).

¹³ Ex. 2106 (Eylea Label, 2/2023, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125387s075lbl.pdf).

3. Commercial Success

- (16) In 2011, the FDA approved Regeneron’s EYLEA (aflibercept) injection.¹⁴ EYLEA is a prescription medicine approved for the treatment of patients with a variety of angiogenic eye diseases and is the subject of this proceeding.¹⁵ Eylea has achieved commercial success as a treatment for angiogenic eye disorders, and in particular as a treatment for DME and DR (with or without DME).¹⁶ This commercial success is demonstrated by the large number of patients who have benefitted from Eylea since its launch, as shown from Eylea’s sales since launch and by its performance relative

¹⁴ Ex. 2069 (Regeneron Website, History, <https://www.regeneron.com/about/history> (accessed 1/15/2024)).

Ex. 2070 (Eylea Label, 11/2011, at 1, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125387lbl.pdf).

¹⁵ Ex. 2107 (Regeneron, Form 10-K, 2020, at 3).

¹⁶ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

to other available treatments. These sales have a nexus to the method of treatment covered by the claims of the '601 Patent, including the 8-week fixed dosing interval. Eylea's historical commercial performance is discussed below.

3.1. U.S. Eylea sales

(17) Eylea's U.S. net sales grew [REDACTED]

[REDACTED] Eylea's successful growth of net and gross sales has been driven by its increasing use by physicians. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3.2. Eylea's share of anti-VEGF sales

(18) In addition to sales since launch, a product's performance relative to other available products provides evidence of commercial performance that may demonstrate commercial success for purposes of U.S. patent law, providing context necessary for evaluating whether a patented product was commercially successful. Moreover, if a patented product captures sales previously made by other products, the patented product demonstrates that it offers, at least for some consumers, a value proposition superior to that offered by the previously available products. Given a nexus to the

patented features, these captured sales demonstrate demand for the patented features and show that the patented feature directly contributed to the commercial success of the product.

3.2.1. Data sources

- (19) For analysis of relative sales performance among potential treatments for the relevant angiogenic eye disorders, I rely on three data sources: Medicare Part B physician treatment data provided by the Centers for Medicare & Medicaid Services (CMS), Vestrum data (which I understand are used by Regeneron in the course of business), and Regeneron's Awareness, Trial, and Usage (ATU) surveys. I consider all three data sources as each has its respective merits. However, all of the data sources show strong sales growth and overall sales share for Eylea since launch.

3.2.2. Eylea's historic sales share as an indicator of commercial success

- (20) Eylea was approved for sale in the United States by the FDA on November 18, 2011 for the treatment of wet AMD.¹⁷ According to ATU data, by the first quarter of 2012

¹⁷ Ex. 2075 (Drugs.com Website, Eylea FDA Approval History, <https://www.drugs.com/history/eylea.html> (accessed 1/16/2024)).

Ex. 2070 (Eylea Label, 11/2011, at 1, available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125387lbl.pdf).

it achieved [REDACTED]

[REDACTED]

[REDACTED] By the end of 2012, [REDACTED]

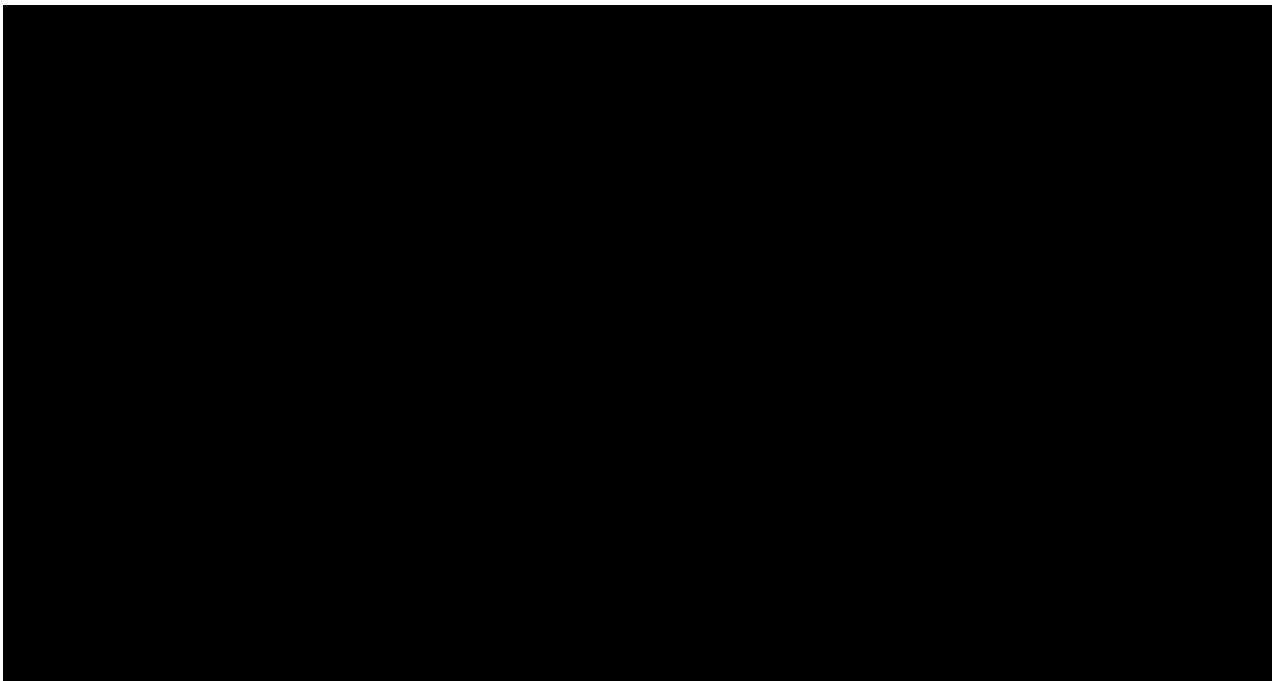
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Chart 1 illustrates the rapid rise in Eylea's patient share since its launch. See Attachment C-6.

**Chart 1: Eylea's Sales Share Across Different Data Sources –
All Indications¹⁸**



¹⁸ Attachment C-6.

(21) This trend of success holds true across each indication for which Eylea is approved.

As noted above, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(22) Eylea was approved to treat DME in July 2014.²¹ As shown in Chart 2, for DME, Eylea achieved a sales share [REDACTED] in 2014. By the end of 2021, Eylea’s sales

19

20

For DR without DME, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21

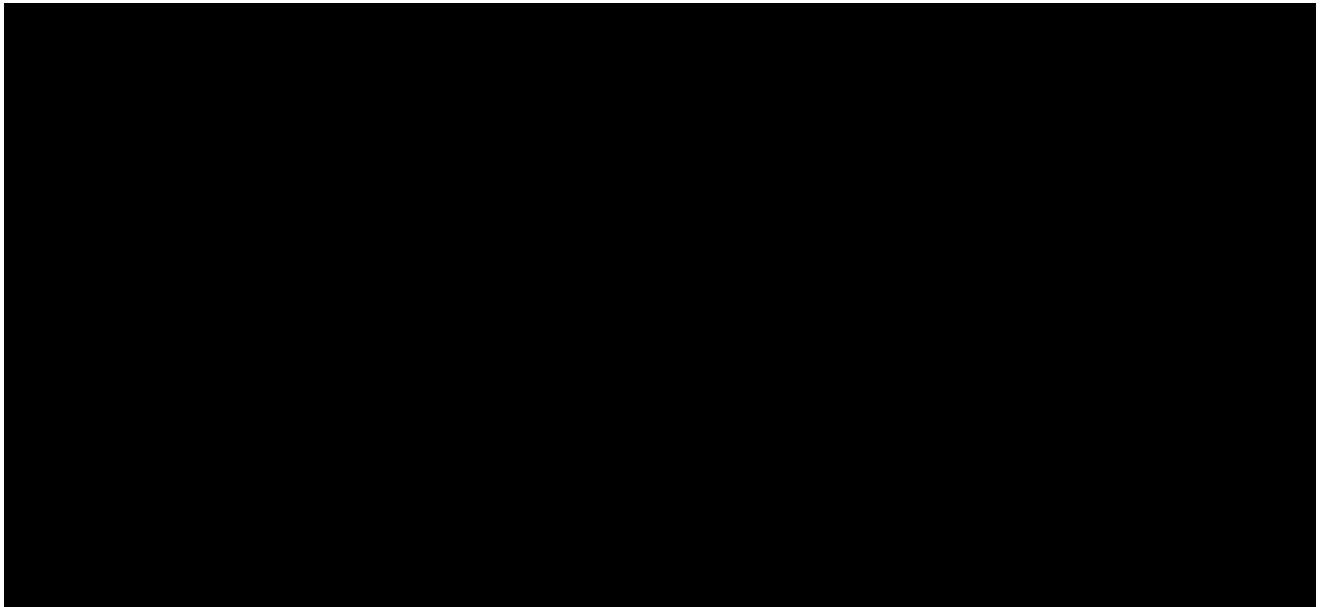
Ex. 2076 (Regeneron Press Release, “Eylea (Aflibercept) Injection Receives FDA Approval for the Treatment of Diabetic Macular Edema (DME),”

share in the DME indication was [REDACTED]

[REDACTED]

[REDACTED]

Chart 2: Eylea's Sales Share Across Data Sources – DME²²



- (23) Measures of sales share for patients with DR without DME vary more greatly across data sources than measures for other indications. [REDACTED]
- [REDACTED]

[REDACTED] As shown in Chart 3, Eylea's sales share for DR

7/29/2014, <https://investor.regeneron.com/news-releases/news-release-details/eylear-aflibercept-injection-receives-fda-approval-treatment>).

²² Attachment C-7.

without DME patients has grown since it was first tracked. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

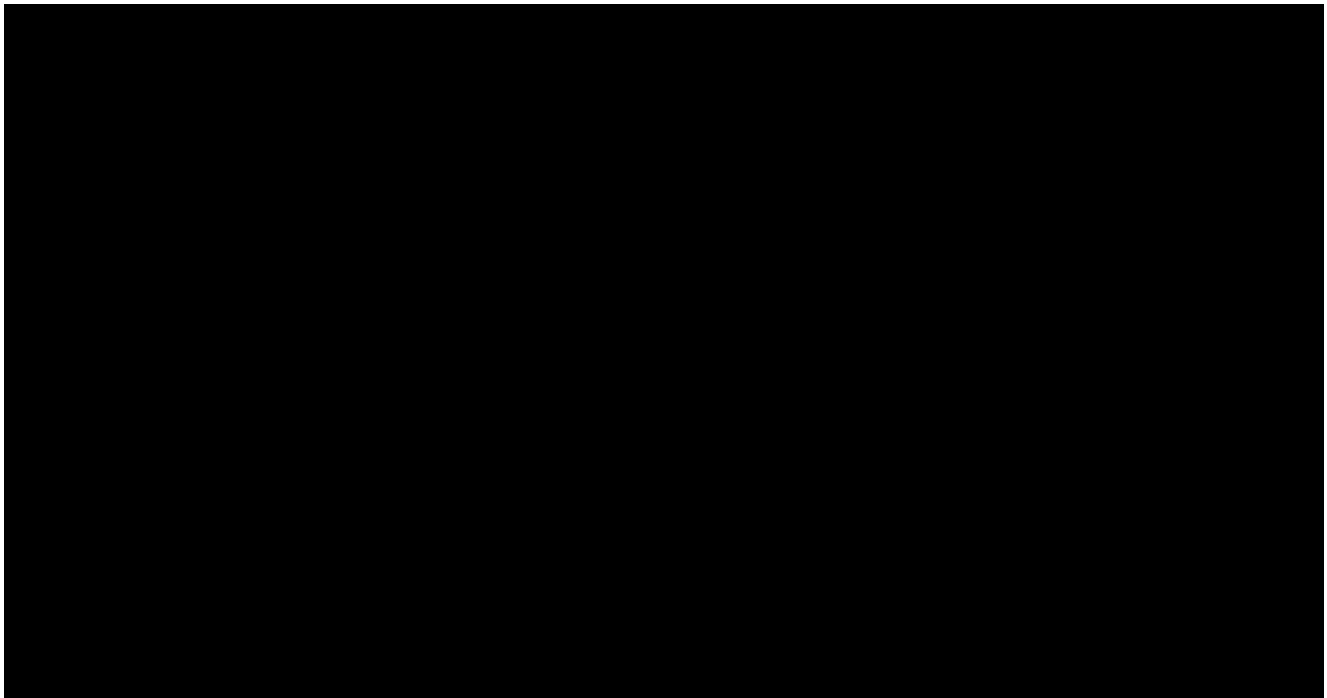
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Chart 3: Eylea's Sales Share Across Data Sources – DR without DME²³



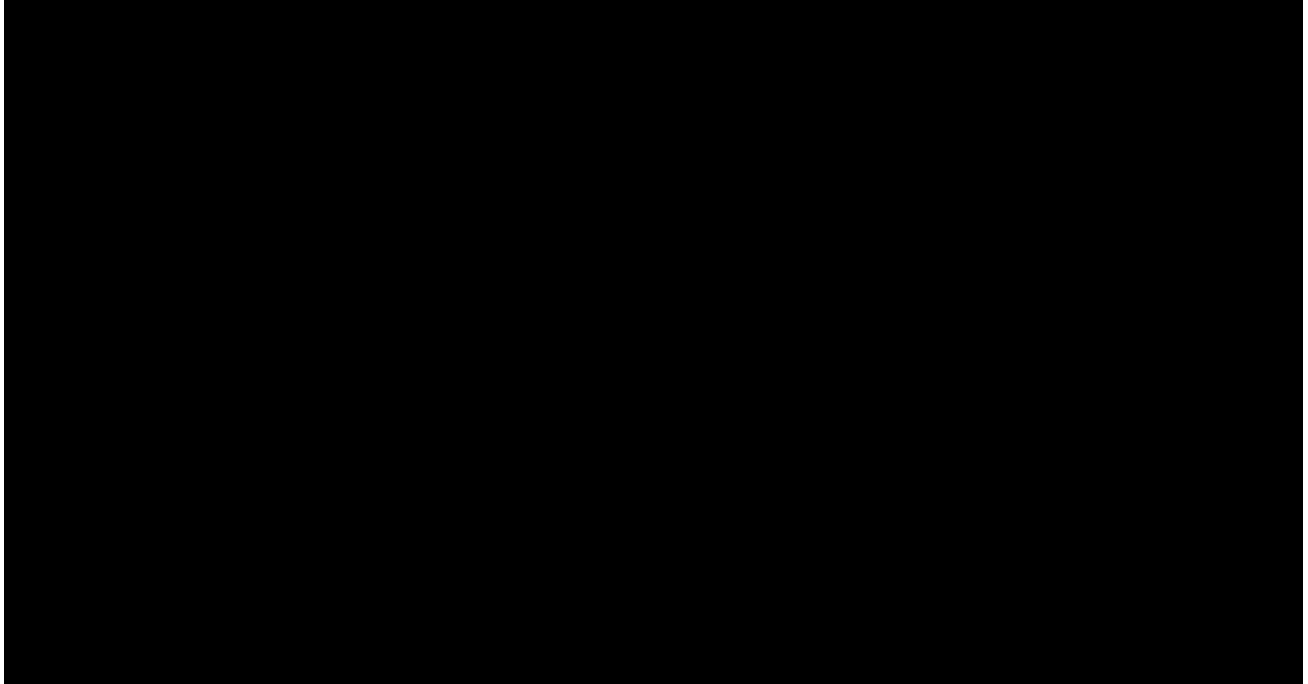
²³ Attachment C-8.

- (24) Similar patterns can be seen for the other indications [REDACTED]
[REDACTED] See Attachments C-4, C-5, C-9, and C-10.

3.2.3. Eylea's sales growth trends as an indicator of commercial success

- (25) Eylea's increased utilization has come both from contributing to overall growth in the use of anti-VEGF treatments as well as by switching patients to Eylea from two available and established anti-VEGF treatments, Avastin and Lucentis, which had been in wide use for several years before Eylea's introduction. Chart 4 below provides a summary of the number of unique Medicare patients treated with Eylea, Lucentis, and Avastin each year from 2012 to 2021.

Chart 4: Medicare Part B Patients Treated, By Year and Treatment²⁴



(26) As seen in Chart 4, the number of Medicare patients for which Eylea was used increased annually, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Additionally, from 2019 to

²⁴ Attachment E-4.

²⁵ Moreover, even in years during which all three anti-VEGF treatments were used on more patients, had Eylea not been available it is likely that Avastin and

2020 the number of total treated patients in the anti-VEGF category declined [REDACTED]

[REDACTED] Similarly, from 2020 to 2021, the number of total treated patients in the anti-VEGF category declined [REDACTED]

- (27) This is further supported by the fact that Eylea is the dominant option for second-line therapy. According to the National Cancer Institute, second-line therapy is a “[t]reatment that is given when initial treatment (first-line therapy) doesn’t work, or stops working.”²⁶ [REDACTED]

Lucentis would have been used for at least some of the patients who historically were treated with Eylea. Even in such years, some portion of Eylea sales would represent sales that were in some sense taken from Avastin or Lucentis.

²⁶ Ex. 2077 (NCI, Second-Line Therapy, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/second-line-therapy> (accessed 1/16/2024)).

²⁷ Ex. 2078 (Regeneron, “Q4 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME,” 1/29/2021, at 67).

[REDACTED]

[REDACTED]

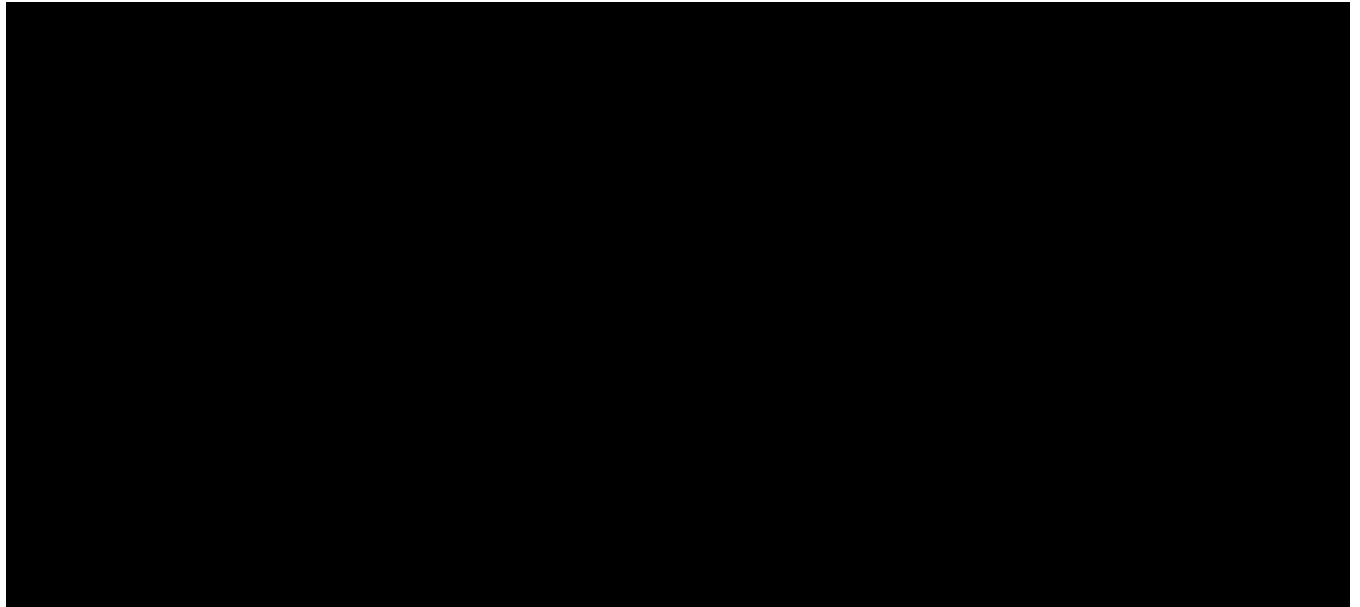
Therefore, a portion of Eylea’s growth has come from patients previously treated with Avastin and Lucentis.

- (28) The relative change in sales shares since Eylea’s launch further supports the conclusion that Eylea has taken sales from Avastin and Lucentis. [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED] Chart 5 below shows the cumulative percentage point change in sales shares since Eylea launched. See Attachment C-11.

²⁸ Ex. 2078 (Regeneron, “Q4 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME,” 1/29/2021, at 72, 82).

**Chart 5: Percentage Point Change in Sales Share
Since Eylea Launch – All Indications, ATU Data²⁹**



3.2.4. Eylea status as physicians’ most used treatment

- (29) Therapy choices of individual practitioners further illustrate Eylea’s commercial success as it has displaced Avastin and Lucentis in therapeutic use. Generally, rather than using only a single treatment for all patients, physicians utilize a variety of the treatment options depending upon the circumstances of the patient.³⁰ That said,

²⁹ Attachment C-11.

Similar patterns are present in Medicare Part B data. See Attachment C-12.

³⁰ Ex. 2079 (Manning, Richard, et al. (2015), “Similar Products at Different Prices: Can Biopharmaceutical Companies Segment Markets?” *International*

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As of 2021, Eylea has become the most commonly used treatment option for a larger share of practitioners than any other treatment option, [REDACTED]

[REDACTED] Table 1 below illustrates this change in most common use by practitioners.

[REDACTED]

Journal of the Economics of Business 22(2): 231–243, at 241. (“Rather, it is consistent with the notion that physicians typically exercise medical judgment or are responsive to other factors on a patient-by-patient basis.”))

³¹ Table 1 presents only anti-VEGF treatment options. A more complete presentation of treatment options (including Macugen, corticosteroids, etc.) is presented in Attachment E-1.

4. Dosing Regimen is An Important Driver of Demand for Eylea

- (30) The eye diseases treated by Eylea and the other products discussed here impose a very large cost on patients. Loss of vision is one of the most serious health insults an individual can experience, imposing substantial physical, social, and economic burdens on individuals.³² Adults with vision impairment often have lower rates of workforce participation and higher rates of depression and anxiety.³³ In older adults,

³² Ex. 2080 (Centers for Disease Control and Prevention, “Vision Loss: A Public Health Problem,” 12/19/2022, https://www.cdc.gov/visionhealth/basic_information/vision_loss.htm).

(“People with vision loss are more likely to report depression, diabetes, hearing impairment, stroke, falls, cognitive decline, and premature death. Decreased ability to see often leads to the inability to drive, read, keep accounts, and travel in unfamiliar places, thus substantially compromising quality of life. The cost of vision loss, including direct costs and lost productivity, is estimated to exceed \$35 billion[.]”))

³³ Ex. 2081 (World Health Organization, “Blindness and Vision Impairment Fact Sheet,” 8/10/2023, <https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment>.)

vision impairment can “contribute to social isolation, difficulty walking, [and] a higher risk of falls and fractures[.]”³⁴ Hence, a treatment that meaningfully diminishes the likelihood of vision loss or that extends the time until vision deteriorates is something on which most patients, and, in turn, their treating physicians, would place a very high value.³⁵

4.1. Eylea’s 8-week fixed dosing interval addressed an unmet need for longer dosing intervals

- (31) Frequent dosing, and the risk of significant harm to vision if doses are missed, represents a significant treatment burden for patients with the relevant angiogenic eye disorders. Physicians identified the need to alleviate this treatment burden as an unmet need in treating these disorders prior to the launch of Eylea. [REDACTED]
- [REDACTED]

³⁴ Ex. 2081 (World Health Organization, “Blindness and Vision Impairment Fact Sheet,” 8/10/2023, <https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment>.)

³⁵ I have not seen evidence demonstrating that other factors, such as marketing or rebates, were the driving force behind Eylea’s commercial success. I reserve the right to amend or supplement my opinions to address any contrary showing if attempted by Petitioner.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The ongoing

need for increased dosing intervals means that the 8-week fixed dosing interval would be a relevant consideration for physicians and patients selecting treatment options.

- (32) Dr. Stewart, Regeneron’s technical expert, identifies various aspects of the treatment burden associated with more frequent visits, including travel and time burden for both the patient and assisting caregiver; risks associated with frequent injections, such as infections that can lead to blindness; and financial costs.³⁸ Dr. Stewart explains that because of these downsides, the retinal community was in search of a

³⁶ Ex. 2082 (American Society of Retina Specialists, “2009 Preferences and Trends Membership Survey,” c. 2009, at slide 92).

³⁷ Ex. 2082 (American Society of Retina Specialists, “2009 Preferences and Trends Membership Survey,” c. 2009, at slide 92).

³⁸ Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § XIV).

treatment regimen that reduced the frequency of injections required to effectively treat patients, which Eylea made possible.³⁹

(33) Dr. Stewart further explained that there is a consensus among treating physicians that:

- Less frequent dosing was a preferred option due to the nature of intravitreal injections.⁴⁰
- Intravitreal injections can cause significant pain and discomfort. Every intravitreal injection carries a risk of infection, and those infections can lead to blindness. Fewer injections would reduce these negative outcomes.⁴¹
- The cost and inconvenience of monthly visits and injections can be a major drawback for patients, many of whom are elderly, who cannot drive due to their deteriorating vision. These drawbacks and risks were a recognized concern in the mid- and late-2000's.⁴²

³⁹ Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § XIV).

⁴⁰ Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § XIV).

⁴¹ Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § XIV).

⁴² Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § XIV).

4.2. Eylea’s 8-week fixed dosing interval is a key differentiating factor

(34) As compared to other anti-VEGF treatments available for the relevant diseases, Eylea’s 8-week fixed dosing interval is a key differentiating factor. I understand that when seeking initial FDA approval, clinical testing of Eylea sought to show non-inferiority as compared to Lucentis (i.e., that Eylea and Lucentis had similar efficacy) using an extended dosing regimen.⁴³ Evidence that the 8-week fixed dosing interval is a key differentiating factor for Eylea is discussed below.

a.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴³ Ex. 2027 (Declaration of Michael W. Stewart, M.D., 1/25/2024, at § VI.C).

⁴⁴ Ex. 2083 (Regeneron, “DME Market Assessment,” 8/2014, at 46).

⁴⁵ Ex. 2083 (Regeneron, “DME Market Assessment,” 8/2014, at 46).

[REDACTED]

[REDACTED]

b. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

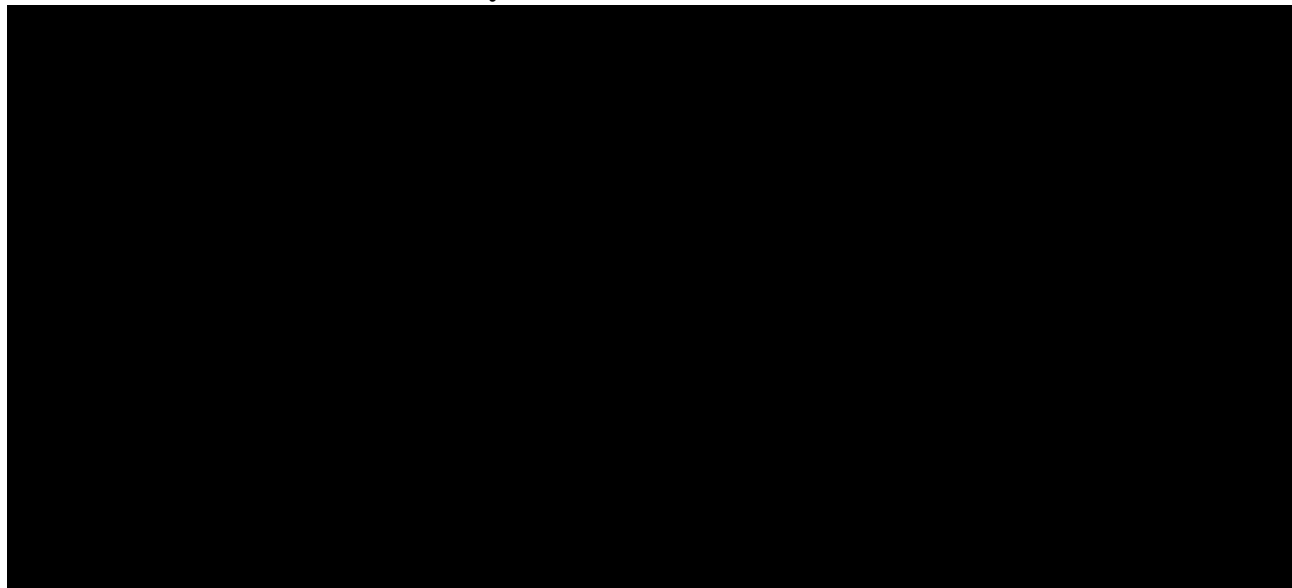
⁴⁶ Ex. 2083 (Regeneron, “DME Market Assessment,” 8/2014, at 46).

⁴⁷ Ex. 2084 (American Society of Retina Specialists, “2015 Preferences and Trends (PAT) Survey,” c. 2015, at 84).

Ex. 2085 (American Society of Retina Specialists, “2016 Preferences and Trends (PAT) Survey,” c. 2016, at 73).

The 2015 survey omitted the word “agent” and the italicized the word “most” from the question.

Table 2: Share of Respondents Identifying Each Anti-VEGF Agent as Most Likely to Extend Treatment Duration⁴⁸

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4.3. The most common fixed dosing interval for Eylea is approximately eight weeks

- (35) Physician survey data regarding treatment dosing provides additional evidence of the importance of the 8-week fixed dosing interval to Eylea’s commercial success.

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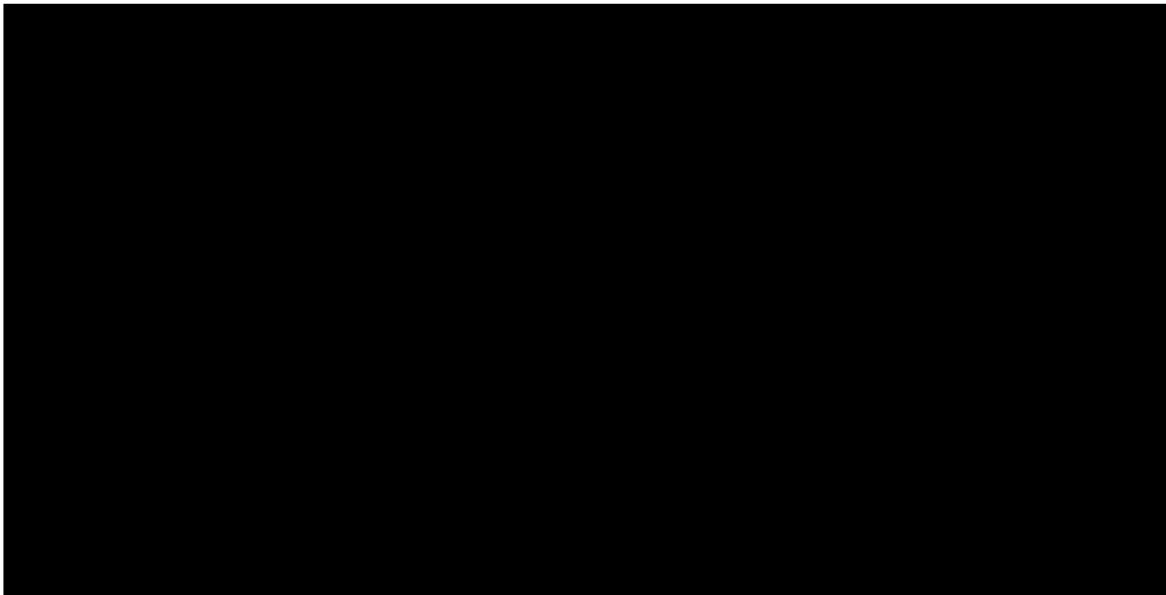
⁴⁸ Ex. 2084 (American Society of Retina Specialists, “2015 Preferences and Trends (PAT) Survey,” c. 2015, at 84).

Ex. 2085 (American Society of Retina Specialists, “2016 Preferences and Trends (PAT) Survey,” c. 2016, at 73).

[REDACTED]

[REDACTED] For example:

Screenshot: ATU Dosing Update⁵⁰



(36) Data [REDACTED] show [REDACTED]

[REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

⁵⁰ Ex. 2086 (Regeneron, “Q4 2018 Performance Update Wet AMD, DME, & MEfRVO“, 2/2019, at 62).

[REDACTED] See Attachment E-3. Table 3 below summarizes the results for DME. See Attachment E-3.

51

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

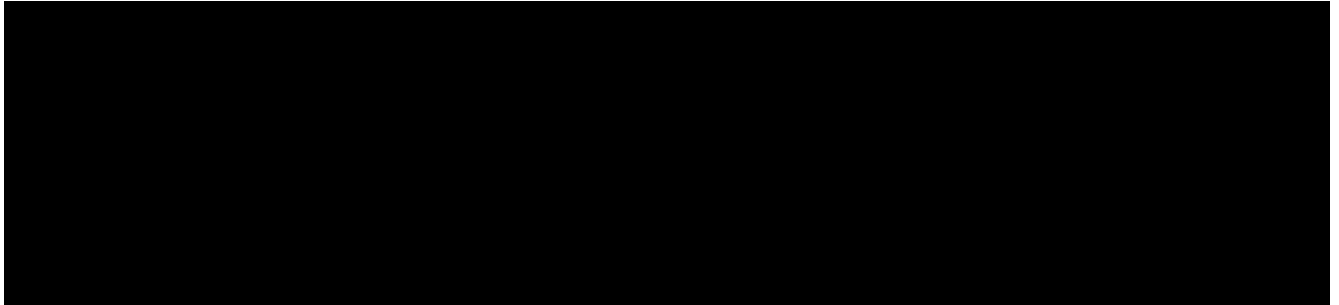
[REDACTED]

[REDACTED]

[REDACTED]

Ex. 2087 (Regeneron, “Q2 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME,” 7/30/2020, at 94.)

Table 3: Summary of Most Common Dosing Interval Used by Physicians (ATU Surveys, DME, Overall Physicians and Treatment Regimens)⁵²

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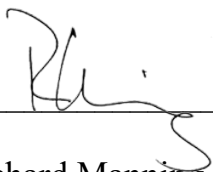
- (37) Physician responses regarding their use of the various Anti-VEGF treatments confirm that physicians actually use the 8-week dosing interval and do so more commonly than other treatment intervals. This corroborates the stated importance of the dosing regimen reported by physicians and Regeneron discussed in Section 4.2.

⁵² Percentages reflect the projected percentage of treated eyes receiving the dosing interval. Similar patterns hold for other indications with available data. See Attachment E-3.

CONFIDENTIAL MATERIAL – SUBJECT TO PROTECTIVE ORDER

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both under Section 1001 of Title 18 of the United States Code.

Dated: January 26, 2024



Richard Manning, Ph.D.

Washington, D.C.

Attachment A-1

January 2024

Richard Manning, Ph.D.
Managing Director

Dr. Richard Manning is a Managing Director at Intensity, LLC. He provides economic and data-driven insights to help clients solve complex problems arising in a variety of disputes and business settings with emphasis on biopharmaceuticals in both prescription and Over the Counter (OTC) products, life sciences, and animal health. His areas of expertise include:

- Economic Valuation and Damages
 - Intellectual Property
 - Breach of Contract, Fraud, and other Commercial Litigation
 - Securities Litigation
- Tax, Antitrust and Competition
- Public Policy

Dr. Manning has testified in U.S. District Court, U.S. Bankruptcy Court, the Delaware Court of Chancery, the United States Patent Trial and Appeals Board, and the International Chamber of Commerce; served as consulting expert and prepared reports and commentary on a wide range of issues in the biopharmaceutical (both innovative and follow-on sectors) and healthcare industries. His career includes 14 years as an executive in multinational pharmaceutical companies where he led economic analysis and strategy development to shape practices related to emerging business concerns.

Examples of Dr. Manning's work include:

- Economic analysis and strategy relative to challenges affecting pricing, reimbursement, marketing, manufacturing, R&D investments, and intellectual property protection, including commercial success, Paragraph IV and reverse settlements.
- Economic valuation of early-stage companies and strategic investments; evaluating profitability; mergers and acquisitions; and other financial analyses.
- Analyzing healthcare benefit design; healthcare system reforms; FDA regulatory reform, including biosimilars review processes and product safety.

Prior to joining Intensity, Dr. Manning was a Partner at Bates White, an economic consulting firm offering analysis and expert testimony services to law firms, Fortune 500 companies, and government agencies. Previously, Dr. Manning was Executive Director at Merck & Co., Inc., and

he was Senior Director at Pfizer, Inc. Dr. Manning was also a Director in the Advisory Strategy Group at PricewaterhouseCoopers.

Dr. Manning was an economics professor at Brigham Young University and a visiting professor in the Graduate School of Business at the University of Chicago. As an academic, his teaching and research focused on price theory, the economic analysis of law, industrial organization, and the economics of government regulation.

Dr. Manning received his Ph.D. in Economics from the University of Chicago. He earned his B.A. in Economics from Brigham Young University.

Education

PhD, Economics, University of Chicago, 1989.

MA, Economics, University of Chicago, 1984.

BA, Economics, Brigham Young University, magna cum laude, 1982.

Professional Experience

Intensity, LLC. Managing Director, 2021 to present.

Bates White Economic Consulting, Washington, DC. Partner, 2012–2021.

Merck & Co., Inc., Whitehouse Station, NJ. Executive Director, 2010–2011.

PricewaterhouseCoopers, LLP, New York, NY. Director, Advisory Strategy, 2008–2010.

Pfizer, Inc., New York, NY. Senior Director, 2003–2008.

Pfizer, Inc., New York, NY. Director, 2000–2003.

Pfizer, Inc., New York, NY. Assistant Director, 1999–2000.

Pfizer, Inc., New York, NY. Manager, 1997–1999.

Department of Economics, Brigham Young University Assistant Professor, 1990–1997.

Graduate School of Business, University of Chicago. Visiting Assistant Professor, 1995–1996.

Expert Testimony and Selected Consulting Experience

(Client is underlined.)

Breach of Contract, Fraud, and other Commercial Litigation

1. Fortis Advisors LLC, solely in its capacity as representative of former stockholders of Auris Health, Inc. v. Johnson & Johnson, et al., Court of Chancery of the State of Delaware, Case No. 2020-0881. Submitted expert report (May 2023); testified in deposition (Sept. 2023) and trial (Jan. 2024). (Retained by Selendy & Gay.)
2. Served as expert witness for respondent in arbitration before the American Arbitration Association regarding damages due to an alleged breach of obligations in a supply agreement for Covid-19 tests. Submitted witness statement (December 2022). (Retained by Hueston Hennigan.)
3. Sorrento Therapeutics, Inc., and Scilex Pharmaceuticals, Inc. v. Anthony Mack and Virpax Pharmaceuticals, Inc. Court of Chancery of the State of Delaware, Case No. 2021-0210-PAF. Submitted expert report (July 2022); testified in deposition and trial (Sept. 2022). (Retained by Ballard Spahr.)
4. Don Cleveland, et al. v. Ludwig Institute for Cancer Research LTD. Et al. United States District Court, Southern District of California, Case No. 3:19-cv-02141. Submitted rebuttal expert report (May 2022) and testified in deposition (May 2022). (Retained by Milbank.)
5. Perrigo v. United States of America. United States District Court, Western District of Michigan, Case No. 1:17-cv-00737. Submitted expert report (January 2019) and testified in deposition (March 2019) and trial (June 2021). (Retained by U.S. Department of Justice.)
6. Served as expert witness for claimant in arbitration before the International Chamber of Commerce regarding damages due to an alleged breach of obligations to market a newly launched prescription medication. Submitted witness statement (April 2019), rebuttal statement, and testified in hearing. (Retained by Reed Smith.)
7. Merix Pharmaceutical Corp. v. Clinical Supplies Management, Inc. (CSM). United States District Court, Northern District of Illinois, Case No. 1:11-cv-03318. Retained as testifying expert on behalf of CSM in connection with alleged fraud and breach of contract claims related to the performance of a clinical trial for an over-the-counter medication. Authored expert report (2013) and provided deposition testimony (July 2013) that assessed damages assertions made by plaintiff's experts. Judge Matthew F. Kennelly, of the US District Court for the Northern District of Illinois Eastern Division, granted summary judgment on a number of Merix's damages claims. A jury ultimately found in CSM's favor at trial. (Retained by Segal McCambridge.)
8. National Union Fire Insurance Company of Pittsburgh, Pennsylvania v. Tyco Integrated Security, LLC. United States District Court, Southern District of Florida, Case No. 9:13-cv-80371. Authored an expert report (January 2015) and testified in deposition (March 2015) regarding damages arising from a theft of prescription drugs from a pharmaceutical company warehouse. In April 2016, a Florida federal jury found in Tyco's favor, finding the security company not liable in the insurer's negligence suit. (Retained by Shook, Hardy and Bacon.)

9. *Elorac v. Sanofi-Aventis Canada*. United States District Court, Northern District of Illinois, Case No. 1:14-cv-01859. Authored an expert report (2016) and provided deposition testimony (June 2016) assessing damages in a breach of contract federal district court action on behalf of the plaintiff, asserting that the defendant failed to perform its duties to commercialize plaintiff's product under a licensing agreement. (Retained by Barnes and Thornburg.)
10. *Fera Pharmaceuticals LLS v. Akorn Inc.* United States District Court, Southern District of New York, Case No. 1:12-cv-07694. Retained as the testifying expert on behalf of Fera. Authored expert report (2017) and provided deposition testimony (December 2017) evaluating damages, including diminished asset value, resulting from alleged breach of contract, fraudulent inducement, and misappropriation of trade secrets related to Fera's portfolio of prescription ophthalmic anti-infective ointment products. The matter settled on the eve of trial for an undisclosed amount. (Retained by Napoli Shkolnik.)
11. Served as damages expert for plaintiff on a matter related to losses allegedly suffered by a large academic medical center related to a natural disaster. Work included evaluating the value of destroyed and delayed biomedical research projects funded by a large administrative agency and other third parties, and business interruption associated with the loss. The court accepted a motion for summary judgment before reports were filed. (Retained by Pillsbury.)
12. Served as consulting expert to provide liability and damages analysis for defendant multinational pharmaceutical company in a qui tam case involving potential violations of state law in its marketing practices. (Retained by Hogan Lovells.)
13. Retained as testifying and consulting expert to analyze the economics of a pharmacy services contract evaluation and award process for a leading institutional pharmacy plaintiff in a dispute with a large state's Department of Public Safety and Correctional Services.
14. Retained as consulting expert by a class of state Medicaid claimants to evaluate the state's application of an econometric model for benefit determination decisions. (Retained by Herzfeld and Piotrowski.)

Intellectual Property

15. *Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc.* United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2023-00442, Patent No. 10,130,681 B2. Submitted Expert Declaration (October 2023) and testified in deposition (December 2023). (Retained by Arnold & Porter.)
16. *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.* United States District Court Northern District of West Virginia, Clarksburg Division, Case No. 1:22-cv-00061. Patent Nos. 10,888,601, 11,253,572 and 11,084,865. Submitted Expert Report and testified in deposition (April 2023). Submitted Supplemental Expert Report (May 2023) and testified in deposition (May 2023). (Retained by Williams & Connolly and Kellogg Hansen.)
17. *Mylan Pharmaceuticals Inc., Celltrion, Inc., and Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc.* United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2022-01226, Patent No. 10,888,601. Submitted Expert

- Declaration (April 2023) and testified in deposition (June 2023). (Retained by Arnold & Porter.)
18. *Mylan Pharmaceuticals Inc., Celltrion, Inc., and Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.* United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2022-01225, Patent No. 10,130,681. Submitted Expert Declaration (April 2023) and testified in deposition (June 2023). (Retained by Arnold & Porter.)
 19. *Mylan Pharmaceuticals Inc., Celltrion, Inc., and Apotex, Inc. v. Regeneron Pharmaceuticals, Inc.* United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2021-00881, Patent No. 9,254,338 B2. Submitted Expert Declaration (February 2022) and testified in deposition (May 2022). (Retained by Arnold & Porter.)
 20. *Baxalta Incorporated and Baxalta GmbH v. Genentech, Inc. and Chugai Pharmaceutical Co., Ltd.* United States District Court, District of Delaware, Case No. 17-cv-00509. Submitted rebuttal expert report (June 2021) and testified in deposition (August 2021). The matter concluded with a summary judgment for Genentech. (Retained by Paul Weiss Rifkind Wharton & Garrison.)
 21. *Purdue Pharma v. Alvogen Pine Brook.* United States District Court, District of Delaware, Case No. 1:17-cv-00677. Retained as testifying expert to assess the commercial success of a prescription drug in a patent infringement litigation related to certain Abbreviated New Drug Applications (ANDAs) filed by defendant. Submitted expert reports and provided deposition testimony (March 2018). The matter settled on the eve of trial. (Retained by Norton Rose.)
 22. *In re Covered Business Method Post-Grant Review of U.S. Patent No. 8,036,916, CoreSource v. Quality Healthcare Intermediary.* United States District Court, Northern District Court of Illinois, Case No. 1:13-cv-05182. Submitted declarations to US Patent Trial and Appeals Board (January 2014) involving methods for optimizing healthcare services management. Patent owner respondent terminated its claims. (Retained by McCarter & English.)
 23. Retained as consulting expert on behalf of defendant in a breach of contract matter between biopharmaceutical companies before the International Chamber of Commerce. Plaintiff was seeking damages for alleged lost profits related to a joint marketing agreement. Provided support to testifying expert in preparing a rebuttal report regarding the impact of adoption and pricing of biosimilar products entering the marketplace in certain Asian countries. (Retained by Winston & Strawn.)
 24. Served as consultant to plaintiff university assessing damages against a consumer products company by an unauthorized filing of patents on property owned by the university. Submitted a declaration (December 2015) to U.S. District Court of Utah, Central Division, addressing recommended economic principles and methodologies for assessing the university's intellectual property market value. (Retained by Parr Brown Gee & Loveless.)
 25. Provided consulting expert supporting leading academic expert for respondent in an arbitration between large mobile telecommunications companies regarding royalties to be paid for standard-essential patents.

26. Served as consulting expert supporting leading academic expert for claimant medical device manufacturer in an International Trade Commission (ITC) matter seeking to enjoin importation of surgical devices on basis of harm to public interest.

Securities Litigation & Bankruptcy

27. *In re: Retrotope, Inc.* United States Bankruptcy Court, District of Delaware, Case No. 22-10228 (JTD). Retained by counsel for dissident Retrotope shareholders. Expert report and testified in deposition and evidentiary hearing (July 2022). (Retained by Buchalter.)
28. *Wells Fargo Bank et al. v. Merrimack Pharmaceuticals, Inc.* Court of Chancery of the State of Delaware. Retained as testifying expert on behalf of plaintiffs. The plaintiffs alleged that the company's asset sale was a sale of "substantially all" of the assets, which was a fundamental change, and Merrimack was required to repurchase the convertible notes. Submitted primary and rebuttal reports (September 2017) that valued Merrimack's pipeline of oncology drugs and opined that the sale of Merrimack's sole commercial product constituted a fundamental change of the company. Following the exchange of reports, the parties settled. (Retained by Friedman Kaplan.)
29. *Neogenix Oncology v. Peter Gordon et al.* United States District Court, Eastern District of New York, Case No. 2:14-cv-04427. Submitted a witness statement (March 2019) regarding the value of an early-stage biopharmaceutical company. The parties settled. (Retained by Friedman Kaplan.)
30. *In re: Purdue Pharma L.P. et al., Debtors.* United States Bankruptcy Court Southern District of New York, Chapter 11 Case No. 19-23649 (RDD). Retained by counsel to provide consulting support to Special Committee assessing the arm's-length nature of asset transfers and royalty agreements between Purdue Pharma and the Sackler Families and the Sackler Entities. (Retained by Davis Polk.)

Antitrust and Competition

31. *Pharmaceutical Solutions, Inc. (VetSource) v. Nevada State Board of Pharmacy et al.* United States District Court, District of Nevada, Case No. 2:16-cv-171-RFB-VCF. Retained as the testifying expert on behalf of VetSource, which sued in federal court in response to a cease and desist action that alleged illegal kickbacks. Authored expert report (September 2017) evaluating the market for pet medications in Nevada and the VetSource business model to assess whether the company competes with other retail pharmacies in this market. The parties settled the federal lawsuit on undisclosed terms. VetSource continues to operate in the state under its previously existing business model, and the complaint from the Nevada Board of Pharmacy was rescinded. (Retained by Kutak Rock.)
32. Conducted detailed economic analysis on behalf of Eli Lilly in connection with its \$5.4 billion acquisition of Novartis Animal Health (2014). Both firms were active in developing and marketing animal health products, including medications used to treat pets and livestock. Team assessed overlaps in several areas, and presented results of its analysis to the FTC. The FTC approved the merger after an eight-month investigation, with divestiture required in one product area, canine parasiticides.

Selected Policy and Business Consulting Experience

- Retained by industry trade organization to assess economic profitability of US industries accounting for differing levels of financial investment and cost of capital across industries and to prepare white paper on topic including periodic updates.
- Retained by a multinational pharmaceutical company to develop a tool based on economic theory to help the company optimize its participation in price-related contract negotiations with foreign purchasers of generic drug products and biosimilars. The tool provides the predicted win probability for a given bid and calculates expected profits based on observed market factors.
- Retained to provide consulting services to a start-up pharmaceutical manufacturing company pursuing opportunities in underserved product spaces in both public and private sector markets.
- Retained by a coalition of health insurance companies to assess the costs of compliance with proposed federal regulation regarding transparency and provision of information to customers.
- Evaluated strategic opportunities for commercializing the academic and clinical research undertaken by faculty at a major academic medical institution involved in research and development of gene-based diagnostics.
- Analyzed the prospective impact of the “Cadillac tax” section of the Affordable Care Act on employer and employee choices regarding insurance options, healthcare spending, and federal revenue. Used the Congressional Budget Office health insurance simulation model and predicted that the tax would lead to a lower offer rate of health benefits by employers and an increase in overall healthcare spending, and that the tax would have disproportionate effects on minority populations.
- Retained as consulting expert for a multinational manufacturer of injectable blood plasma derivatives to evaluate the economics of manufacturing and distribution of plasma-based medications and the potential impact of regulatory restrictions on certain business practices.
- Retained as consulting expert for a global life sciences company to evaluate the economics of biosimilar entry in the United States and key international markets. The focus is on market penetration and pricing of medicines entering under a new regulatory framework for follow-on biologics.
- Retained by a leading healthcare company to prepare a report analyzing the economics of the market for blood plasma products in response to changing demand and cost conditions.
- Retained by a multinational life sciences company to analyze the market for oncology products with respect to the sustainability of current and projected future trends in pricing, utilization, and reimbursement.
- Retained by a multinational life sciences and healthcare company to analyze links between health status and economic well-being across countries and over time.
- Prepared a report for research-based pharmaceutical and biotechnology companies evaluating potential compliance costs resulting from Affordable Care Act price reporting requirements to government agencies.

- Performed an economic impact analysis of research and development activities for a leading non-profit stem cell foundation, working with scientists to evaluate programs and assess impact on future economic activity.

Selected Corporate Experience

- Led teams in the assessment of emerging strategic challenges facing a major biopharmaceutical company in both human and animal health businesses related to industry pricing, marketing and other business practices, managed care and government payor access restrictions, intellectual property protection, litigation threats, healthcare reform proposals, etc.
- Led teams working on mergers and acquisitions analysis for both human and animal health divisions of biopharmaceutical companies, undertaking commercial due diligence, evaluating target companies and market conditions, and providing economic analysis of divestiture options in response to regulatory concerns.
- Worked with leadership of disease management subsidiary of major biopharmaceutical company overseeing studies of health benefits design on issues including medication adherence, cost, and medical outcomes.
- Participated in an executive-level initiative on individualized medicine focused on identifying and evaluating future opportunities in the business of human genetics as it related to the development of gene-based diagnostics and therapeutics.
- Served as company spokesperson on major economic issues and as the company representative on key industry trade organization teams responsible for conducting research projects that addressed the value of innovation, pricing and reimbursement threats, intellectual property protection, international trade-related pricing challenges, etc.
- Developed and provided training on economics of drug discovery and development for research scientists at a global biopharmaceutical company.

Journal Articles

“Comment on ‘Market Exclusivity for Drugs with Multiple Orphan Approvals (1982–2017) and Associated Budget Impact in the US.’” *PharmacoEconomics*. 38, 1373–1374 (2020).
<https://doi.org/10.1007/s40273-020-00975-7>

“The Clinical and Economic Impact of the Early Detection and Diagnosis of Cancer,” with Peter J. Deckers, Tricia Laursen, Stacey Worthy, and Shruti Kulkarni, *Health Law & Policy Brief* XIV, no. 2 (2020): 1–20.

“Prices and Related Controversies in the Biopharmaceutical Industry,” *International Journal of the Economics of Business* 25, no. 1 (2018): 157–66.

“Vaccination and GDP Growth Rates: Exploring the Links in a Conditional Convergence Framework,” with Neal A. Masia, Jonathan Smerling, Tendayi Kapfudz, and Mark Showalter, *World Development* 103 (2018): 88–99.

“Risk-based Decision Making and Ethical Considerations in Donor Compensation for Plasma-derived Medicinal Products,” with Mark Skinner, Ann Hedlund Hoppe, Henry Grabowski, Raffi Tachdjian, James Crone, and Stuart Youngner, *Transfusion* (2016): 1–6.

“An Economic Analysis of Global Policy Proposals to Prohibit Compensation of Blood Plasma Donors,” with Henry Grabowski, *International Journal of the Economics of Business* 23, no. 2 (2016): 149–66.

“Similar Products at Different Prices: Can Biopharmaceutical Companies Segment Markets?” with Christopher Stomberg, Benjamin Scher, Kathleen Twigg, and Andrew Huson, *International Journal of the Economics of Business* 22, no. 2 (2015): 231–44.

“Pharmaceutical Risk Sharing Agreements,” with Joseph Cook and John Vernon, *Pharmacoeconomics* 26, no. 7 (2008): 551–56.

“Special Issue on Economics of Pharmaceutical Industry,” co-editor with John Vernon, *Managerial and Decision Economics* 28, no. 4–5 (2007): 229–522.

“The Benefits of Switching Smoking Cessation Drugs to OTC,” with Teh-wei Hu, Hai-Yen Sung, Theodore E. Keeler, Martin Marciniak, and Alison Keith, *Health Economics* 11, no. 5 (2002): 389–402.

“Economic Impact of Product Liability in US Prescription Drug Markets,” *International Business Lawyer* 29, no. 3 (2001): 104–09.

“Have Changing Liability Rules Compensated Workers Twice for Occupational Hazards? Earnings Premiums and Cancer Risk,” with John R. Lott, Jr., *Journal of Legal Studies* 29 (2000): 99–130.

“The Length of Time Necessary to Break Even after Converting to Digital Mammography,” with Mark D. Hiatt and J. Jeffrey Carr, *Journal of Telemedicine and Telecare* 6, no. 4 (2000): 222–24.

“Products Liability and Prescription Drug Prices in Canada and the United States,” *Journal of Law and Economics* 40 (1997): 203–44.

“How Term Limits Enhance the Expression of Democratic Preferences,” with Einer Elhauge and John R. Lott, Jr., *Supreme Court Economic Review* 5 (1997): 59–80.

“Is the Insurance Aspect of Producer Liability Valued by Consumers? Liability Changes and Childhood Vaccine Consumption,” *Journal of Risk and Uncertainty* 12 (1996): 343–58.

“Logit Regressions with Continuous Dependent Variables Measured with Error,” *Applied Economics Letters* 3 (1996): 183–84.

“Changing Rules in Tort Law and the Market for Childhood Vaccines,” *Journal of Law and Economics* 37 (1994): 247–75.

Corporate Publications

Economic Realities in Health Care Policy, monograph series, Editor, Pfizer Inc., 1998–2005.

- “The Competitive Advantage of a Healthy Workforce,” Editor, with Alison Keith, 1998.
- “Pharmaceutical Prices: What’s Missing from the Public Discussion,” with Alison Keith, 2000.
- “Prescription Drug Advertising: Empowering Consumers through Information,” 2002.
- “Pharmaceutical Innovation: Lowering the Price of Good Health,” 2002.
- “Pharmaceutical Prices: What’s Missing from the Public Discussion, Updated,” with Neal Masia, 2002.

- “Pharmaceutical Marketing and Promotion: Creating Access to Innovation,” with Neal Masia, 2003.
- “Who Invents New Medicines?” Editor, with Neal Masia, 2005.

Other Publications

“Economic Profitability of the Biopharmaceutical Industry 2022,” with Anushree Subramaniam, September 22, 2022, *available at* <https://intensity.com/news/economic-profitability-of-the-biopharmaceutical-industry-2022>.

“Public Comment to Multilateral Pharmaceutical Merger Task Force” with Kira Stearns, Kyle Kost, and Richard Brady, June 2021, *available at* <https://www.regulations.gov/comment/FTC-2021-0025-0038>.

“Risks In Moving Too Quickly, Or Slowly, On COVID-19 Vaccine” Law360, December 2020, *available at* <https://www.law360.com/articles/1336937>.

“An Integrated Supply Chain: A White Paper on Addressing Essential Medicine Shortages” with Anthony Flammia, Kristina McKean, and Patricia Watson, August 2020, *available at* https://www.phlow-usa.com/wp-content/uploads/Phlow_SAPIR_Whitepaper_091020.pdf

“Economic Profitability of the Biopharmaceutical Industry: 2020 Update,” with Saurav Karki, Policy Brief, May 2020, *available at* <https://www.bateswhite.com/newsroom-insight-Economic-Profitability-Biopharmaceutical-Industry-2020-update.html>.

“Estimating the Burden of the Proposed Transparency in Coverage Rule,” with Arun Sharma and Zachary Mozenter, Bates White Economic Consulting White Paper, January 2020, *available at* https://www.bateswhite.com/media/publication/183_Estimating%20Burden%20of%20Proposed%20TCR.pdf.

“Policies to Reduce Prices of Prescription Medicines,” Policy Brief, September 2019, *available at* https://www.bateswhite.com/media/publication/181_Policy%20Brief%20on%20price%20control%20measures.2019.09.18.pdf.

“The International Pricing Index for Medicare Part B Drugs,” Policy Brief, February 2019, *available at* https://www.bateswhite.com/media/publication/170_International%20Pricing%20Index%20for%20Medicare%20Part%20B%20Drugs.pdf.

“Continuous Manufacturing in Pharmaceuticals: Economic and Policy Issues,” with Richard Sciacca, October 2018, *available at* https://www.bateswhite.com/media/publication/171_Continuous%20Manufacturing.pdf.

“Economic Profitability of the Biopharmaceutical Industry,” with Saurav Karki, Policy Brief, September 2018, *available at* https://www.bateswhite.com/media/publication/167_Economic%20profitability%20of%20the%20drug%20industry.pdf.

“*Commentary on Biotech vs. Pharma Investments*,” Carlson School of Management, Medical Industry Leadership Institute *Exchange* 19, Summer 2018.

“Key Economic and Value Considerations in the US Market for Plasma Protein Therapies,” with Henry Grabowski, February 2018.

“Biosimilar Coding and Reimbursement under Medicare Part B,” with Christopher Stomberg and Ben Wolfert, November 2017.

“Poorly Executed Analyses of Drug Research and Development Is Useless.” *The Hill*. September 29, 2017, *available at* <http://thehill.com/opinion/healthcare/353072-poorly-executed-analyses-of-pharmaceutical-rd-is-useless?rnd=1506695357>.

“Penalizing Generic Drugs with the CPI Rebate Will Reduce Competition and Increase the Likelihood of Drug Shortages,” with Fred Selck, September 2017, *available at* <https://www.accessiblemeds.org/sites/default/files/2017-09/Bates-White-White-Paper-Report-CPI-Penalty-09-12-2017.pdf>.

“Drug Prices and Medical Innovation: A Response to Yu, Helms, and Bach,” with Henry Grabowski, *Health Affairs* Blog, June 2, 2017, *available at* <http://healthaffairs.org/blog/2017/06/02/drug-prices-and-medical-innovation-a-response-to-yu-helms-and-bach/>.

“Oncology Product Sales and Patent Expiration: A Policy Brief,” with Fred Selck, June 2017, *available at* <http://www.bateswhite.com/insight-173.html>.

“The Role of Value and Cost in Prescription Drug Pricing,” *Law360*, September 27, 2016.

“Tax Inversions: How Do Financial Metrics of Foreign Acquisitions Compare?” with Richard Sciacca and Alan Alford, Apr. 6, 2016.

“Tax Inversions: A Preliminary Review of Company Financial Data,” with Richard Sciacca and Alan Alford, Jan 12, 2016.

“Our Best Shot: Expanding Prevention through Vaccination in Older Adults,” with Fred Selck and Kathleen Chandler, July 29, 2015.

Recent Presentations and Panels

- GCR Live: Antitrust in Pharmaceuticals, Looking to the future of antitrust in the pharmaceutical sector, “Pricing reforms – what to expect?” Panel discussion, New York, NY, December 1, 2022.
- “15th Meeting of the American College of Business Court Judges, “Pharmaceutical Regulation: Lessons and Enduring Impacts of Deregulatory Incentives Embraced During a Pandemic,” Panel discussion, George Mason University Antonin Scalia Law School Law and Economics Center, Savannah, GA, October 30, 2020.
- Global Plasma Summit 2020, “The Plasma Industry and Possible Effects of the COVID Pandemic,” Presenter, virtual conference, October 30, 2020
- Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaborations: The Role of Intellectual Property, “Academics’ and Economists’ Views on Collaboration and Competition,” Joint DOJ/USPTO Antitrust Webinar panelist, September 24, 2020
- Meeting of the Association of Blood Service of Ukraine and the Ukrainian Society of Immunology, Allergology and Immunorehabilitation, “Assessing Value for Plasma Protein Therapies,” Presentation, Kiev, Ukraine, September 19, 2019
- 8th Annual American Society of Health Economics meeting, “Setting Drug Prices in Medicare: Toward a Competitive Market?” Policy Roundtable moderator, Washington, DC, June 24, 2019.

- 2019 Plasma Protein Therapeutics Association, Plasma Forum, “Assessing Value for Plasma Protein Therapies,” Panel discussion, Reston, VA, June 18, 2019.
- Symposium on the Legal, Economic, and Regulatory Environment of the Pharmaceutical Industry, “Who Really Pays for Drugs and How Much? Marketing, Pricing, and Transparency,” Panel discussion, George Mason University Antonin Scalia Law School, Arlington, VA, April 15, 2019.
- 15th Annual Symposium of the Journal of Law, Economics, and Policy: Health Care Cost, Quality, and Transparency, “Why Do Drugs Cost so Much? What (If Anything) Should We Do About It?” Panel discussion, George Mason University Antonin Scalia Law School, Arlington, VA, November 16, 2018.
- Pneumococcal Vaccination Pharmacoeconomic Summit, “Childhood Vaccination and Economic Growth,” Presentation, Dubai UAE, February 24, 2018.
- George Mason University Center for the Protection of Intellectual Property Summer Institute, “The Challenges of Encouraging Long-Term Innovation,” Panel discussion, Beaver Creek, CO, July 12, 2017.
- International Health Economics Association, Boston 2017 Congress, “Global Spending Patterns for Oncology Medications,” Presentation, Boston, July 9, 2017.
- George Mason University Center for the Protection of Intellectual Property Fourth Annual Fall Conference, “Assessing the Economic Case for Patents,” Panel discussion, Arlington, VA, October 7, 2016.
- AcademyHealth Annual Research Meeting, “Building a Successful HSR Career Outside the Ivory Tower,” Panel discussion, Boston, MA, June 27, 2016.
- Sidley Austin’s Global Drug Pricing Conference, “Options for Responding to Price Scrutiny, including Value Based Contracting,” Washington, DC, April 20, 2016.
- Bates White Life Sciences Symposium, “Anti-Kickback Statute,” Panel moderator, Washington, DC, June 8, 2015.
- George Mason University Center for the Protection of Intellectual Property Roundtable, “Patented Innovation in the Pharmaceutical and Biotech Industries,” Hilton Head, SC, May 28–29, 2015.
- George Mason University Attorneys General Education Program, “Pharmaceutical Marketing: Economic and Legal Issues,” Arlington, VA, March 26, 2015.
- Bates White Life Sciences Symposium, “Oncology Case Study,” Washington, DC, June 13, 2014.
- Bates White Life Sciences Symposium, “Litigation Landscape since Last Year’s Supreme Court Decision in *FTC v. Actavis*,” Panelist, Washington, DC, June 12, 2014.
- Bates White Healthcare & Life Sciences Symposium, “Co-pay Coupons Case Study,” Washington, DC, June 10, 2013.
- Indian Institute of Management Bangalore Roundtable, “Ethical Issues in the Health Care Sector in India,” March 2013.
- ACI’s West Coast Edition Paragraph IV Disputes Conference, “Damages Analysis,” San Francisco, CA, December 5, 2012.
- McGuireWoods’ 4th Annual Medical Device and Life Sciences Conference, “Key Economic and Legal Issues in Prescription Drug Marketing,” Chicago, IL, November 8, 2012.

- George Mason University Attorneys General Education Program, “Marketing and Advertising of Prescription Drugs: An Economic Perspective,” Arlington, VA, May 3, 2012.
- Medical Industry Leadership Institute, Carlson School of Management, University of Minnesota, Panel discussion, May 2011.
- PhRMA Asia Pacific Meeting, Panel discussion chair, Singapore, January 2011.
- Incisive Media 7th Annual Healthcare M&A and Business Development Conference, Presentation, Atlanta, GA, September 2009.
- The Deal Healthcare Dealmaking Symposium, Presentation, New York, NY, March 2009.
- Drug Industry Association Annual Meeting, Presentation, 2008.

Professional Activities and Service

- National Advisory Council member, College of Family, Home and Social Sciences, Brigham Young University, Provo, UT
- Advisory Board, Medical Industry Leadership Institute, Carlson School of Management, University of Minnesota
- Business Research Advisory Committee Member and Price Index Committee Chair, US Bureau of Labor Statistics
- Advisory Board, Rutgers Business School, Lerner Center for Pharmaceutical Management
- Founding Member and Advisory Board, Center for Value Based Insurance Design, University of Michigan
- Corporate Council Member, Brookings Institution
- Editorial Board, *Managerial and Decision Economics*
- Ad hoc referee for *International Journal of the Economics of Business*, *Journal of Political Economy*, *Journal of Law and Economics*, *Journal of Legal Studies*, *Journal of Industrial Economics*, *Health Affairs*, *Forum for Health Economics and Policy*, *The Social Science Journal*

PROFESSIONAL ASSOCIATIONS AND RECOGNITIONS

- IAM Patent 1000, Recognized Economic Expert, 2023
- American Economic Association
- International Society for Pharmacoeconomics and Outcomes Research
- Economic Club of New York
- American Society of Health Economists
- National Association of Business Economists
- American Law and Economics Association



Attachment A-2

January 2024

Richard Manning, Ph.D.
Managing Director

Testimony at Deposition or Trial since January 2020

(Client is underlined.)

1. Fortis Advisors LLC, solely in its capacity as representative of former stockholders of Auris Health, Inc. v. Johnson & Johnson, et al., Court of Chancery of the State of Delaware, Case No. 2020-0881. Submitted expert report (May 2023); testified in deposition (Sept. 2023) and trial (Jan. 2024). (Retained by Selendy & Gay.)
2. Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc. United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2023-00442, Patent No. 10,130,681 B2. Submitted Expert Declaration (October 2023) and testified in deposition (December 2023). (Retained by Arnold & Porter.)
3. Mylan Pharmaceuticals Inc., Celltrion, Inc., and Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc. United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2022-01226, Patent No. 10,888,601. Submitted Expert Declaration (April 2023) and testified in deposition (June 2023). (Retained by Arnold & Porter.)
4. Mylan Pharmaceuticals Inc., Celltrion, Inc., and Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc. United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2022-01225, Patent No. 10,130,681. Submitted Expert Declaration (April 2023) and testified in deposition (June 2023). (Retained by Arnold & Porter.)
5. Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc. United States District Court Northern District of West Virginia, Clarksburg Division, Case No. 1:22-cv-00061, Patent Nos. 10,888,601, 11,253,572 and 11,084,865. Submitted Expert Report and testified in deposition (Apr 2023). Submitted Supplemental Expert Report and testified in deposition (May 2023). (Retained by Williams & Connolly and Kellogg Hansen.)
6. Sorrento Therapeutics, Inc., and Scilex Pharmaceuticals, Inc. v. Anthony Mack and Virpax Pharmaceuticals, Inc. Court of Chancery of the State of Delaware, Case No. 2021-0210-PAF. Submitted expert report (July 2022); testified in deposition and trial (Sept. 2022). (Retained by Ballard Spahr.)

Attachment A-2

7. *In re: Retrotope, Inc.* United States Bankruptcy Court, District of Delaware, Case No. 22-10228 (JTD). Retained by counsel for dissident Retrotope shareholders. Expert report and testified in deposition and evidentiary hearing (July 2022). (Retained by Buchalter.)
8. *Don Cleveland, et al. v. Ludwig Institute for Cancer Research LTD. Et al.* United States District Court, Southern District of California, Case No. 3:19-cv-02141. Submitted rebuttal expert report (May 2022) and testified in deposition. (Retained by Milbank.)
9. *Mylan Pharmaceuticals Inc., Celltrion, Inc., and Apotex, Inc. v. Regeneron Pharmaceuticals, Inc.* United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2021-00881, Patent No. 9,254,338 B2. Submitted Expert Declaration (February 2022) and testified in deposition. (Retained by Arnold & Porter.)
10. *Perrigo v. United States of America.* United States District Court, Western District of Michigan, Case No. 1:17-cv-00737. Submitted expert report (January 2019) and testified in deposition and trial (June 2021). (Retained by U.S. Department of Justice.)
11. *Baxalta Incorporated and Baxalta GmbH v. Genentech, Inc. and Chugai Pharmaceutical Co., Ltd.* United States District Court, District of Delaware, Case No. 17-cv-00509. Submitted rebuttal expert report (June 2021) and testified in deposition. The matter concluded with a summary judgment for Genentech. (Retained by Paul Weiss Rifkind Wharton & Garrison.)

Attachment B-1

Dosing Directions on FDA Labels

Indication	Brand	Source	First Label for Each Brand and Indication	Most Recent Label
Wet AMD	Eylea	[A]	- The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). - Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.	- The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). - Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months). - Although not as effective as the recommended every 8 week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly.
Wet AMD	Lucentis	[B]	- LUCENTIS 0.5 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month. - Although less effective, treatment may be reduced to one injection every three months after the first four injections if monthly injections are not feasible. Compared to continued monthly dosing, dosing every 3 months will lead to an approximate 5-letter (1-line) loss of visual acuity benefit, on average, over the following 9 months. Patients should be evaluated regularly.	- LUCENTIS 0.5 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days). - Although not as effective, patients may be treated with 3 monthly doses followed by less frequent dosing with regular assessment. - Although not as effective, patients may also be treated with one dose every 3 months after 4 monthly doses. Patients should be assessed regularly.
Wet AMD	Beovu	[C]	BEOVU is administered by intravitreal injection. The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) monthly (approximately every 25-31 days) for the first three doses, followed by one dose of 6 mg (0.05 mL) every 8-12 weeks.	BEOVU is administered by intravitreal injection. The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) monthly (approximately every 25-31 days) for the first three doses, followed by one dose of 6 mg (0.05 mL) every 8-12 weeks[.]
Wet AMD	Susvimo	[D]	- For intravitreal use via SUSVIMO ocular implant. - The recommended dose of SUSVIMO (ranibizumab injection) is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO implant with refills every 24 weeks (approximately 6 months). - Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary.	- For intravitreal use via SUSVIMO ocular implant. - The recommended dose of SUSVIMO (ranibizumab injection) is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO implant with refills every 24 weeks (approximately 6 months). - Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary.
Wet AMD	Vabysmo	[E]	The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.	The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

Indication	Brand	Source	First Label for Each Brand and Indication	Most Recent Label
RVO	Eylea	[F]	• The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (monthly).	• The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly).
RVO	Lucentis	[G]	• LUCENTIS 0.5 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days). In the RVO clinical studies, patients received monthly injections of LUCENTIS for six months. In spite of being guided by optical coherence tomography and visual acuity re-treatment criteria, patients who were then not treated at Month 6 experienced on average, a loss of visual acuity at Month 7, whereas patients who were treated at Month 6 did not. Patients should be treated monthly[.]	• LUCENTIS 0.5 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days).
RVO	Beovu	[H]	n/a	n/a
RVO	Susvimo	[I]	n/a	n/a
RVO	Vabysmo	[J]	n/a	n/a

Indication	Brand	Source	First Label for Each Brand and Indication	Most Recent Label
DME	Eylea	[K]	- The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). - Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.	- The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). - Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).
DME	Lucentis	[L]	LUCENTIS 0.3 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days).	LUCENTIS 0.3 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days).
DME	Beovu	[M]	n/a	The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) every six weeks (approximately every 39-45 days) for the first five doses, followed by one dose of 6 mg (0.05 mL of 120 mg/mL solution) every 8-12 weeks.
DME	Susvimo	[N]	n/a	n/a
DME	Vabysmo	[O]	VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days $\pm$ 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses.	VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days $\pm$ 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses.

Indication	Brand	Source	First Label for Each Brand and Indication	Most Recent Label
DR	Eylea	[P]	• The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). • Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).	• The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). • Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).
DR	Lucentis	[Q]	• LUCENTIS 0.3 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days).	• LUCENTIS 0.3 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days).
DR	Beovu	[R]	n/a	n/a
DR	Susvimo	[S]	n/a	n/a
DR	Vabysmo	[T]	n/a	n/a

Notes and sources:

First Label:

- [A] Ex. 2070 (Eylea label, 11/2011, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125387lbl.pdf.)
- [B] Ex. 2108 (Lucentis label, c. 2006, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/125156lbl.pdf.)
- [C] Ex. 2109 (Beovu label, 10/2019, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761125s000lbl.pdf.)
- [D] Ex. 2110 (Susvimo Label, 10/2021, at 8, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761197s000lbl.pdf.)
- [E] Ex. 2111 (Vabysmo Label, 1/2022, at 7, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761235s000lbl.pdf.)
- [F] Ex. 2161 (Eylea label, 9/2012, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125387s004lbl.pdf.)
- [G] Ex. 2112 (Lucentis label, 6/2010, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/125156s053lbl.pdf.)
- [H] Beovu is not approved for treatment outside of Wet AMD and DME.
- [I] Susvimo is not approved for treatment outside of Wet AMD.
- [J] Vabysmo is not approved for treatment outside of Wet AMD and DME.
- [K] Ex. 2113 (Eylea label, 10/2014, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125387s043lbl.pdf.)
- [L] Ex. 2114 (Lucentis label, 8/2012, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125156s0069s0076lbl.pdf.)
- [M] Beovu is not approved for treatment outside of Wet AMD and DME.
- [N] Susvimo is not approved for treatment outside of Wet AMD.
- [O] Ex. 2111 (Vabysmo Label, 1/2022, at 7, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761235s000lbl.pdf.)
- [P] Ex. 2115 (Eylea label, 5/2019, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125387s061lbl.pdf.)
- [Q] Ex. 2134, (Lucentis label, 4/2017, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125156s114lbl.pdf.)
- [R] Beovu is not approved for treatment outside of Wet AMD and DME.
- [S] Susvimo is not approved for treatment outside of Wet AMD.
- [T] Vabysmo is not approved for treatment outside of Wet AMD and DME.

Indication	Brand	Source	First Label for Each Brand and Indication	Most Recent Label
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Most Recent Label:

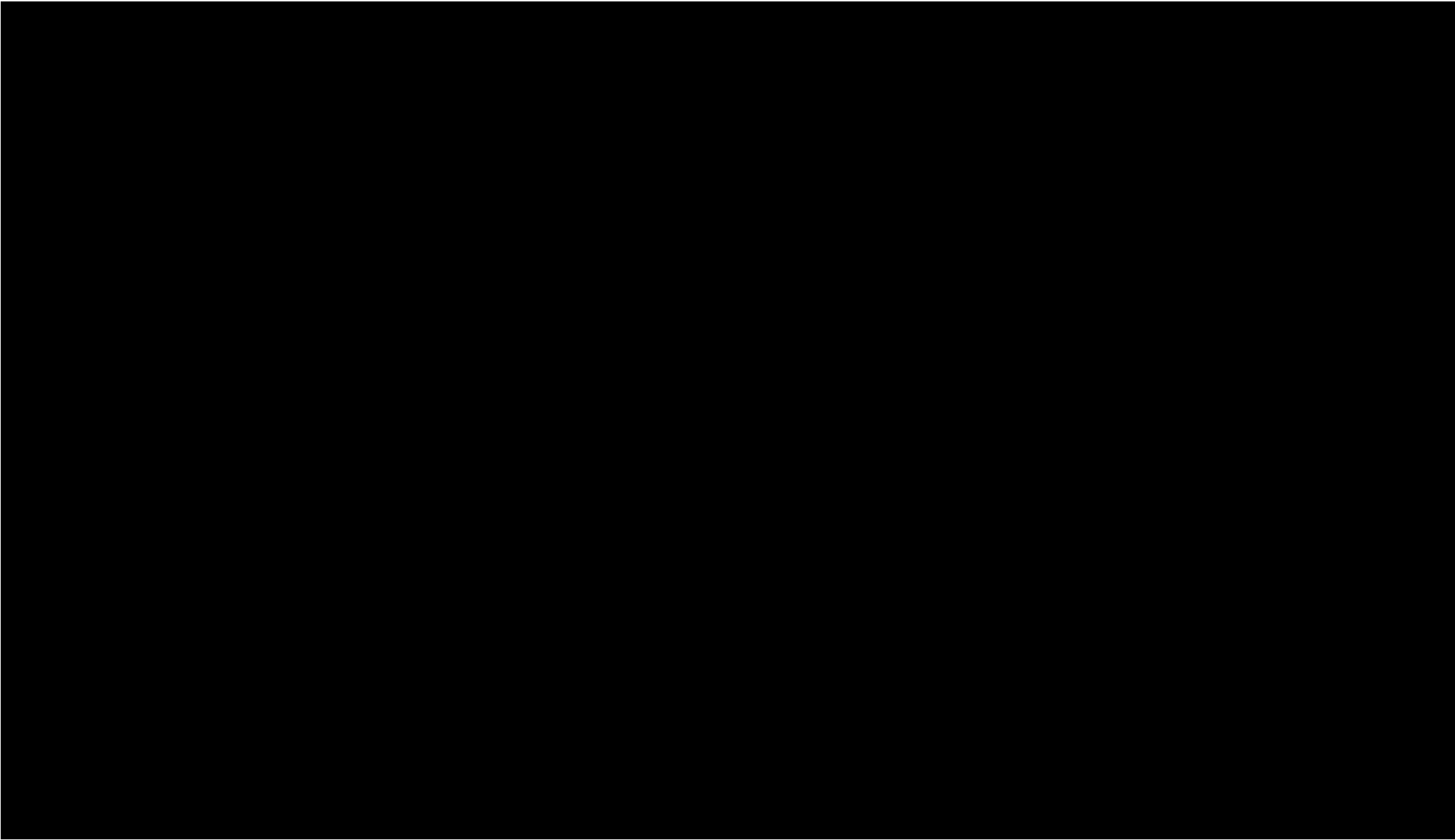
- [A] Ex. 2106 (Eylea label, 2/2023, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125387s075lbl.pdf.)
- [B] Ex. 2116 (Lucentis label, 3/2018, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125156s117lbl.pdf.)
- [C] Ex. 2117 (Beovu label, 12/2022, at 3, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761125s017lbl.pdf.)
- [D] Ex. 2118 (Susvimo Label, 4/2022, at 3, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761197s002lbl.pdf.)
- [E] Ex. 2119 (Vabysmo Label, 1/2023, at 4, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761235s001lbl.pdf.)
- [F] Ex. 2106 (Eylea label, 2/2023, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125387s075lbl.pdf.)
- [G] Ex. 2116 (Lucentis label, 3/2018, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125156s117lbl.pdf.)
- [H] Beovu is not approved for treatment outside of Wet AMD and DME.
- [I] Susvimo is not approved for treatment outside of Wet AMD.
- [J] Vabysmo is not approved for treatment outside of Wet AMD and DME.
- [K] Ex. 2106 (Eylea label, 2/2023, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125387s075lbl.pdf.)
- [L] Ex. 2116 (Lucentis label, 3/2018, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125156s117lbl.pdf.)
- [M] Ex. 2117 (Beovu label, 12/2022, at 3, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761125s017lbl.pdf.)
- [N] Susvimo is not approved for treatment outside of Wet AMD.
- [O] Ex. 2119 (Vabysmo Label, 1/2023, at 4, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761235s001lbl.pdf.)
- [P] Ex. 2106 (Eylea label, 2/2023, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125387s075lbl.pdf.)
- [Q] Ex. 2116 (Lucentis label, 3/2018, at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125156s117lbl.pdf.)
- [R] Beovu is not approved for treatment outside of Wet AMD and DME.
- [S] Susvimo is not approved for treatment outside of Wet AMD.
- [T] Vabysmo is not approved for treatment outside of Wet AMD and DME.

On February 8th, 2023, the FDA approved Eylea for the treatment of Retinopathy of Prematurity (ROP).

This indication was not included in our report as its approval date placed it outside the scope of our data on commercial performance.

Attachment C-1

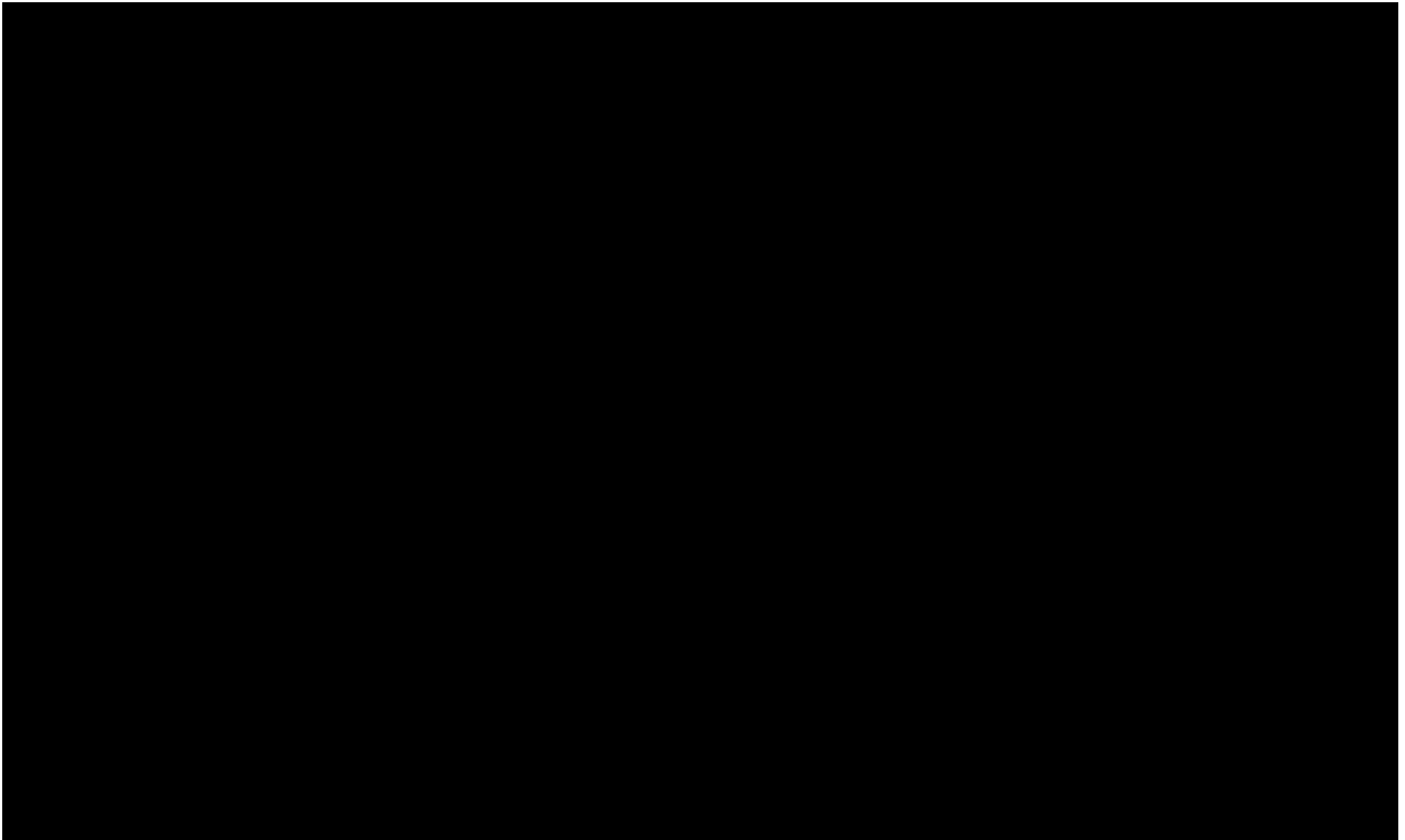
Sales Share Summary - All Indications



[REDACTED]

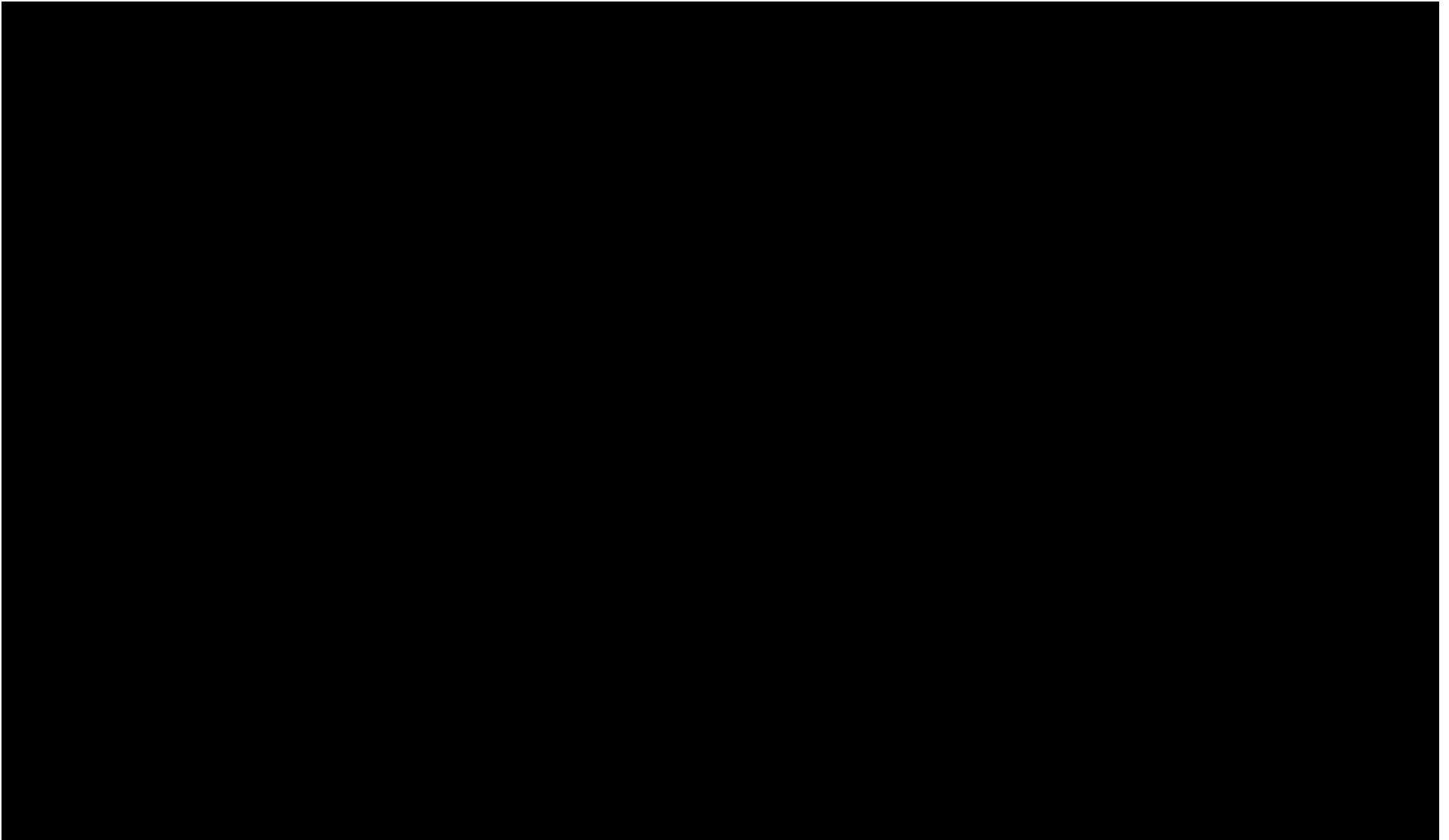
Attachment C-2

Sales Share Summary - DME



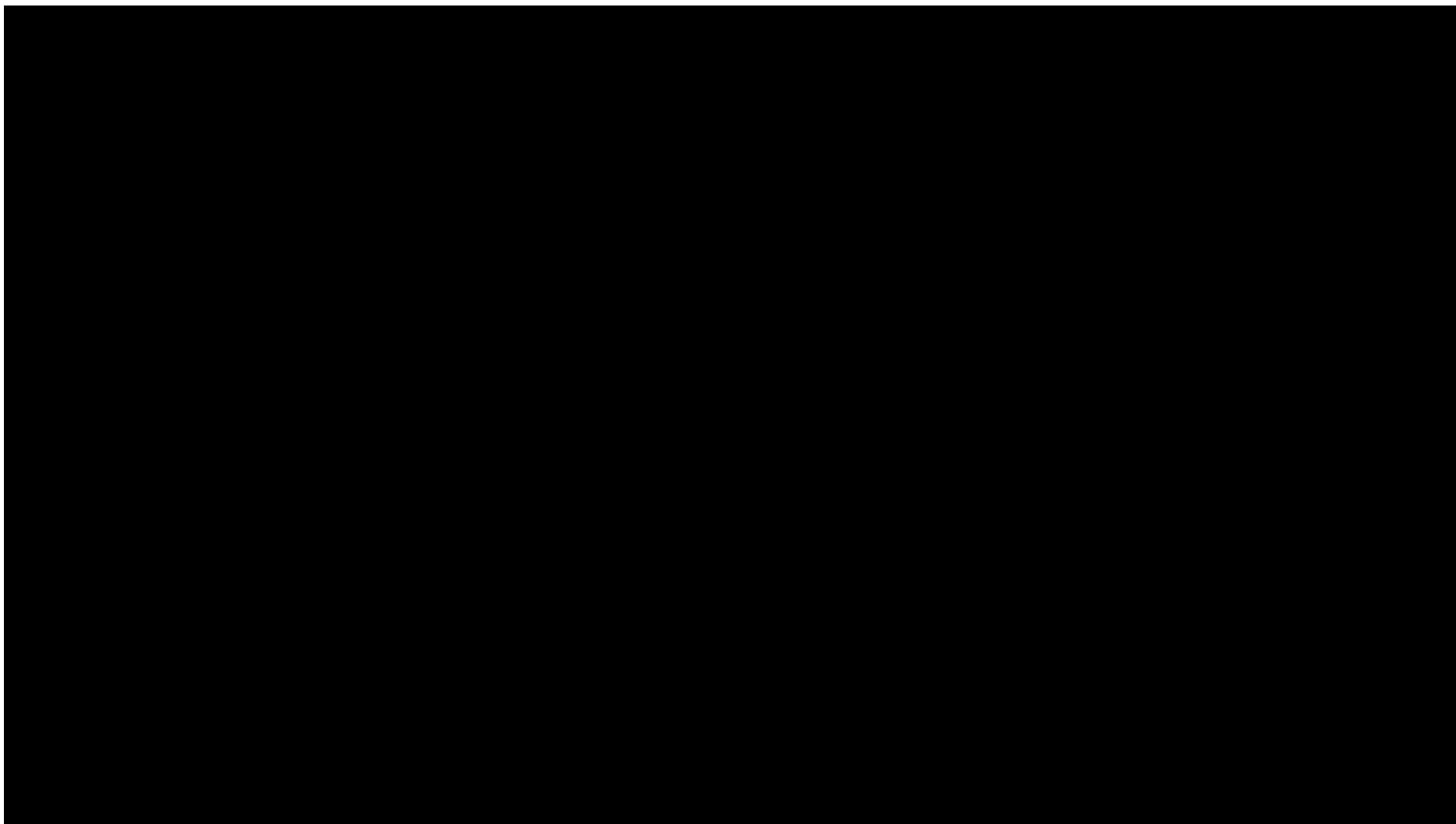
Attachment C-3

Sales Share Summary - DR without DME



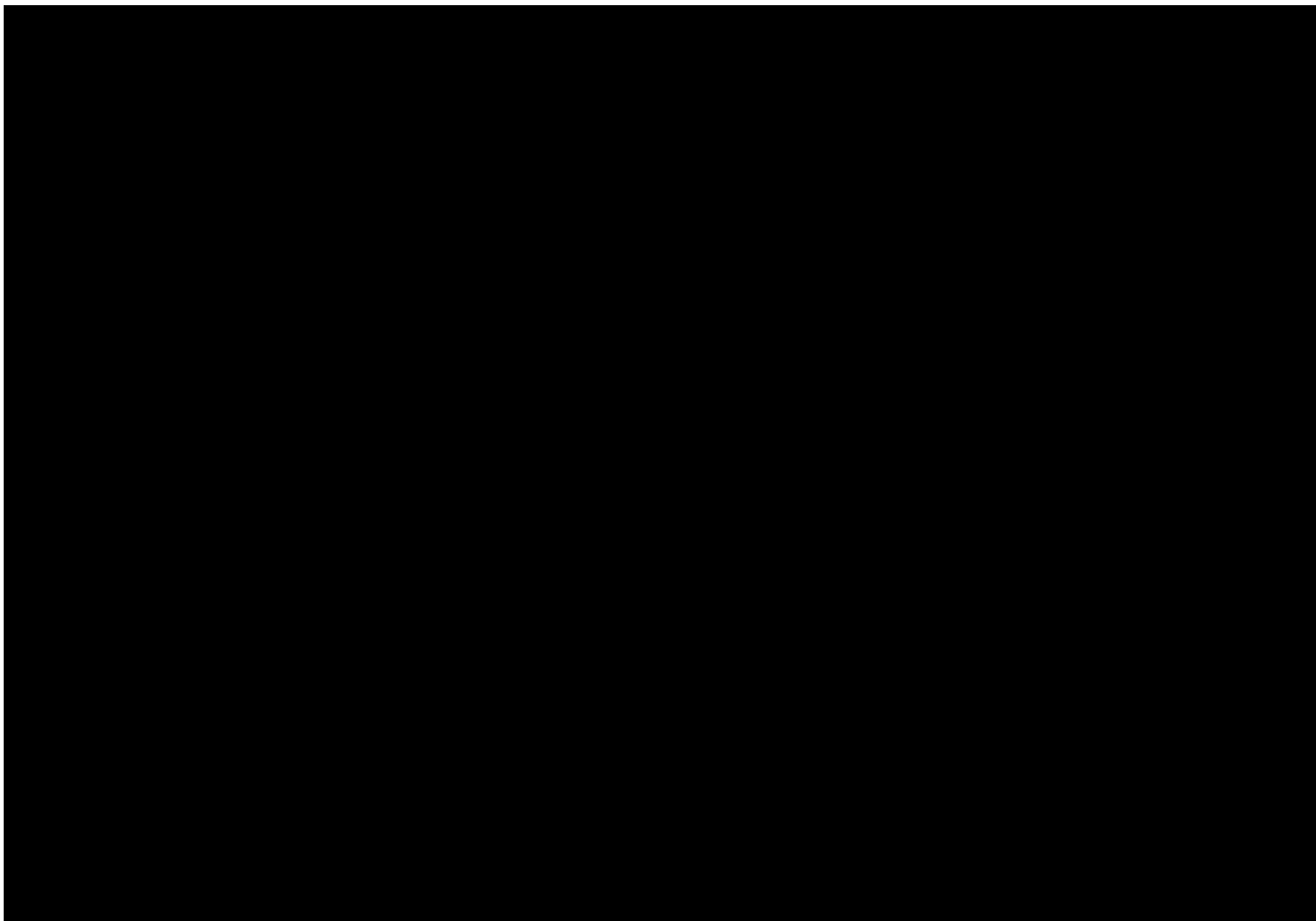
Attachment C-4

Sales Share Summary - Wet AMD



Attachment C-5

Sales Share Summary - RVO

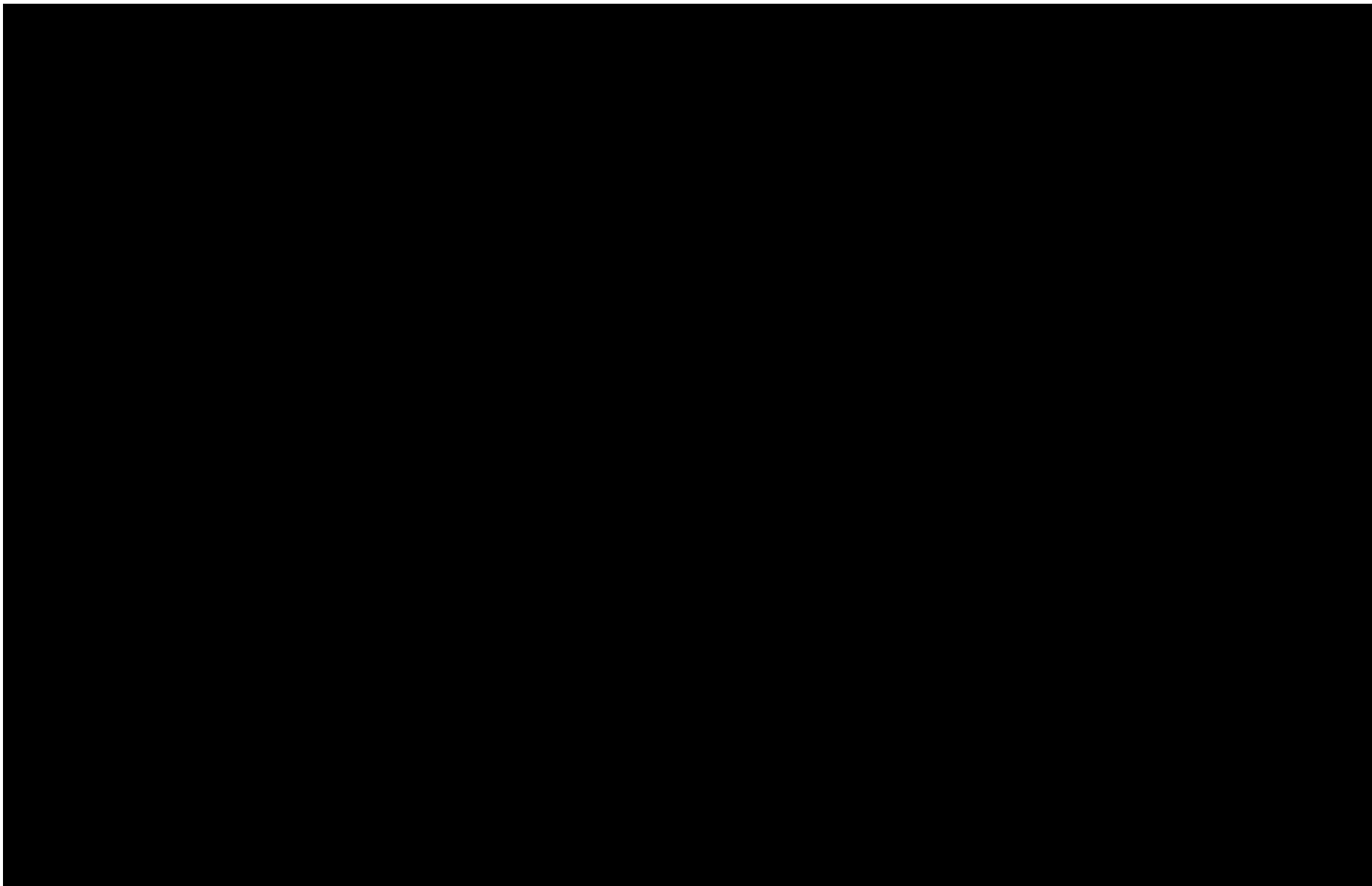


PROTECTIVE ORDER MATERIAL

Attachment C-5
Page 1 of 1

Attachment C-6

Eylea's Sales Share Across Different Data Sources - All Indications



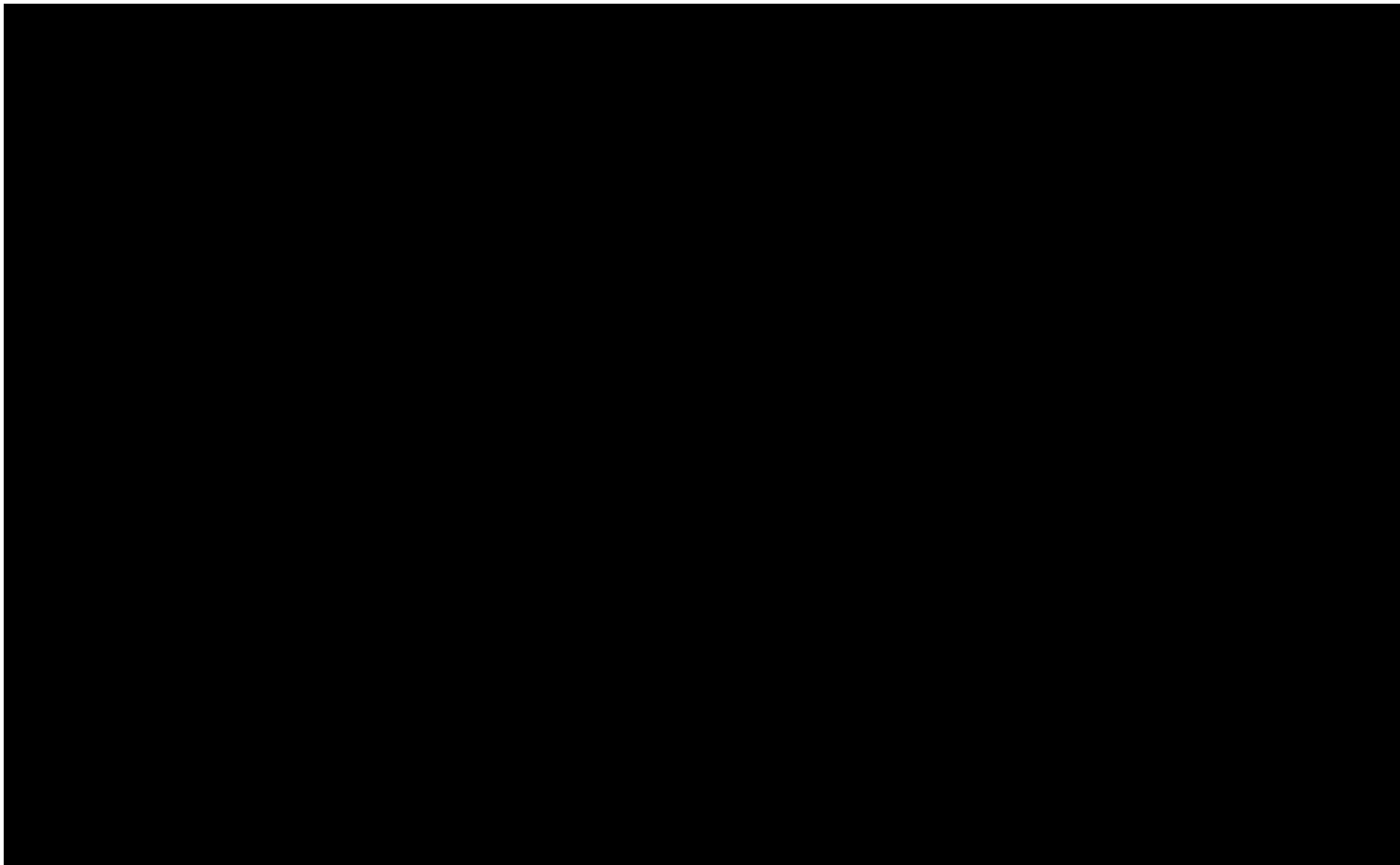
PROTECTIVE ORDER MATERIAL

Attachment C-6

Page 1 of 1

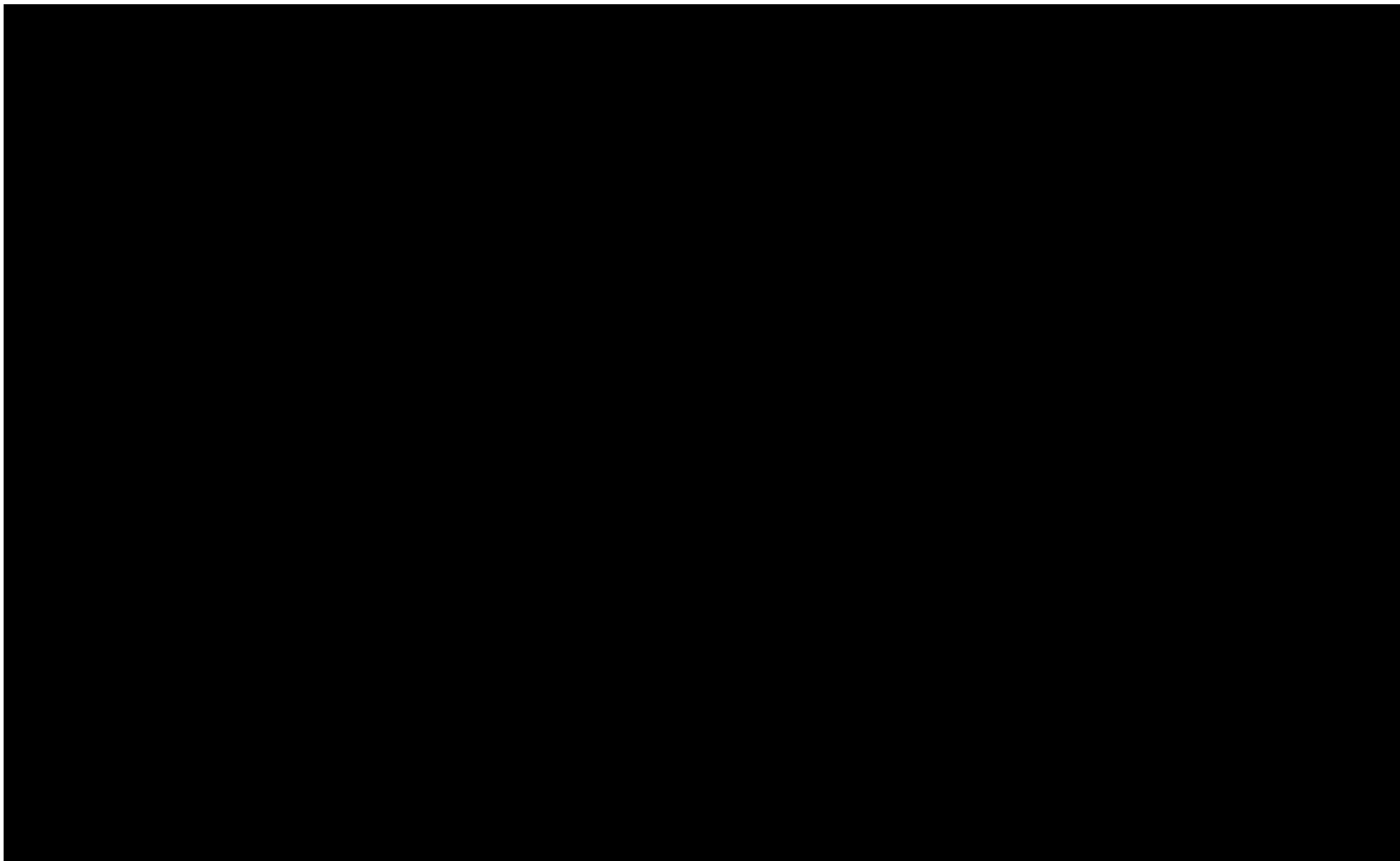
Attachment C-7

Eylea's Sales Share Across Different Data Sources - DME



Attachment C-8

Eylea's Sales Share Across Different Data Sources - DR without DME



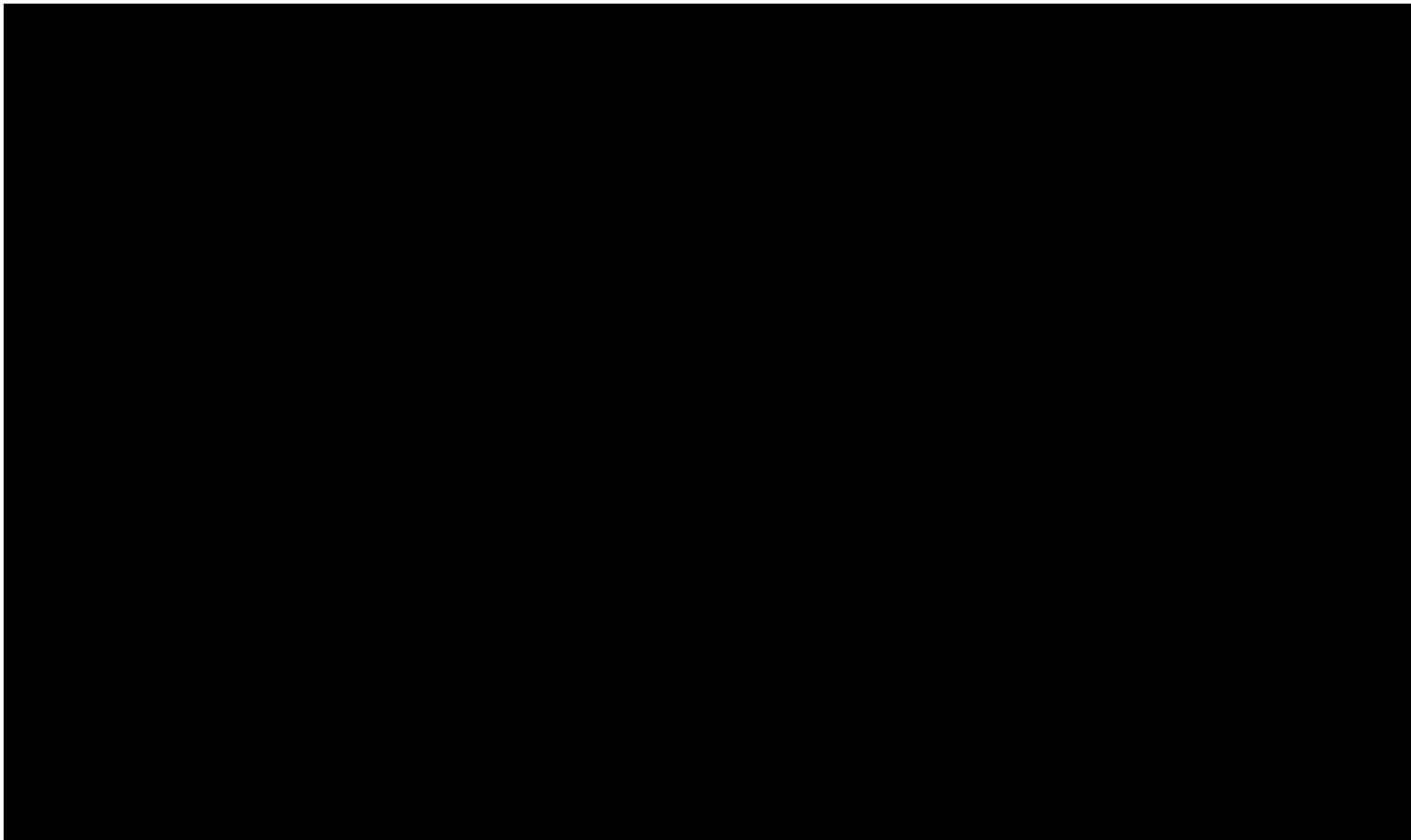
PROTECTIVE ORDER MATERIAL

Attachment C-8

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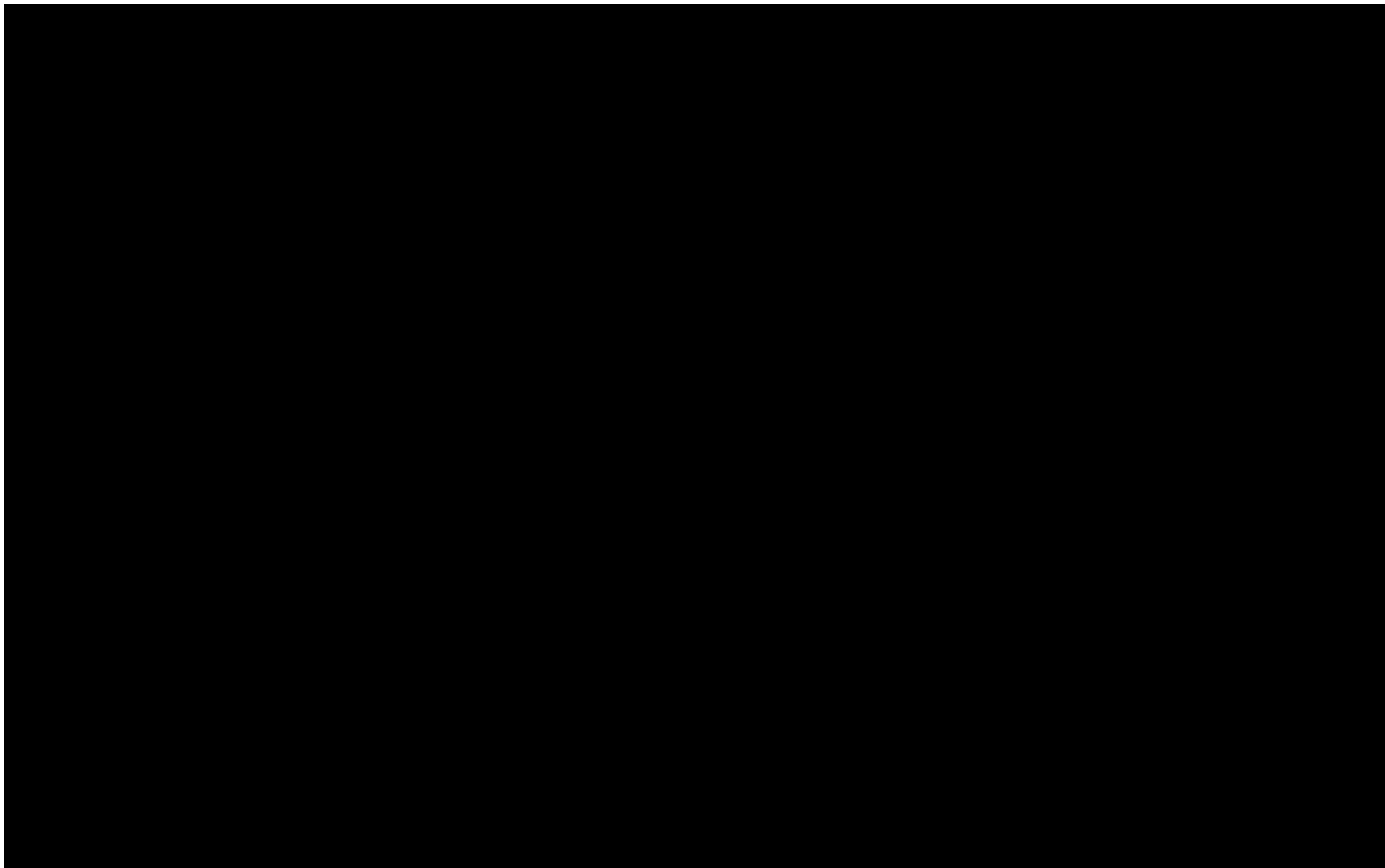
Attachment C-9

Eylea's Sales Share Across Different Data Sources - Wet AMD



Attachment C-10

Eylea's Sales Share Across Different Data Sources - RVO



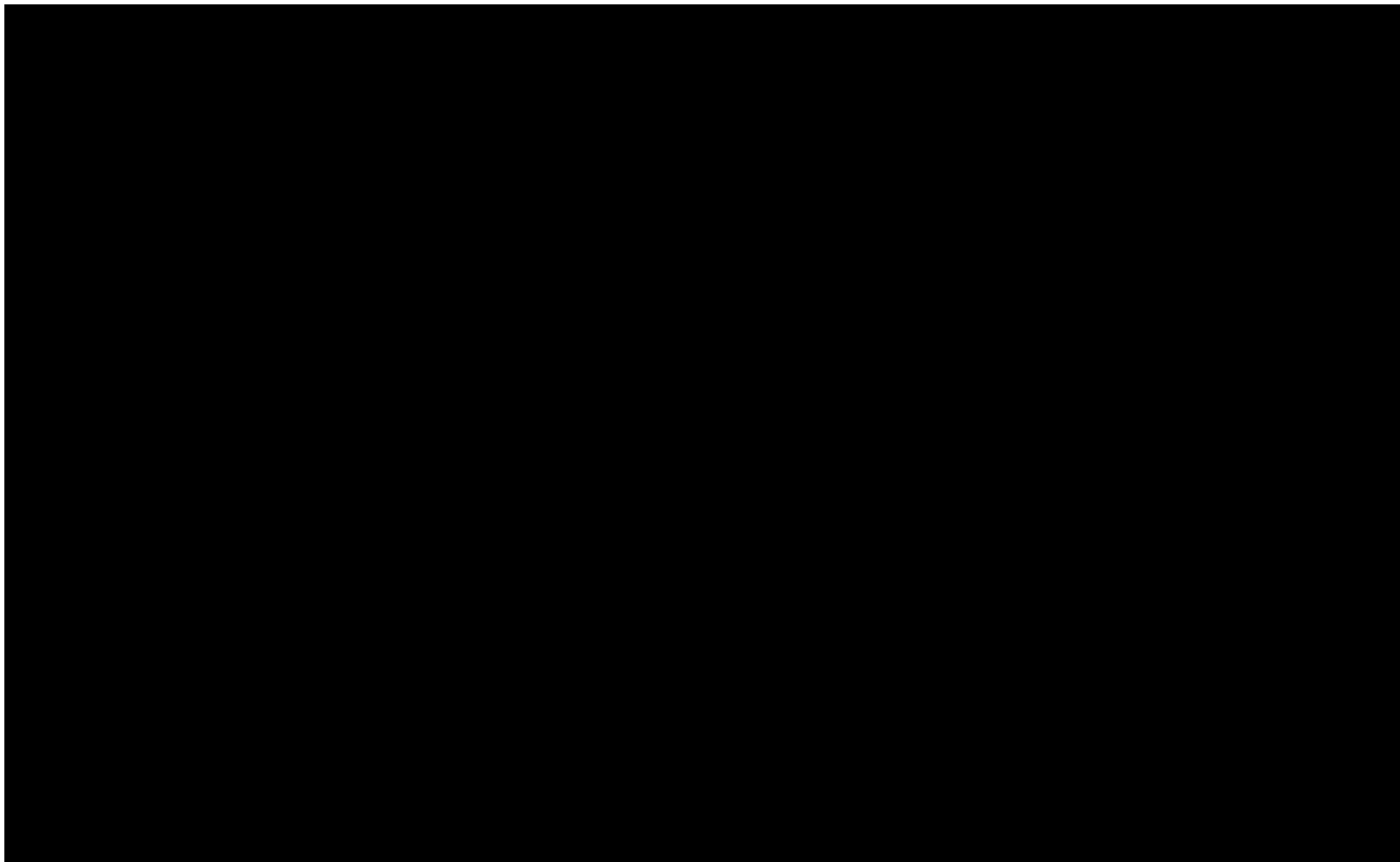
PROTECTIVE ORDER MATERIAL

Attachment C-10

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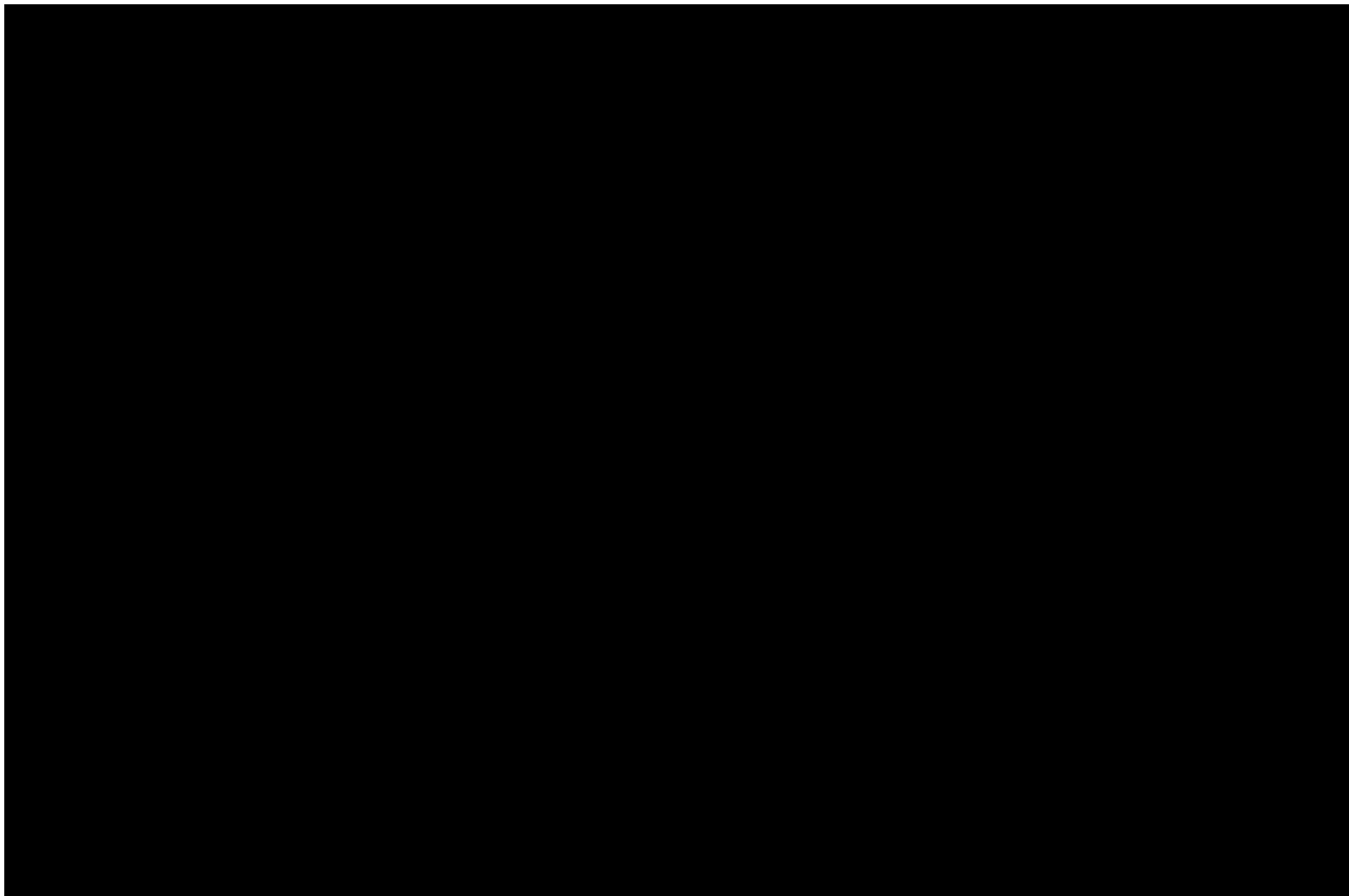
Attachment C-11

Percentage Point Change in Total Sales Share Since Eylea Launch – ATU Data



Attachment C-12

Percentage Point Change in Total Sales Share Since Eylea Launch – Medicare Part B Data



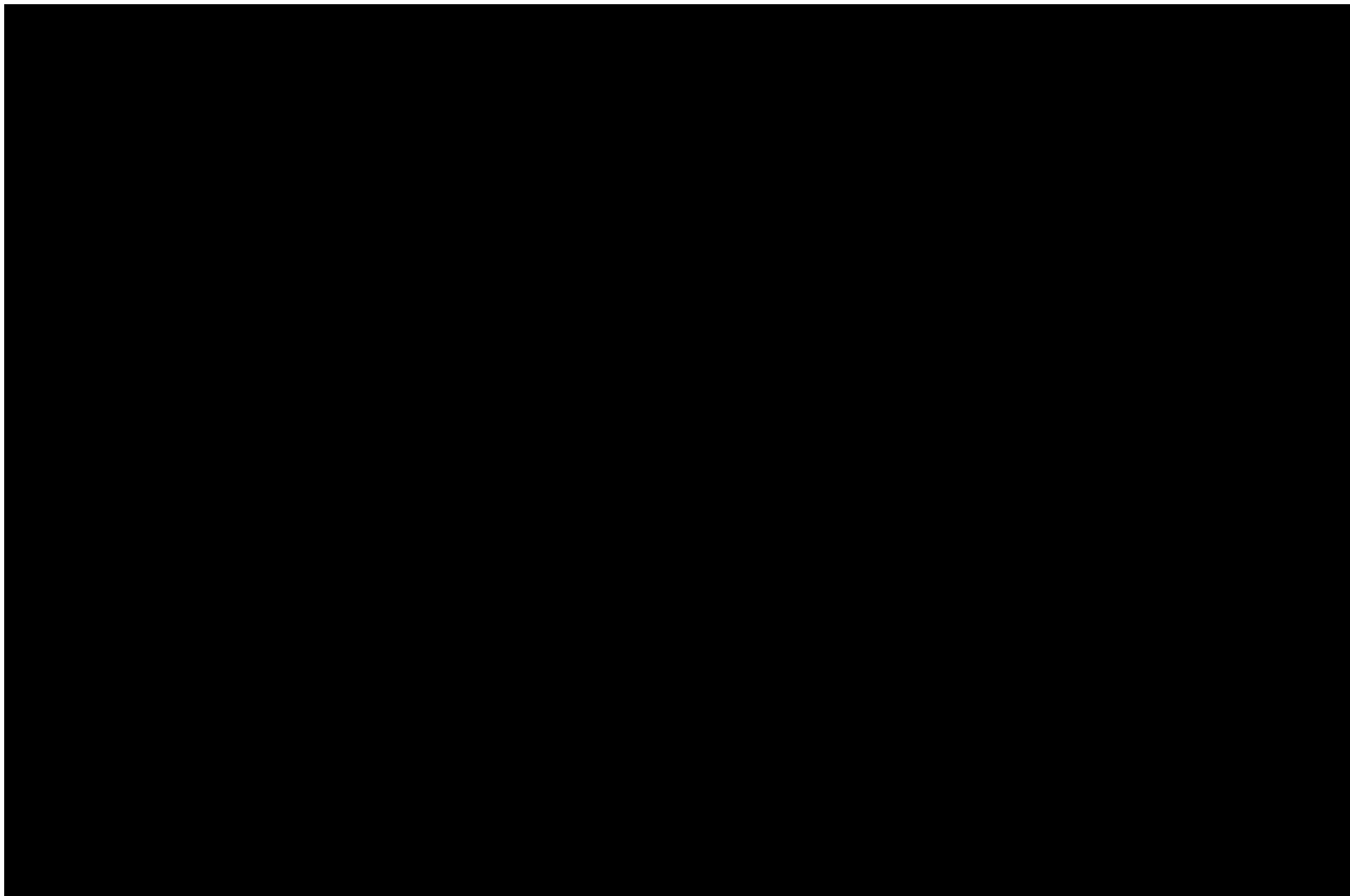
PROTECTIVE ORDER MATERIAL

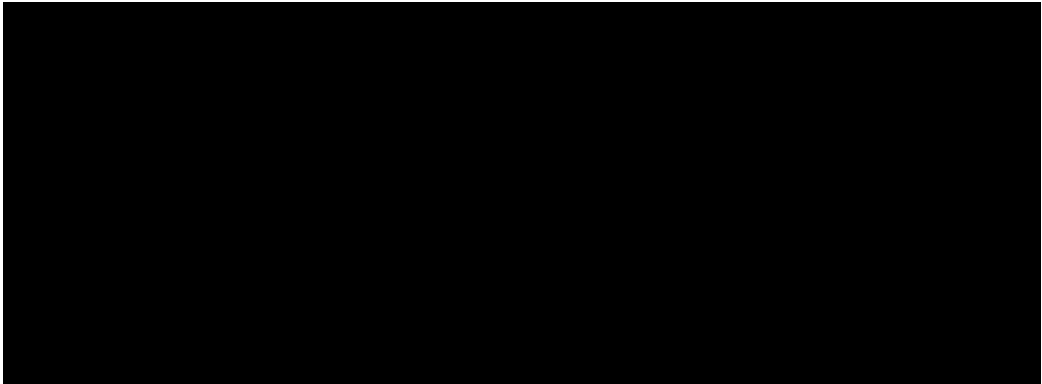
Attachment C-12

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Attachment D-1

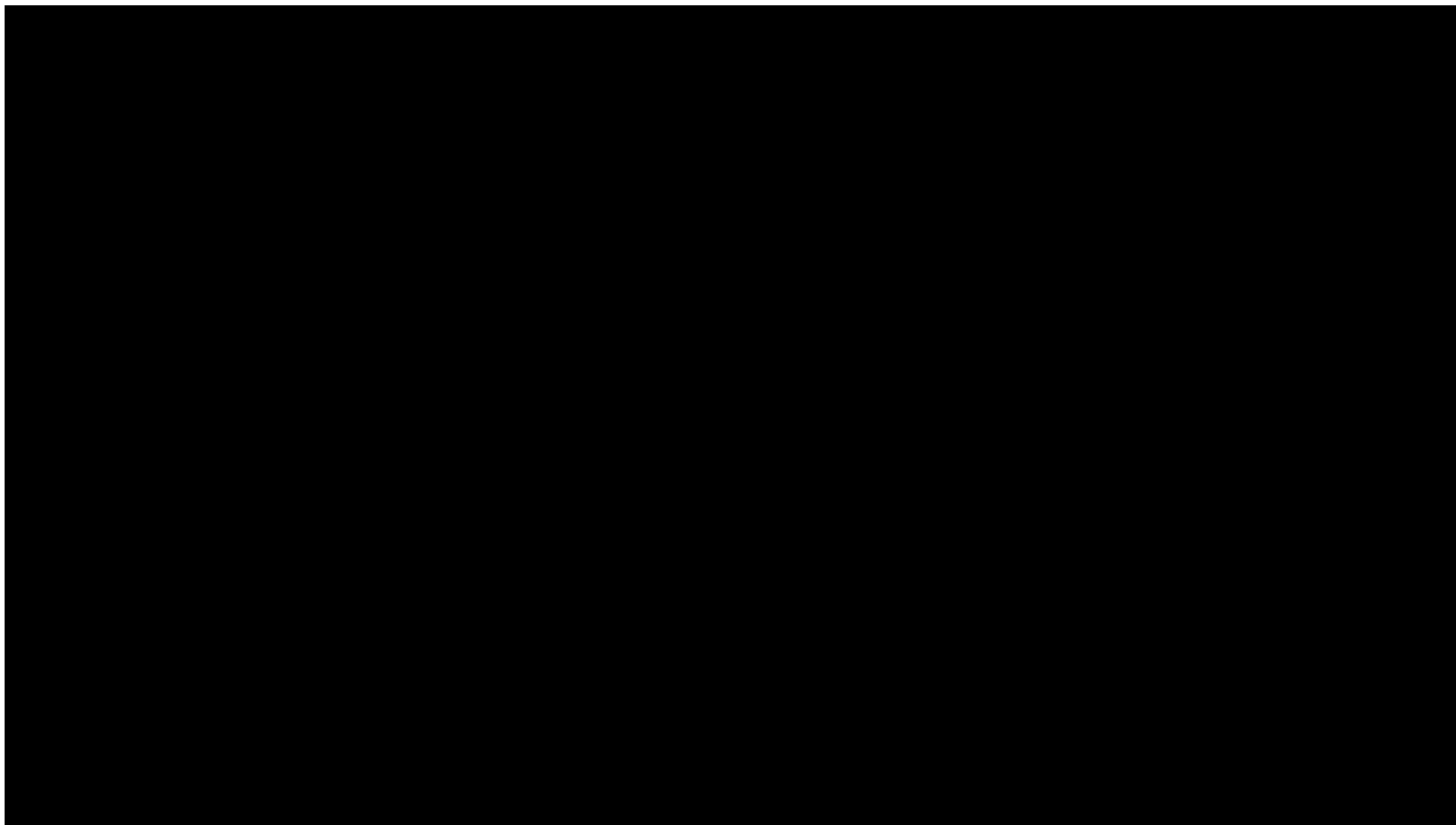
Eylea Profit and Loss Data (Actuals, 2011–2021)

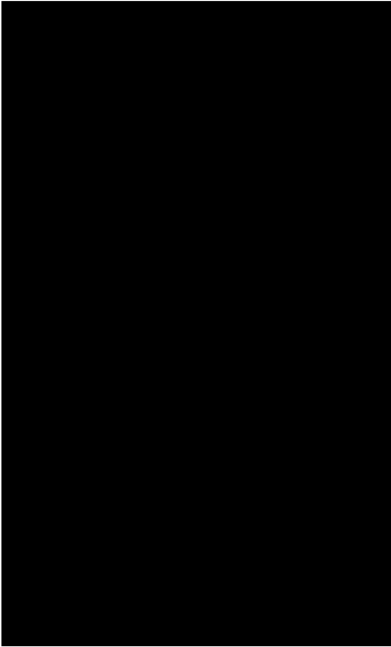




Attachment D-2

Eylea Volume and Revenue Performance (2011–2021)



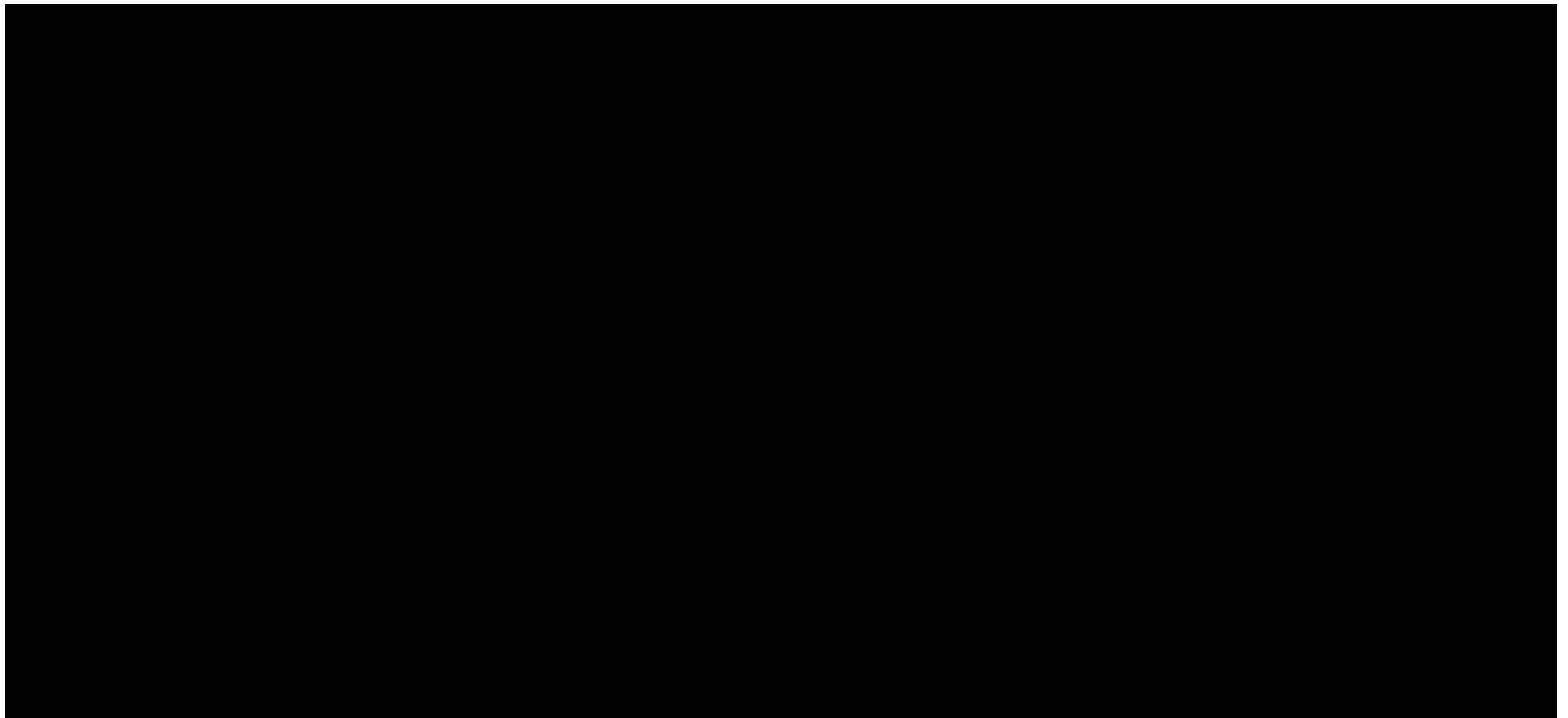


PROTECTIVE ORDER MATERIAL

Attachment D-2
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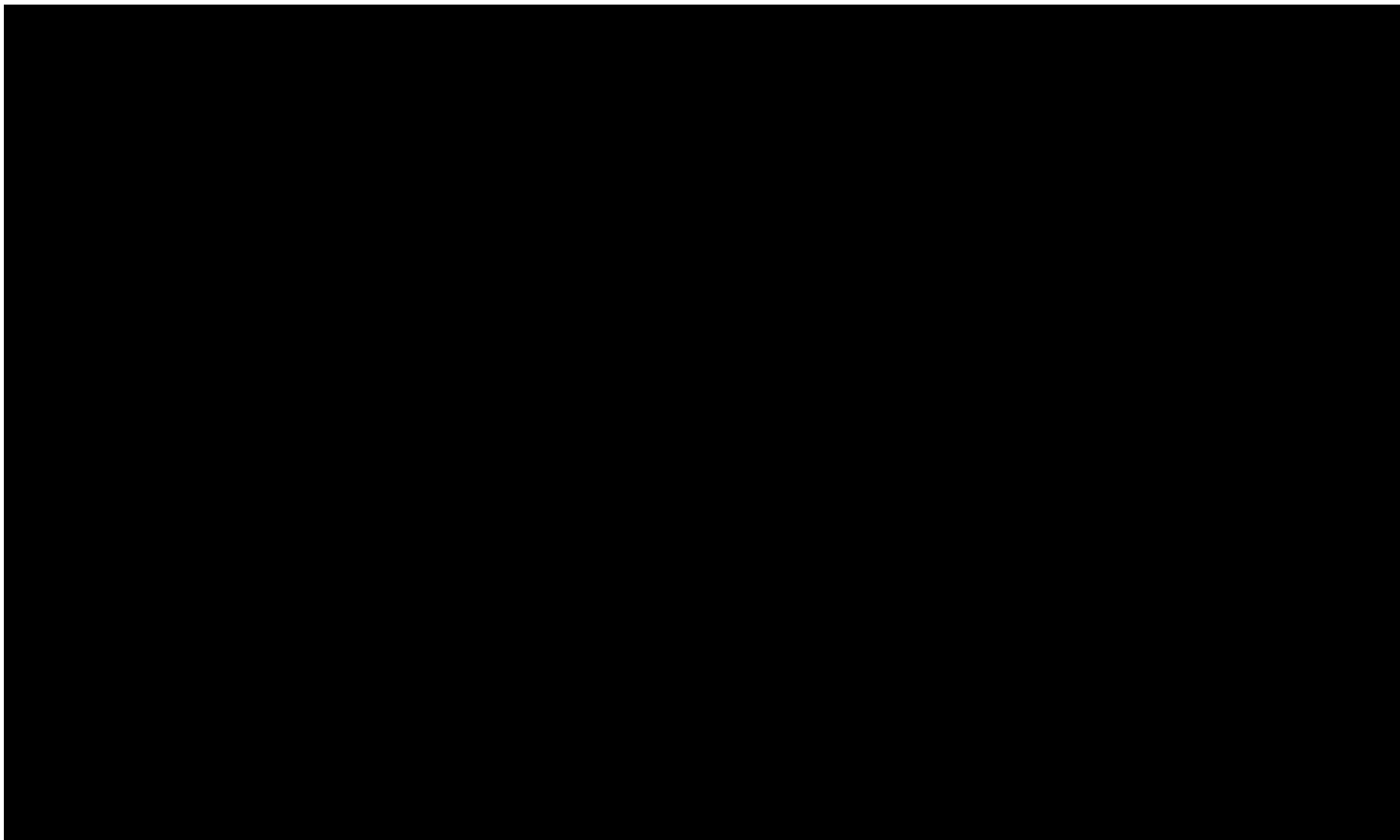
Attachment E-1

Most Prescribed Treatment Options (2012–2020)



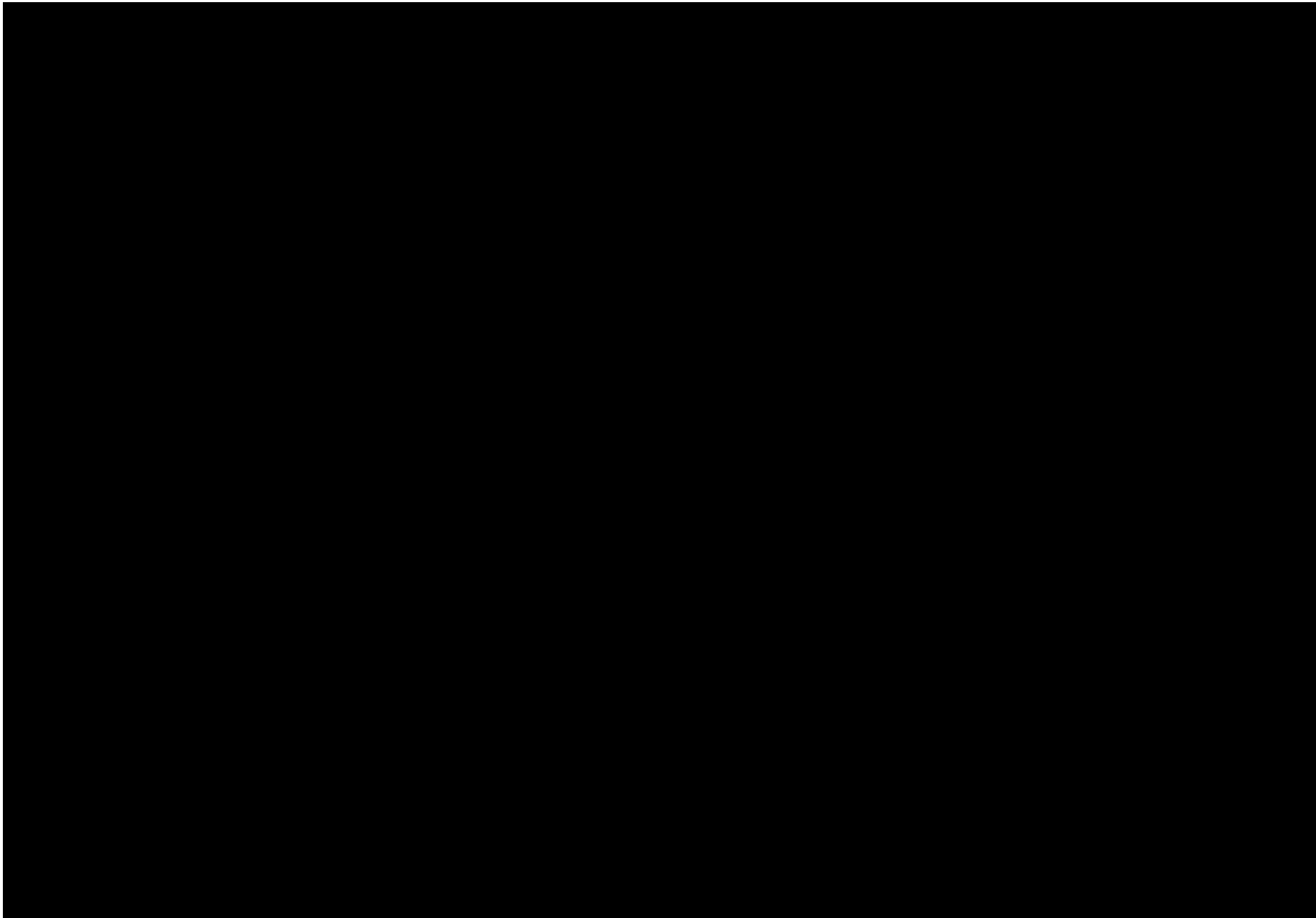
Attachment E-2

Volume of Medicare Patients by Brand – Medicare Part B



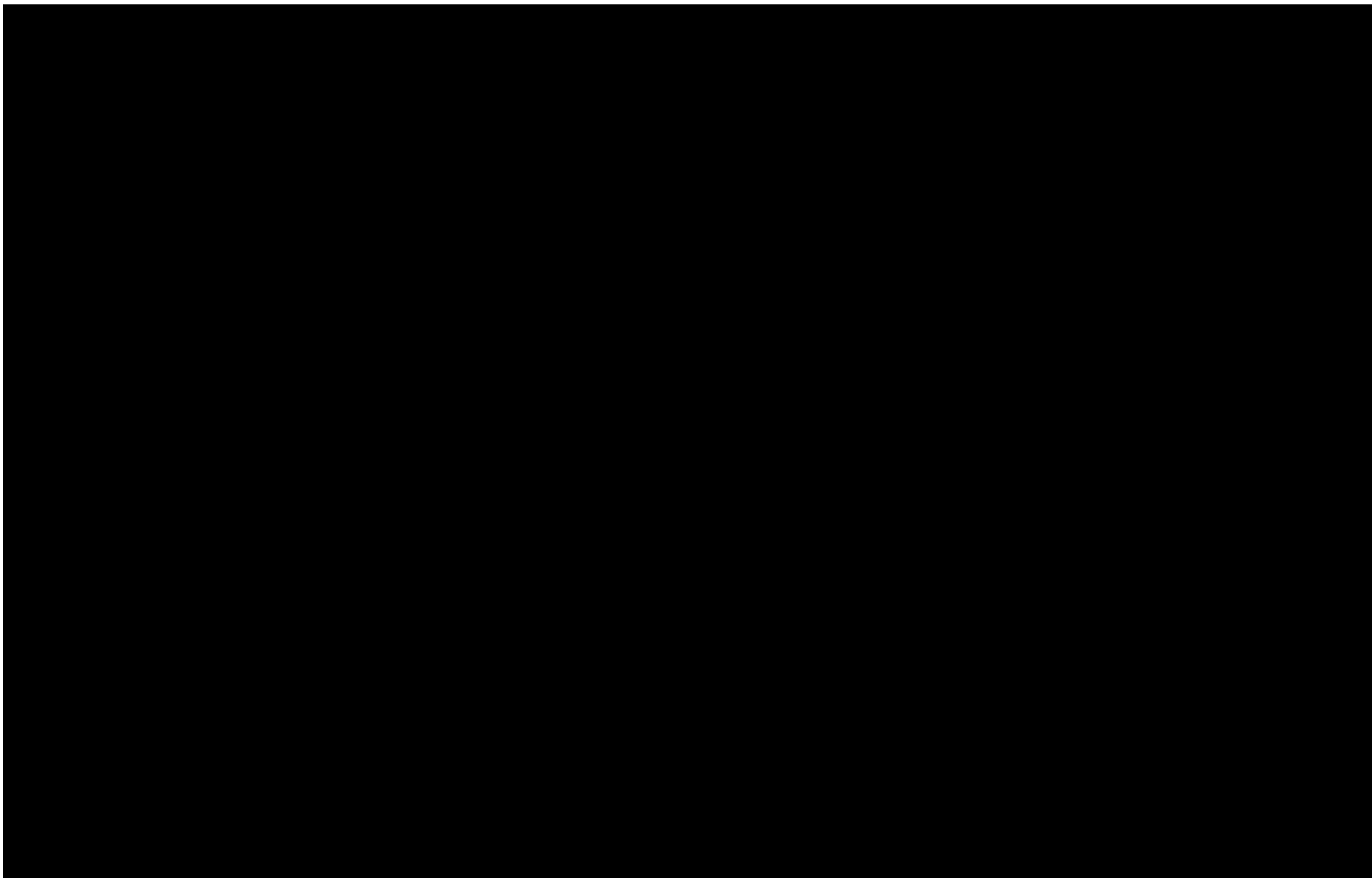
Attachment E-3

Summary of Most Common Dosing Intervals for DME According to ATU Surveys



Attachment E-4

Medicare Part B Patients Treated, By Year and Treatment (2012 – 2021)



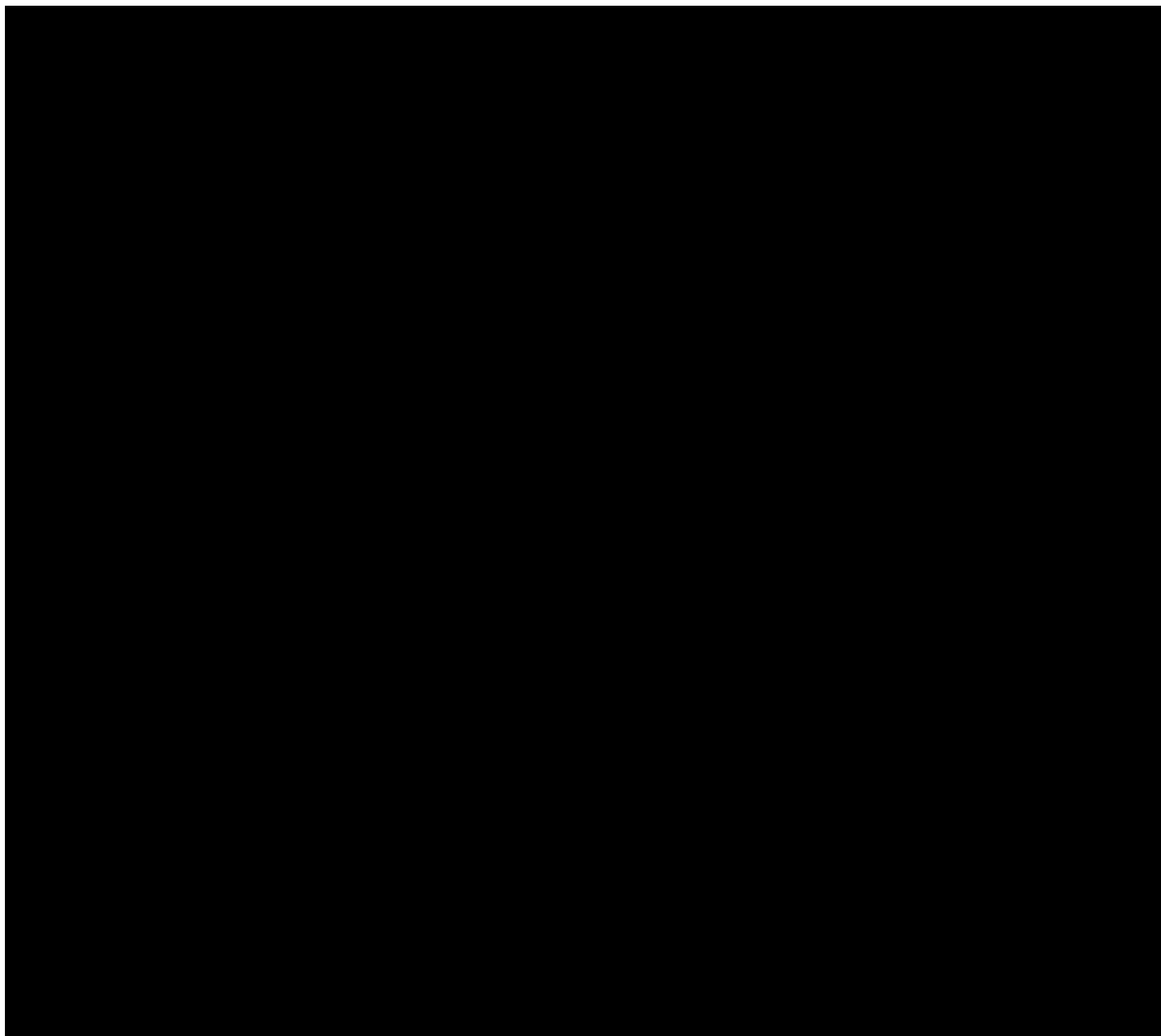
PROTECTIVE ORDER MATERIAL

Attachment E-4

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Attachment X-1

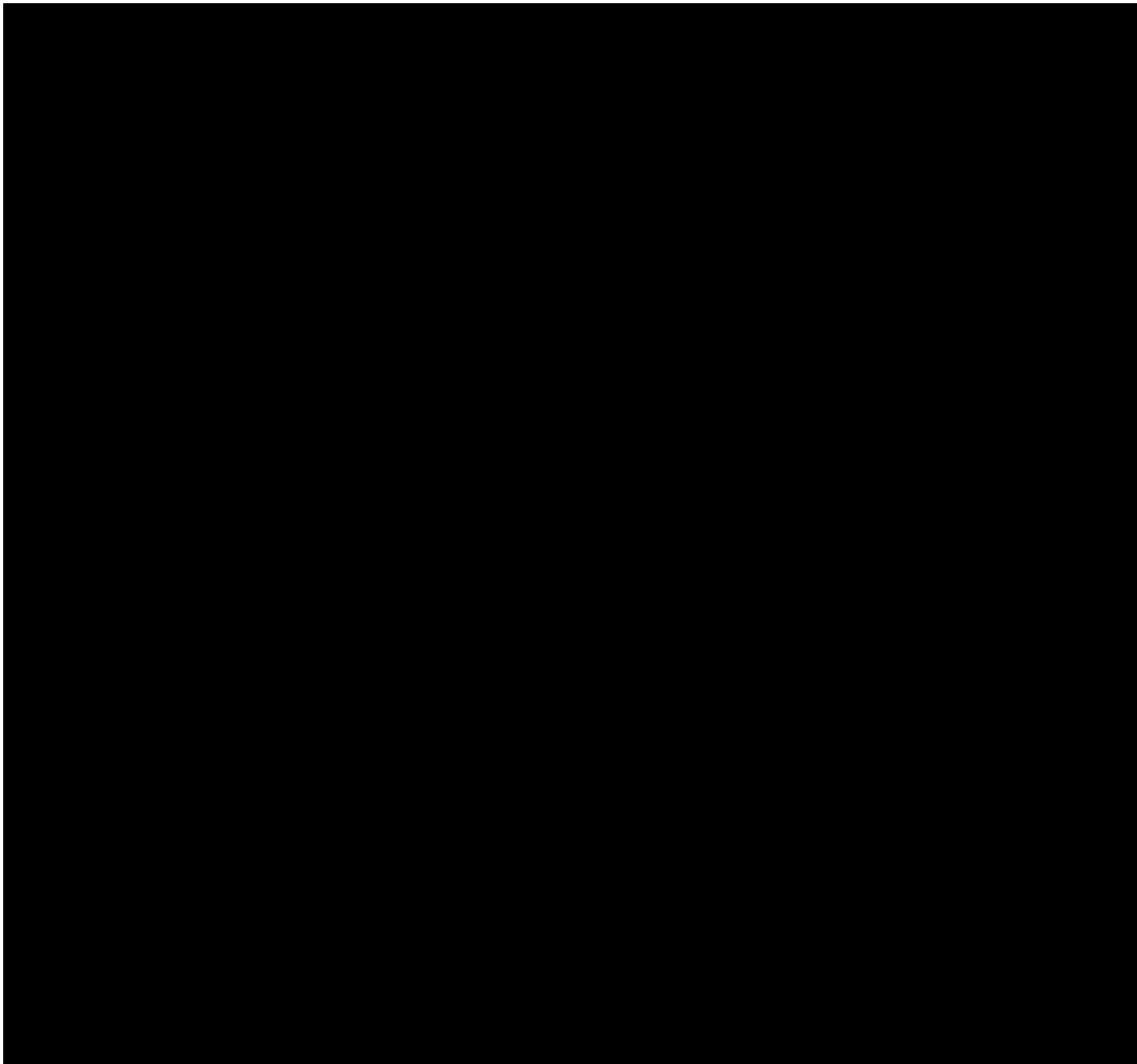
Vestrum Sales Share Data by Indication



PROTECTIVE ORDER MATERIAL

Attachment X-1

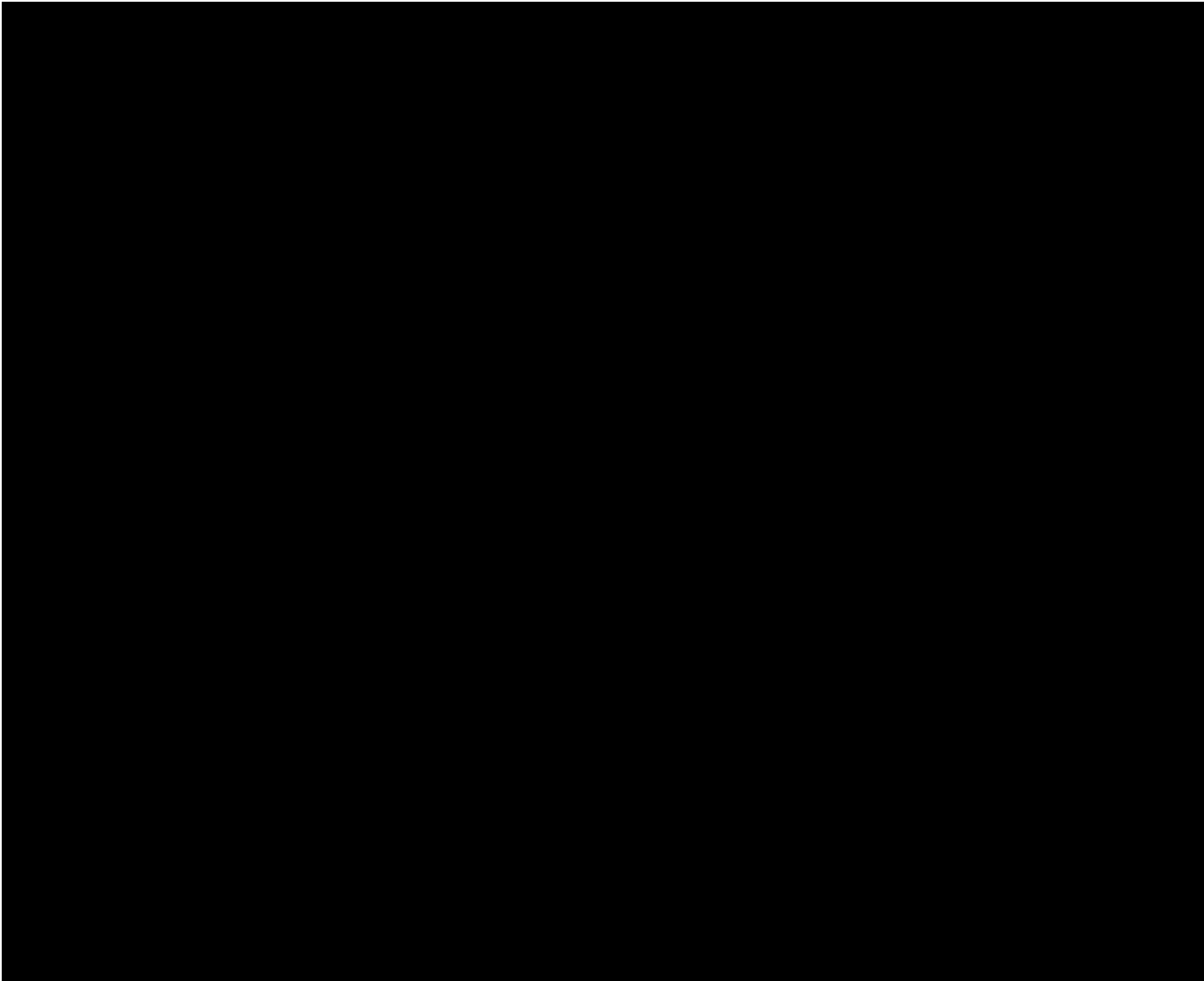
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PROTECTIVE ORDER MATERIAL

Attachment X-1

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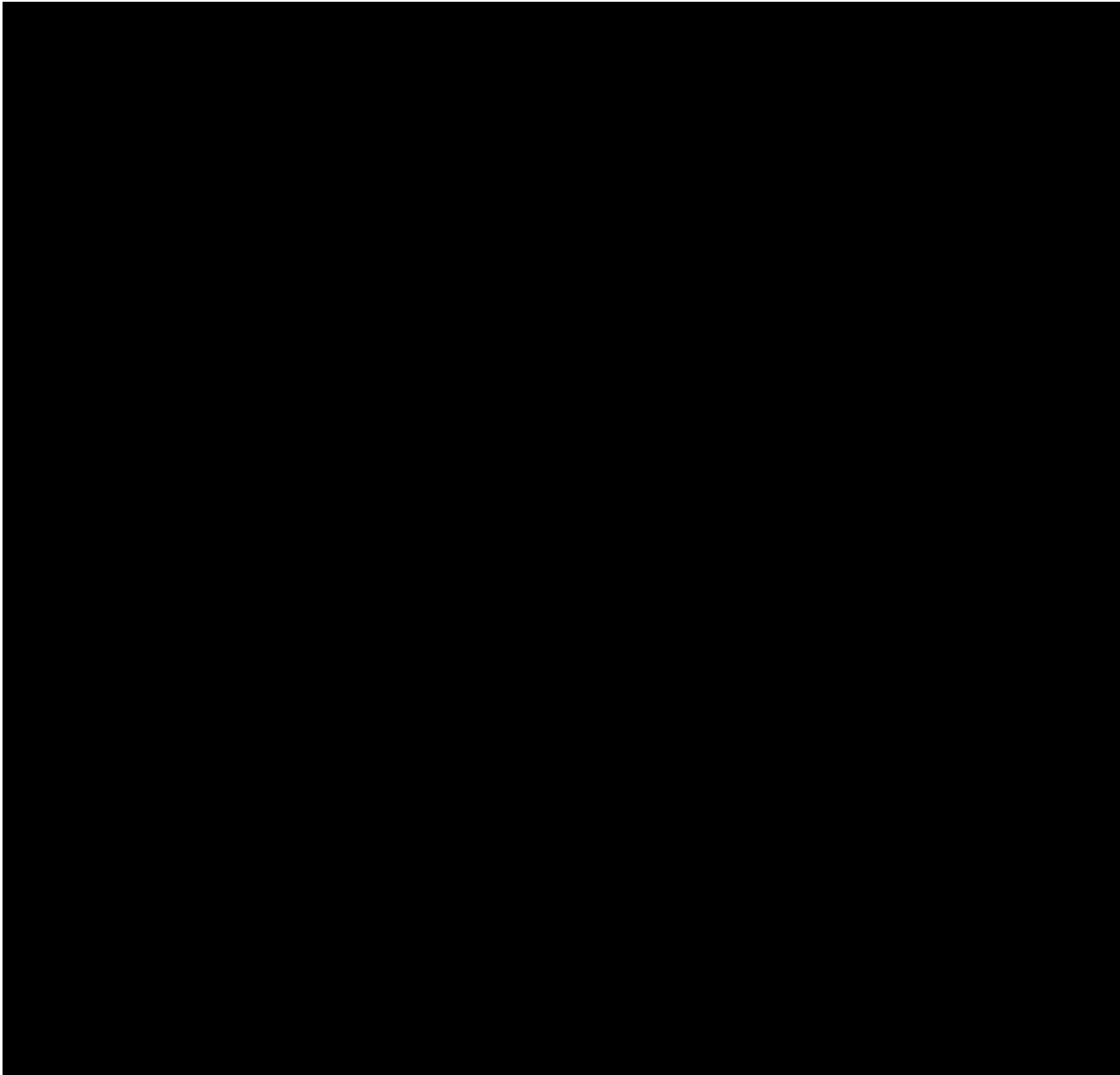


PROTECTIVE ORDER MATERIAL

Attachment X-1
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Attachment X-2

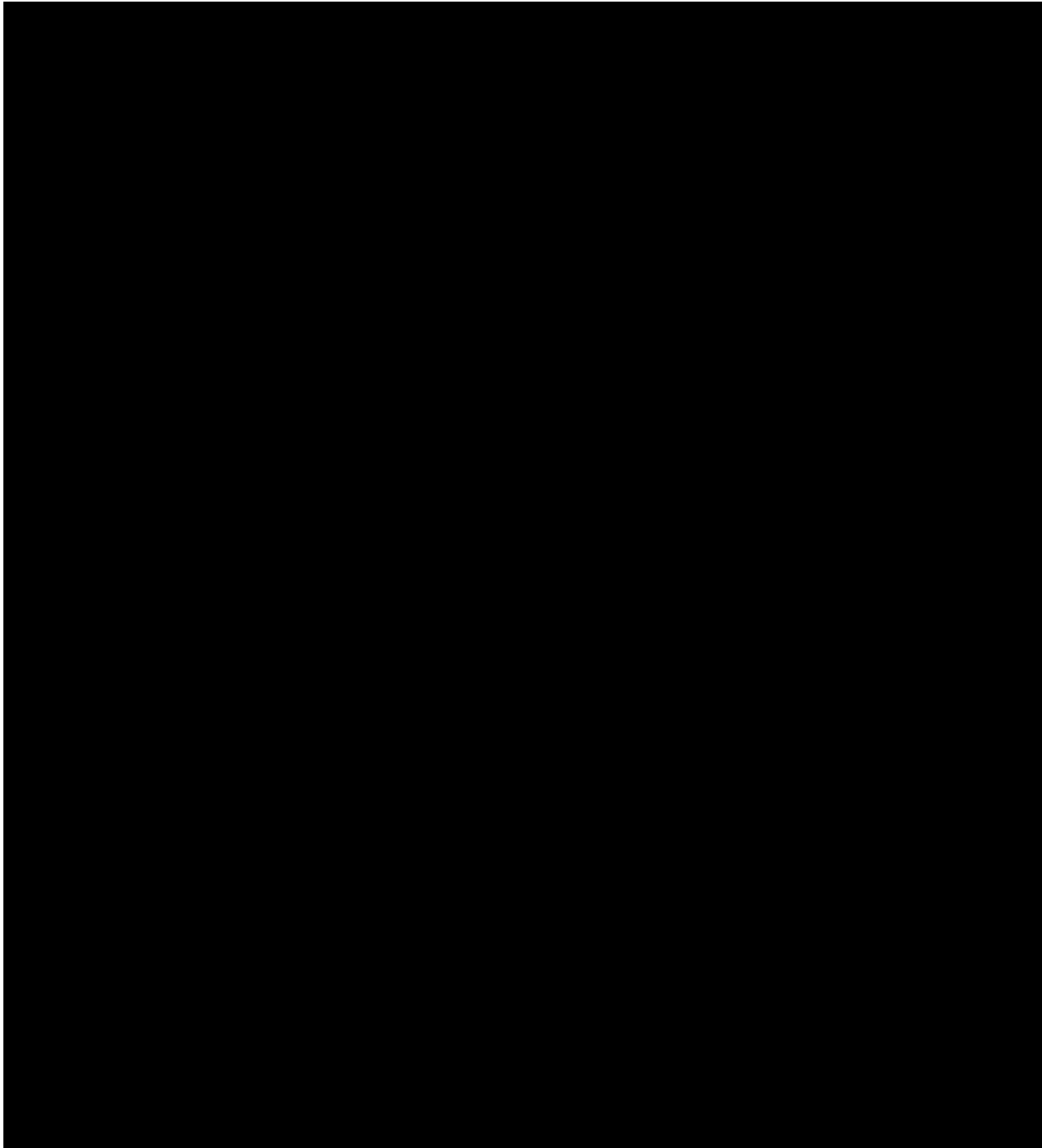
ATU Sales Share Data by Indication



PROTECTIVE ORDER MATERIAL

Attachment X-2

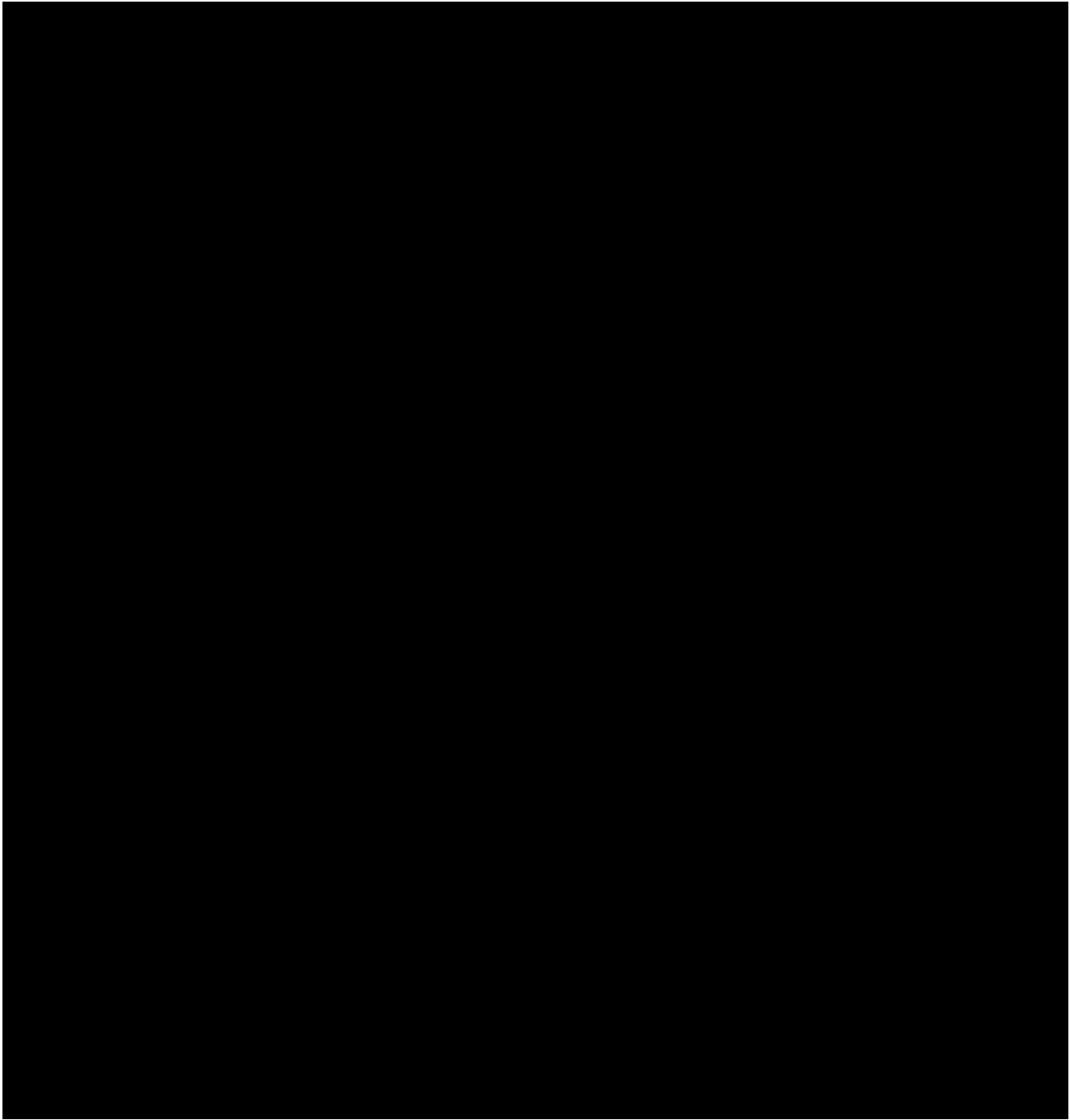
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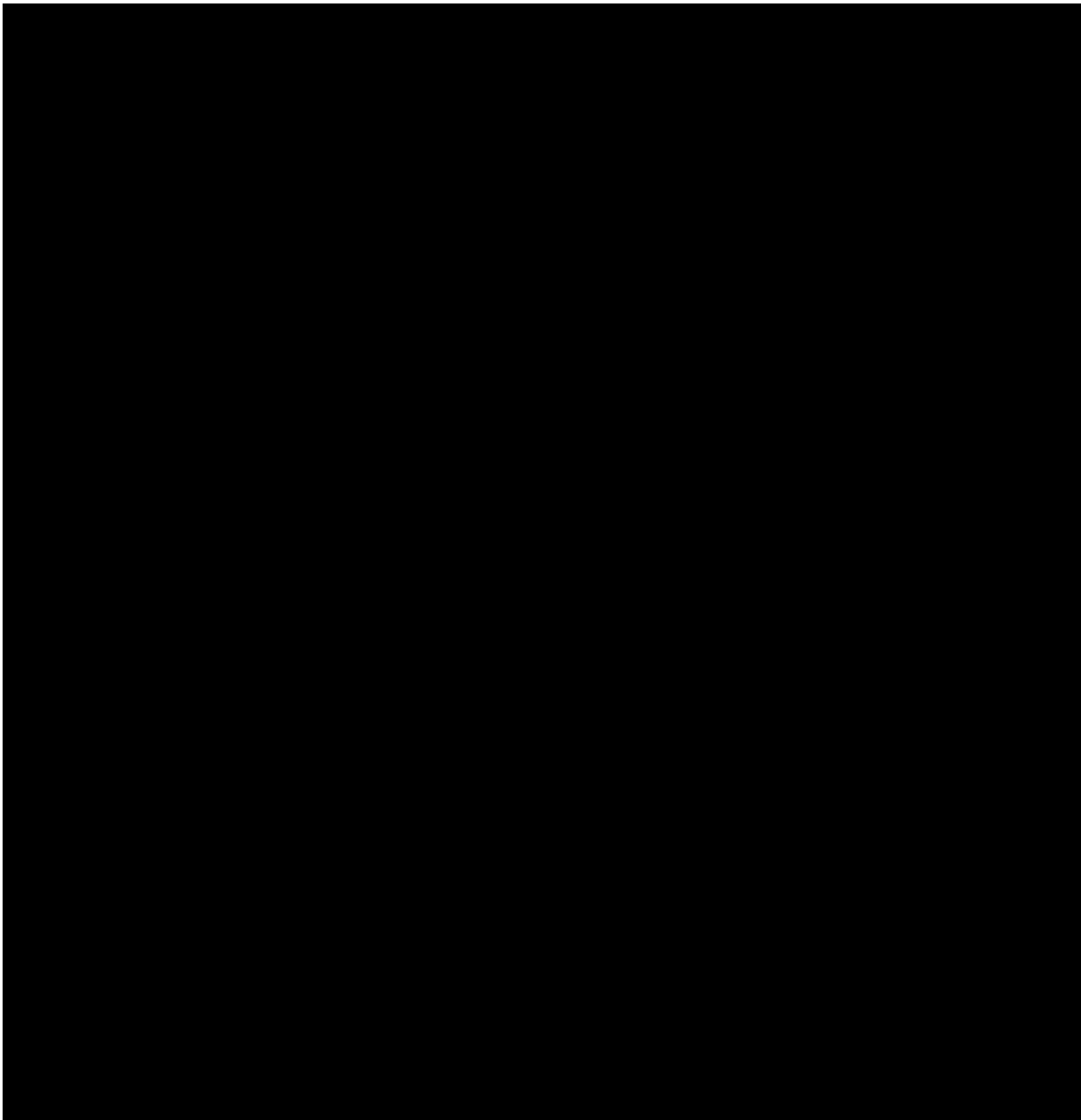


PROTECTIVE ORDER MATERIAL

Attachment X-2

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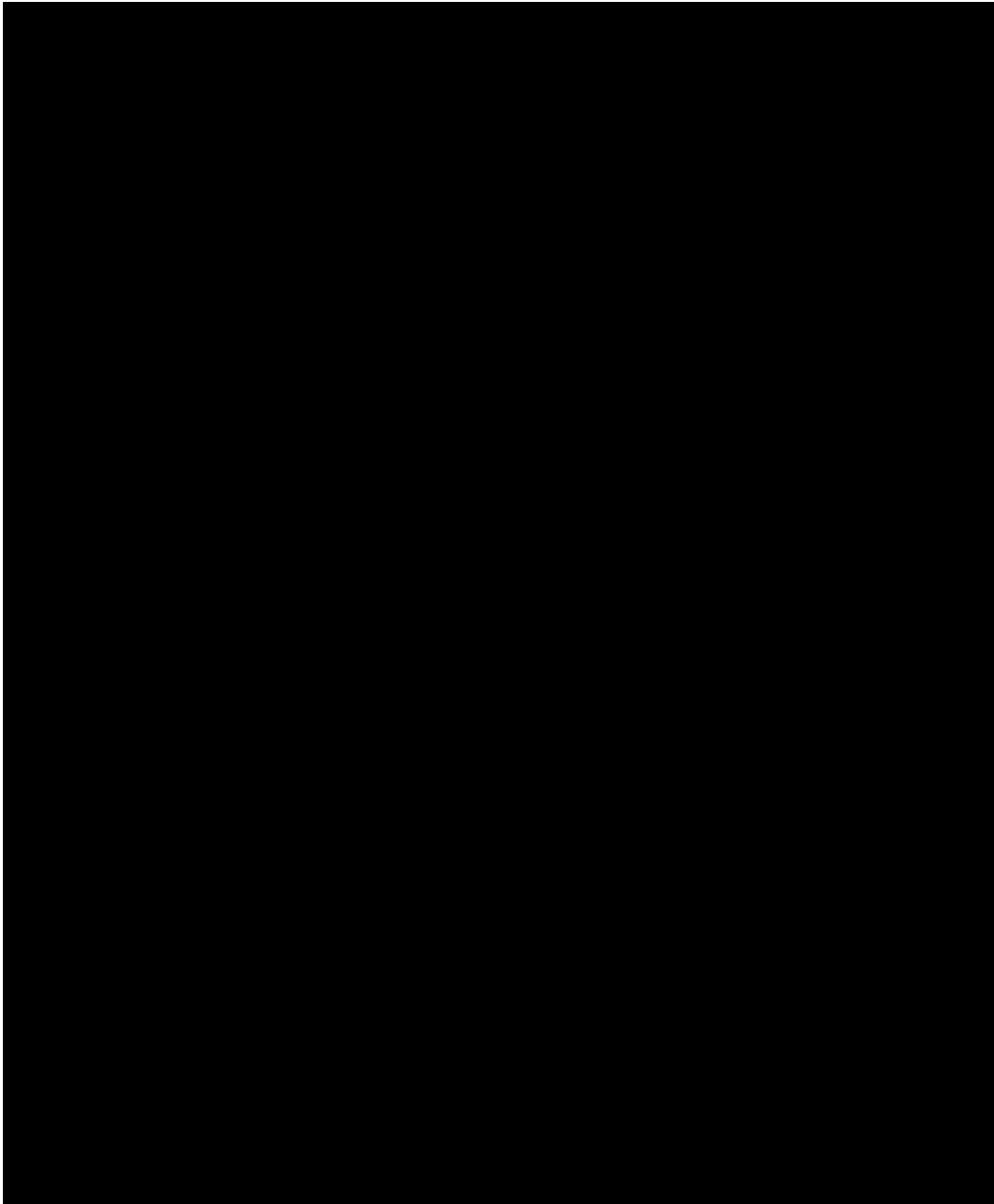
PROTECTIVE ORDER MATERIAL

Attachment X-2

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Attachment X-3

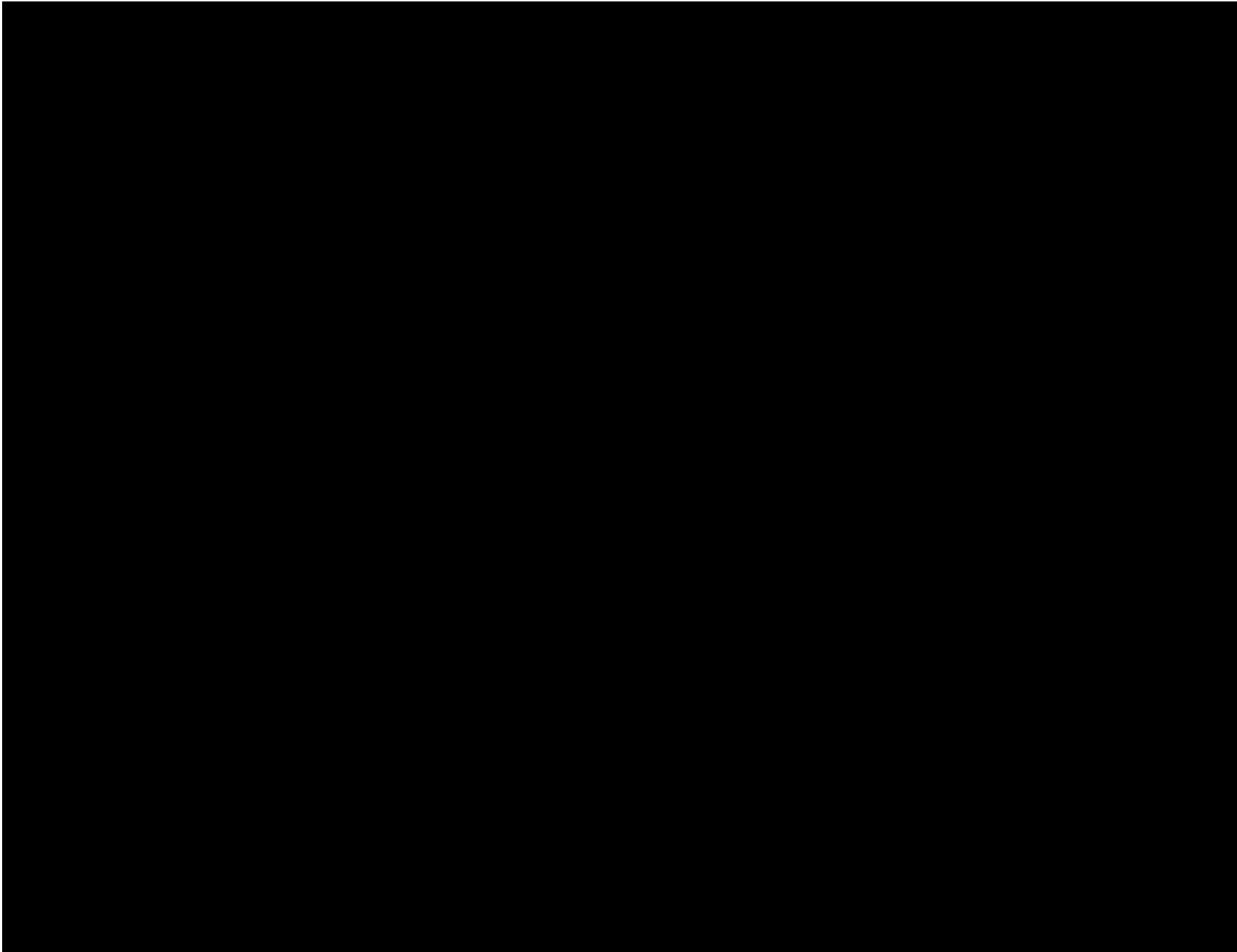
Medicare Part B Sales Shares Data (2012–2021)



PROTECTIVE ORDER MATERIAL

Attachment X-3

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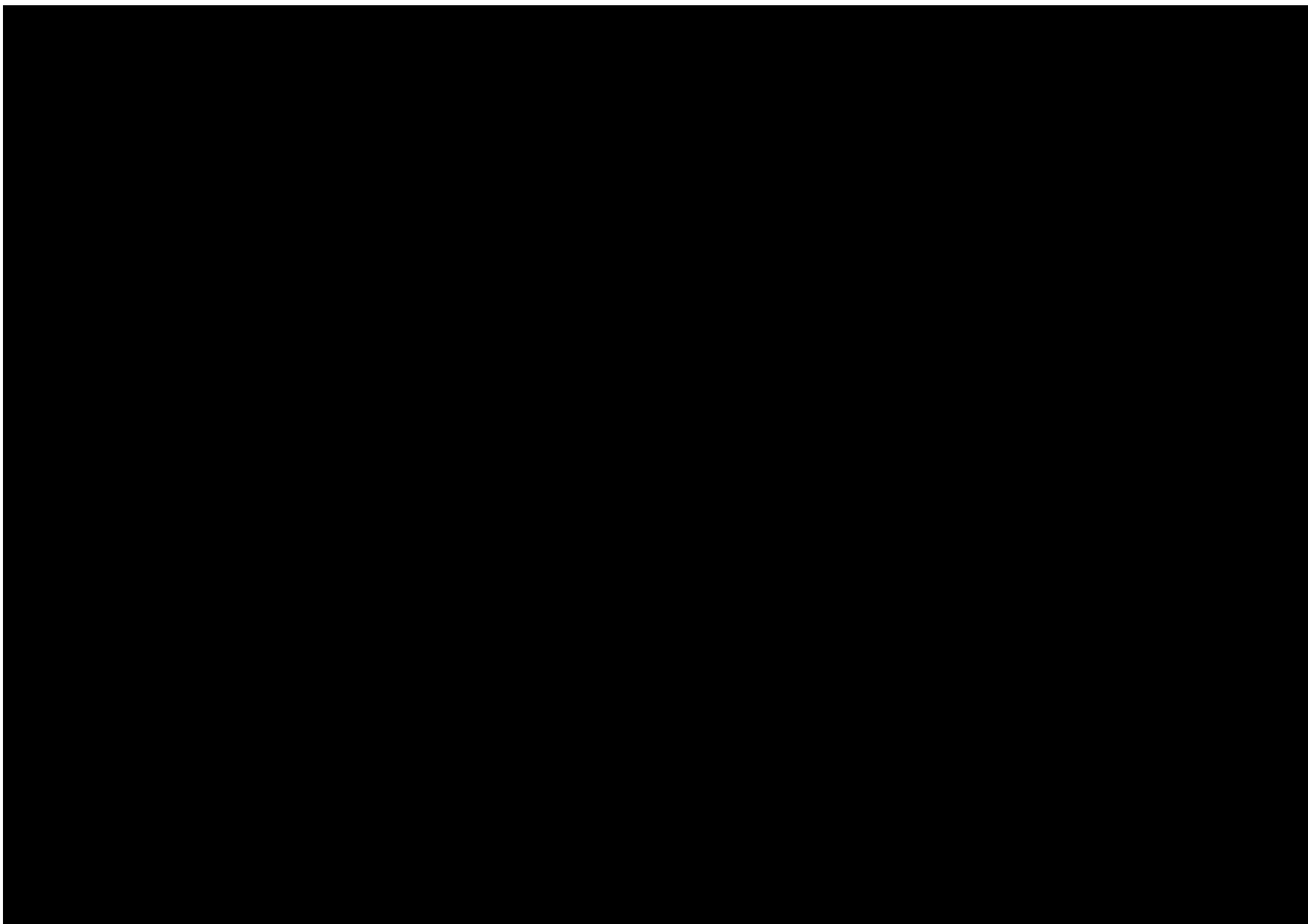
PROTECTIVE ORDER MATERIAL

Attachment X-3

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Attachment X-4

HCPCS Code to Brand Name Mapping



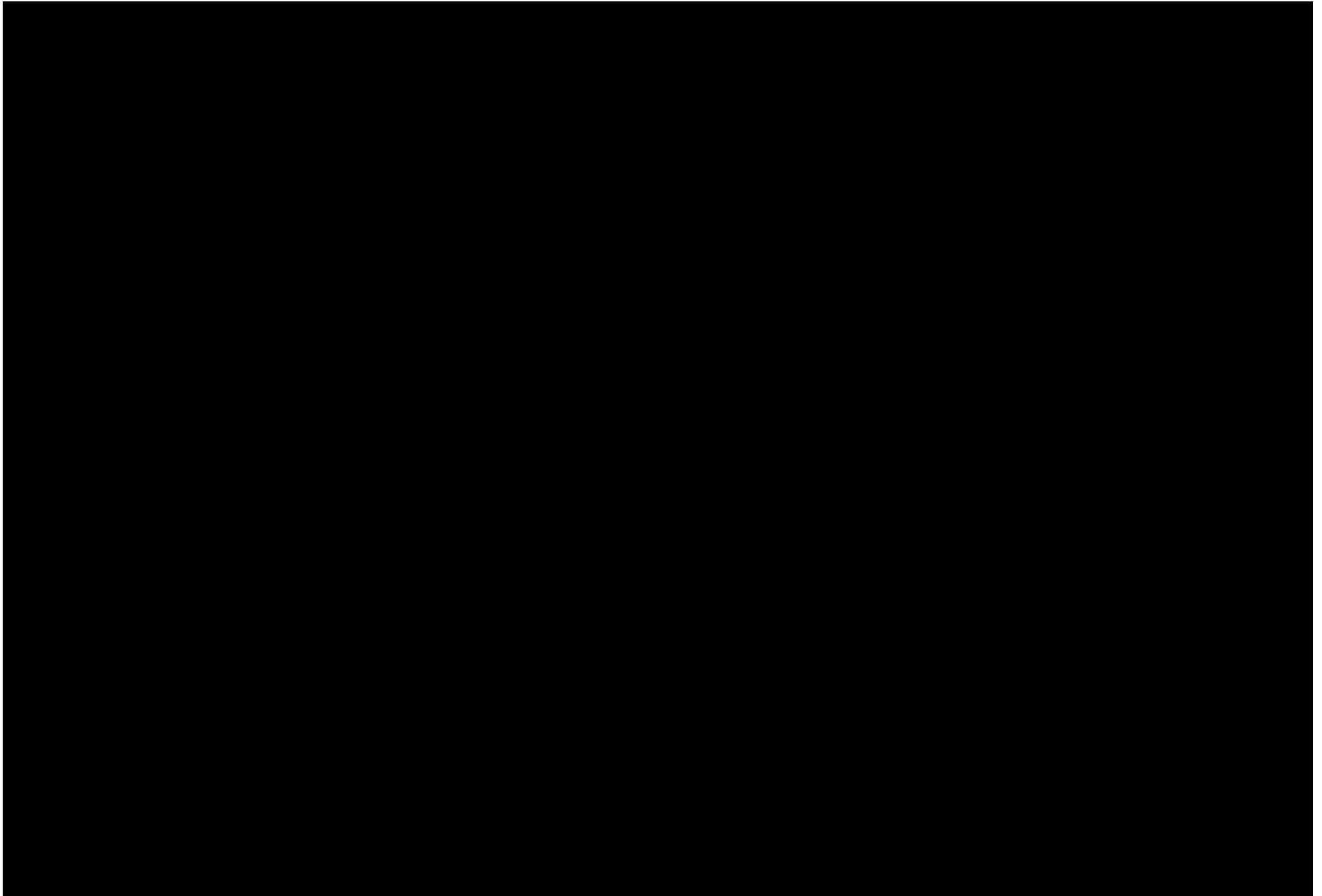
PROTECTIVE ORDER MATERIAL

Attachment X-4

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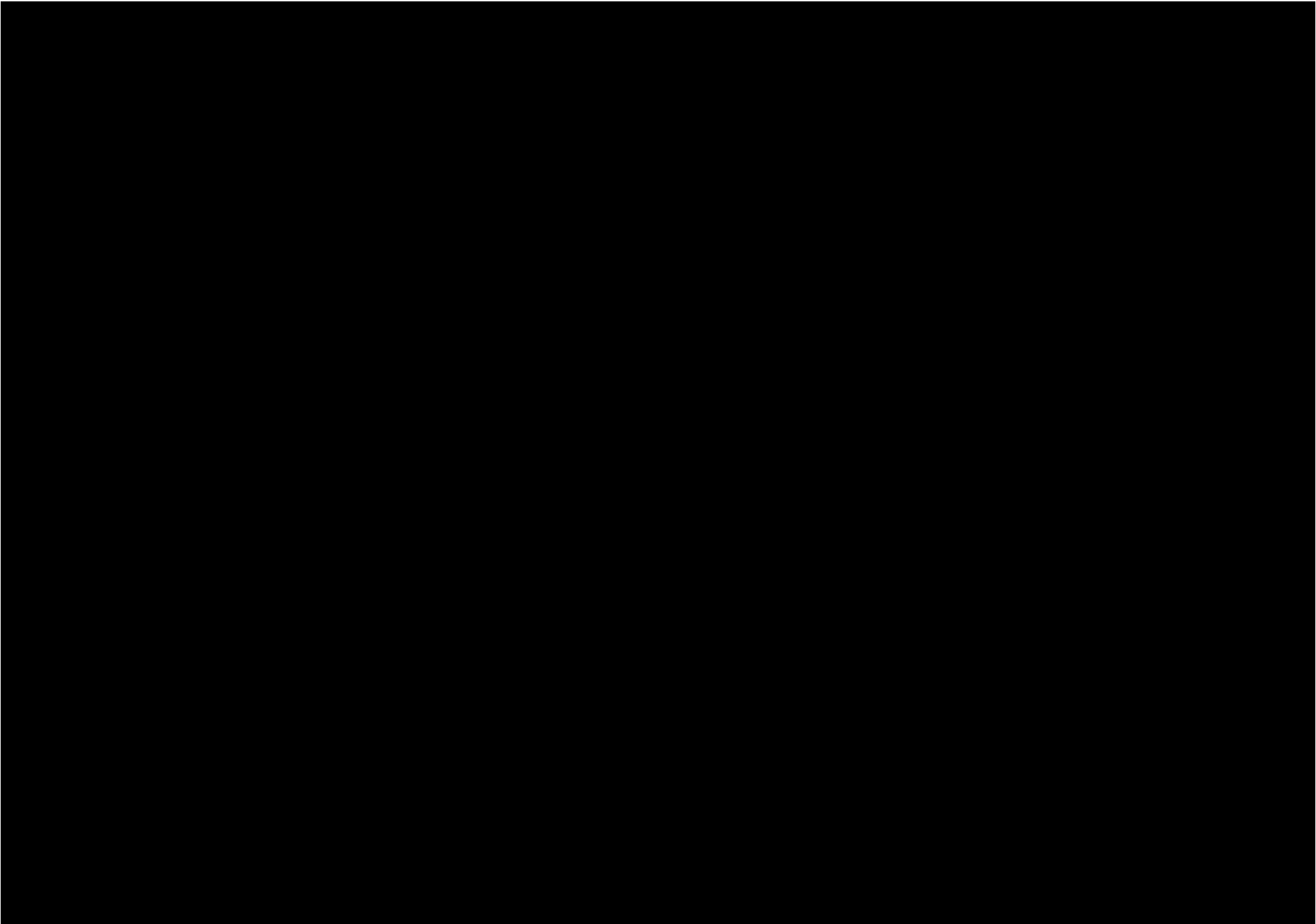
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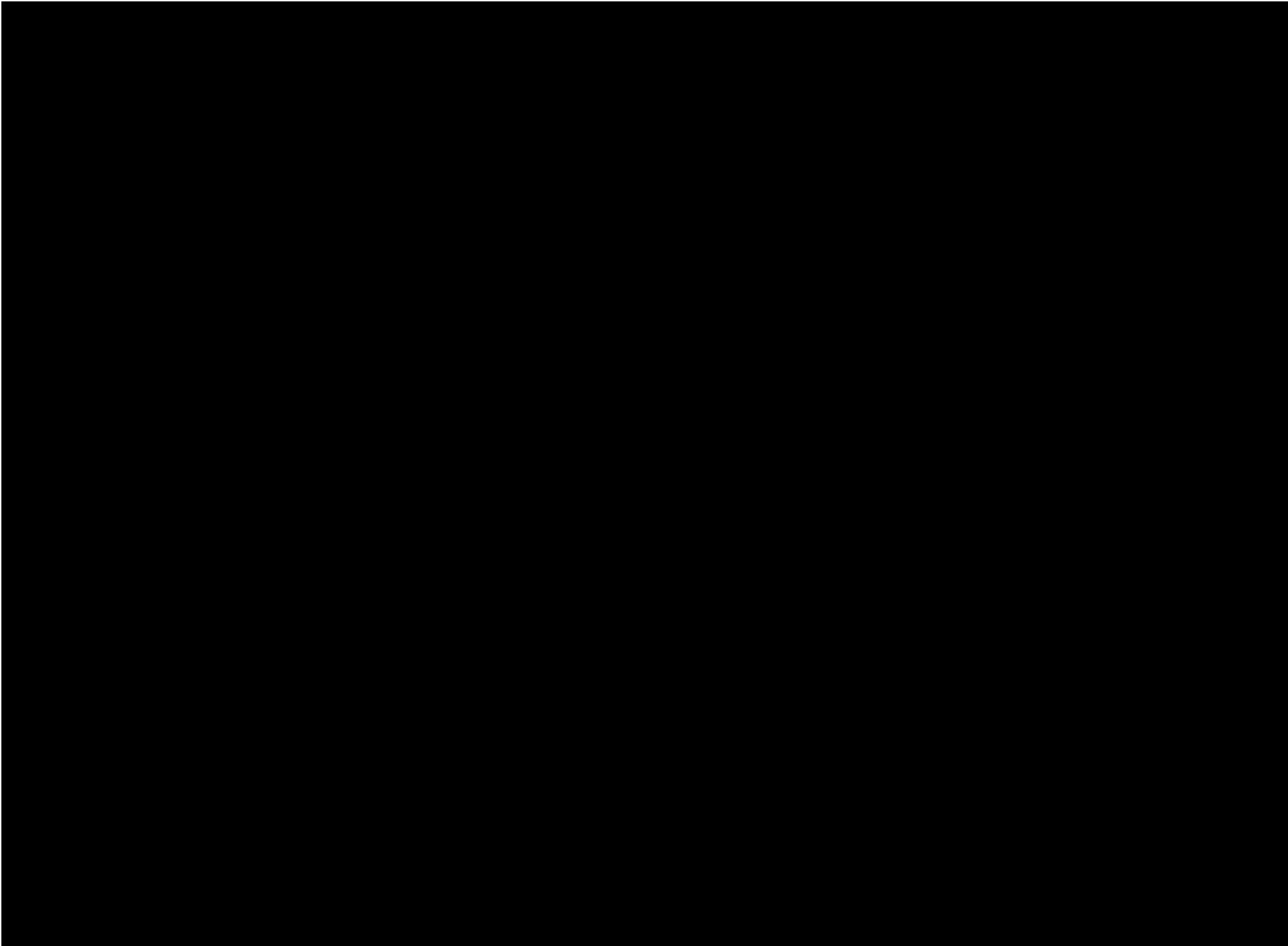
Summary of ATU Survey Reports: Dosing Frequencies by Indication and Treatment

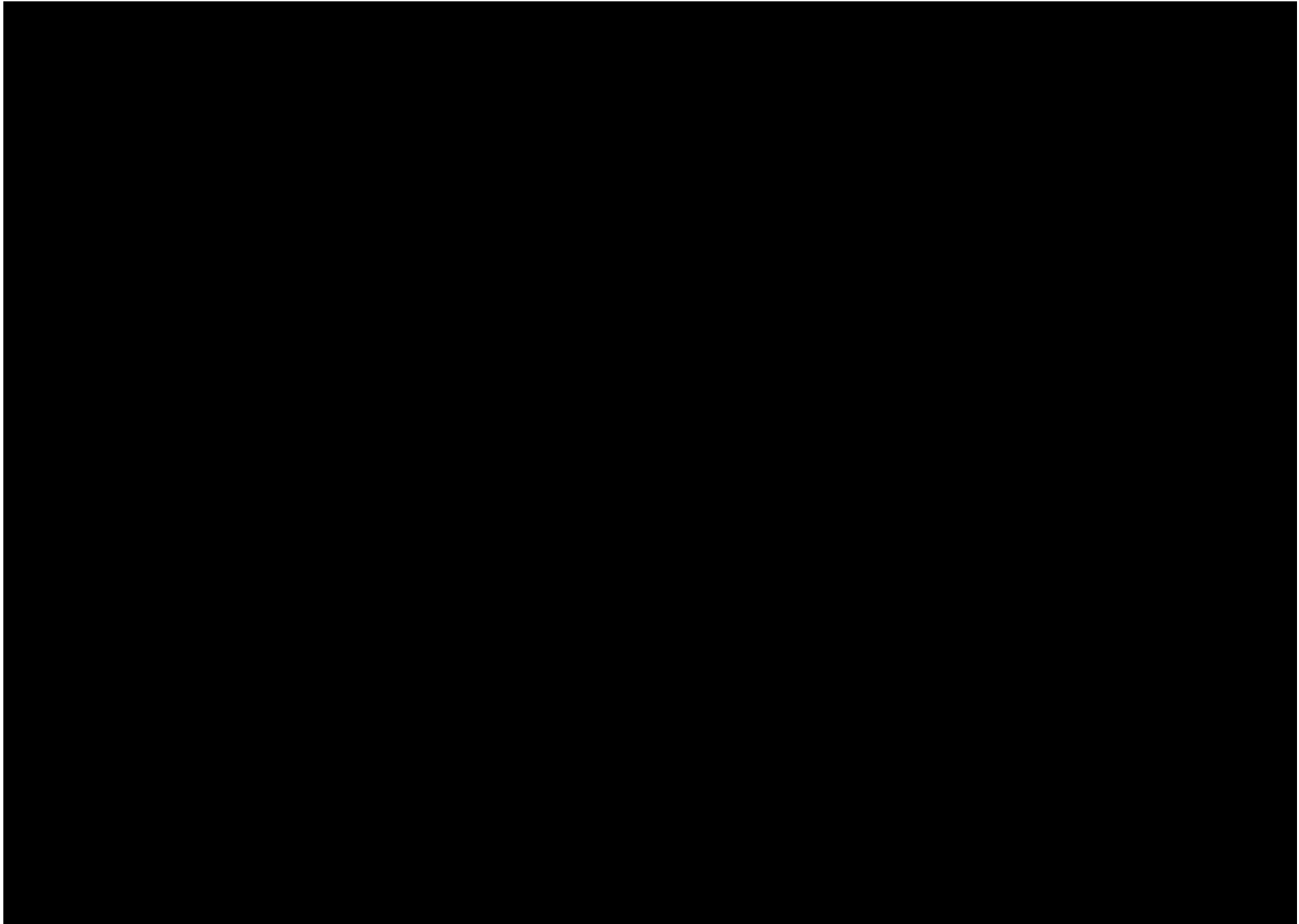


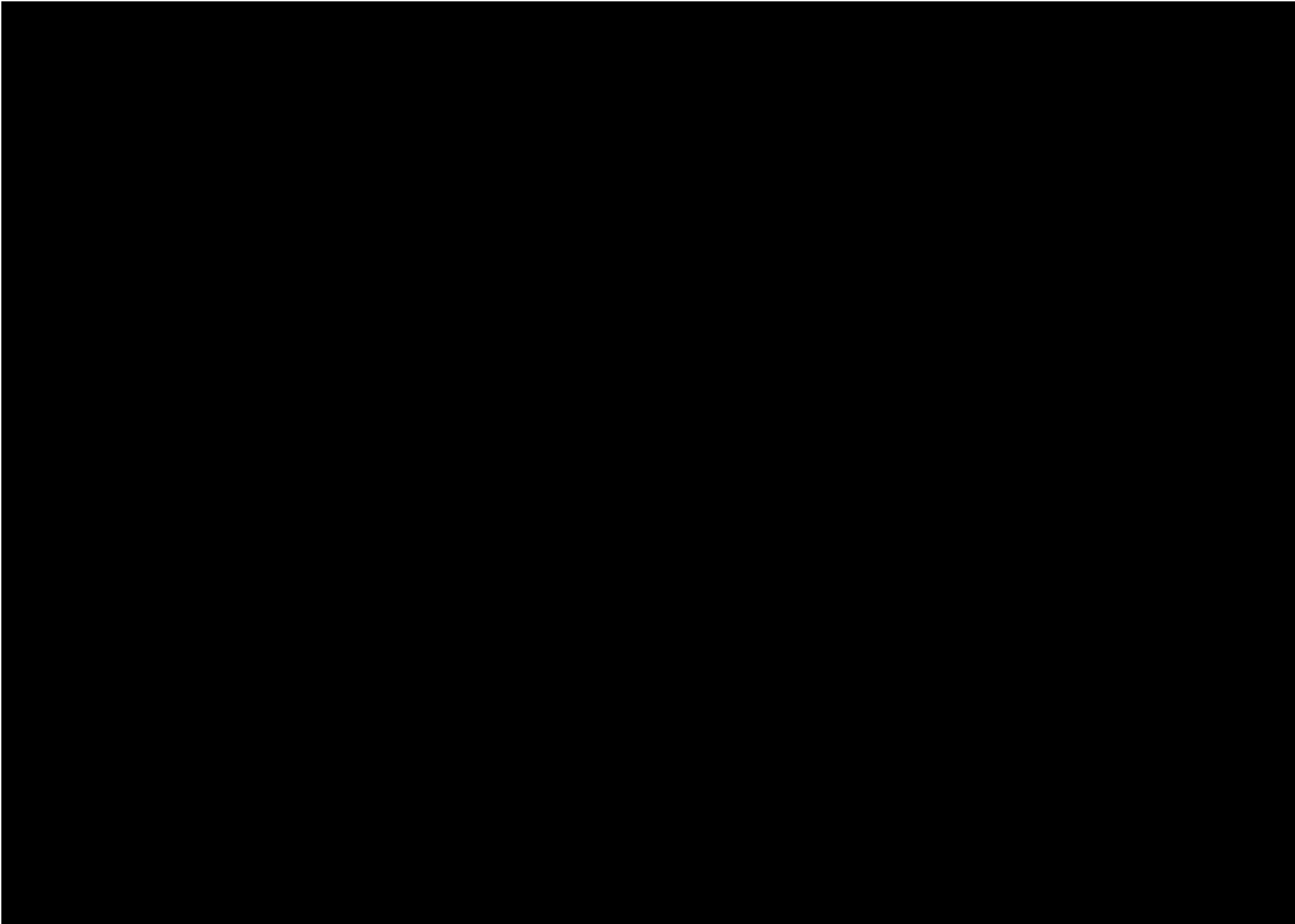
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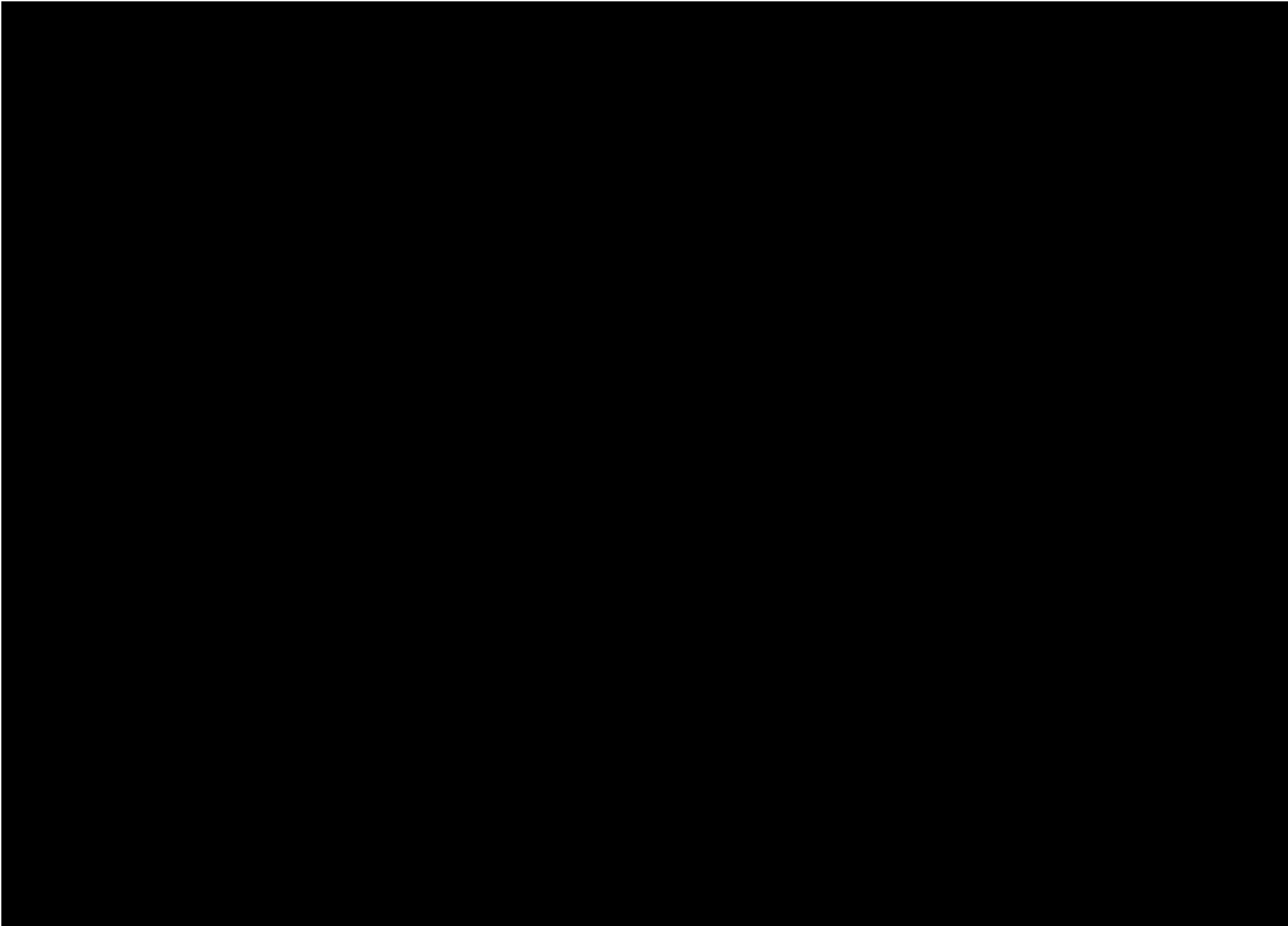
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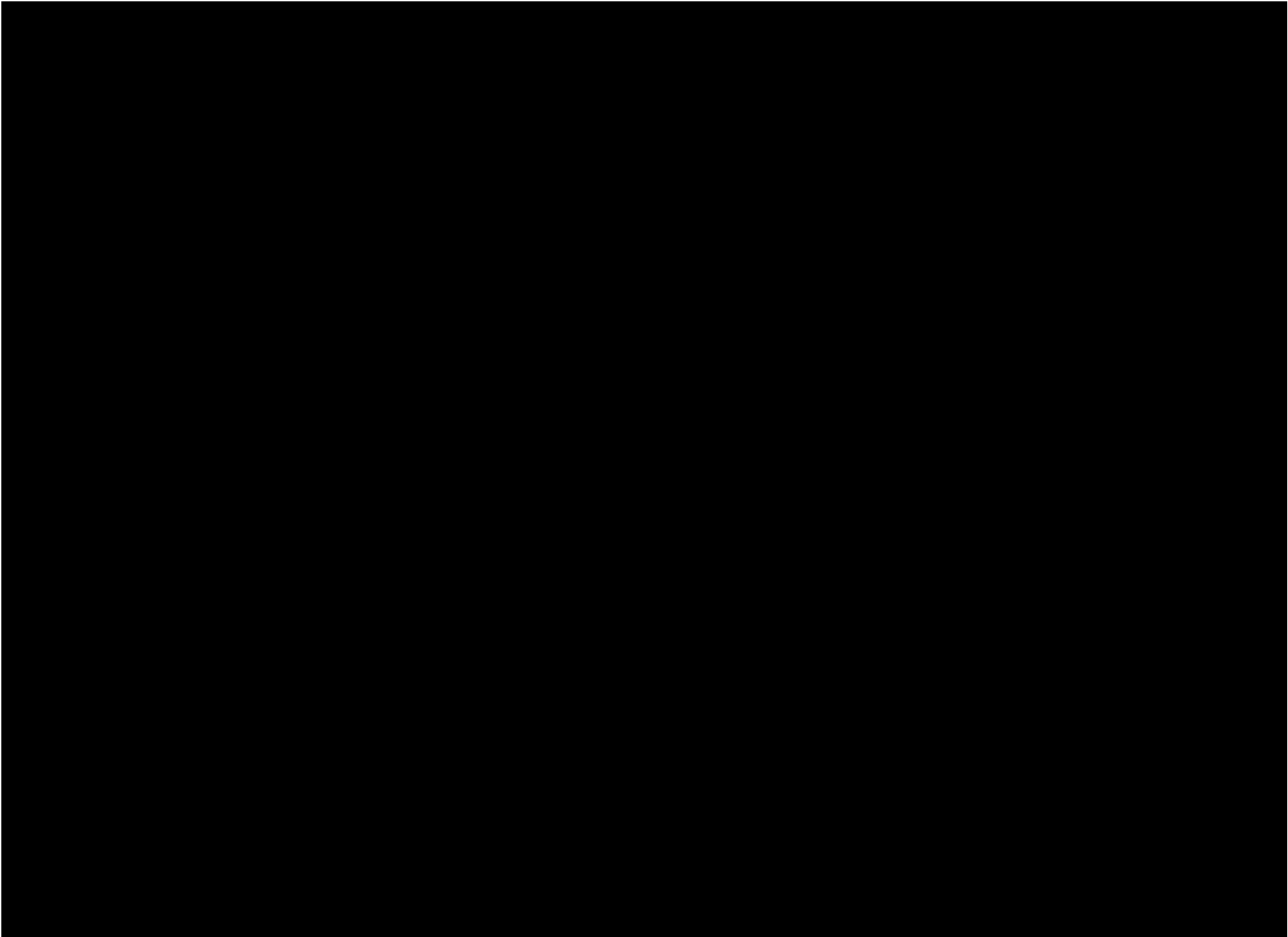


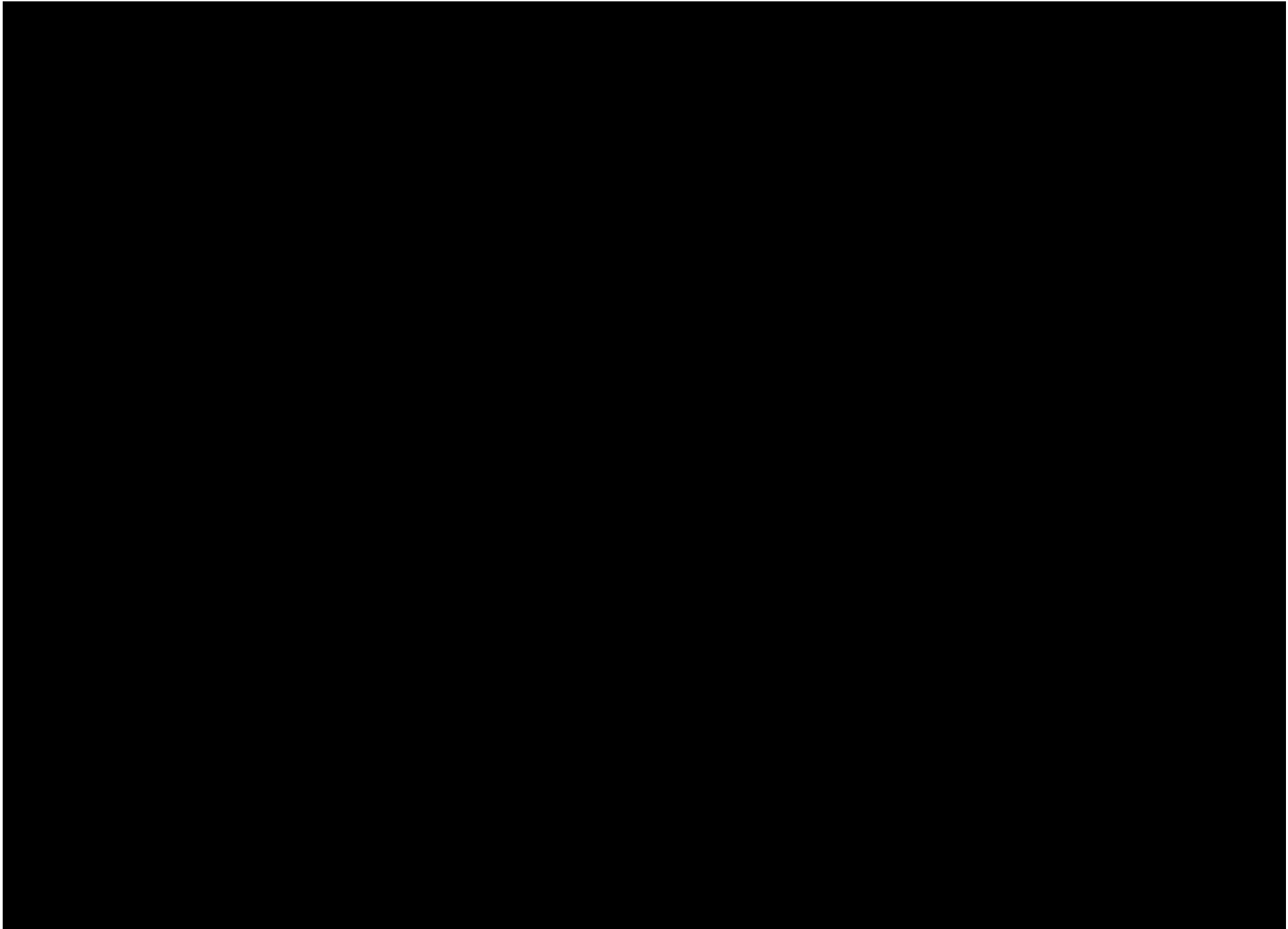


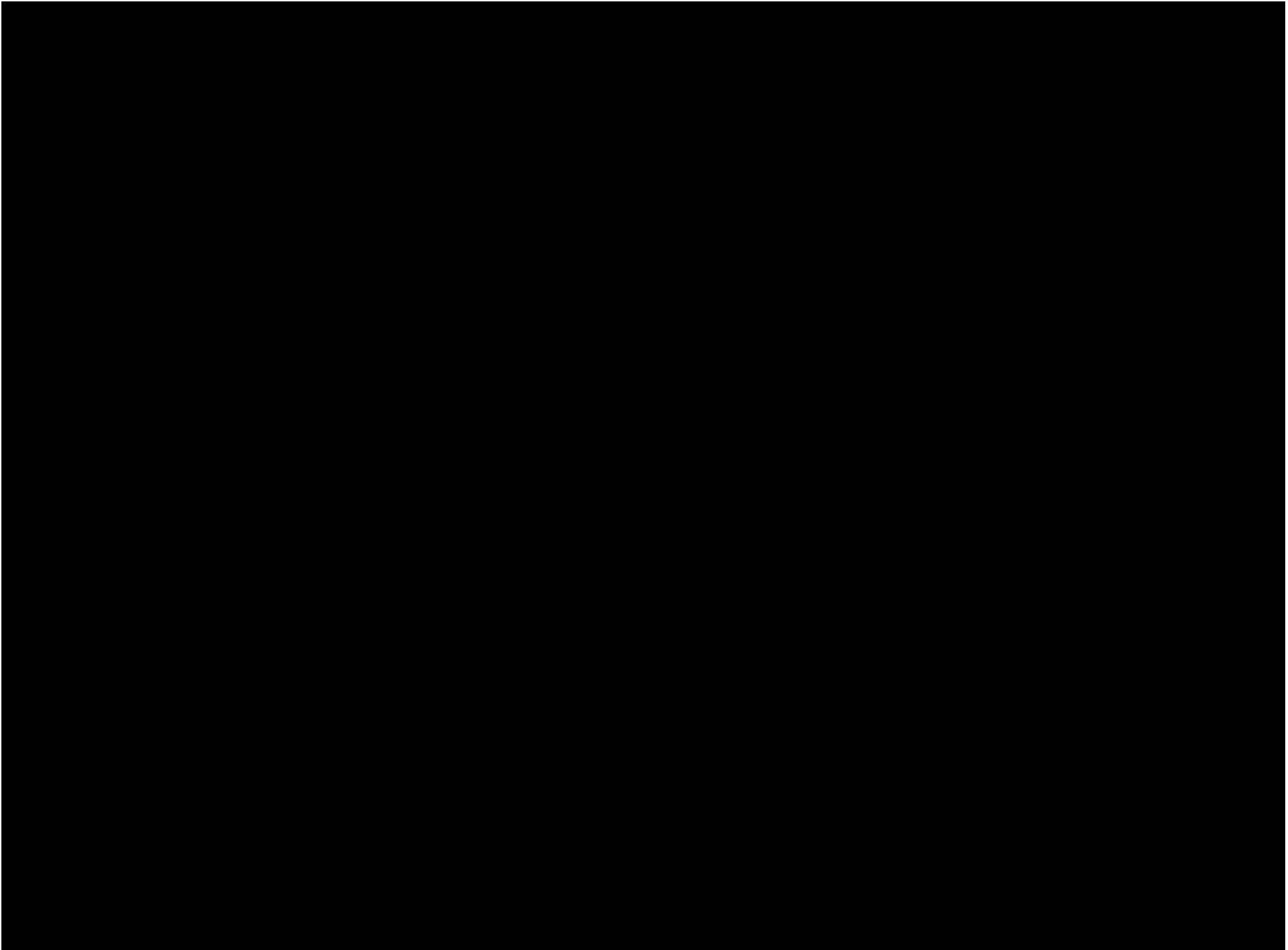


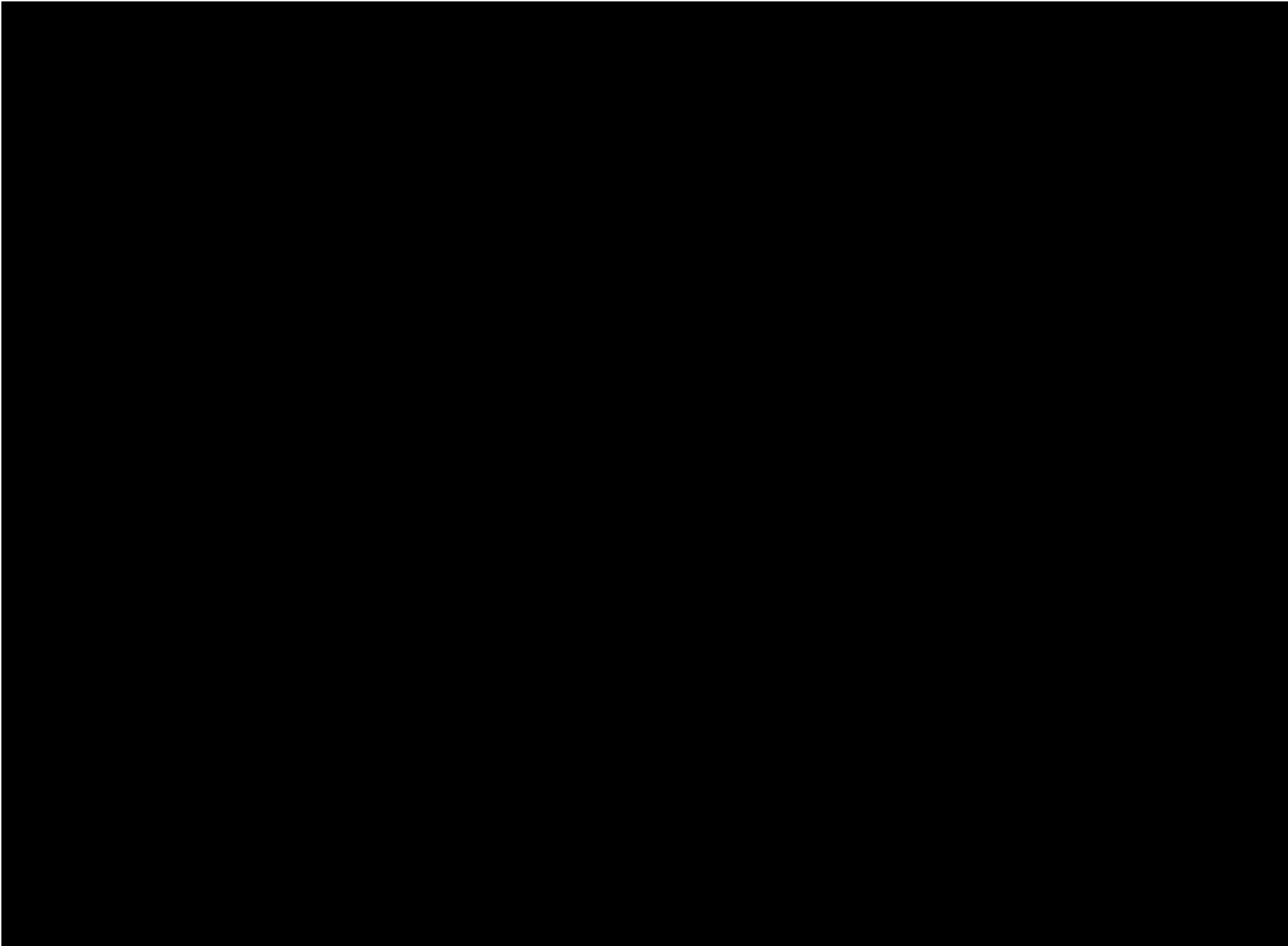


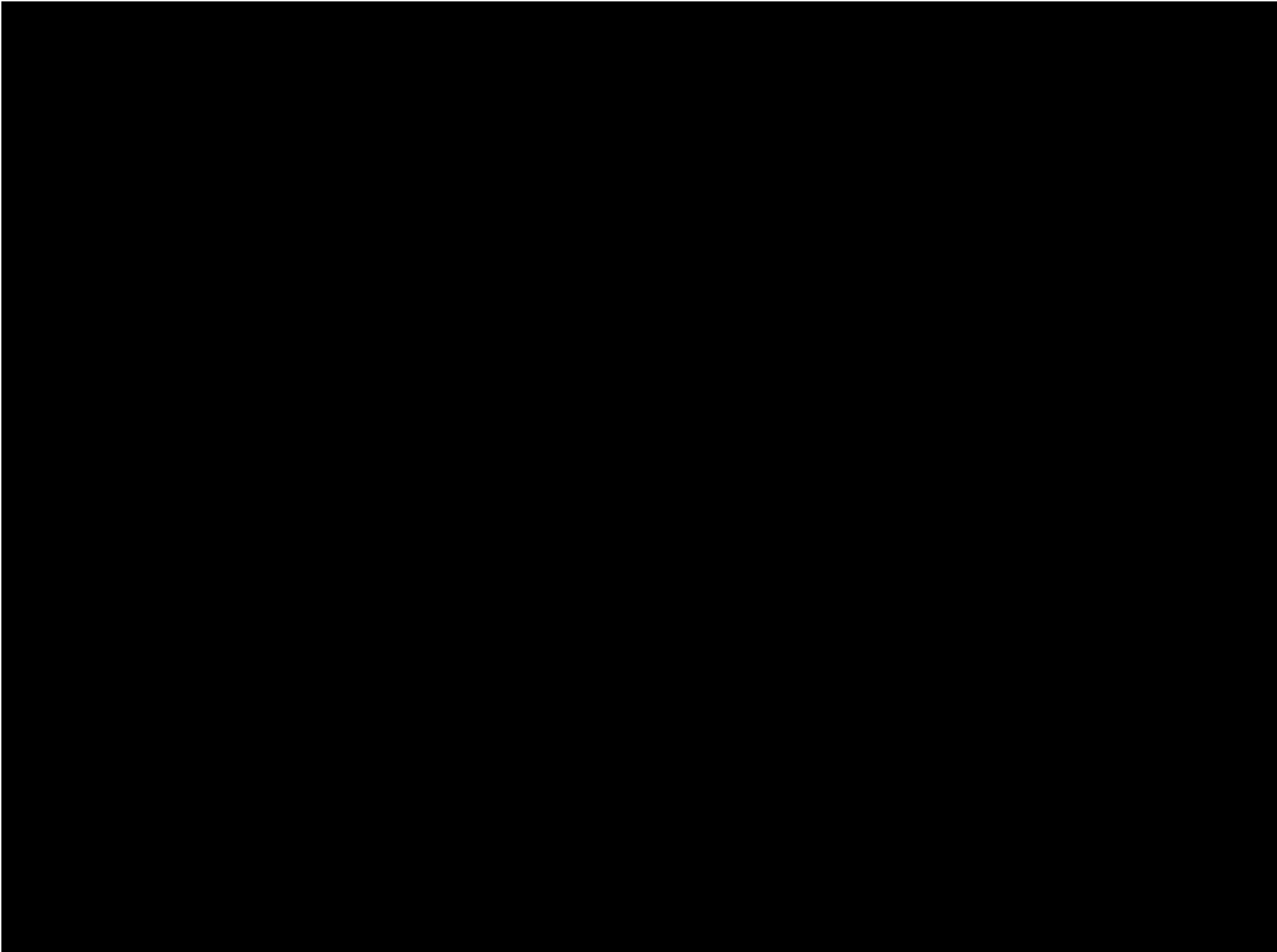


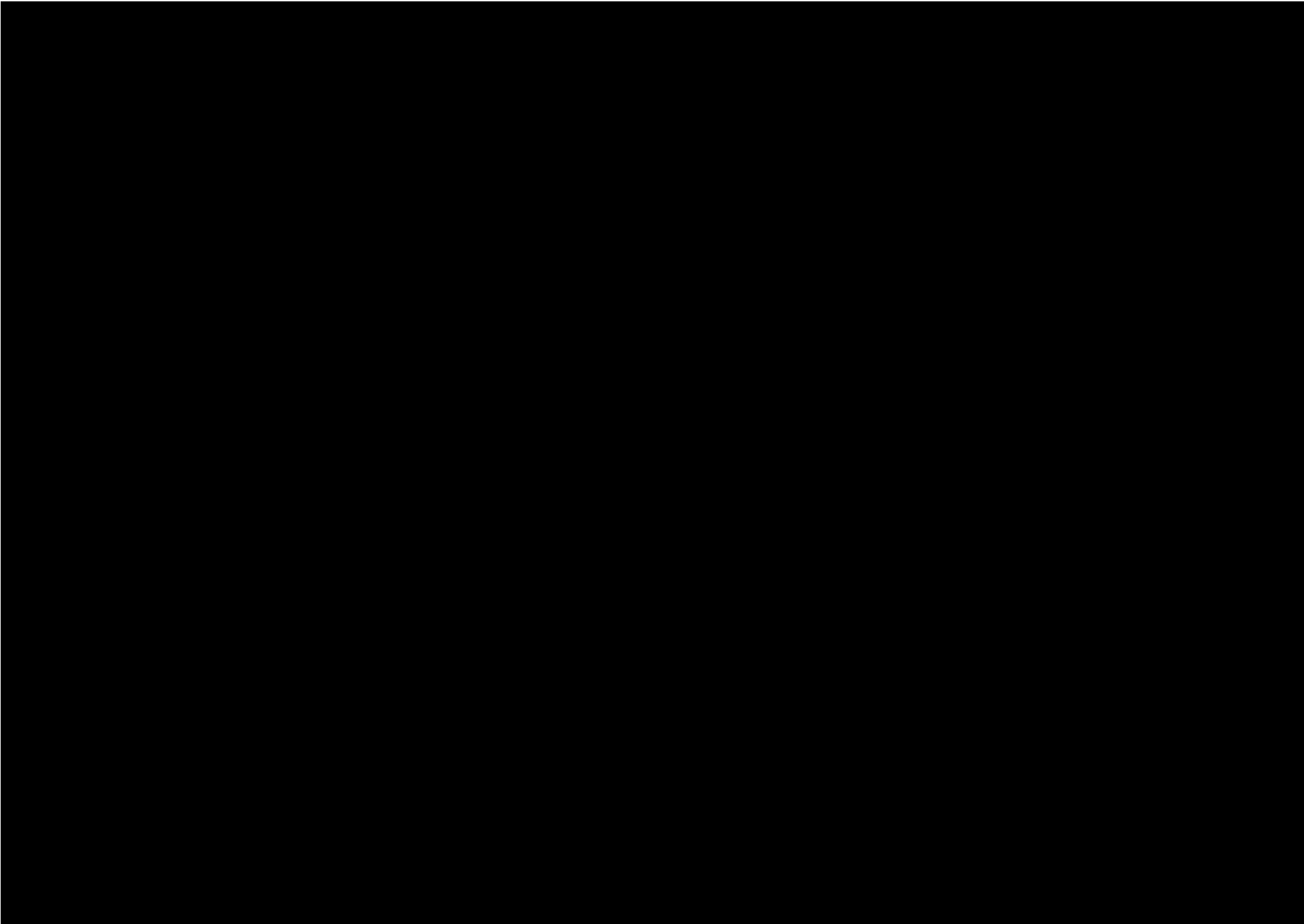


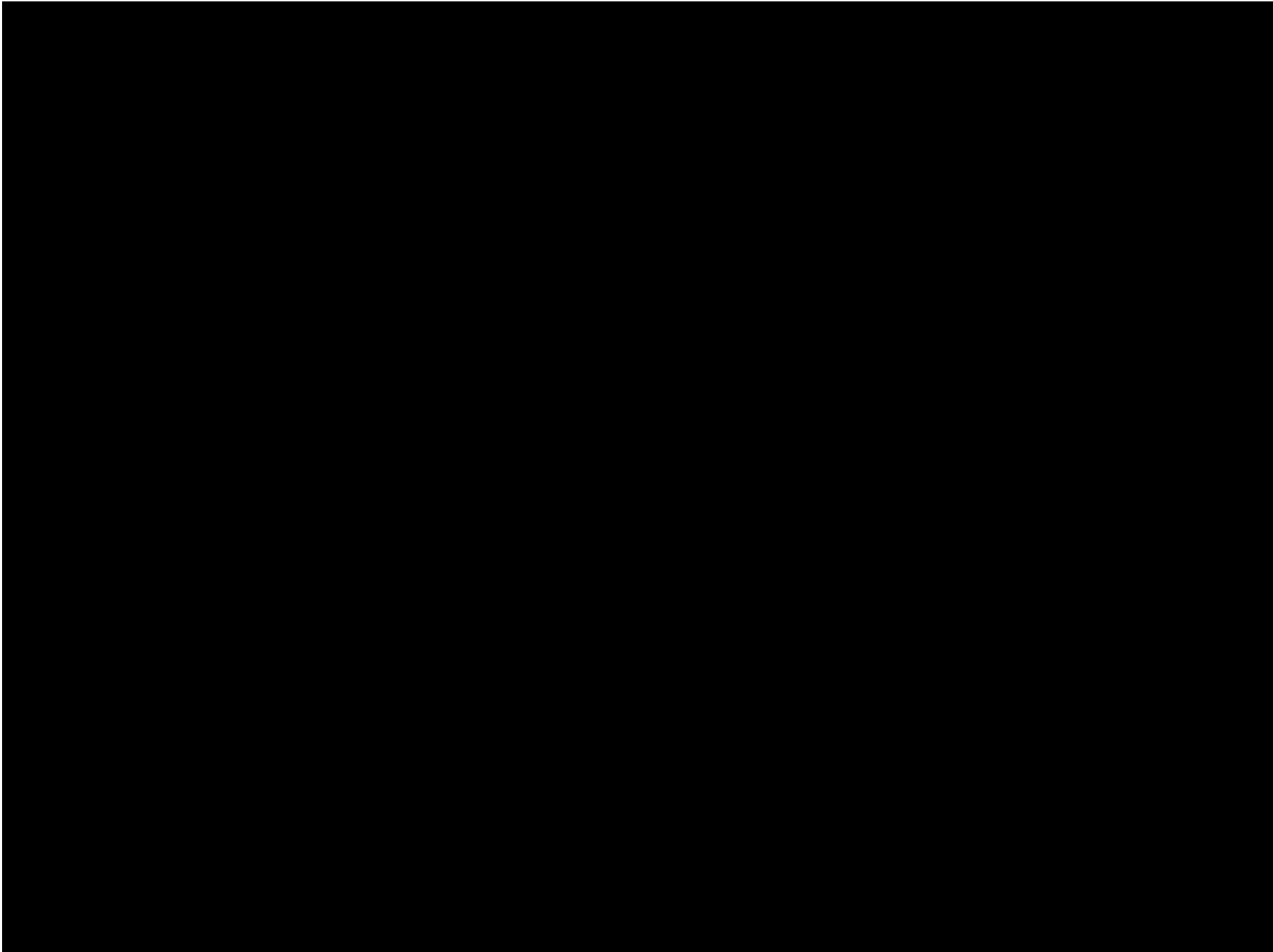






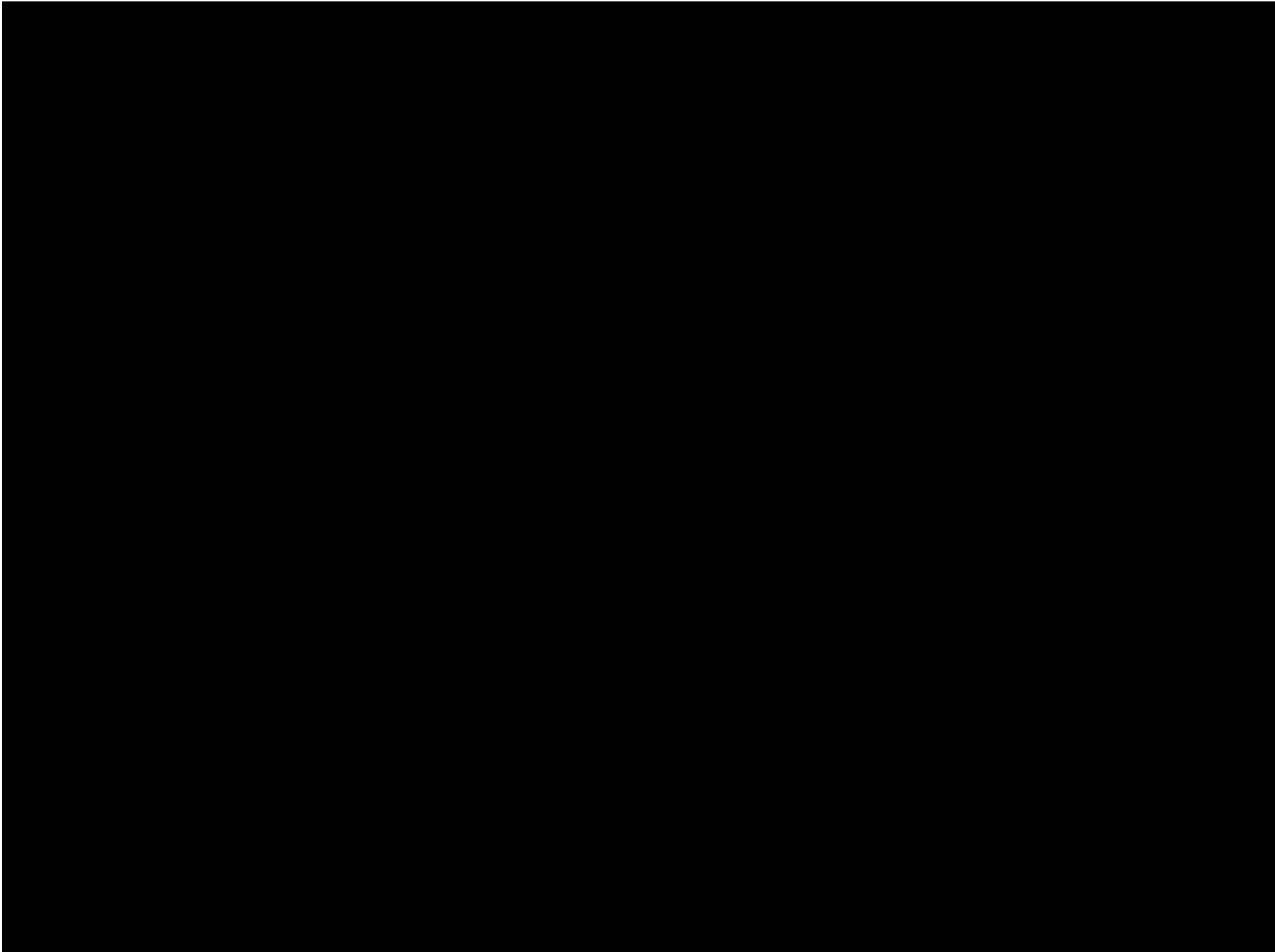


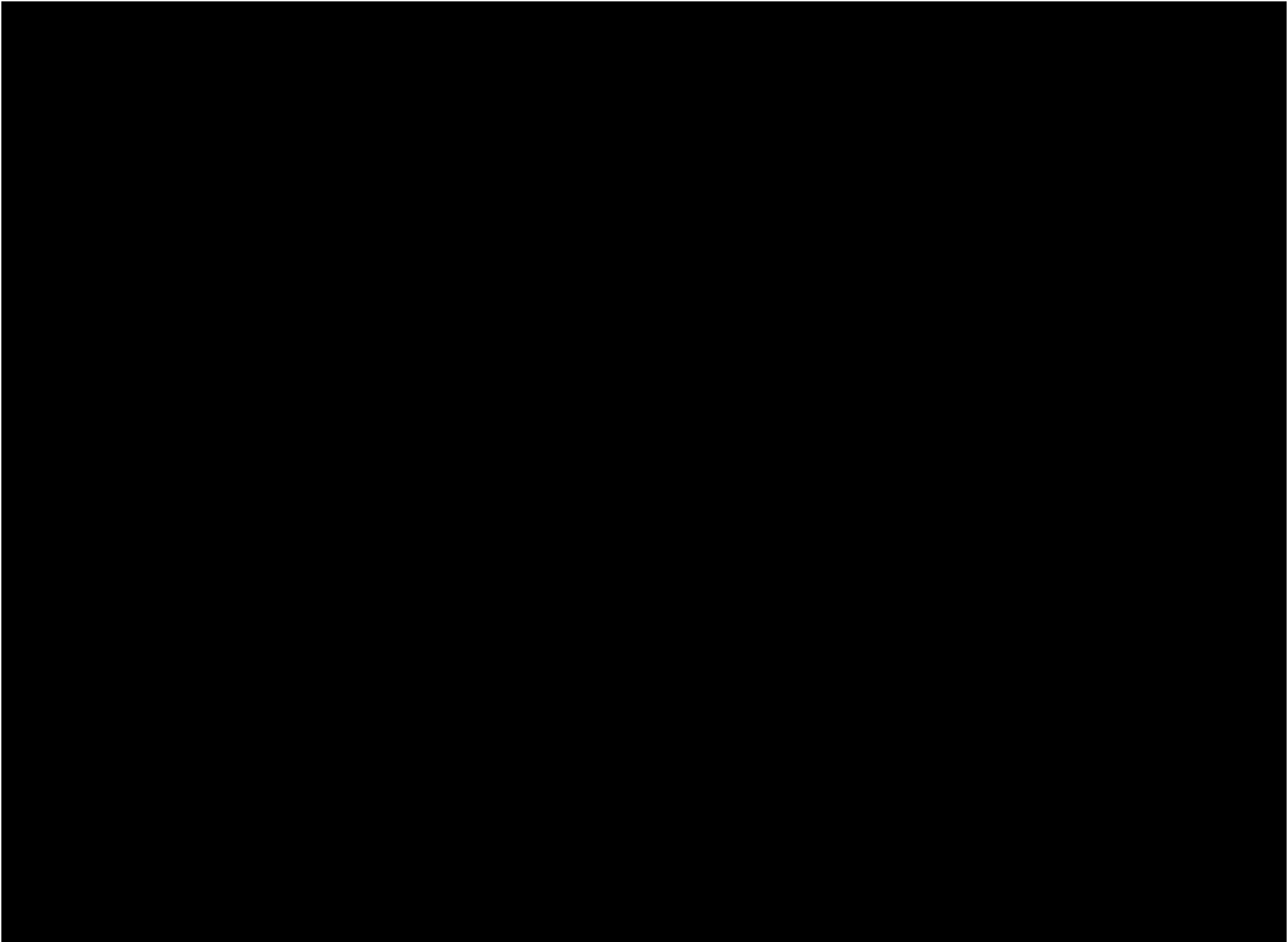


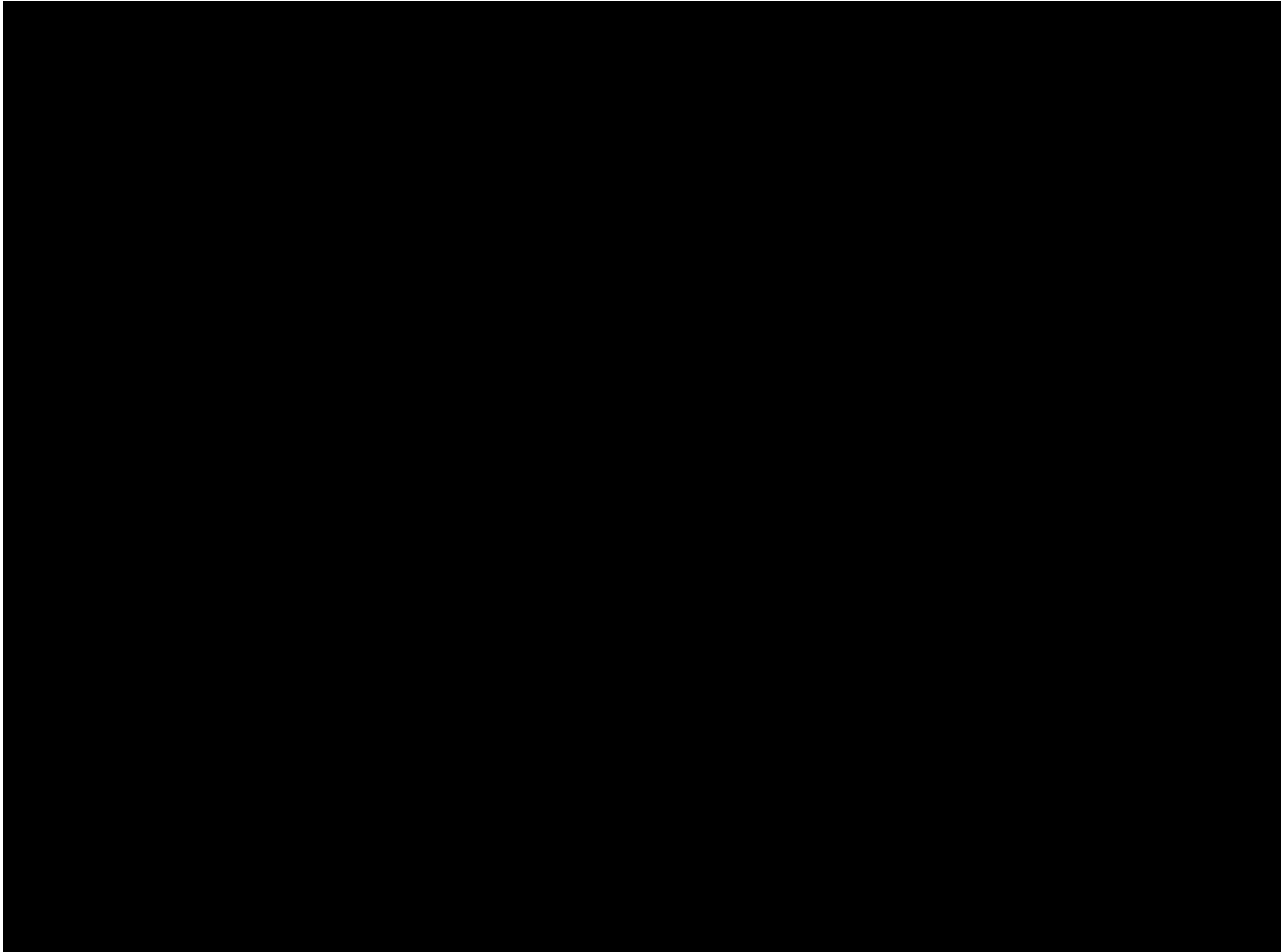


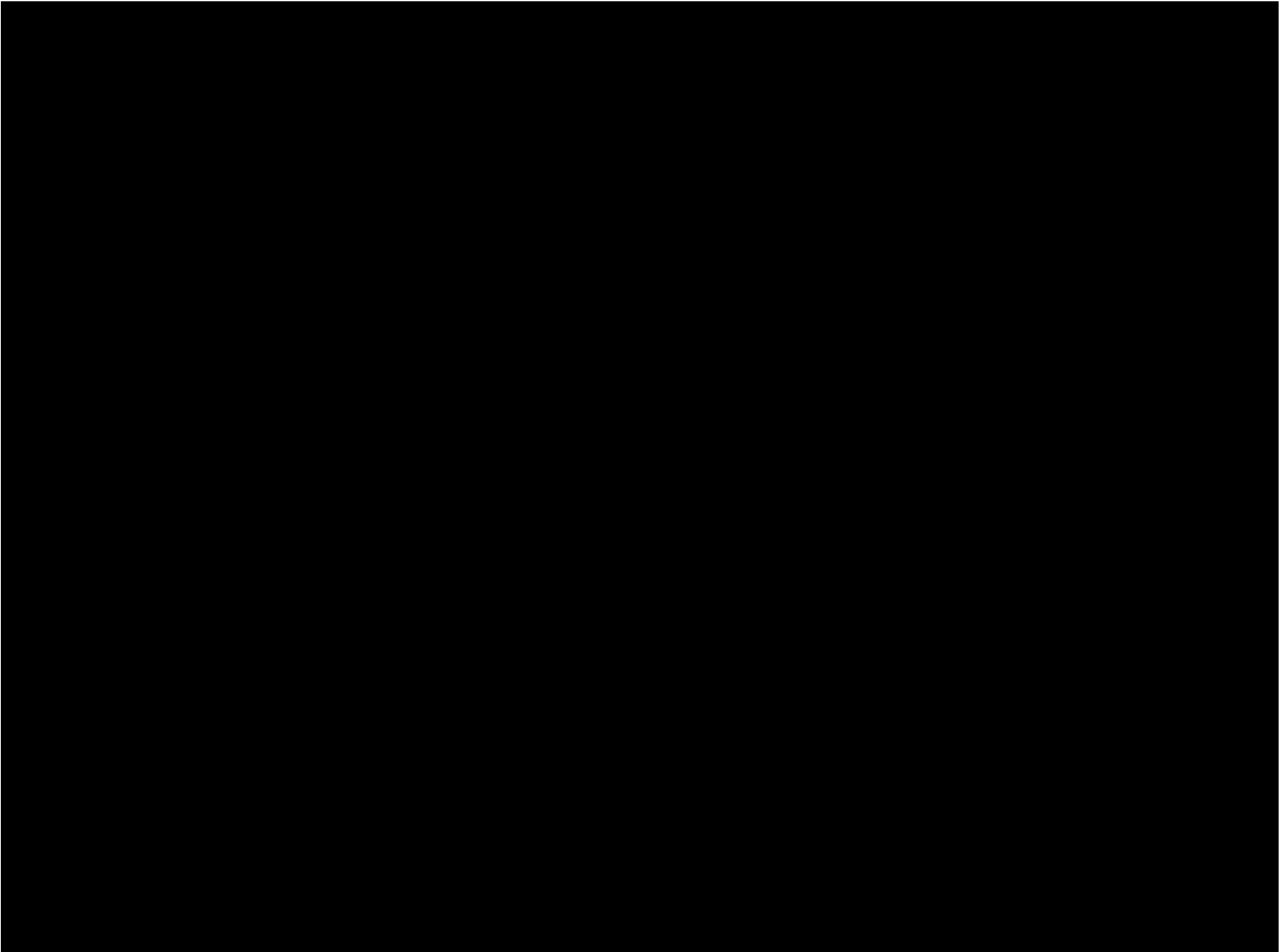
PROTECTIVE ORDER MATERIAL

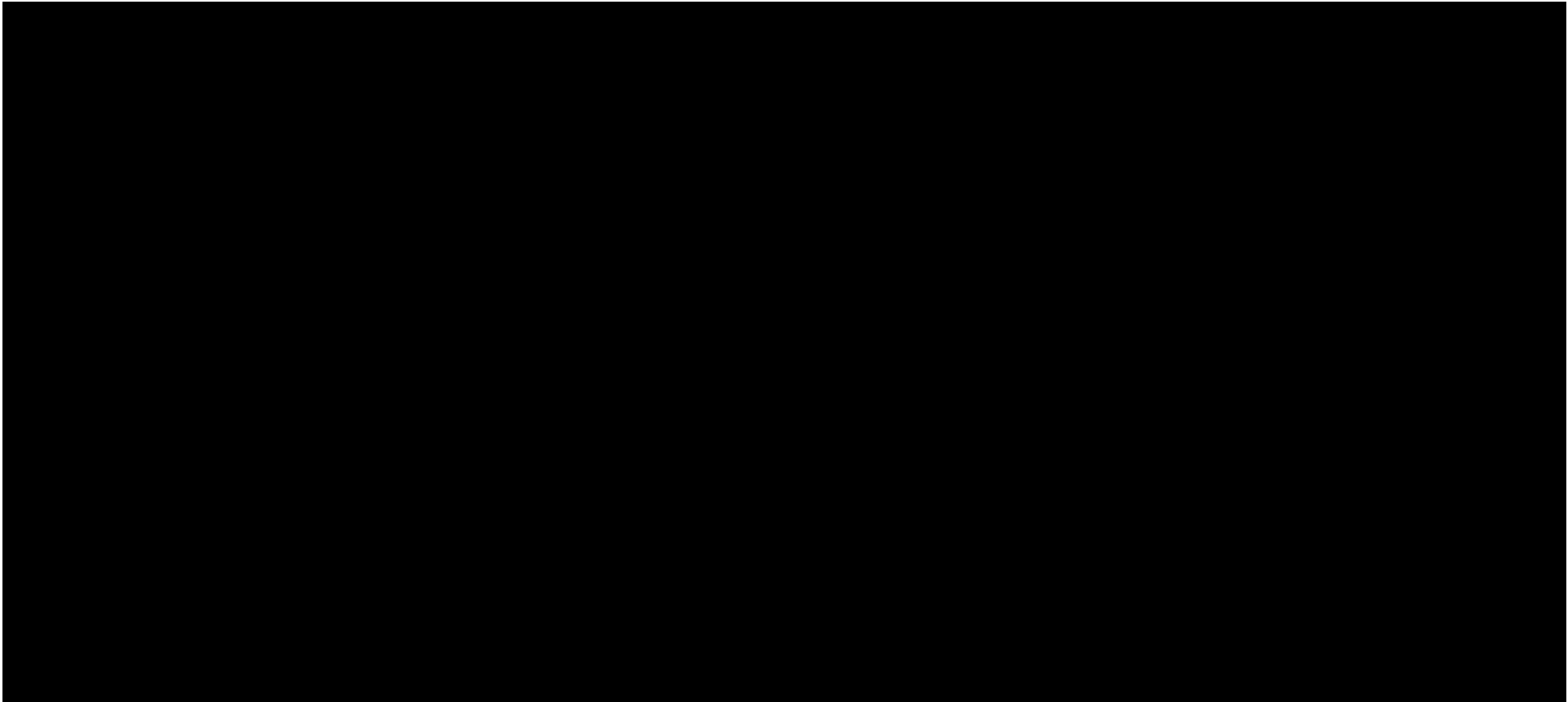
Attachment X-5
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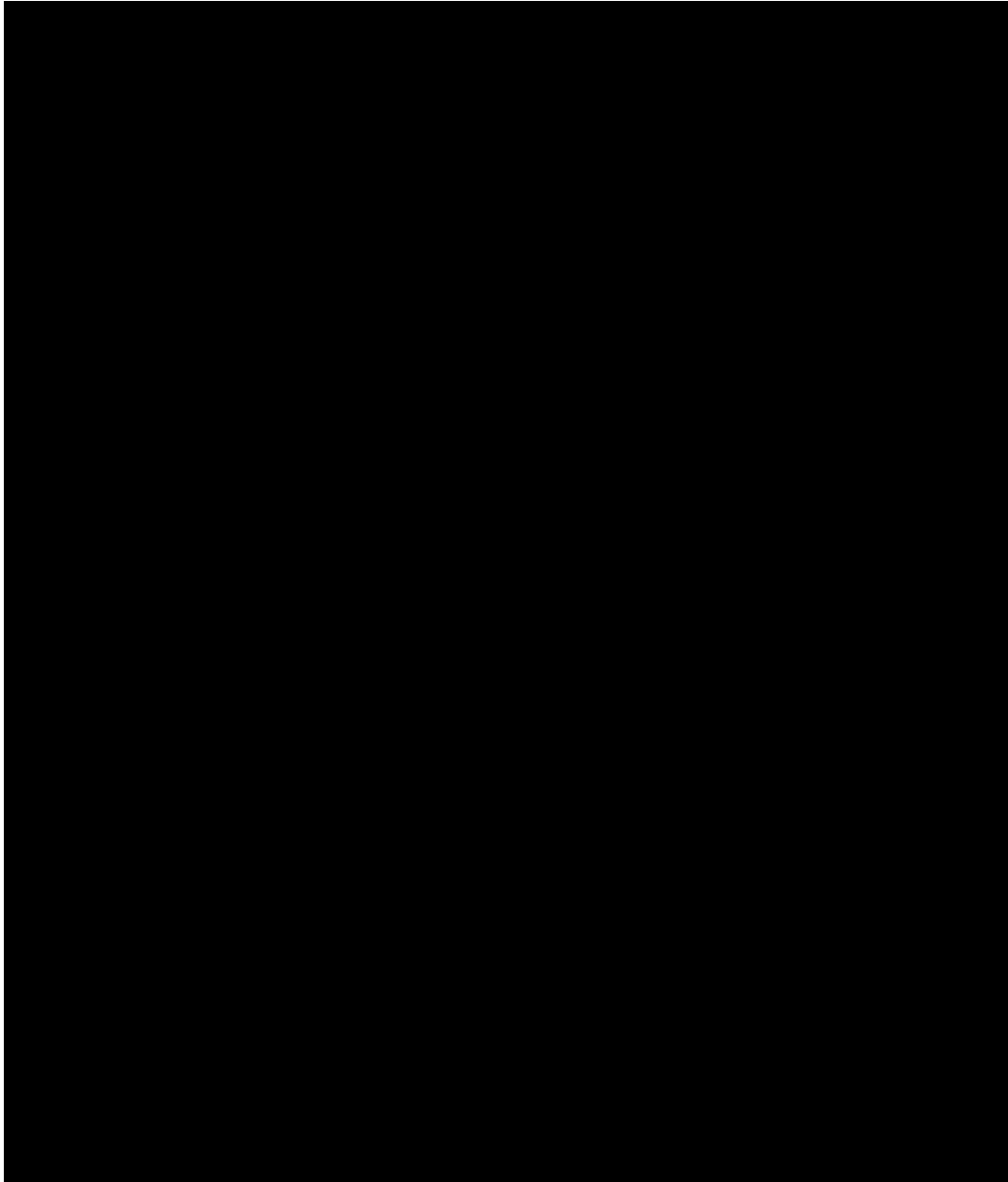






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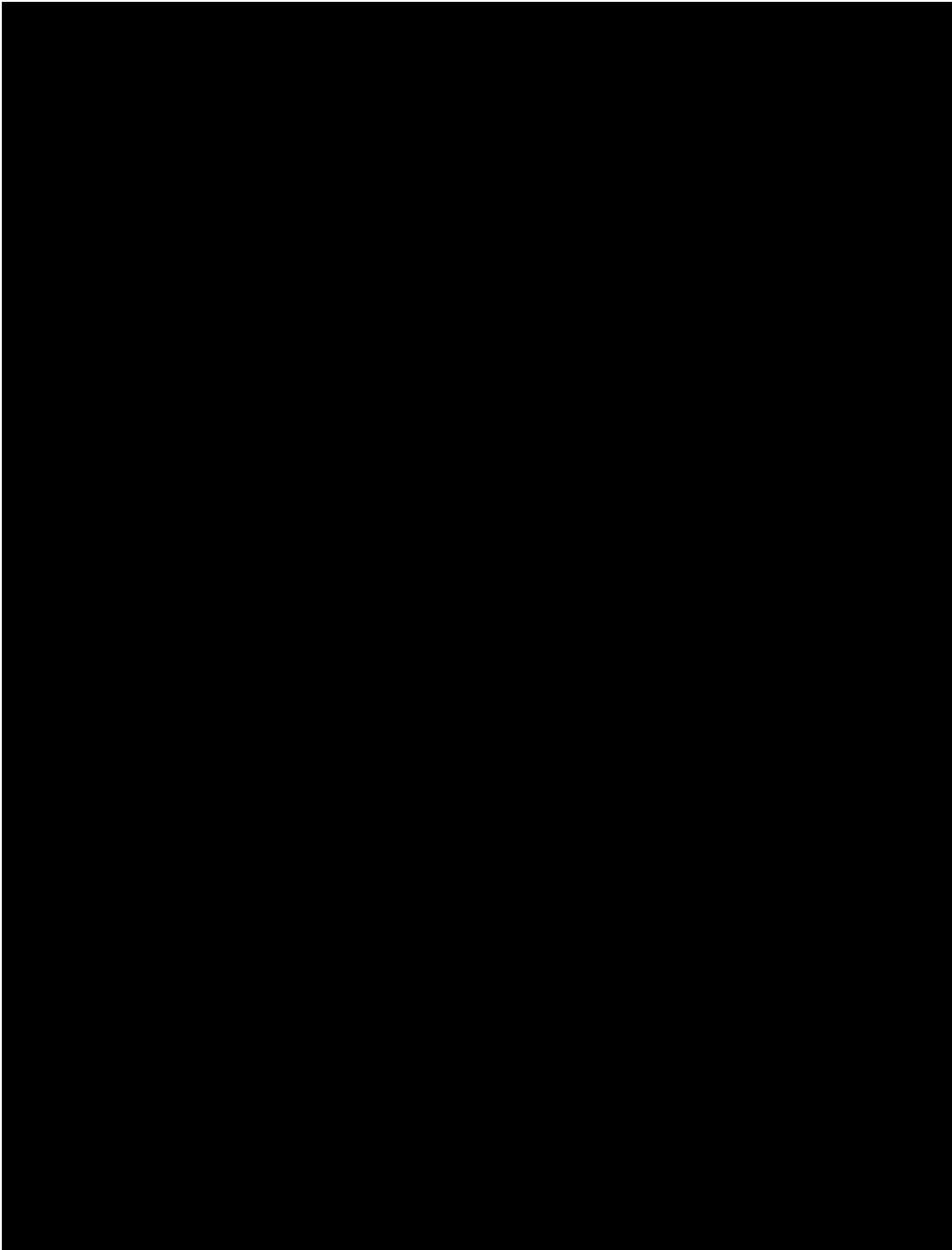
Log File for Importing 2021 CMS Medicare Part B Data



PROTECTIVE ORDER MATERIAL

Attachment Y-1

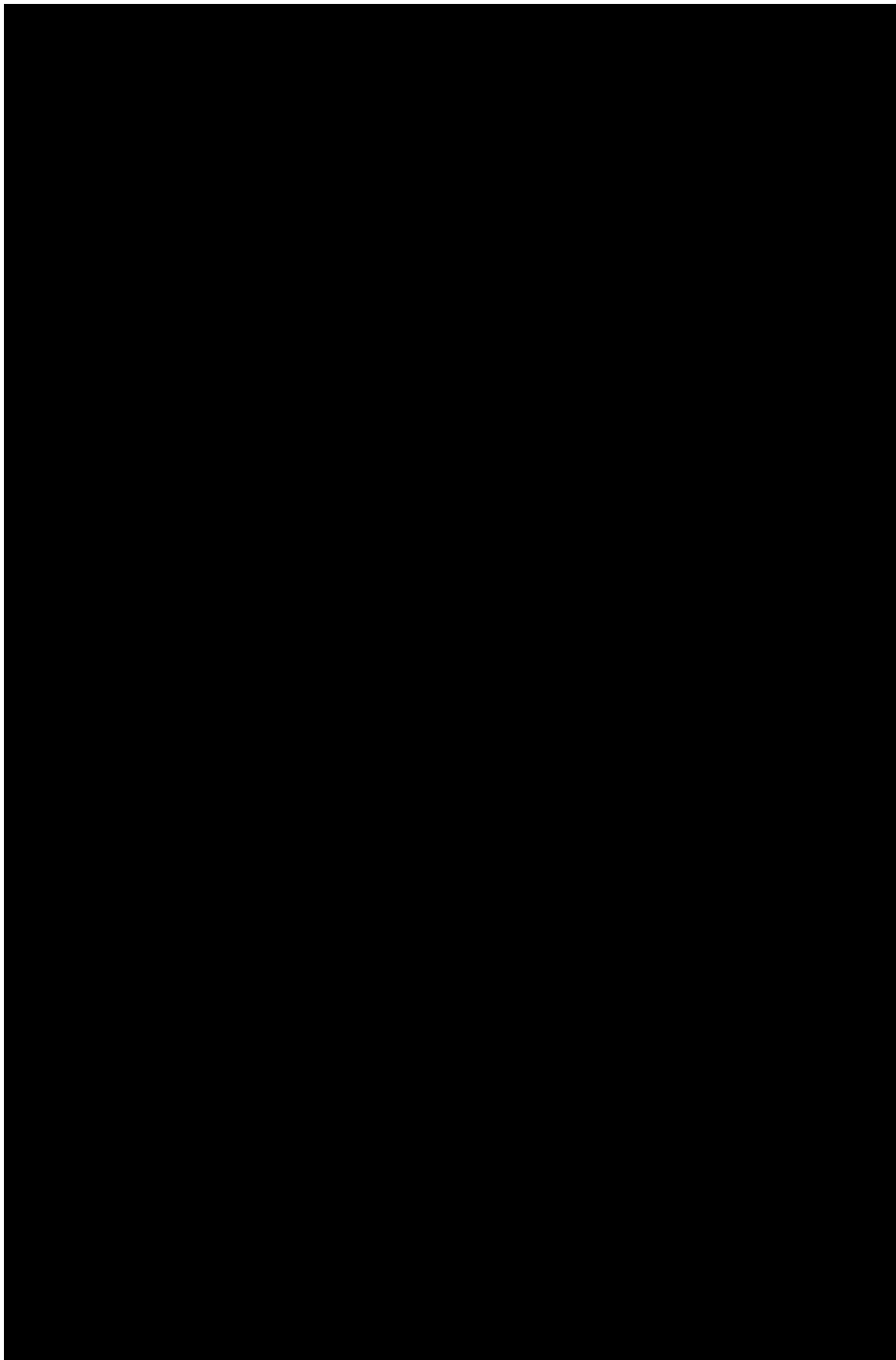
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PROTECTIVE ORDER MATERIAL

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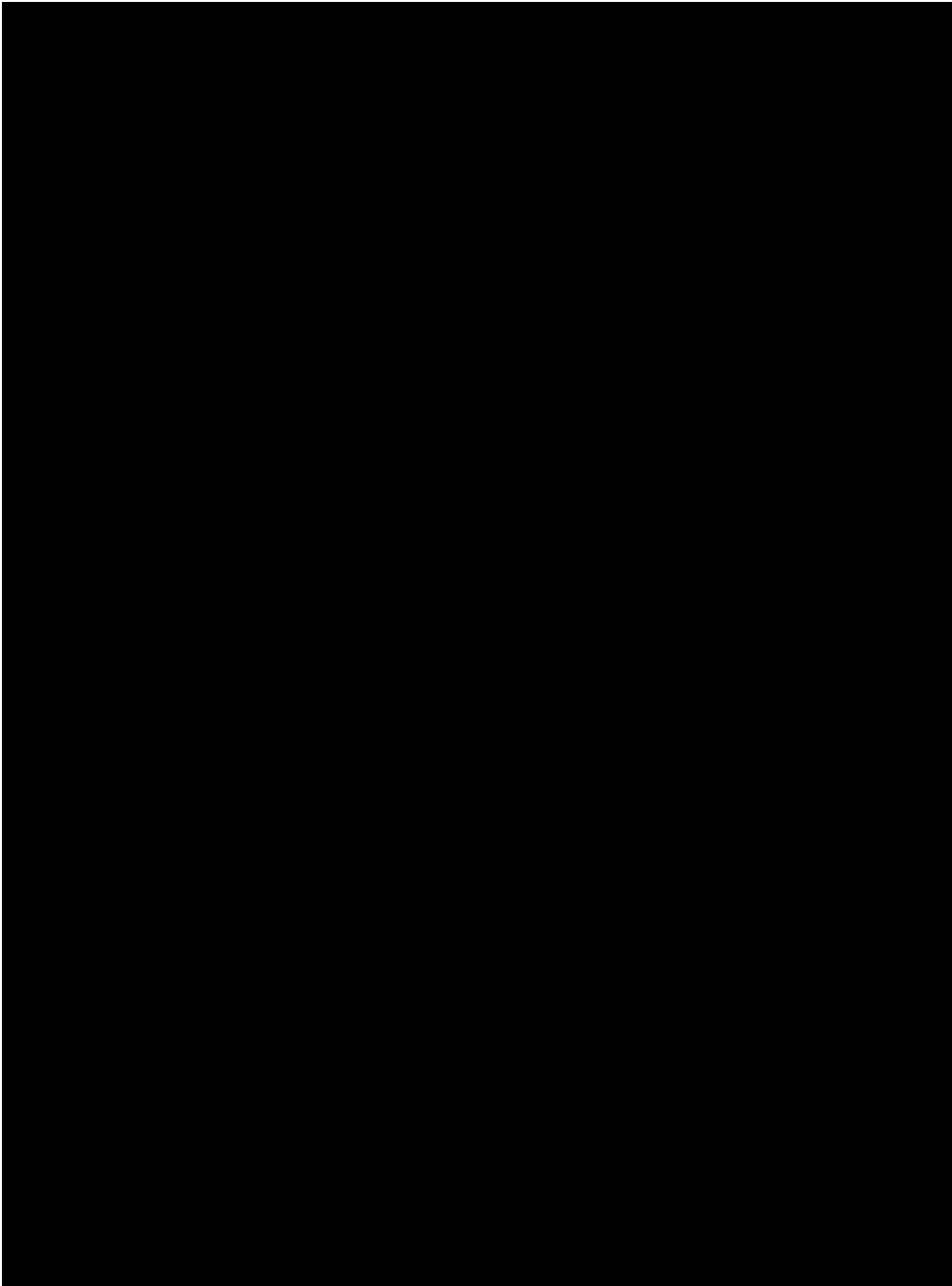
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PROTECTIVE ORDER MATERIAL

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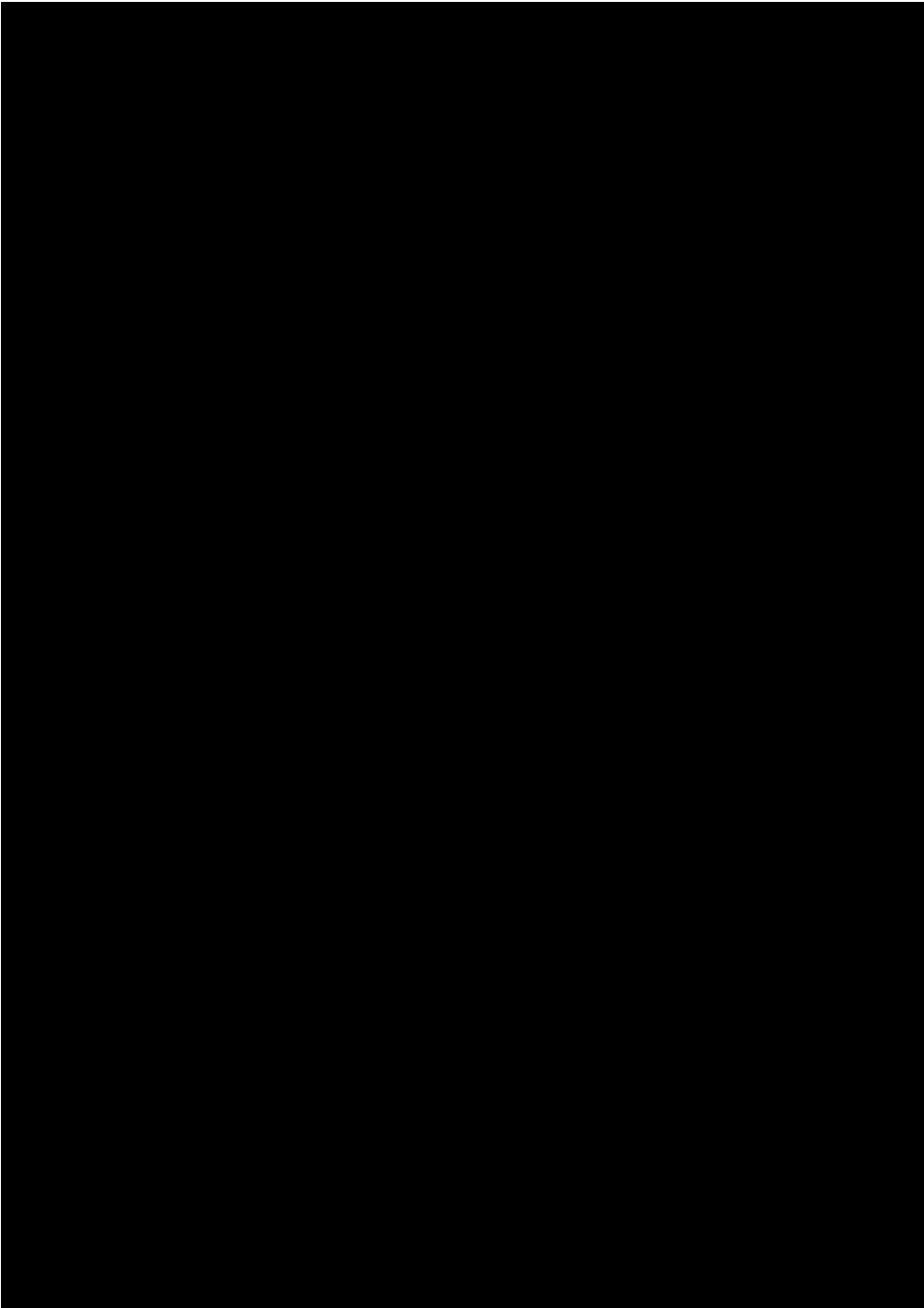
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PROTECTIVE ORDER MATERIAL

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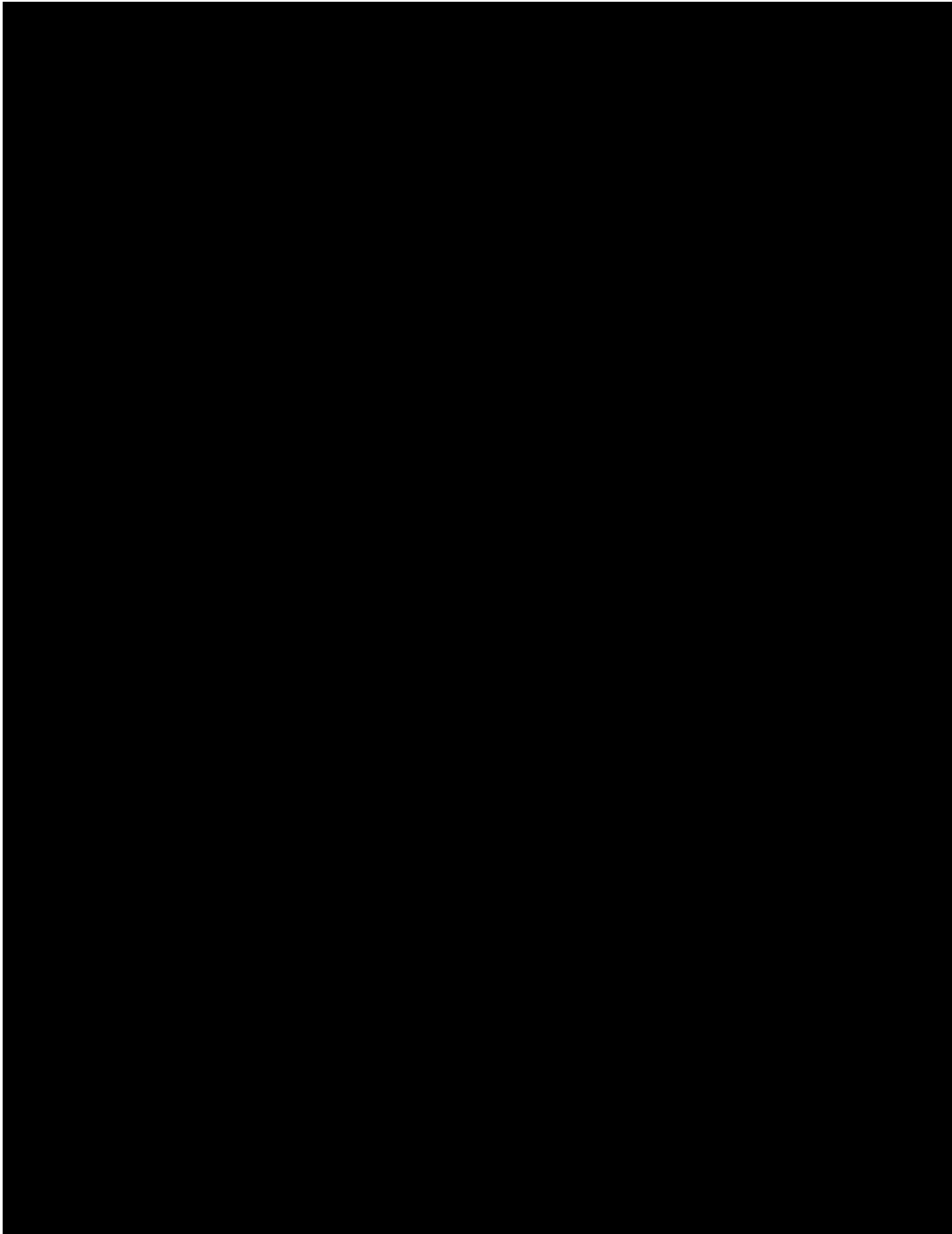
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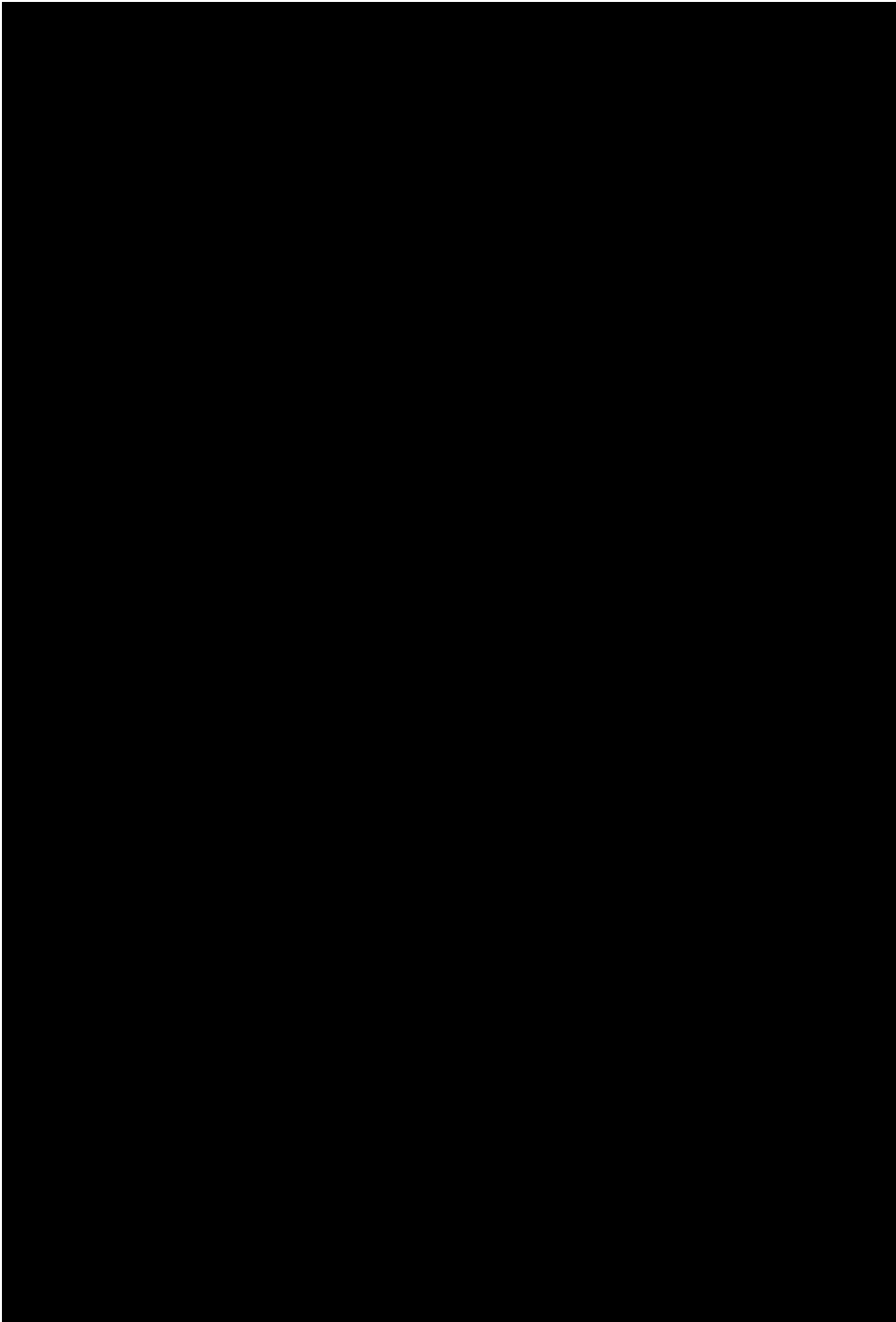
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Attachment Y-1

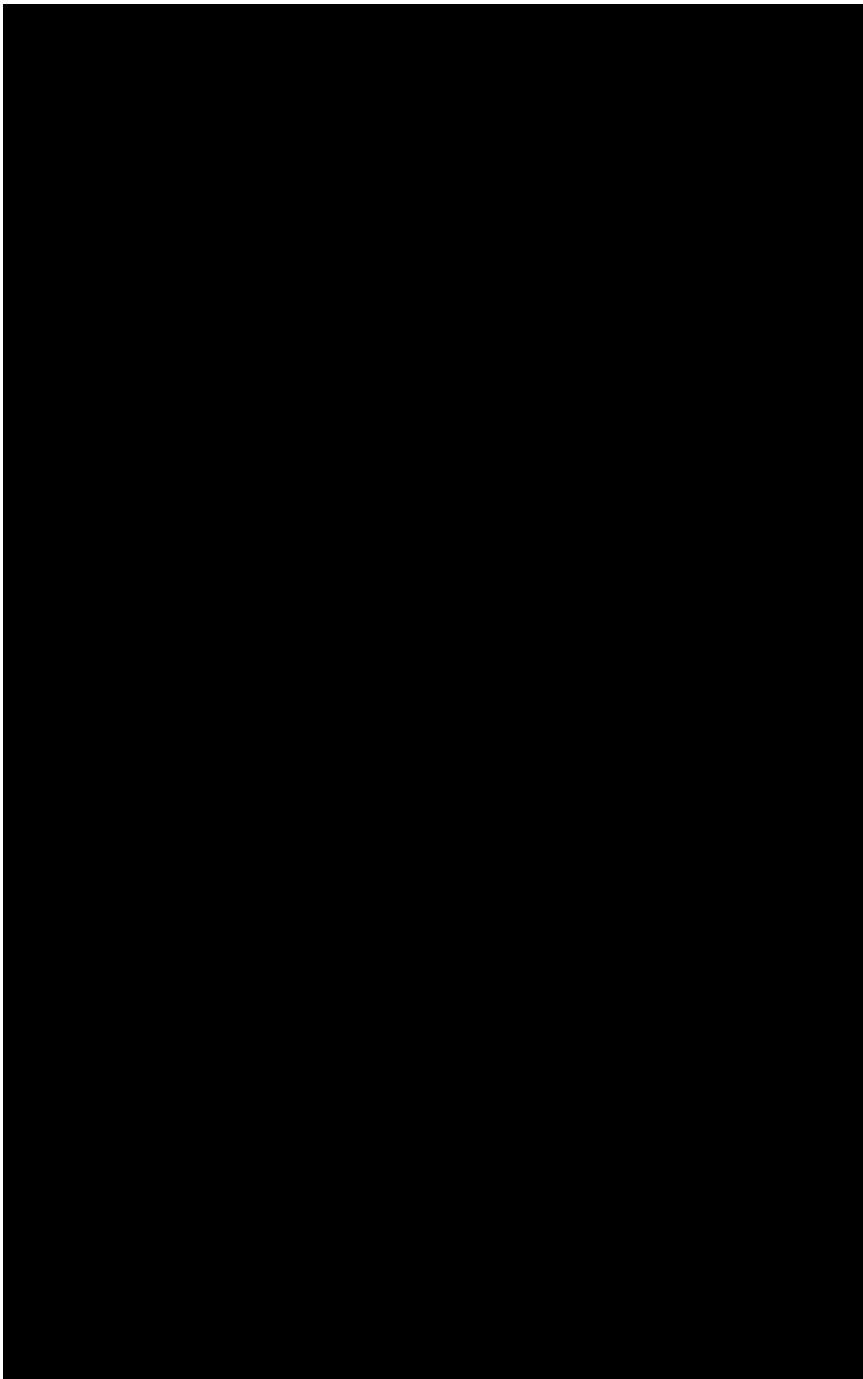
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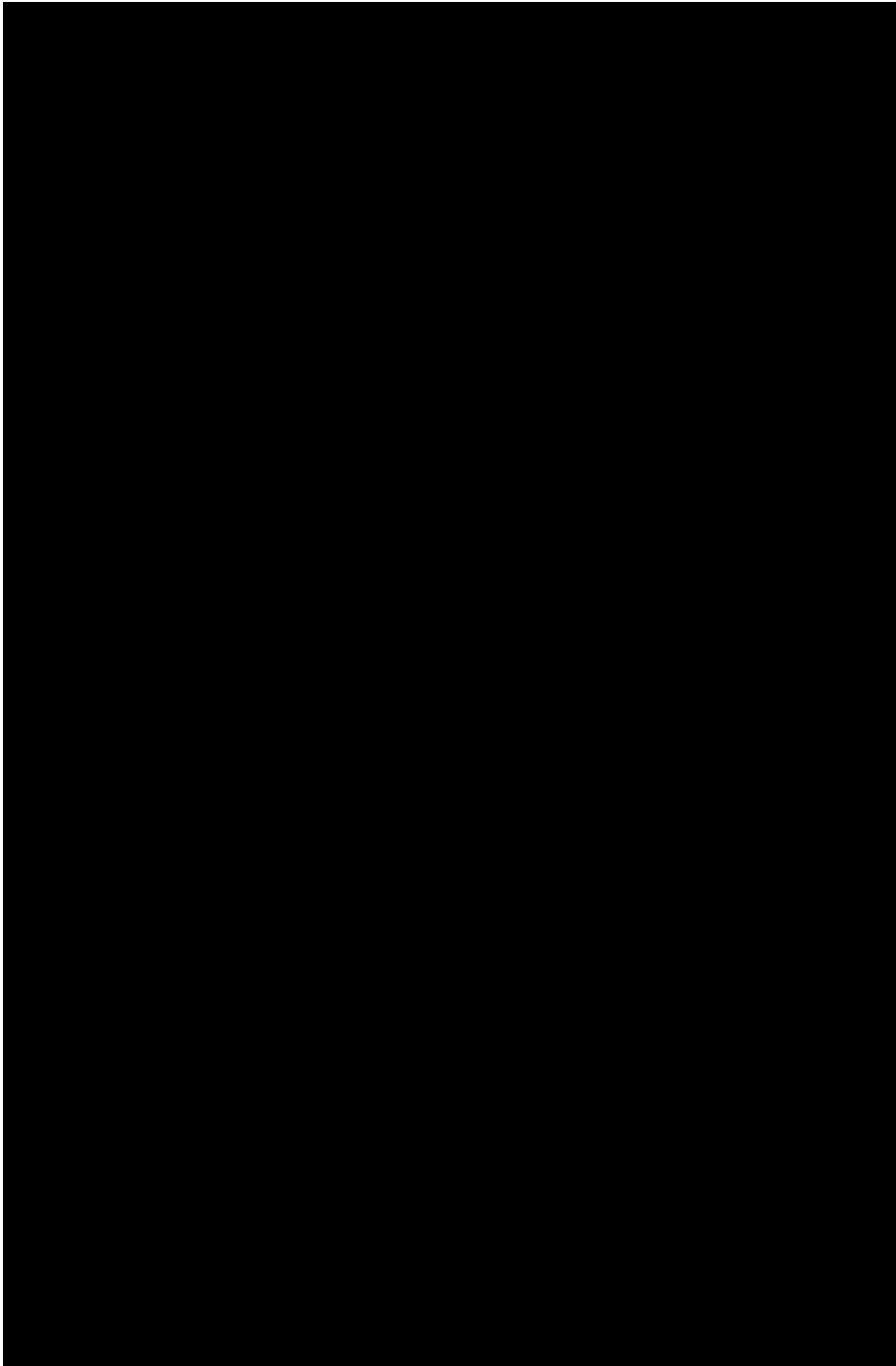
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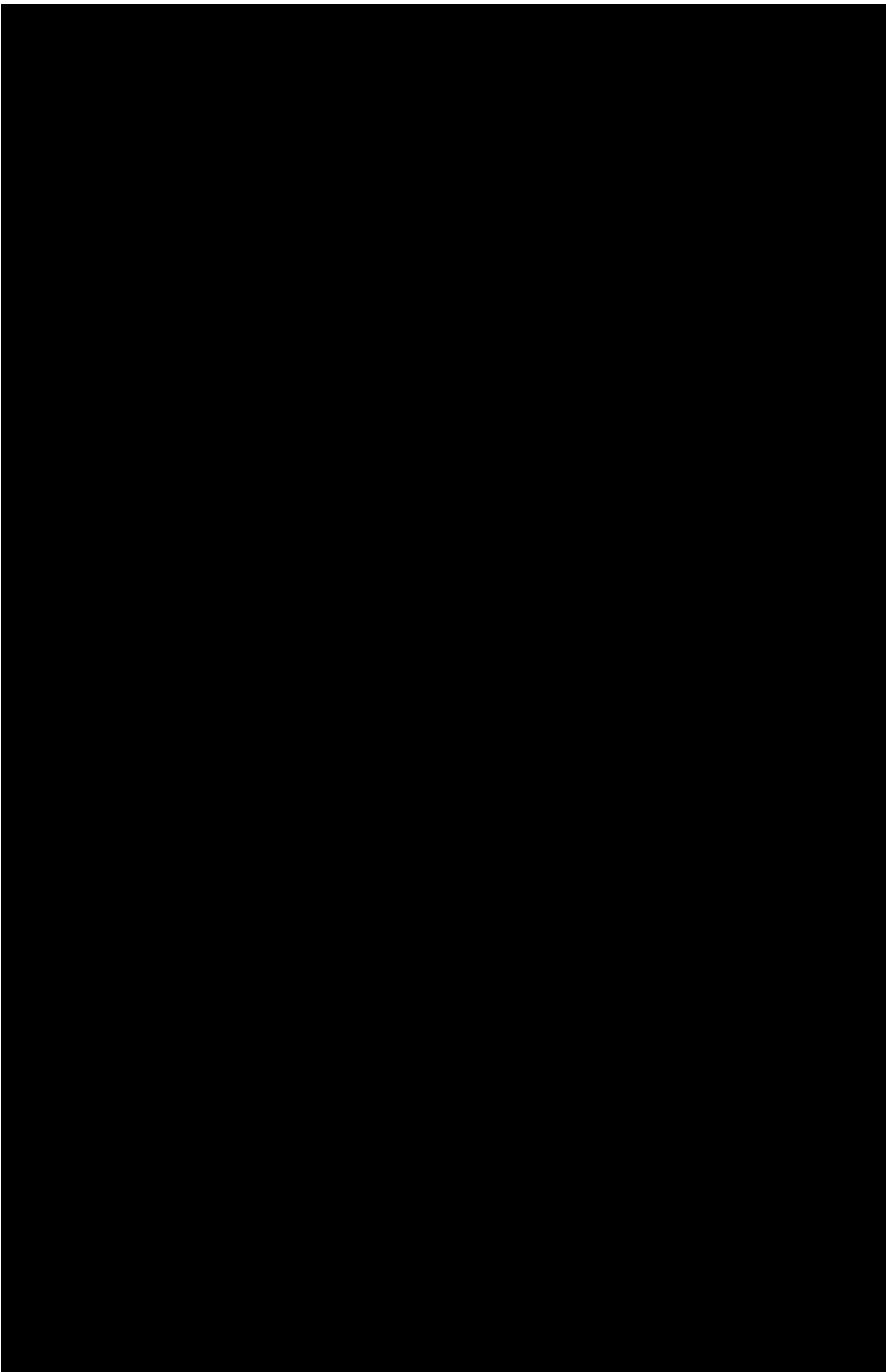
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Attachment Y-1

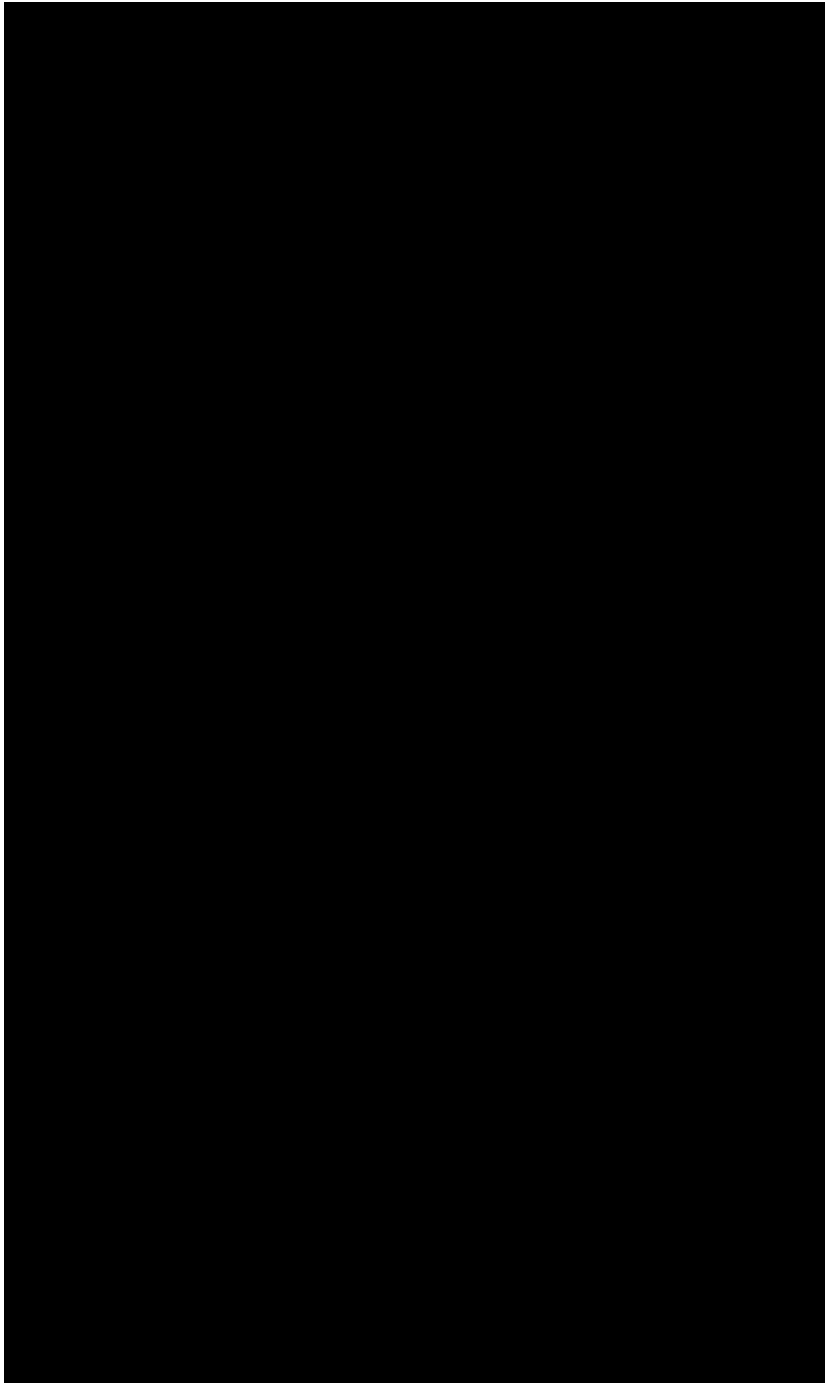
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Attachment Y-1

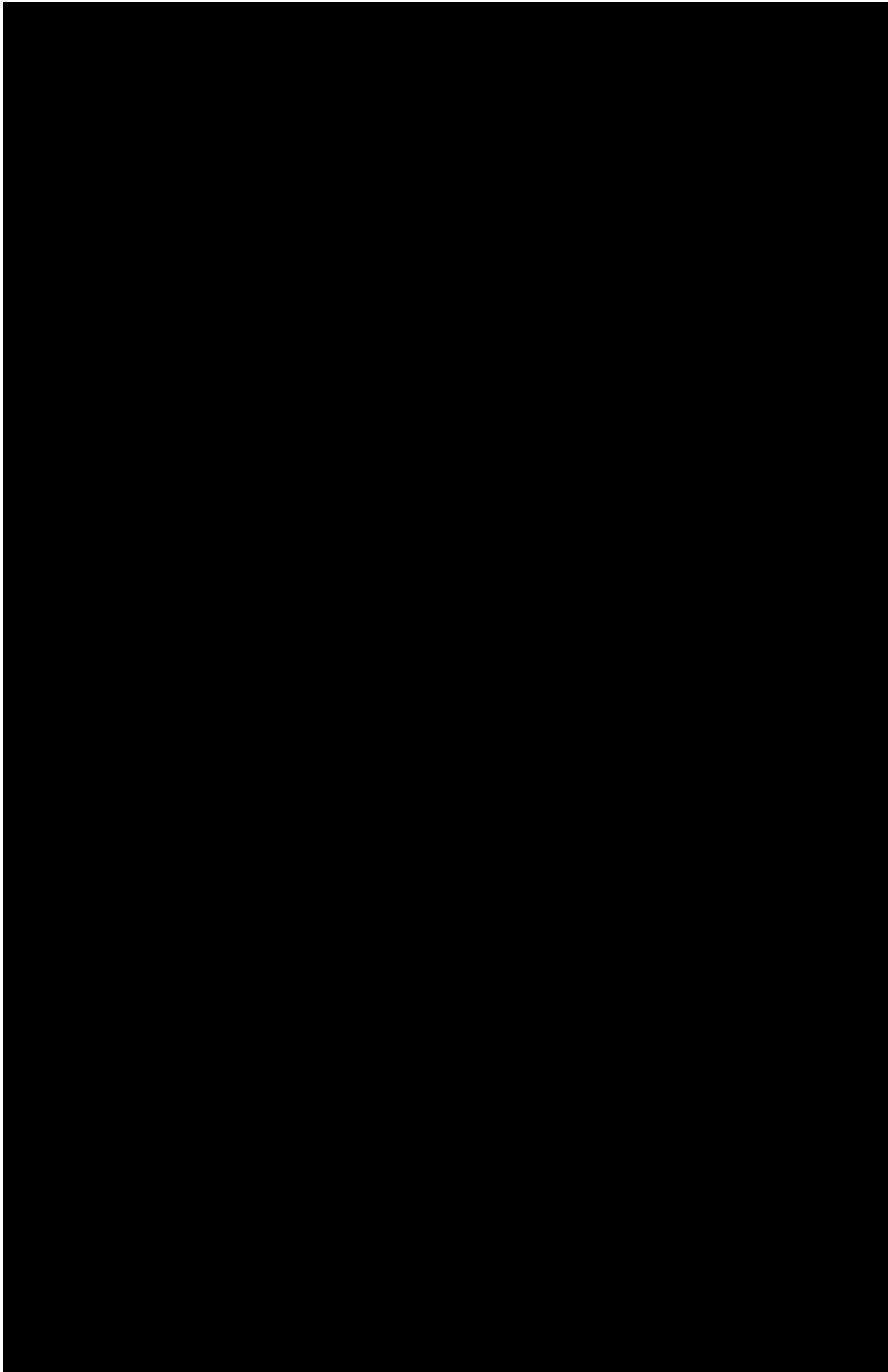
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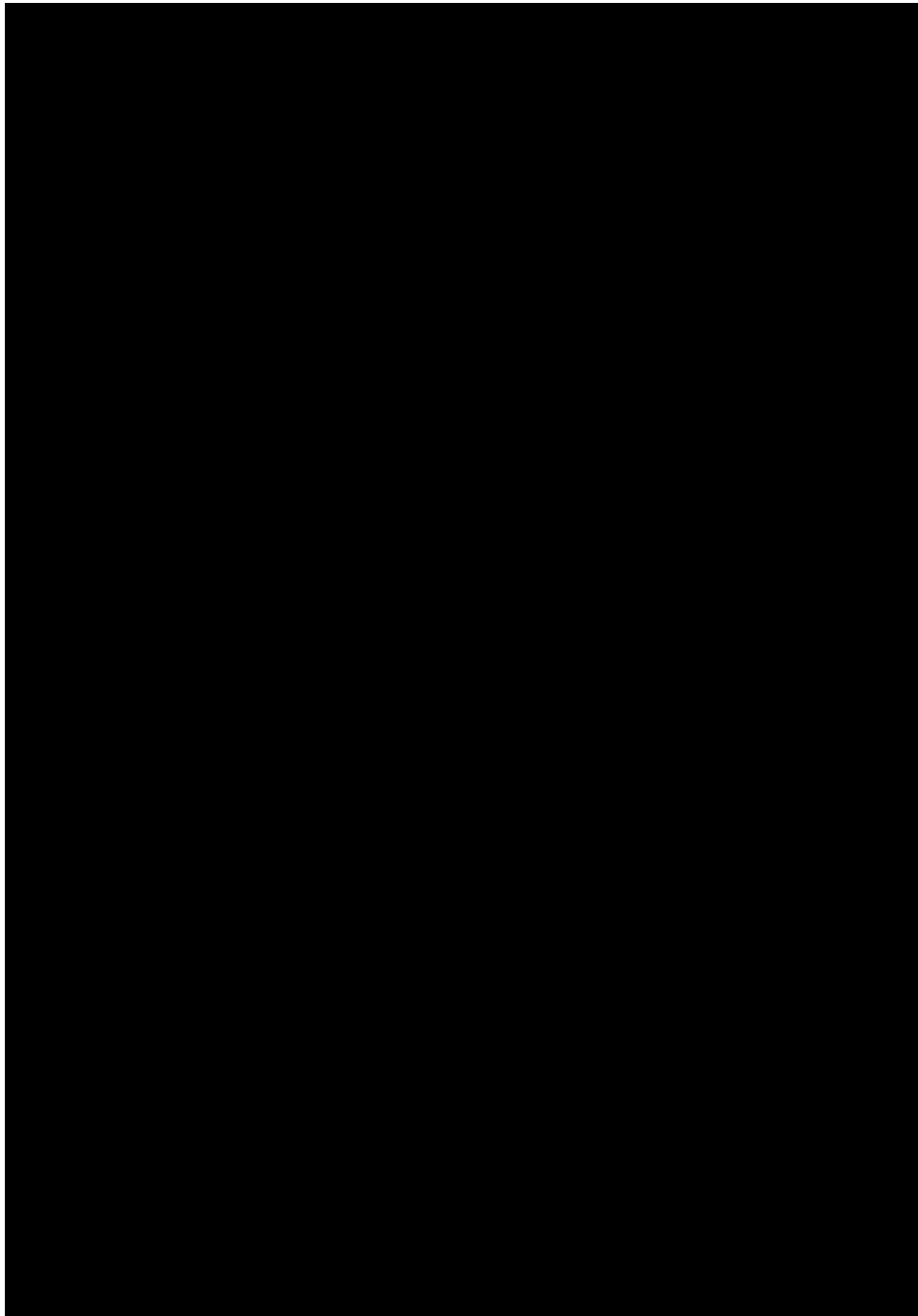
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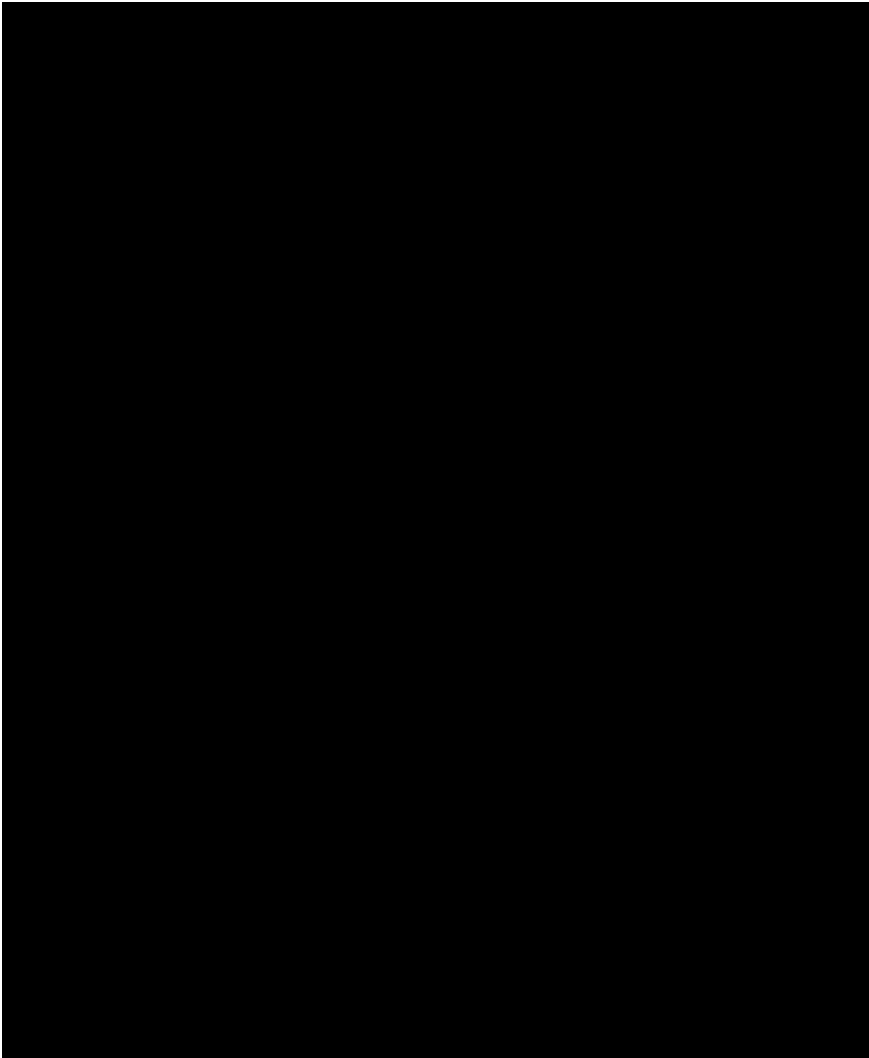
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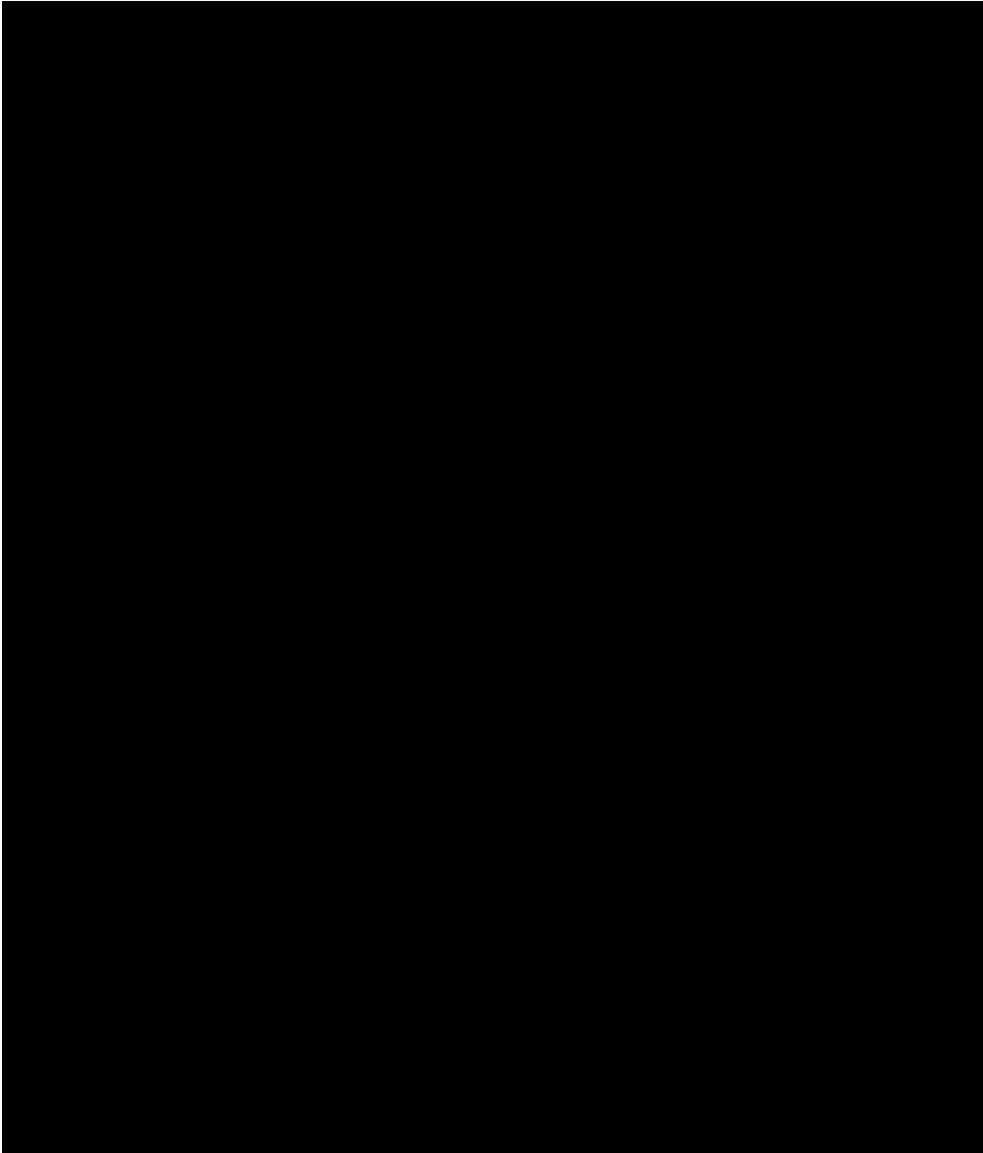
PROTECTIVE ORDER MATERIAL

Attachment Y-1

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Attachment Y-2

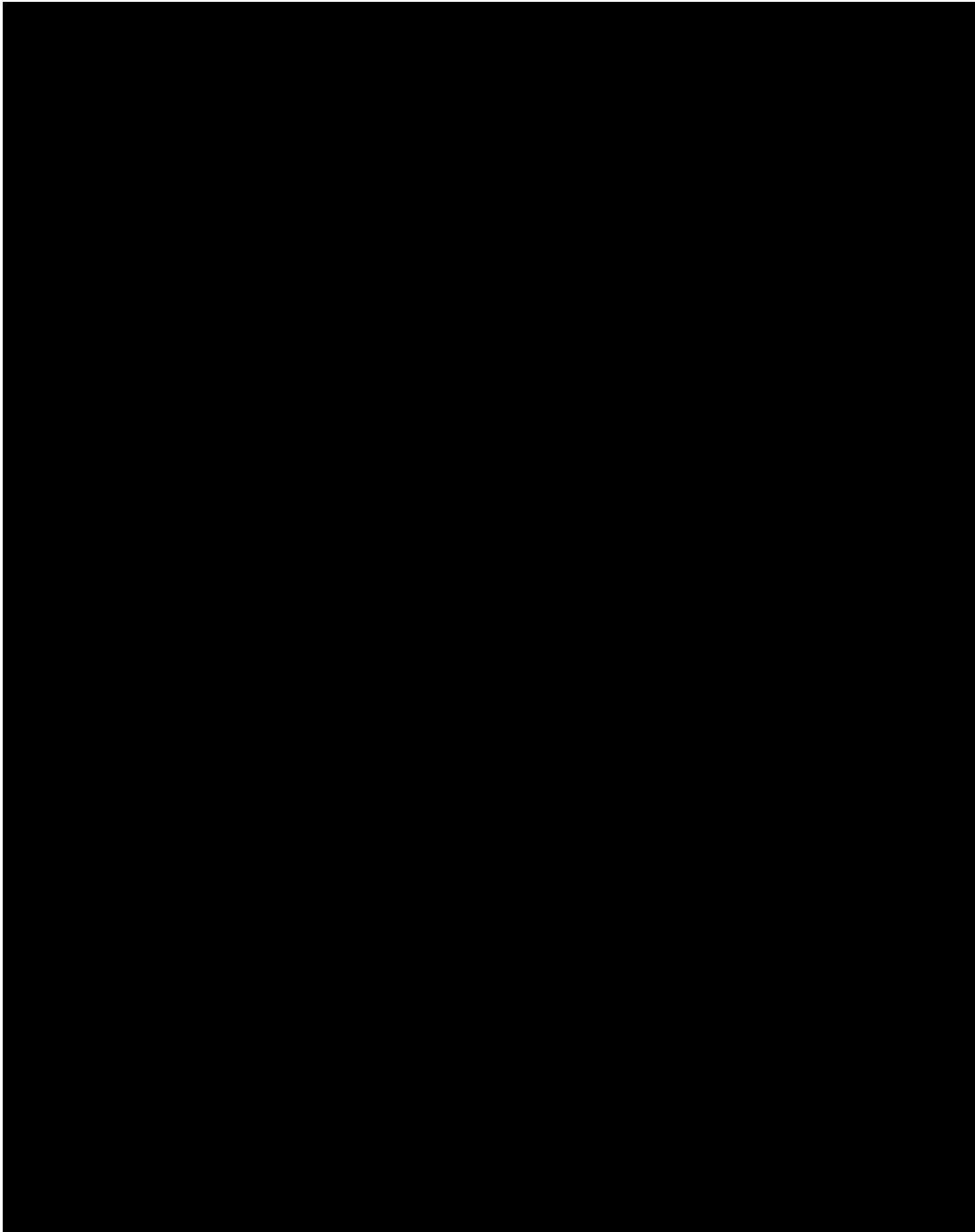
Log File for Appending Data into Final Complete Dataset



PROTECTIVE ORDER MATERIAL

Attachment Y-2

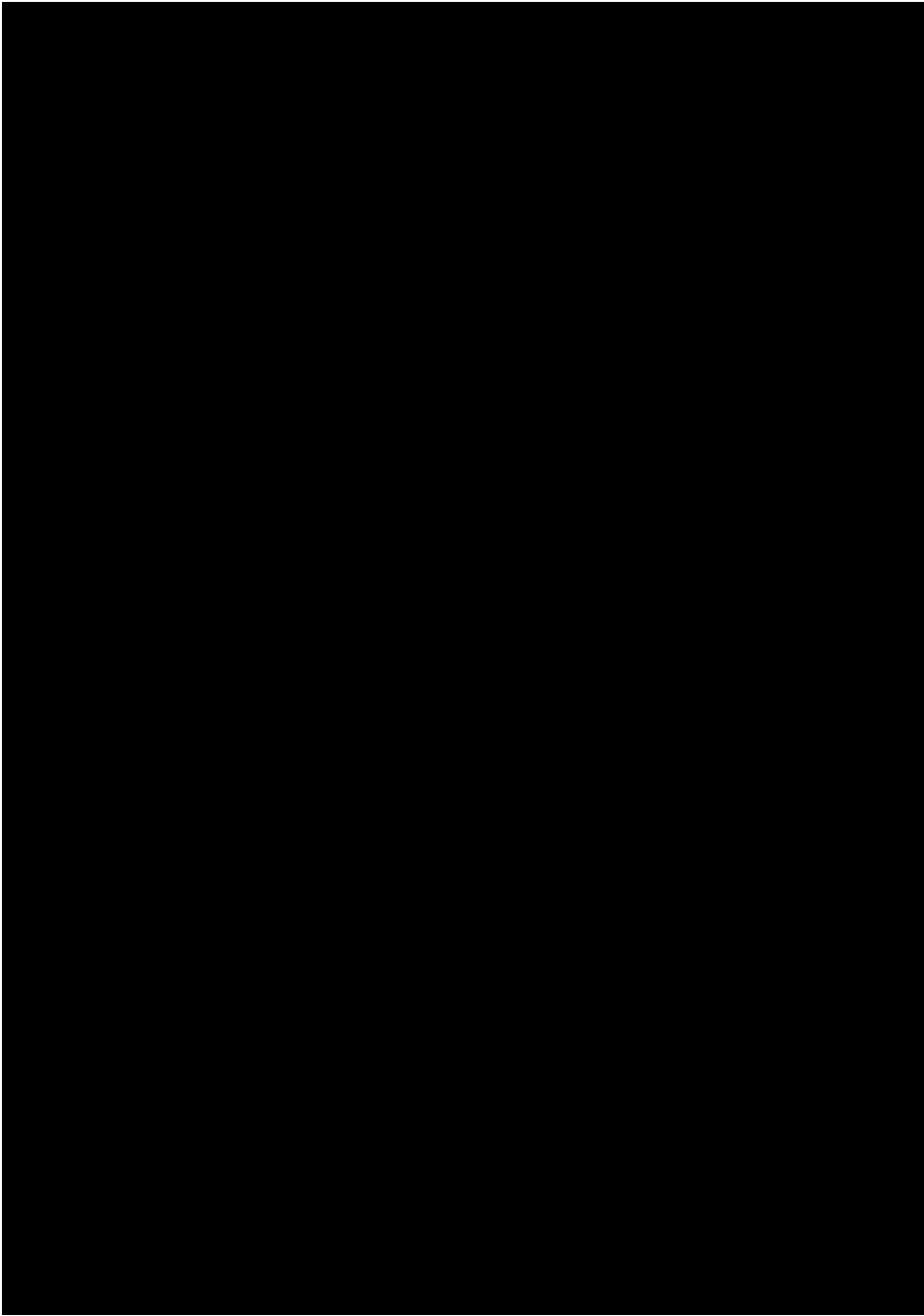
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Attachment Y-2

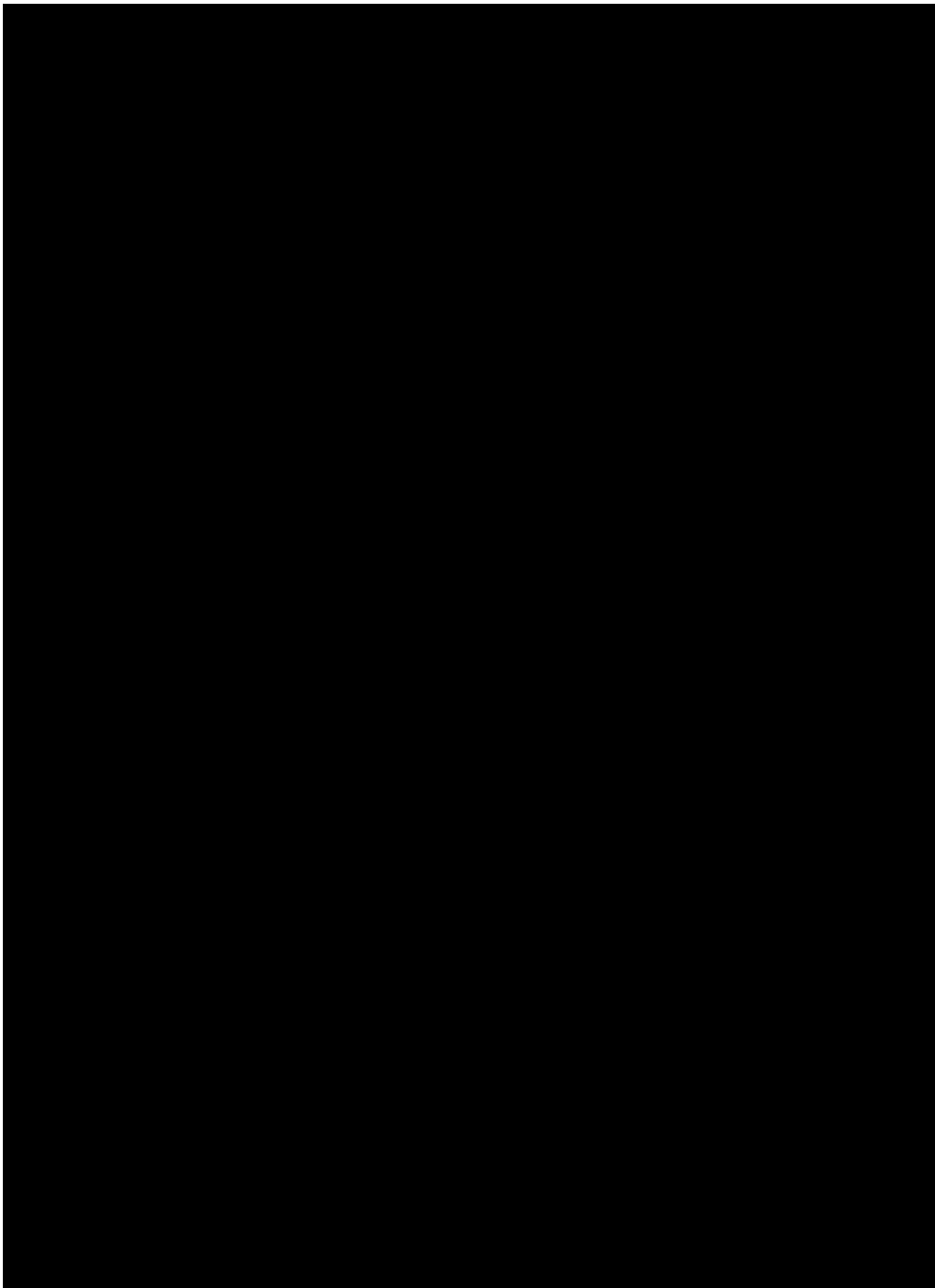
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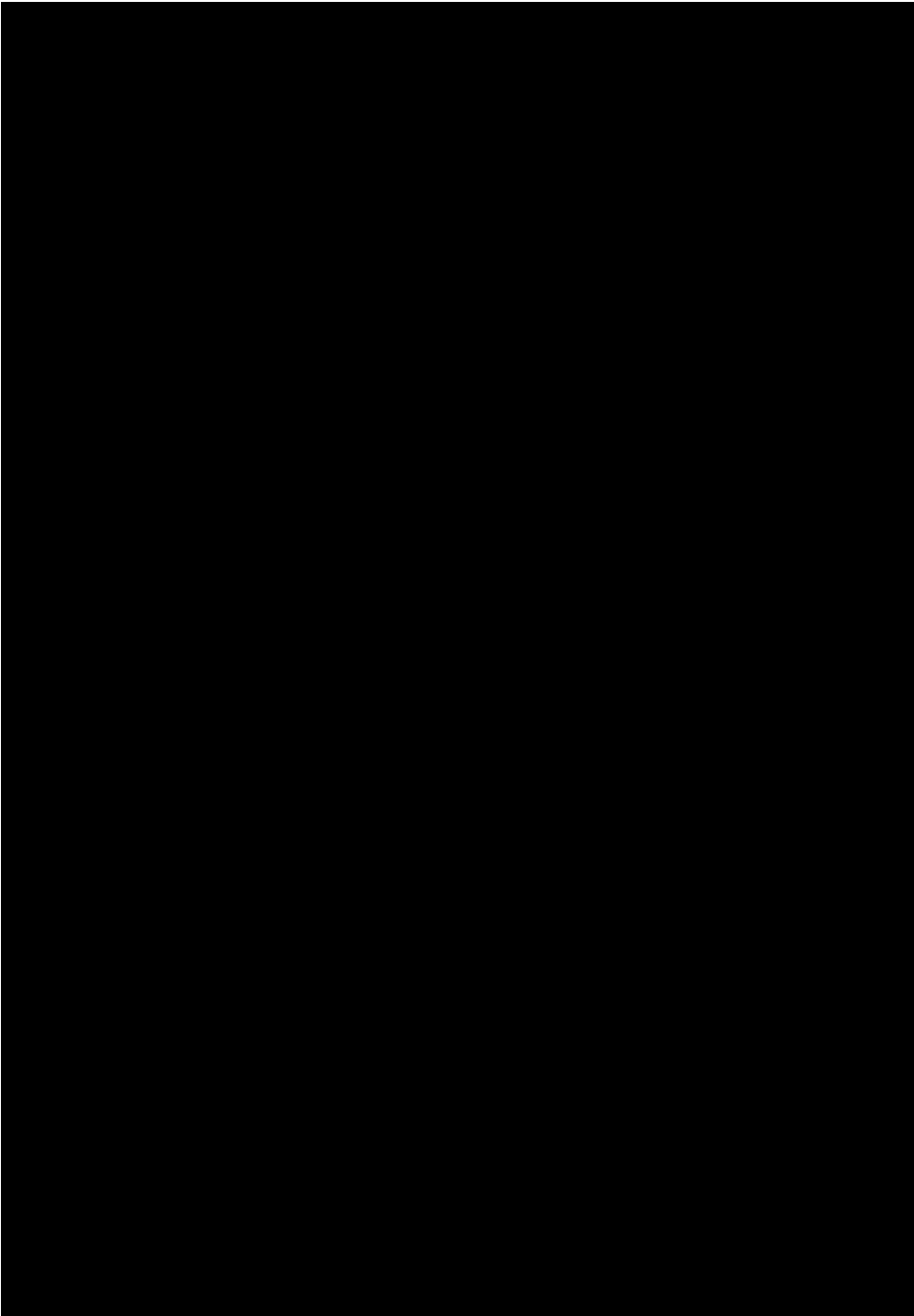
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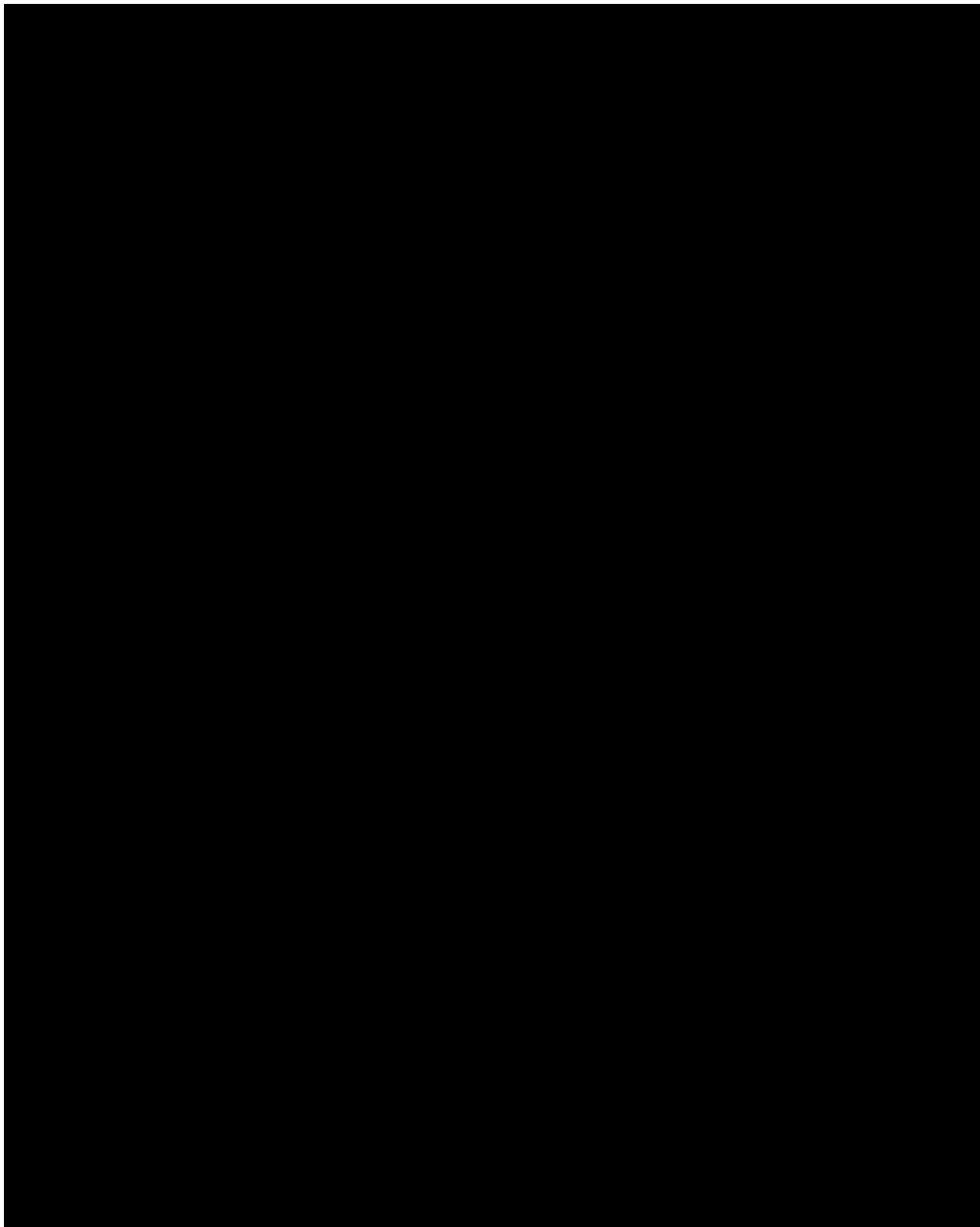
PROTECTIVE ORDER MATERIAL

Attachment Y-2

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Attachment Y-3

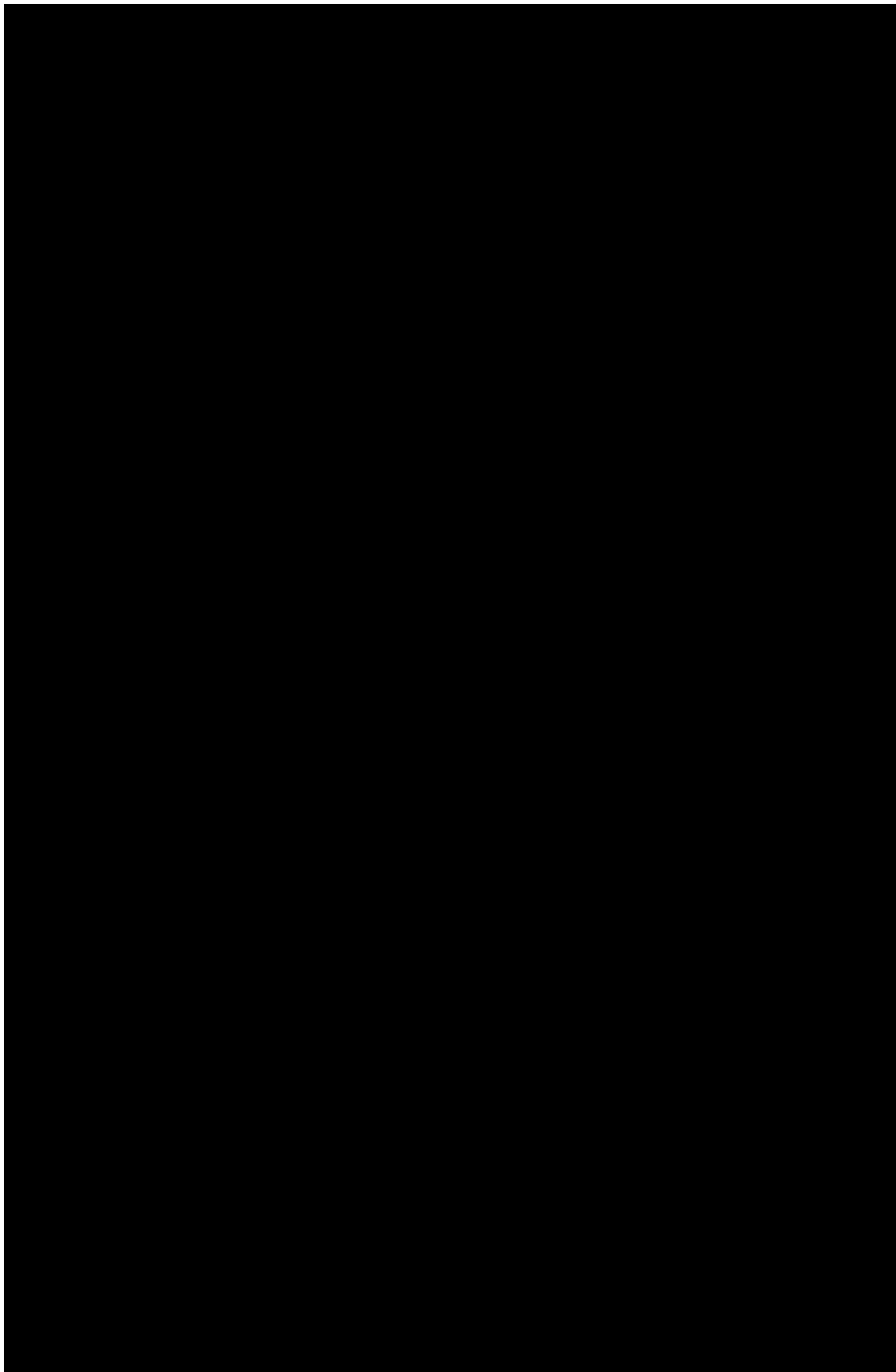
Log File for Attachment X-3



PROTECTIVE ORDER MATERIAL

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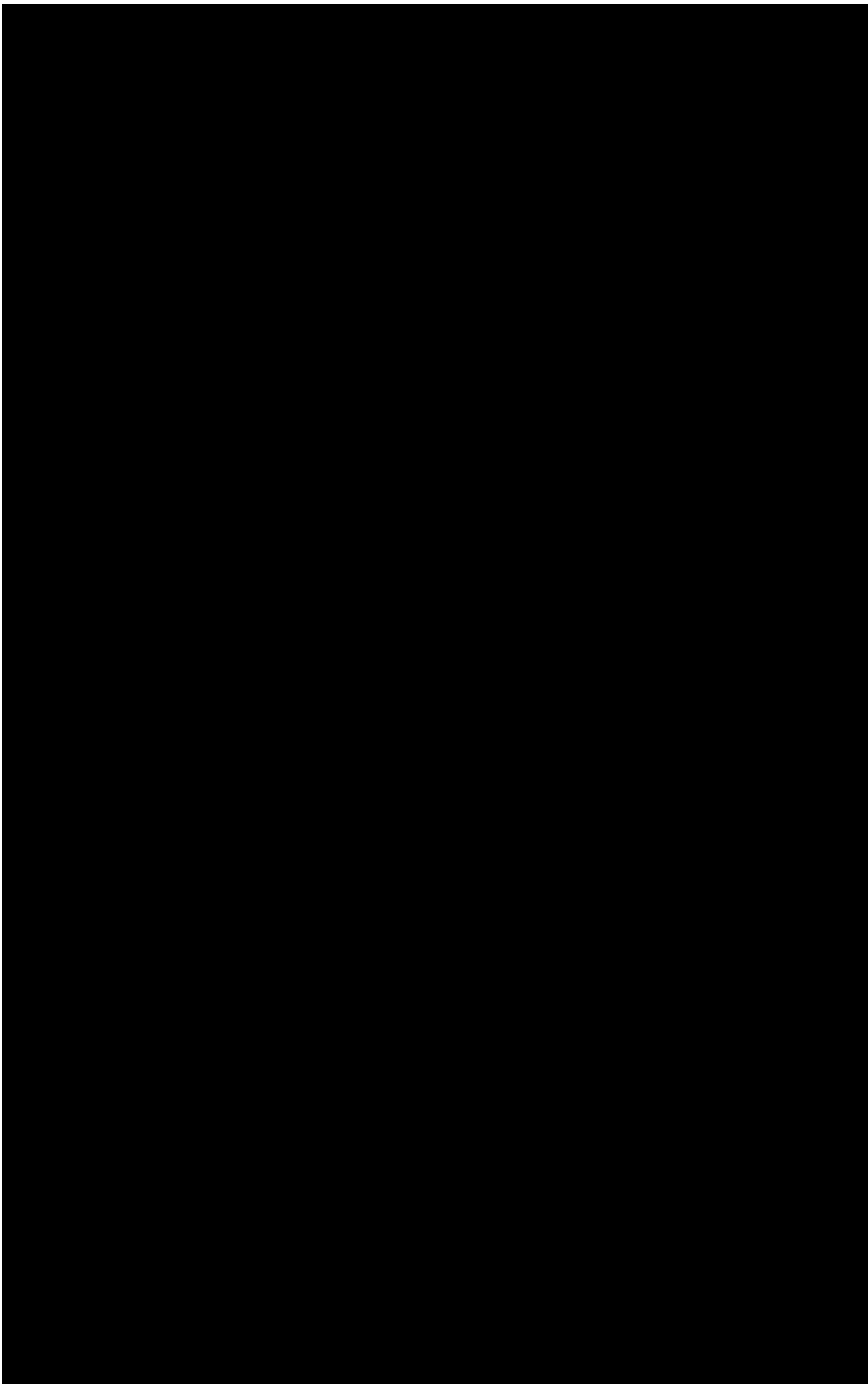
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Attachment Y-3

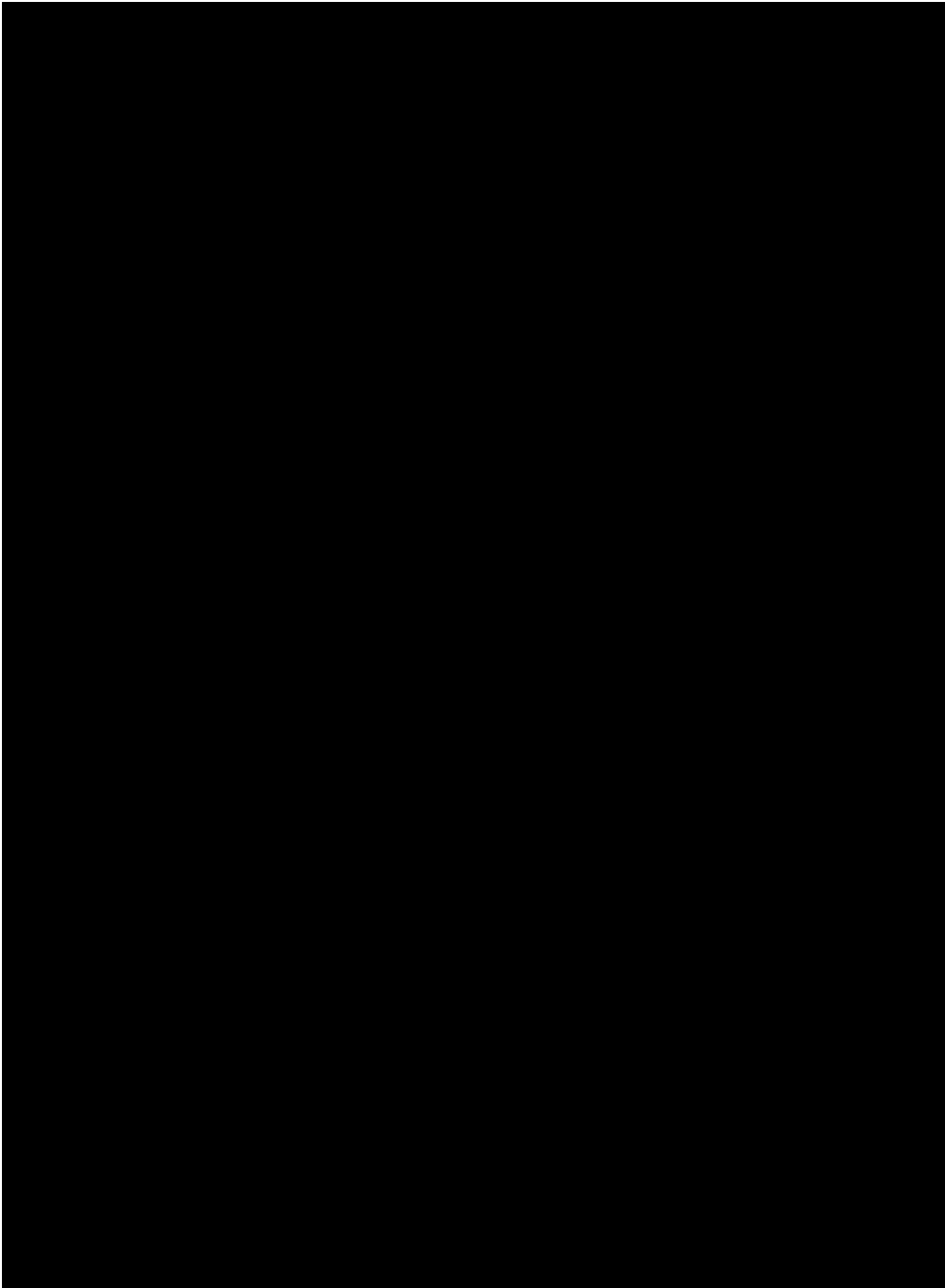
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Attachment Y-3

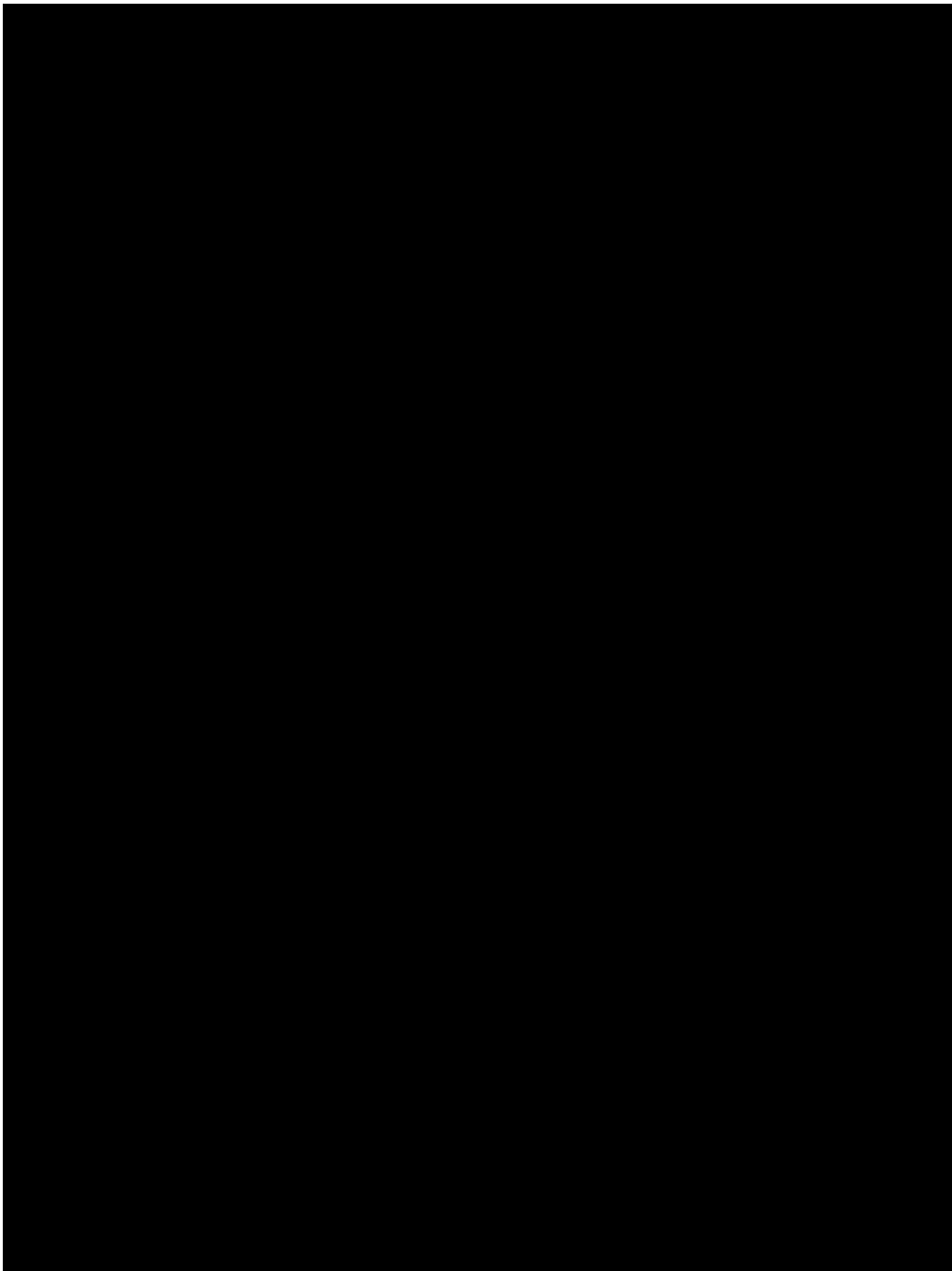
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Attachment Y-3

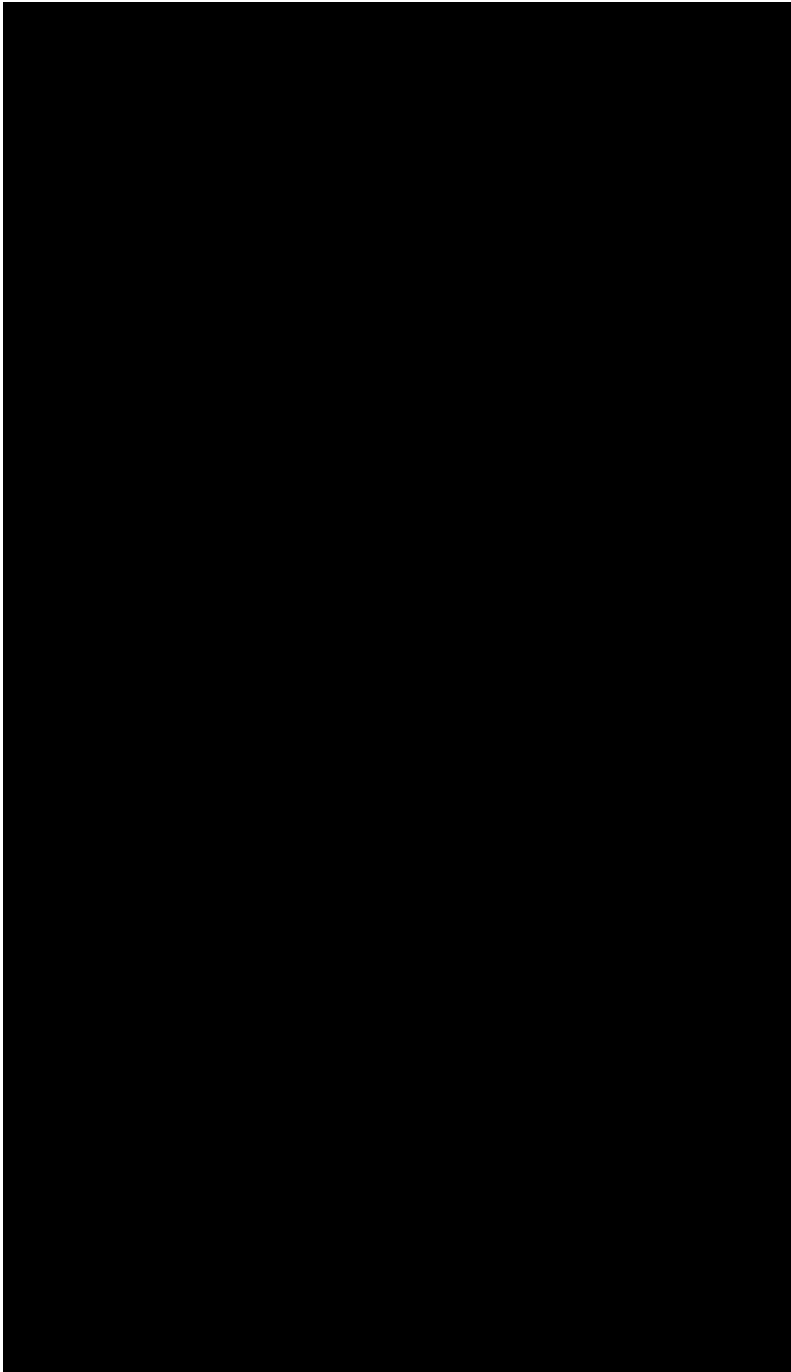
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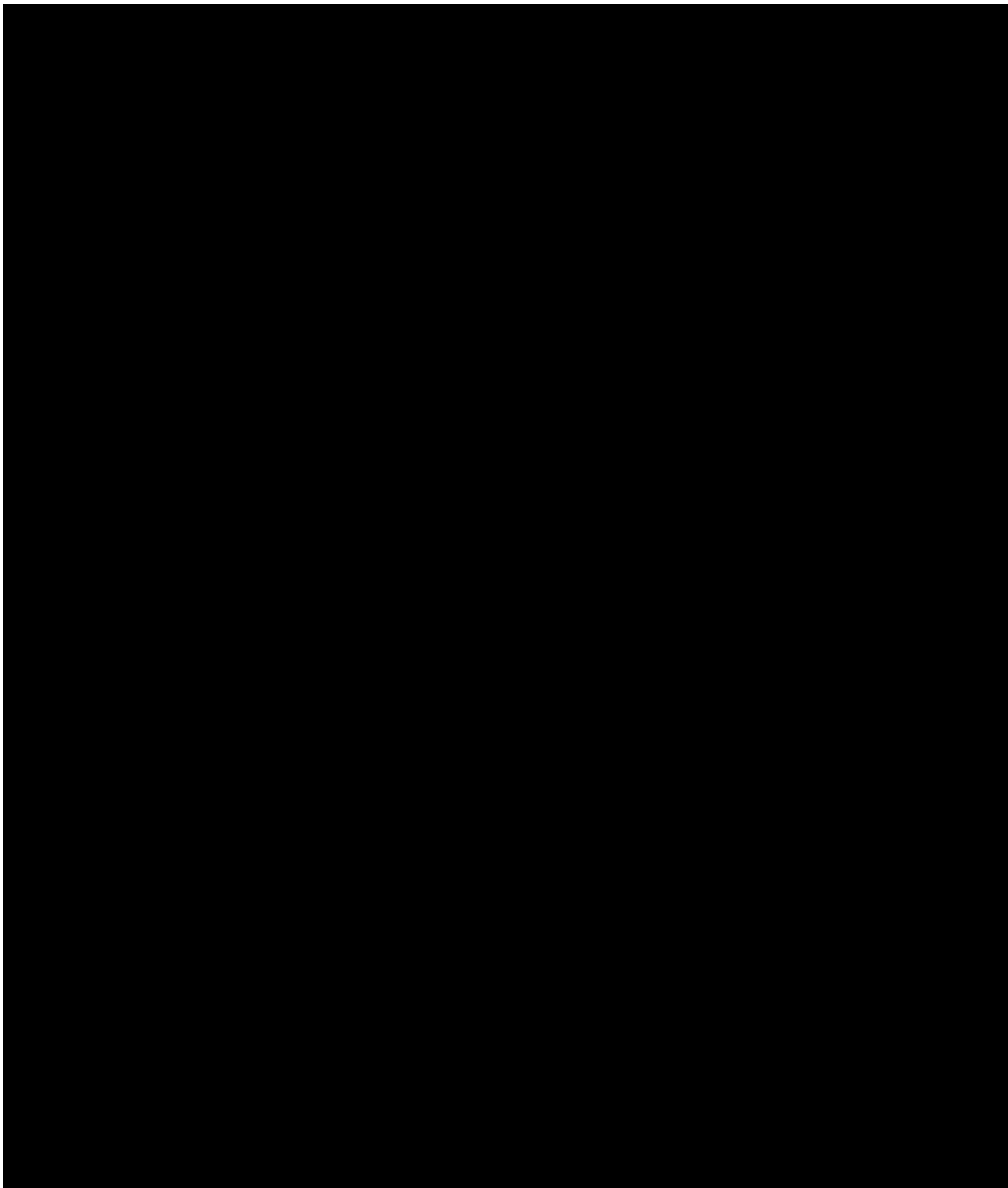
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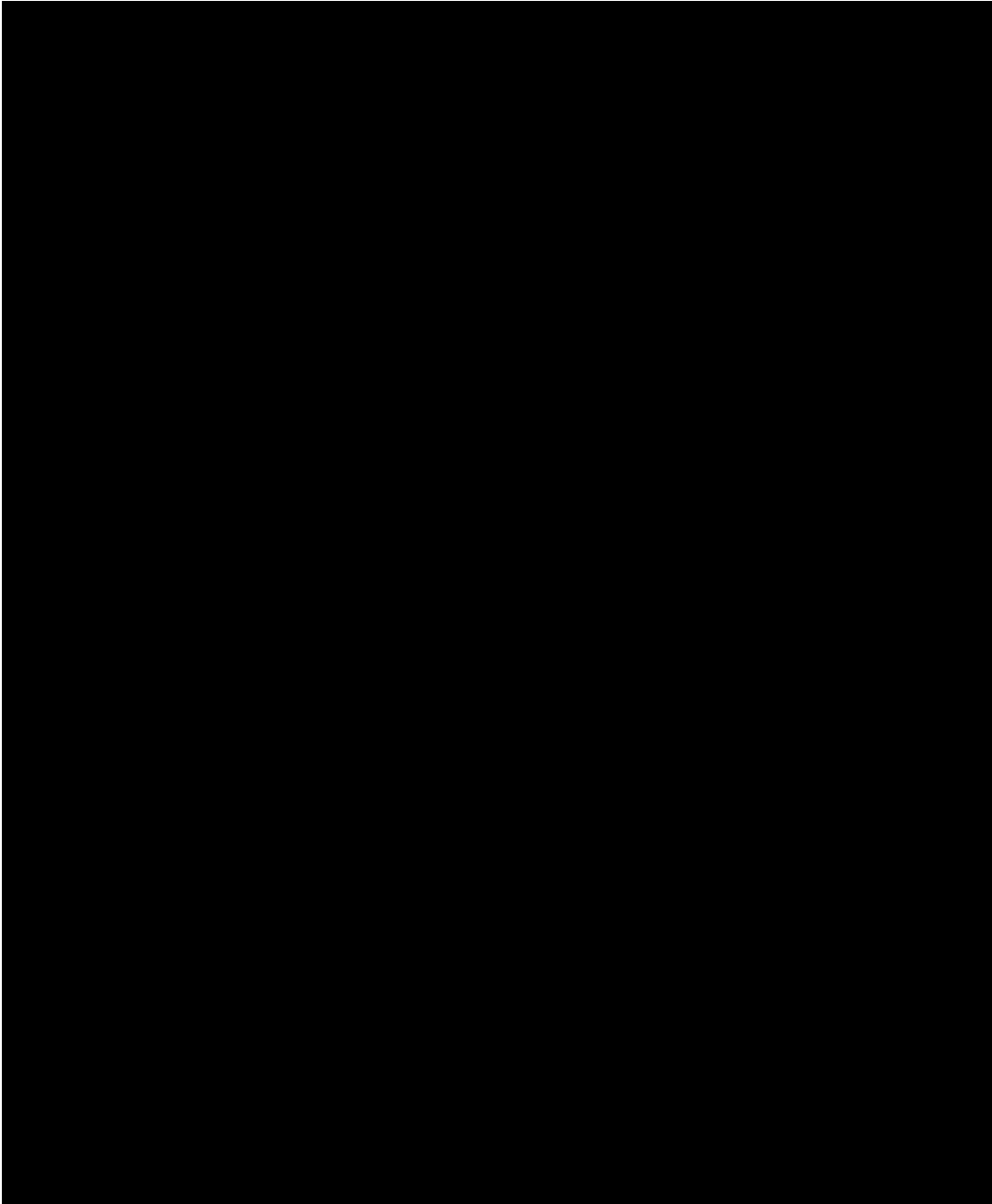
PROTECTIVE ORDER MATERIAL

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Attachment Y-4

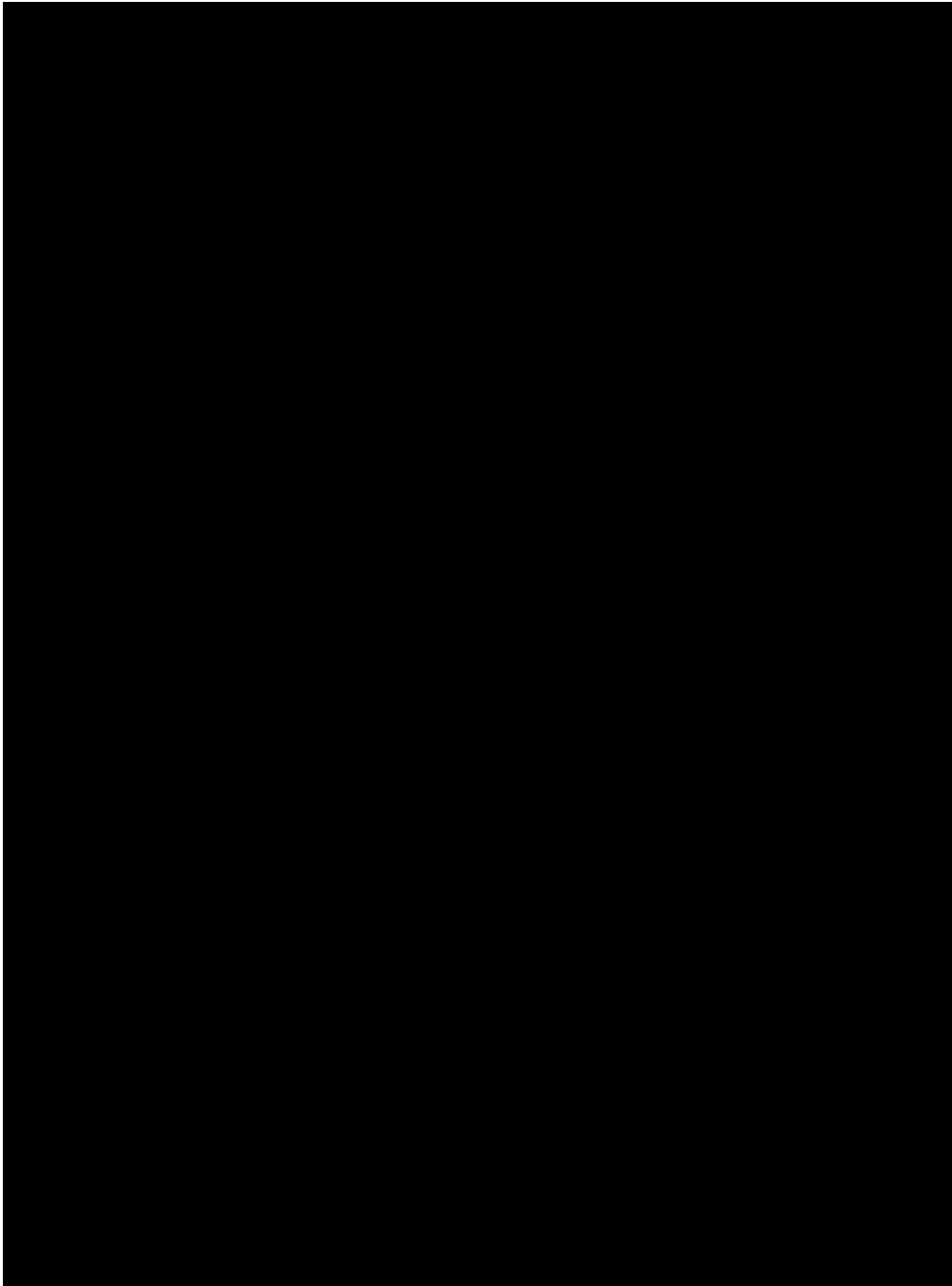
Log File for Attachment E-1



PROTECTIVE ORDER MATERIAL

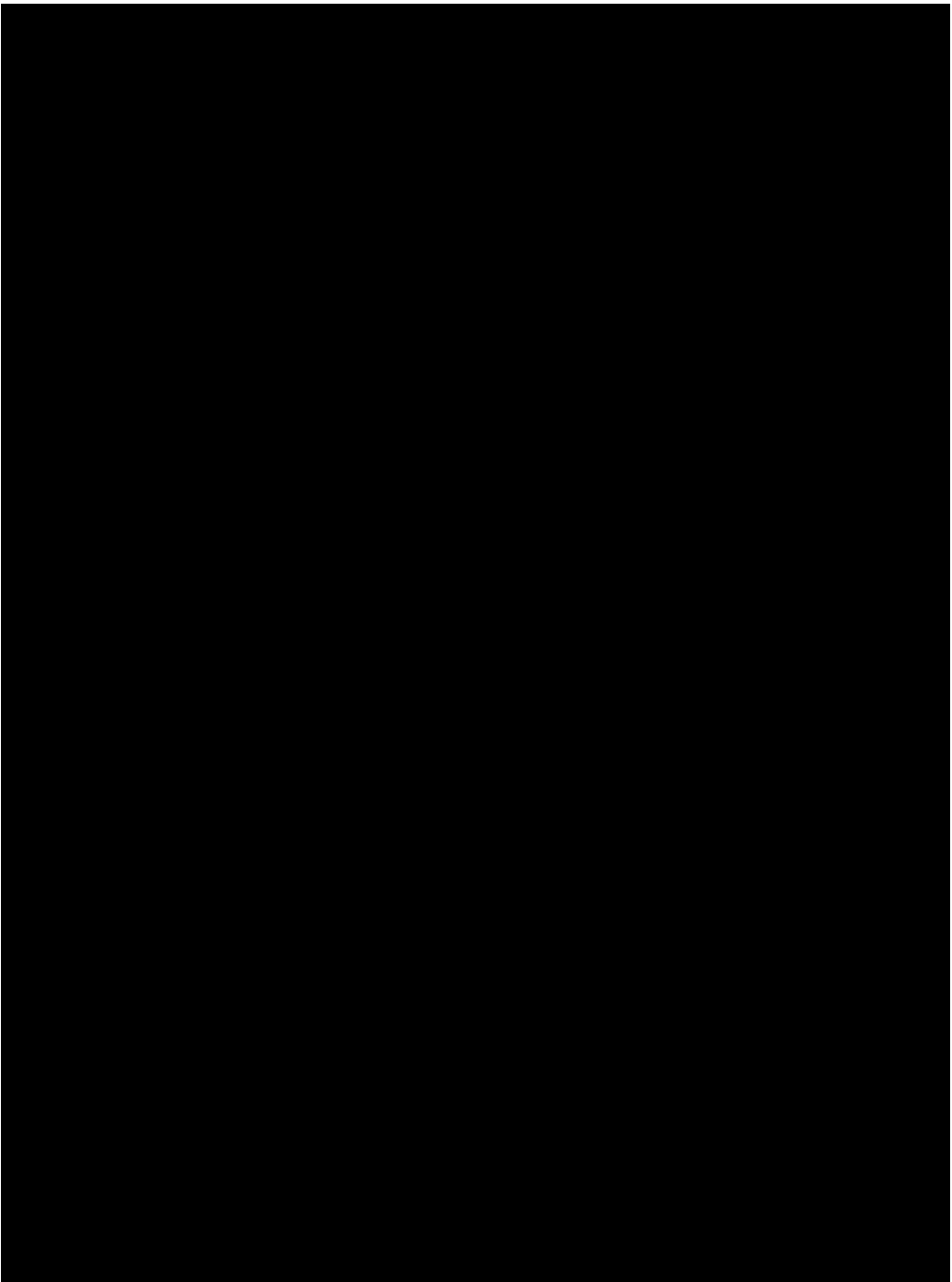
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PROTECTIVE ORDER MATERIAL

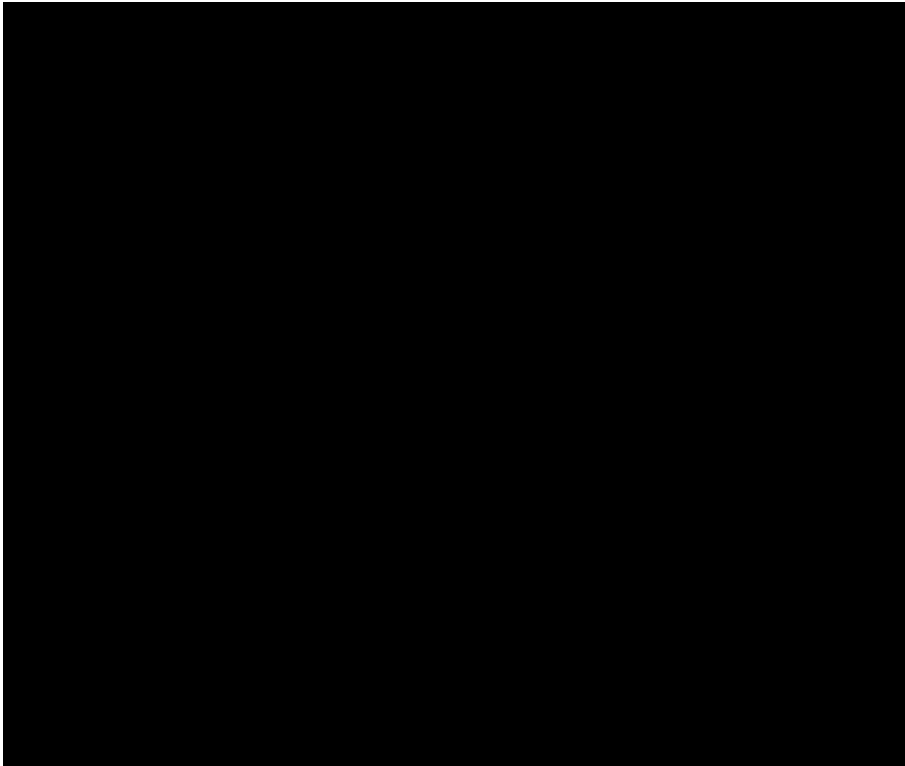
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Attachment Y-4

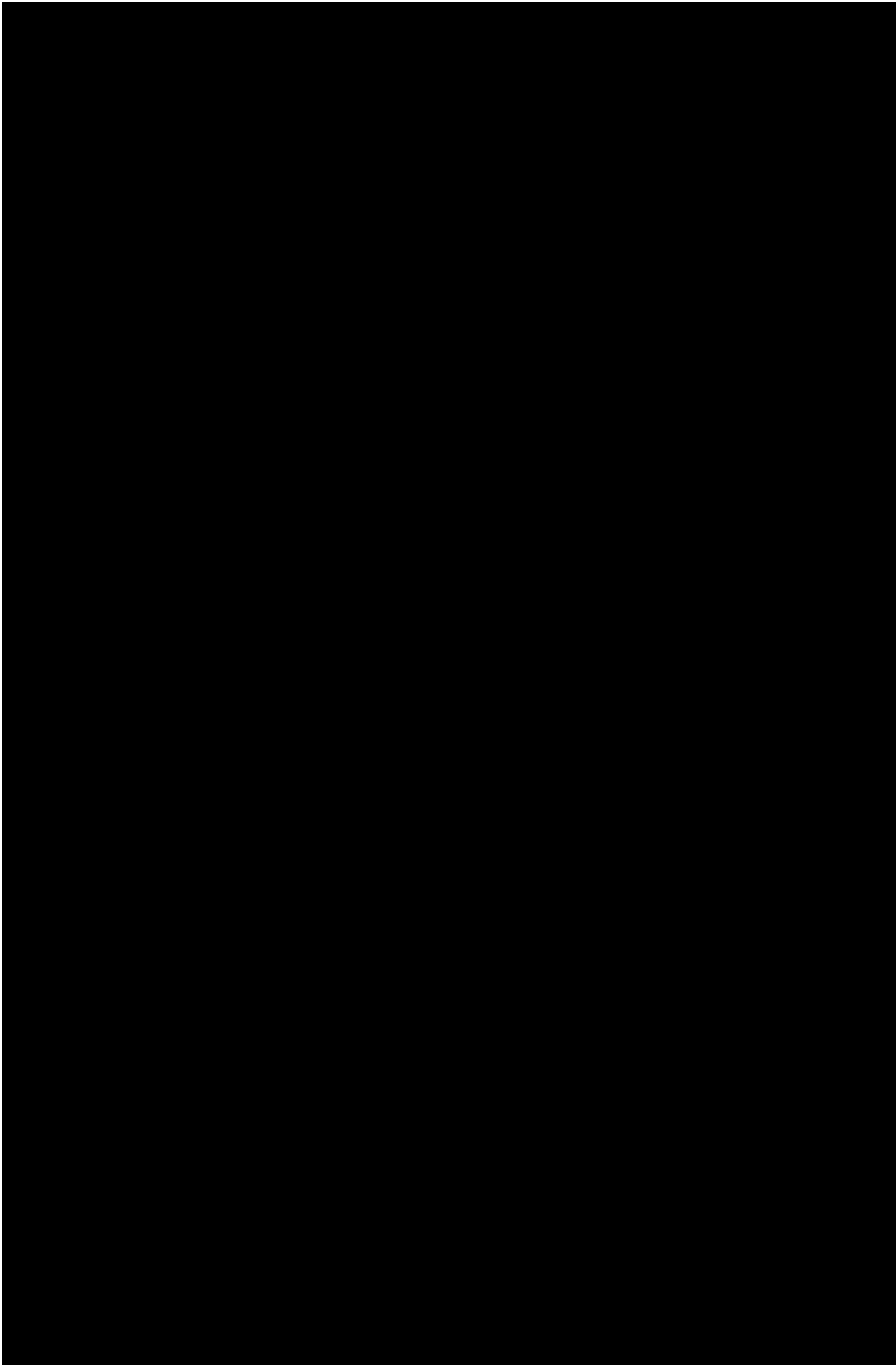
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Attachment Y-4

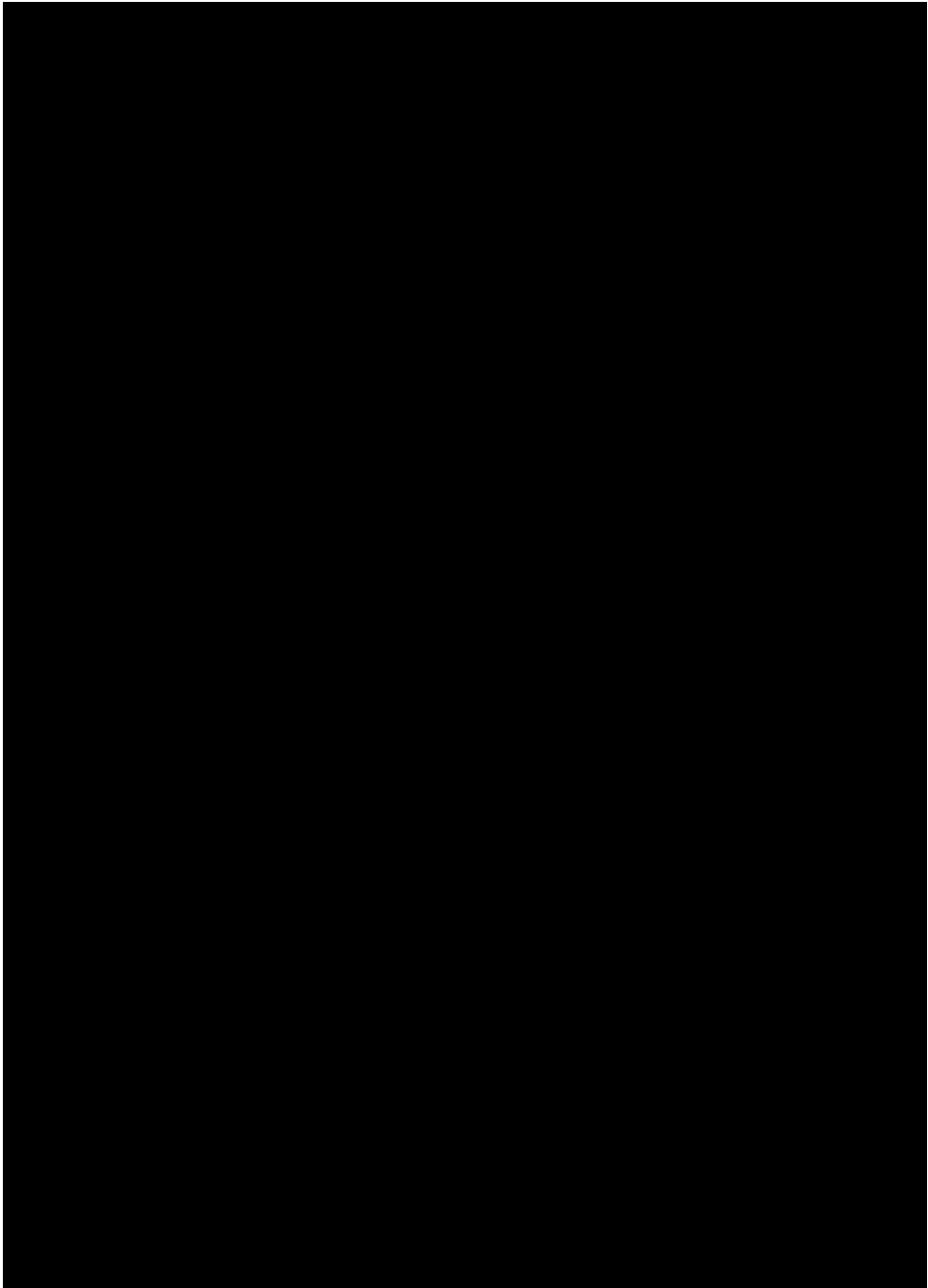
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Attachment Y-4

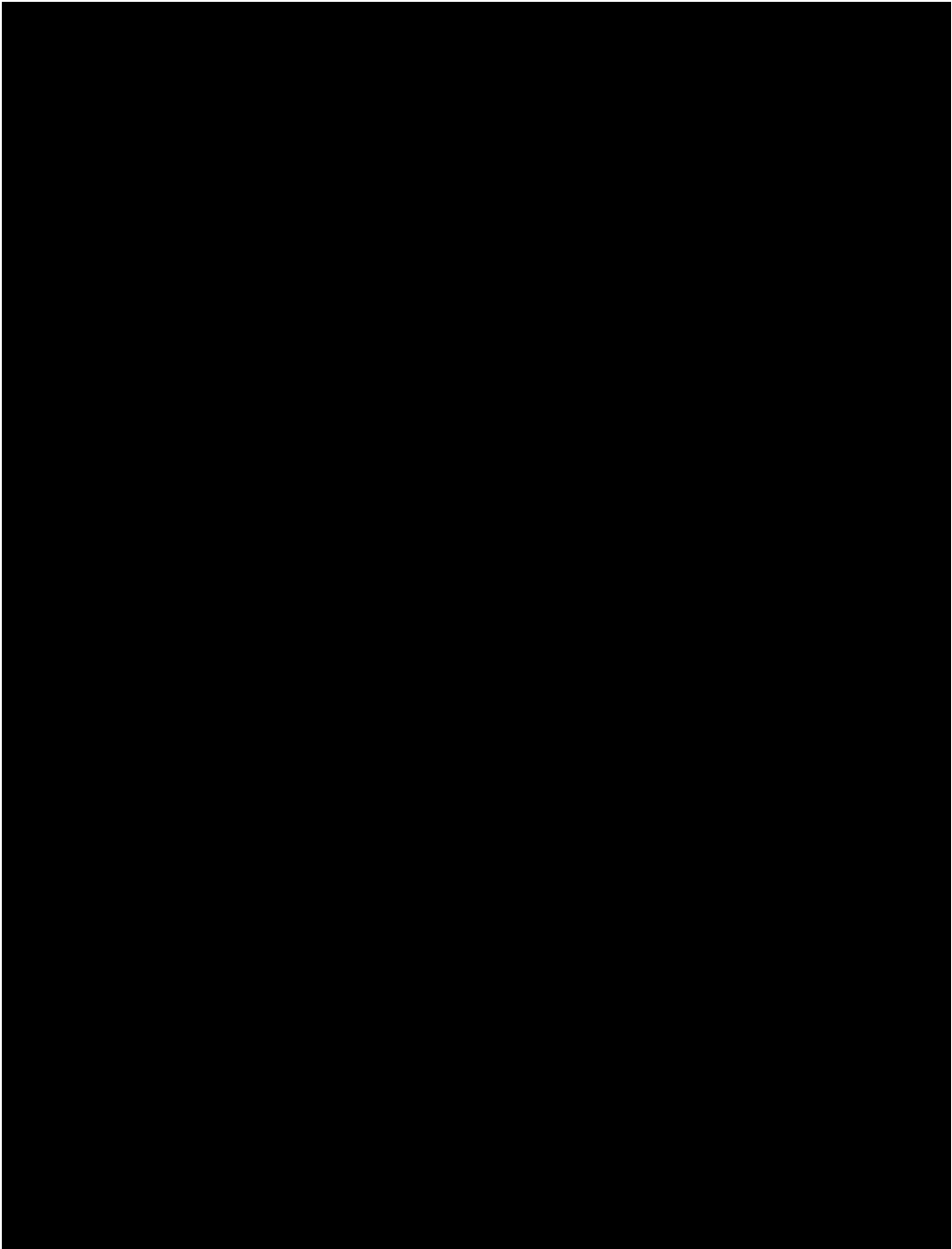
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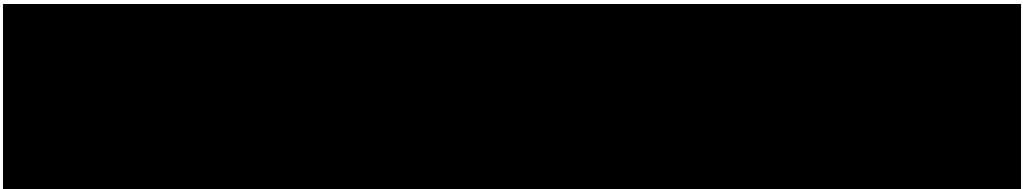
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