

**Tabela 215.**
**Definicje punktów końcowych ocenianych w badaniach jednoramiennych włączonych do analizy efektywności klinicznej deferazyroksu**

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## 10.6. Ocena homogeniczności

Nie wykonywano oceny homogeniczności dla badań jednoramiennych, ponieważ ze względu na metodykę tych badań metaanalizy dla nie będą wykonywane.

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## 10.7. Podsumowanie analizy bezpieczeństwa na podstawie badań jednoramiennych

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## II. Przegląd systematyczny – Część II

Część II analizy dotyczy natomiast oceny skuteczności i bezpieczeństwa deferazyroksu w populacji chorych po przeszczepieniu tkanek.

### 11. Metodyka

#### 11.1. Źródła danych

Zgodnie z Wytycznymi AOTM w celu odnalezienia badań pierwotnych i wtórnych, przeszukiwano następujące bazy informacji medycznej:

- Medline (z wykorzystaniem wyszukiwarki Ovid),
- Embase (z wykorzystaniem wyszukiwarki Ovid),
- Cochrane Library (w tym The Cochrane Central Register of Controlled Trials – CENTRAL).

Dodatkowo przeszukano bazę *Centre for Reviews and Dissemination* (CRD) oraz rejestry badań klinicznych: *National Institutes of Health* i *Current Controlled Trials Register*.

W celu wykonania pełnej oceny bezpieczeństwa ocenianej technologii medycznej przeszukano również publikacje urzędów zajmujących się nadzorem i monitorowaniem bezpieczeństwa produktów leczniczych: EMA (ang. *European Medicines Agency* – Europejska Agencja Medyczna), FDA (ang. *Food and Drug Administration* – Amerykańska Agencja ds. Żywności i Leków) oraz Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (URPLWMI PB).

Ponadto przeszukano odniesienia bibliograficzne, zawarte w publikacjach włączonych po selekcji abstraktów.

## 11.2. Kryteria włączenia i wykluczenia badań

Do analizy klinicznej zostały włączane badania spełniające kryteria zdefiniowane zgodnie ze schematem PICOS (ang. *population, intervention, comparison, outcome, study design* - populacja, interwencja, komparatory, punkty końcowe, metodyka), które zostały ustanowione *a priori* w protokole do przeglądu systematycznego.

### Kryteria włączenia badań:

- **populacja:** dorośli chorzy z przewlekłym obciążeniem żelazem, których podano zabiegowi przeszczepienia tkanek<sup>7</sup> (włączane będą również badania dotyczące populacji obejmującej dorosłych oraz dzieci, jeśli dzieci nie stanowiły w badaniu znaczącej większości chorych (powyżej 50% chorych), w przypadku gdy dzieci stanowiły znaczącą większość chorych włączane będą tylko publikacje, w których przedstawiono wyniki w podziale na podgrupy dorosłych i dzieci);
- **interwencja:** deferazyroks w dawce 20-30 mg, chyba że w badaniu podano łączny wynik dla szerszego zakresu dawek<sup>8</sup>;

- [REDACTED]

[REDACTED]

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<sup>7</sup> analiza problemu decyzyjnego wskazuje, że obciążenie żelazem występuje najczęściej u chorych poddawanych przeszczepieniu macierzystych komórek krwiotwórczych;

<sup>8</sup> włączano badania, w których zakres stosowanych dawek był szerszy niż 20 do 30 mg, jednak mediana lub średnia dla dawki leku stosowanej w czasie okresu obserwacji nie różniła się znacząco od zalecanych dawek (nie zaleca się stosowania dawek wyższych niż 40 mg ponieważ istnieje ograniczone doświadczenie z zastosowaniem dawek tej wysokości)

- 
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- [REDACTED]
- [REDACTED]
- **punkty końcowe:** wszystkie istotne klinicznie punkty końcowe, m.in. jakość życia, zmiana poziomu żelaza w wątrobie, zmiana poziomu żelaza w sercu, zmiana poziomu ferrytyny oraz profil bezpieczeństwa;
  - **metodyka:**
    - badania wtórne takie jak: przeglądy systematyczne spełniające kryterium populacji i interwencji (zgodnie z *Rozporządzeniem Ministra Zdrowia z dnia 2 kwietnia 2012 r. w sprawie minimalnych wymagań, jakie muszą spełniać analizy uwzględnione we wnioskach o objęcie refundacją i ustalenie urzędowej ceny zbytu oraz o podwyższenie urzędowej ceny zbytu leku, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego, które nie mają odpowiednika refundowanego w danym wskazaniu*) i metaanalizy;
    - badania eksperymentalne (ocena skuteczności klinicznej i bezpieczeństwa), badania obserwacyjne (ocena skuteczności rzeczywistej i ocena bezpieczeństwa), badania jedno<sup>9</sup> i dwuramienne<sup>10</sup>;

---

<sup>9</sup> W przypadku badań jednoramiennych włączano badania dotyczące jedynie ocenianej interwencji w celu poszerzenia oceny skuteczności i bezpieczeństwa deferazyroksu. Poszerzonej dodatkowej analizy skuteczności i bezpieczeństwa nie przeprowadzono dla deferoksaminy, gdyż jest to lek o udowodnionej skuteczności i bezpieczeństwie, stosowany w Polsce od 20 lat. Wydaje się więc być zasadnym poszerzenie analizy o wyniki z badań jednoramiennych tylko dla deferazyroksu.

<sup>10</sup> W przypadku badań z dwoma lub większą liczbą ramion uwzględniano również dane dla pojedynczych grup chorych;

w przypadku braku badań „head-to-head” włączane będą badania umożliwiające wykonanie porównań pośrednich, publikacje w językach: polskim, angielskim, niemieckim, francuskim.

#### Kryteria wykluczenia badań:

- **populacja:** niezgodna z powyższymi kryteriami włączenia, np. dzieci, chorzy z pierwotnym obciążeniem żelazem;
- **interwencja:** inna niż wyżej wymieniona;
- **komparator:** niezgodne z założonymi w *Analizie problemu decyzyjnego* [rozdział 5], inny niż wyżej wymieniony – kryterium tylko dla bezpośredniego porównania deferazyroksu względem komparatora, dla badań do porównania pośredniego i jednoramiennych komparator nie był powodem wykluczenia;
- **punkty końcowe:** nieistotne w analizie, np. farmakokinetyka, farmakodynamika itp.;
- **metodyka:** przeglądy niesystematyczne (nie spełniające kryteriów Cook'a [22]), opisy pojedynczych przypadków (nie wykluczano jednak badań, w których początkowo włączano grupę chorych, a potem ostatecznie deferazyroks oceniano u pojedynczych chorych), badania opublikowane tylko w postaci abstraktów, opracowania poglądowe, publikacje z poważnymi ograniczeniami metodyki, które w znaczący sposób wpływają na wiarygodność wyników, publikacje w językach innych niż polski, angielski, niemiecki, francuski.

### 11.3. Strategia wyszukiwania

Zastosowano strategię wyszukiwania, zawierającą terminy odnoszące się do populacji docelowej (obciążenie żelazem; przeszczepienia), interwencji badanej (deferazyroks), jak również metodyki (w bazie Cochrane nie uwzględniano terminów odnoszących się do metodyki). W celu odnalezienia słów stanowiących synonimy, do każdego z wyżej wymienionych zapytań wykorzystano słowniki haseł

przedmiotowych *Medical Subject Headings* (MeSH) i *EmTree – Tool* oraz zastosowano przegląd zasobów internetowych.

W bazie CRD jak również na stronach EMA, FDA oraz URPLW MiPB wyszukiwanie prowadzono z użyciem nazw substancji czynnej interwencji badanej, w celu zapewnienia jego czułości.

W rejestrach badań klinicznych szukano badań zakończonych i nieopublikowanych, niezakończonych oraz planowanych dla deferazyroksu w leczeniu przewlekłego obciążenia żelazem w wyniku transfuzji krwi u dorosłych po przeszczepieniu tkanki, dlatego zastosowano zapytanie odnoszące się do interwencji badanej oraz populacji

Zakładanym wynikiem przeglądu było odnalezienie badań porównujących bezpośrednio skuteczność i bezpieczeństwo ocenianej technologii z wybranym komparatorem. W przypadku braku badań porównujących bezpośrednio interwencję z komparatorem odnalezienie badań umożliwiających wykonanie porównania pośredniego.

Strategia wyszukiwania została utworzona w taki sposób, aby odnaleźć oprócz badań eksperymentalnych badania obserwacyjne na podstawie, których zostanie oceniona skuteczność praktyczna i bezpieczeństwo porównywanych technologii medycznych.

Strategię wyszukiwania w bazach głównych wraz z wynikami zaprezentowano w załączniku 28.3.2. Natomiast strategię wyszukiwania, którą wykorzystano do przeszukiwania wybranych baz dodatkowych przedstawiono wraz z wynikami w załączniku 28.4.2.

## **11.4. Selekcja odnalezionych badań**

Odnalezione publikacje w głównych bazach medycznych Medline, Embase i Cochrane Library oraz bazach dodatkowych zostały poddane selekcji na podstawie tytułów i streszczeń, a następnie pełnych tekstów. Selekcji dokonało niezależnie dwóch analityków (ANK, KD). W przypadku braku zgodności decyzje podejmowane były z udziałem trzeciego analityka (AP) na drodze konsensusu. Selekcję oparto na

wcześniej zdefiniowanych kryteriach włączenia i wykluczenia, opisanych w rozdziale 18.2.

## 11.5. Ocena jakości badań

Badania oceniono zarówno w skali NOS jak i NICE (ang. *The National Institute for Health and Clinical Excellence*) [53, 76]. W załączniku 28.10 przedstawiono wzory skali (Tabela 420, Tabela 421).

Dodatkowo, wpływ jakości badań na wyniki poszczególnych punktów końcowych oceniono w skali GRADE [31] (wzór skali w tabeli w załączniku 28.10, Tabela 422).

## 11.6. Analiza statystyczna

Szczegółowy opis dotyczący analizy statystycznej został przedstawiony w rozdziale 7.6.

## 12. Badania włączone na podstawie przeglądu systematycznego

W wyniku przeszukiwania głównych baz informacji medycznej (Medline, Embase, Cochrane Library) odnaleziono 189 publikacji w formie tytułów i abstraktów.

Dodatkowo przeszukano:

- bazę *Centre for Reviews and Dissemination*, w której odnaleziono w sumie 14 publikacji;
- stronę internetową FDA, w której odnaleziono 53 publikacje;
- stronę internetową EMA, w której odnaleziono 351 publikacji;
- stronę internetową URPLW MiPB, w której odnaleziono 1 publikację.

Po przeprowadzeniu selekcji abstraktów i pełnych tekstów ostatecznie do analizy włączono 3 publikacje.



Nie odnaleziono przeglądów systematycznych ani metaanaliz spełniających kryterium populacji i interwencji podane w rozdziale 18.2 (zgodnie z *Rozporządzeniem Ministra Zdrowia z dnia 2 kwietnia 2012 r. w sprawie minimalnych wymagań, jakie muszą spełniać analizy uwzględnione we wnioskach o objęcie refundacją i ustalenie urzędowej ceny zbytu oraz o podwyższenie urzędowej ceny zbytu leku, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego, które nie mają odpowiednika refundowanego w danym wskazaniu*).

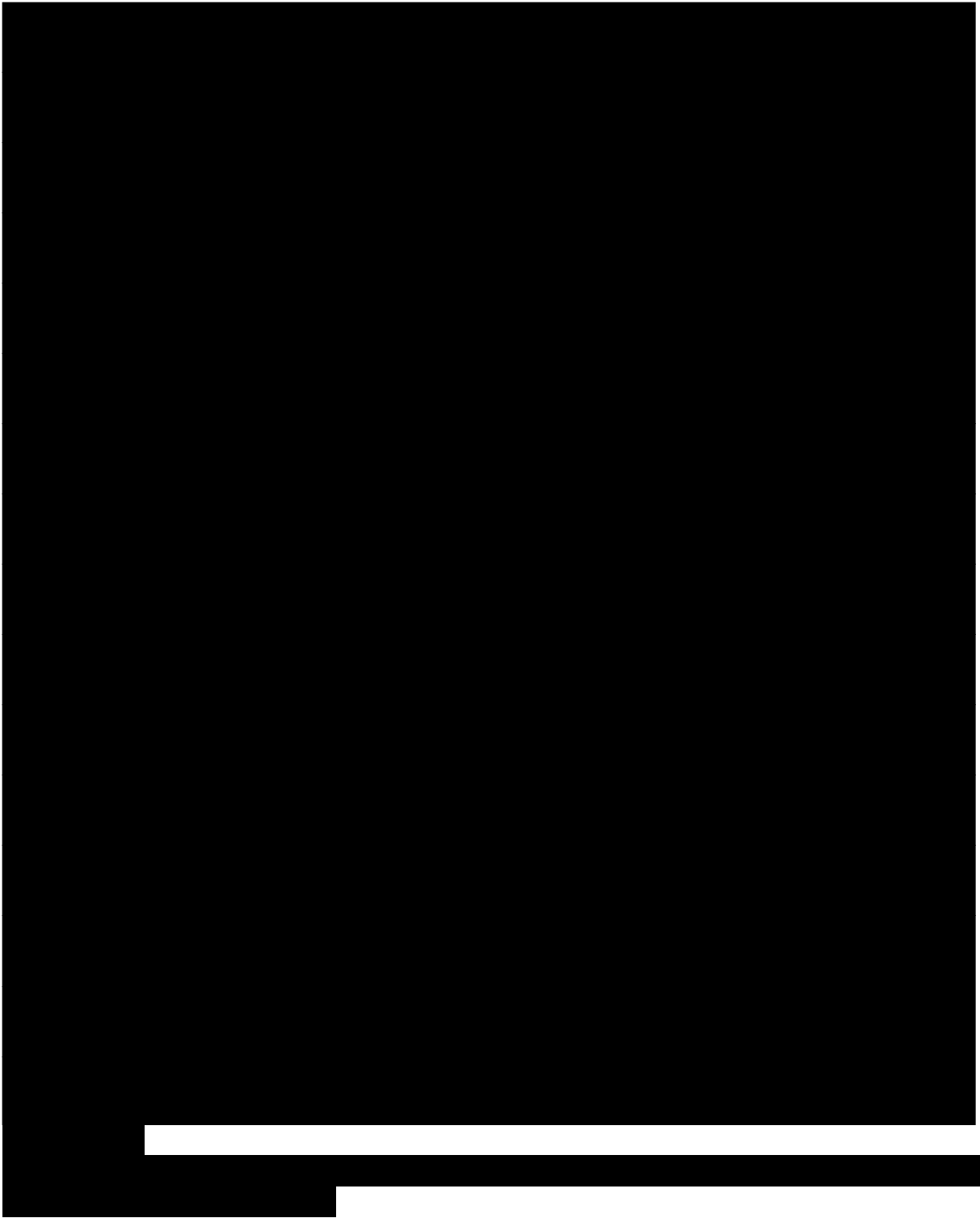
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Poszczególne etapy wyboru publikacji znalezionych w głównych bazach informacji medycznej wraz z przyczynami odrzucenia zostały przedstawione poniżej, na diagramie PRISMA (Rysunek 1). Podczas selekcji tytułów i streszczeń współczynnik zgodności kappa pomiędzy analitykami wynosił 0,96 natomiast w trakcie wyboru pełnych tekstów równy był 1. Powody wykluczenia poszczególnych badań na podstawie ich pełnych tekstów przedstawiono w załączniku 28.11.2.



## 13. Badania włączone do analizy

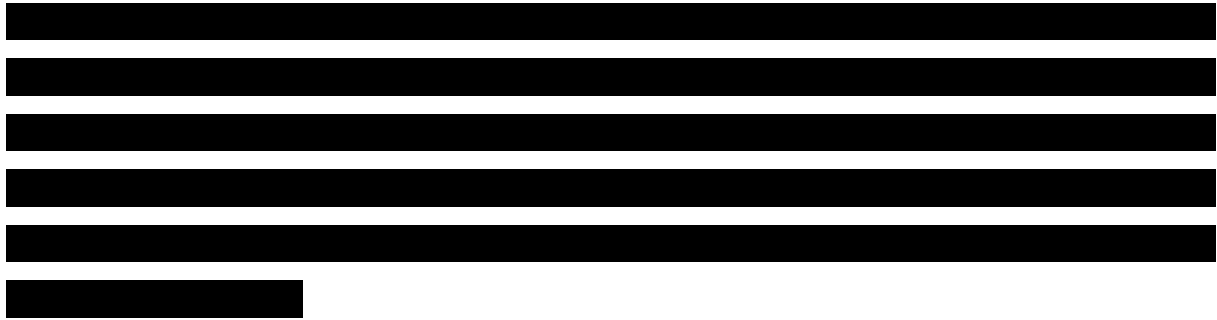
### 13.1. Metodyka włączonych badań

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Szczegółowe zestawienie omówionych badań znajduje się w poniższej tabeli.

**Tabela 397.**  
**Metodyka badań włączonych do analizy**

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

## 13.2. Kryteria włączenia i wykluczenia chorych

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Tabela 398.

Kryteria włączenia i wykluczenia pacjentów w badaniach włączonych do analizy

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	[Redacted]	[Redacted]
	[Redacted]	[Redacted]

I	[REDACTED]	[REDACTED]


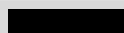
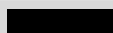



















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### 13.3. Charakterystyka chorych włączonych do badań

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**Tabela 399**  
**Charakterystyka chorych w badaniach włączonych do analizy**



## 13.4. Stosowane interwencje

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**Tabela 400.**  
**Opis interwencji w badaniach włączonych do analizy**

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

## 13.5. Punkty końcowe

W analizie oceniano wszystkie punkty końcowe, które mają znaczenie w leczeniu przewlekłego obciążenia żelazem spowodowanego transfuzjami krwi.

W poniższej tabeli przedstawiono zestawienie analizowanych w poszczególnych badaniach punktów końcowych (Tabela 401).

W sytuacji, kiedy punkt końcowy nie był analizowany w jednym z badań lub nie przedstawiono wystarczających danych umożliwiających ich wykorzystanie w analizie, w tabeli oznaczano go jako nie oceniany.

W analizie uwzględniano również wyniki dla pośrednich okresów obserwacji, dla których raportowano dane w badaniu.

We włączonych badaniach oceniane były między innymi punkty końcowe związane ze zmianami poziomu żelaza w wątrobie, zmianą stężenia ferrytyny oraz dotyczące częstości występowania działań niepożądanych.

**Tabela 401.**
**Charakterystyka punktów końcowych ocenianych w badaniach włączonych do analizy**





### 13.6. Ocena homogeniczności

Nie wykonano oceny homogeniczności dla włączonych badań, ponieważ analizowano z nich wyniki dla pojedynczych ramion, których nie metaanalizowano.

## 14. Ocena skuteczności deferazyroksu u chorych po allogenicznym przeszczepieniu krwiotwórczych komórek macierzystych

Skuteczność deferazyroksu w leczeniu obciążenia żelazem u chorych po allo-HSCT oceniano na podstawie wyników 3 badań: [REDACTED]

[Redacted text block]

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- [Redacted list item]

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[REDACTED]							
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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## 16. Ocena bezpieczeństwa u chorych po allogenicznym przeszczepieniu krwiotwórczych komórek macierzystych

Bezpieczeństwo deferazyroksu zostało ocenione na podstawie wyników 3 badań:

[REDACTED]

Jakość i wagę danych opublikowanych w publikacjach włączonych do analizy bezpieczeństwa stosowania deferazyroksu oceniono według zaleceń GRADE [31].

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## 17. Podsumowanie oceny bezpieczeństwa u chorych po allogenicznym przeszczepieniu krwiotwórczych komórek macierzystych

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## 18. Podsumowanie i wnioski końcowe

W ramach analizy klinicznej oceniono skuteczność i bezpieczeństwo leczenia deferazyroksiem względem [REDACTED] na podstawie badań randomizowanych i nierandomizowanych. Analizę skuteczności i bezpieczeństwa uzupełniono o wyniki badań jednoramiennych z uwagi na fakt, iż dla badań z grupą kontrolną dostępne były tylko dane dla chorych z talasemią i anemią sierpowatokrwinkową [REDACTED]

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Z wyżej opisanych wniosków wynika, że deferazyroks jest lekiem o udowodnionej skuteczności i bezpieczeństwie niezależnie od schorzenia, w przebiegu którego dochodzi do powstania przewlekłego obciążenia żelazem, dlatego zasadnym jest stosowanie ocenianej interwencji w praktyce klinicznej i objęcie jej finansowaniem ze środków publicznych w populacji dorosłych.

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## **19. Załączniki**

### **19.1. Opis chorób związanych z występowaniem przewlekłego obciążenia żelazem w wyniku transfuzji krwi**

#### **19.1.1. Niedokrwistość aplastyczna**

Niedokrwistość aplastyczna to schorzenie powstające w następstwie hipoplazji (zbyt słabe wykształcenie narządu przebiegające ze zmniejszeniem ilości komórek) lub aplazji (zanik funkcji spowodowany chorobą), prowadzące do pancytopenii (niedobór wszystkich prawidłowych elementów morfotycznych krwi) [62].

#### **Obraz kliniczny i rozpoznanie**

Rozróżnia się postać pierwotną i wtórną anemii aplastycznej.

Do pierwotnych (około 20% przypadków) zalicza się niedokrwistość: wrodzoną, Fanconiego oraz inne dziedziczne niedokrwistości takie jak zespół Diamonda i Blackfana, zespół Dubrovitza, rodzinną niedokrwistość aplastyczną [62].

Wtórne (około 80% przypadków) powstają jako skutek reakcji autoimmunologicznej przeciwko krwiotwórczym komórkom macierzystym i pobudzenia apoptozy. Ich przyczynami są m.in. promieniowanie jonizujące, substancje chemiczne, leki o silnym działaniu mielosupresyjnym, zakażenia wirusowe, układowe choroby tkanki łącznej [62].

Rozwój choroby może nastąpić w ciągu kilku dni lub kilku tygodni lub miesięcy. Objawy zależne są od stopnia cytopenii krwi obwodowej. Są to objawy niedokrwistości i niedotlenienia narządów, neutropenii oraz małopłytkowości [62].

Rozpoznanie oparte jest na obecności co najmniej dwóch spośród trzech następujących objawów: neutropenia, małopłytkowość, retikulocytopenia. Obraz kliniczny, rokowanie oraz sposób leczenia zależne są od stopnia nasilenia zmian [62].

## Leczenie

Jako leczenie wspomagające stosowane są transfuzje KKCz i koncentratu krwinek płytkowych, czynniki wzrostu oraz profilaktyka zakażeń bakteryjnych i grzybiczych. Leczenie przyczynowe obejmuje zastosowanie allogenicznego przeszczepienia szpiku, leczenia immunosupresyjnego, cyklofosamid, androgenów [62].

### 19.1.2. Zespoły mielodysplastyczne

Zespoły mielodysplastyczne są to klonalne choroby układu krwiotwórczego, charakteryzujące się nieefektywną hematopoezą oraz częstą transformacją w ostre białaczki [64].

#### Obraz kliniczny i rozpoznanie

Czynniki etiologiczne związane z występowaniem MDS są nieznane, jednak podwyższone ryzyko zachorowania może być związane z narażeniem na związki chemiczne, metale ciężkie, dym tytoniowy, promieniowanie jonizujące, cytostatyki. MDS może też powstać w przebiegu niedokrwistości aplastycznej. Objawy MDS nie są charakterystyczne i związane są u większości chorych z niedokrwistością, neutropenią oraz małopłytkowością [64].

Rozpoznanie ma miejsce w oparciu o wyniki morfologii krwi obwodowej (niedokrwistość normocytowa lub makrocytowa, leukopenia z neutropenią, liczba neutrofilów poniżej 1500/ $\mu$ l, odsetek blastów 0-20%, zmniejszona liczba segmentów jądra neutrofilów, małopłytkowość, pancytopenia, retikulocytopenia, zwiększona wrażliwość erytrocytów na dopełniacz, defekt błony erytrocytu podobny do tego jaki występuje w nocnej napadowej hemoglobinurii). Ponadto przeprowadza się morfologię szpiku (biopsja aspiracyjna szpiku, trepanobiopsja - pobranie fragmentu szpiku wraz z tkanką kostną, badanie cytochemiczne), badania cytogenetyczne i inne badania laboratoryjne (podwyższone stężenie żelaza w surowicy oraz hemoglobiny płodowej) [64].

Podstawowe kryteria rozpoznania to wystąpienie cytopenii obwodowej (1-, 2-, 3-liniowej), nieprawidłowej hematopoezy w zakresie co najmniej 1 linii oraz zmian cytogenetycznych [64].

## Leczenie

Wybór metody leczenia jest zależny od ogólnej wydolności chorego, jego wieku oraz kategorii ryzyka IPSS (ang. *International Prognostic Scoring System*, Międzynarodowy Punktowy System Rokowniczy). Zastosowanie znajdują: allogeniczne przeszczepienie komórek hematopoetycznych (jedyna metoda, która zapewnia wyleczenie), autogeniczne przeszczepienie komórek hematopoetycznych (częste nawroty), chemioterapia (intensywna skojarzona – arabinozy cytozyny i daunorubicyna lub chemioterapia małymi dawkami arabinozydu cytozyny – u osób z przeciwwskazaniem do terapii skojarzonej). Leczenie wspomagające obejmuje przetoczenia KKCz, stosowanie erytropoetyny, leczenie neutropenii i zakażeń, leczenie małopłytkowości oraz stosowanie leków chelatujących żelazo na przykład deferoksaminy. Terapia chelatująca zalecana jest u chorych z przewlekłym obciążeniem żelazem po transfuzjach KKCz, którzy dobrze rokują (chorzy zakwalifikowani do grupy ryzyka małego lub pośredniego zgodnie z IPPS), chorych na RA (ang. *refractory anemia*, niedokrwistość oporna na leczenie), RARS (ang. *refractory anemia with ring sideroblasts*, niedokrwistość oporna na leczenie obecnością pierścieniowych syderoblastów) i zespół 5q-, bez poważnych chorób współistniejących oraz u chorób kwalifikujących się do przeszczepienia komórek krwiotwórczych. Leczenie to stosuje się u chorych, którzy otrzymywali transfuzje KKCz z częstością co najmniej 7 ml/kg m.c. na miesiąc, po transfuzji co najmniej 20 jednostek KKCz [64].

### 19.1.3. Niedokrwistość sierpowatokrwinkowa

Niedokrwistość sierpowatokrwinkowa jest to niedokrwistość hemolityczna spowodowana obecnością nieprawidłowej HbA (hemoglobina A, zawiera 2 łańcuchy alfa i 2 łańcuchy beta) [63].

#### Obraz kliniczny i rozpoznanie

Choroba objawia się nawracającym bólem rąk i stóp, żółtaczką, powiększeniem wątroby i śledziona, owrzodzeniem w okolicy kostek, kamicią żółciową, objawami zatorów w narządach wewnętrznych.

U homozygot jej przebieg jest najcięższy, u heterozygot względem hemoglobiny S (HbS) jest lżejszy i bywa bezobjawowy. U chorych mogą występować przełomy plastyczne lub hemolityczne [63].

Rozpoznanie ma miejsce w oparciu o wyniki morfologii krwi obwodowej (niedokrwistość hemolityczna o średnim nasileniu (Hb ~ 8 mg/dl), MCV (ang. *mean corpuscular volume* - wskaźnik średniej objętości krwinki czerwonej) zwiększona lub w górnej granicy normy; sierpowaty kształt erytrocytów, normochromia (normobarwliwość), ciątka Howella i Jollyego w erytrocytach) oraz innych badań laboratoryjnych (zmiany wspólne dla wszystkich przypadków hemolizy, lekko podwyższone stężenie HbF (hemoglobina F, zawiera 2 łańcuchy alfa i 2 łańcuchy gamma), brak HbA, dodatni wynik testu na obecność krwinek sierpowatych) [63].

## Leczenie

W trakcie leczenia należy zapobiegać ostrym objawom choroby oraz stosować odpowiednią terapię w przypadku ich wystąpienia. Stosuje się profilaktykę i leczenie zakażeń, kwas foliowy, prewencję i leki przeciwbólowe i przeciwkrzepliwe, transfuzje KKCz, częściowe transfuzje wymienne (erytrocytoferaza) [63].

W przypadku wystąpienia przewlekłego obciążenia żelazem stosuje się leczenie zmniejszające stężenie żelaza jak w talasemii, utrzymując stężenie ferrytyny poniżej 2000 µg/l [63].

Dodatkowo w celu zahamowania polimeryzacji HbS (hemoglobina S, główny rodzaj hemoglobiny u osób z SCA) i zwiększenia syntezy HbF stosuje się hydroksykarbamid, allo- lub autogeniczne przeszczepienie komórek krwiotwórczych [63].

### 19.1.4. Talasemia beta

Talasemia beta zaliczana jest do grupy niedokrwistości tarczowatokrwinkowych będących wrodzonymi niedokrwistościami hemolitycznymi wywołanymi nieprawidłową syntezą łańcuchów alfa i beta w cząsteczce hemoglobiny, dlatego też wyróżnia się postać alfa i beta talasemii. Częściej występującą jest postać beta talasemii [61].



## Obraz kliniczny i rozpoznanie

Wyodrębniono 3 podtypy talasemii beta:

### A. Postać heterozygotyczna (*thalassaemia beta minor*)

Przebieg postaci heterozygotycznej jest zazwyczaj bezobjawowy. Zazwyczaj pod koniec pierwszego roku życia następuje powiększenie śledziony. Erytrocyty wykazują zwiększoną oporność osmotyczną, ich kształt jest tarczowaty a nakrapianie zasadowe. Występuje niedokrwistość mikrocytowa i hipochromiczna. Stężenie żelaza w surowicy może być prawidłowe lub zwiększone. Podczas elektroforezy wykrywane jest podwyższone stężenie hemoglobiny A<sub>2</sub> (HbA<sub>2</sub>) i lekko podwyższone stężenie hemoglobiny F (HbF).

Postać ta nie wymaga leczenia [61].

### B. Postać homozygotyczna , tzw. *niedokrwistość Colley'a (thalassaemia beta major)*

Pierwsze objawy występują pomiędzy 3 a 6 miesiącem życia. Są to zazwyczaj: żółtaczka, czasami brązowa pigmentacja skóry, powiększenie wątroby i śledziony, owrzodzenia w okolicy kostek, kamica żółciowa, upośledzenie wzrostu dziecka, czaszka „szczotkowata” w RTG, twarz mongoidalna. Erytrocyty mają cechy takie jak w postaci heterozygotycznej, występuje jednak niedokrwistość hemolityczna. Brak hemoglobiny A (HbA) w elektroforezie hemoglobiny, mała prawidłowa lub zwiększona ilość HbA<sub>2</sub> i zwiększenie stężenia hemoglobiny F (HbF). Dochodzi do opóźnienia w rozwoju, pojawiają się nawracające zakażenia, złamania kości oraz owrzodzenia kończyn dolnych. Dodatkowo dochodzi do rozwoju hemochromatozy, a w związku z częstymi transfuzjami krwi mogą pojawić się zakażenia wirusowe (wirus zapalenia wątroby typu C (HCV), ludzki wirus niedoboru odporności (HIV)).

## Leczenie

### a) Leczenie niedokrwistości:

- transfuzje KKCz, zazwyczaj jedna do trzech jednostek co 3 do 5 tyg.
- splenektomia (częściowe lub całkowite usunięcie śledziony), jej stosowanie zaleca się, gdy występuje ponad 50% wzrost zapotrzebowania na transfuzje KKCz w ciągu roku;
- suplementacja kwasu foliowego, witaminy C i cynku;
- allogeniczne przeszczepienie szpiku kostnego, w przypadku ciężkiego przebiegu choroby

b) Zapobieganie hemosyderozie, gdy stężenie ferrytyny wynosi ponad 1000 µg/l. Stosowana jest deferoksamina (2g infuzji s.c. 10-12 godz. usuwa >115 mg żelaza na dobę). Podanie choremu witaminy C przyspiesza uwalnianie żelaza co daje możliwość wydalania do 300 mg na dobę. Jeśli chory nie toleruje infuzji podskórnych stosowane są infuzje dożylnie (24 godziny). Długotrwała terapia DFO zmniejsza częstość hemosyderozy serca.

c) Leczenie następstw hemosyderozy jeśli wystąpią [61].

## C. Postać pośrednia (*thalassaemia beta intermedia*)

Jest to homozygotyczna talasemia beta, która nie jest zależna od transfuzji krwi. Jest ona genetycznie i klinicznie heterogenna. Hemoglobina (~6-9 g/dl) oraz częstość występowania komplikacji są pośrednie pomiędzy talasemią beta hetero- i homozygotyczną [37].

## Leczenie

W leczeniu talasemii pośredniej znajdują zastosowanie m.in. modulacja produkcji hemoglobiny płodowej oraz przeszczep szpiku kostnego. Można również wykonać transfuzje krwi, jednak nie jest to terapia rutynowa [66].

### 19.1.5. Pierwotna mielofibroza

Pierwotna mielofibroza (samoistne włóknienie szpiku) jest nowotworem mieloproliferacyjnym charakteryzującym się niedokrwistością, odmłodzeniem układu granulocytowego, występowaniem we krwi obwodowej erytroblastów i erytrocytów w kształcie łez, zwłóknieniem szpiku, powiększeniem śledziony, powstawaniem pozaszpikowych ognisk krwiotworzenia. Cechą charakterystyczną jest występowanie we krwi obwodowej wielu progenitorowych komórek hematopoetycznych CD34+ oraz progenitorowych komórek śródbłonna [65].

#### Obraz kliniczny i rozpoznanie

Rozrostowi klonu nowotworowych macierzystych komórek hematopoetycznych towarzyszy wzmożona synteza cytokin, które zwiększają liczbę nieprawidłowych megakariocytów. Wytwarzane przez te komórki oraz przez monocyty czynniki wzrostu, takie jak transformujący czynnik wzrostu  $\beta$ , płytkowo pochodny czynnik wzrostu, czynnik wzrostu fibroblastów, stymulują proliferację fibroblastów. Wytwarzają one włókna retikuliny i kolagenowe, które odkładają się w podścielisku szpiku. Dochodzi do wyparcia prawidłowego utkania szpikowego, z jednoczesnym powstawaniem pozaszpikowych ognisk krwiotworzenia [65].

Rozpoznanie ma miejsce w oparciu o wyniki morfologii krwi obwodowej (niedokrwistość normocytowa; liczba leukocytów zmniejszona, nieco zwiększoną lub prawidłową; liczba płytek krwi przeważnie zwiększona i z nieprawidłowościami morfologicznymi i czynnościowymi; analiza rozmazu, obecne erytrocyty w kształcie łez oraz erytroblasty i młode formy rozwojowe układu granulocytowego). Ponadto przeprowadza się morfologię szpiku (biopsja aspiracyjna szpiku, trepanobiopsja - pobranie fragmentu szpiku wraz z tkanką kostną, badanie cytochemiczne), badania cytogenetyczne, molekularne i inne badania laboratoryjne i pomocnicze (wykrywanie zwiększonej aktywności FAG (fosfataza alkaliczna granulocytów), hiperurykemii, RTG kości długich) [65].

Podstawowe kryteria rozpoznania to:

- wystąpienie proliferacji linii megakariopoetycznej z towarzyszącą atypią megakariocytów, zwykle z obecnością włóknienia retikulinowego lub/i kolagenowego (dodatkowo w przypadku mało zaznaczonego włóknienia retikulinowego zmianom morfologii megakariocytów musi towarzyszyć zwiększona komórkowość szpiku);
- wykluczenie czerwienicy prawdziwej i innych chorób nowotworowych układu neutrofilopoetycznego;
- obecność mutacji V617F genu *JAK-2* lub innego klonalnego markera genetycznego, następnie w przypadku ich braku, stwierdzenie nie występowania cech włóknienia szpiku związanego z inną chorobą nowotworową lub zapalną (włóknienie odczynowe) [65].

Dodatkowymi kryteriami tzw. „małymi” są: leukoerytoblastoza we krwi obwodowej, zwiększona aktywność dehydrogenazy mleczanowej w surowicy, niedokrwistość, powiększenie śledziony stwierdzone palpacyjnie [65].

## Leczenie

Nie ma skutecznego leczenia przyczynowego. W początkowym okresie choroby, gdy hematopoeza jest wydolna, uważa się za słuszne stanowisko wyczekujące [65].

Za jedyną metodę dającą szansę całkowitego wyleczenia przyjmuje się allogeniczny przeszczep szpiku. Technologia ta zalecana jest u młodych chorych z co najmniej 2 czynnikami ryzyka, o przewidywanym czasie przeżycia 1-3 lat [65].

Leczenie cytoredukcyjne stosuje się u chorych z leukocytozą, nadpłytkowością, powiększeniem śledziony i krwiotworzeniem pozaszpikowym, w mniejszych dawkach niż w innych zespołach mieloproliferyjnych. Leki stosowane w tej terapii to hydroksymocznik, melfalan, interferon alfa lub w przypadku utrzymywania się nadpłytkowości anagrelid. Żaden w wymienionych leków nie wydłuża przeżycia [65].

W przypadku małej skuteczności leczenia cytostatycznego, znacznego powiększenia śledziony, z towarzyszącymi dolegliwościami bólowymi, pojawieniem się płynu w jamie otrzewnowej wskazane jest napromieniowanie śledziony [65].

W leczeniu niedokrwistości stosowane są androgeny, prednizon, erytropoetyna lub talidomid (lub lenalidomid u chorych opornych) [65].

Splenektomia lub napromienianie śledziony mogą być zastosowane u chorych ze znacznym powiększeniem bądź bolesnością śledziony, niedokrwistością hemolityczną oporną na leczenie, małopłytkowością oporną na leczenie lub nadciśnieniem wrotnym. Napromienianie śledziony stosowane jest dodatkowo również w przypadkach bólu towarzyszącego zawałom śledziony [65].

W leczeniu stosuje się również substytucję, czyli uzupełnianie brakujących elementów krwi [32].

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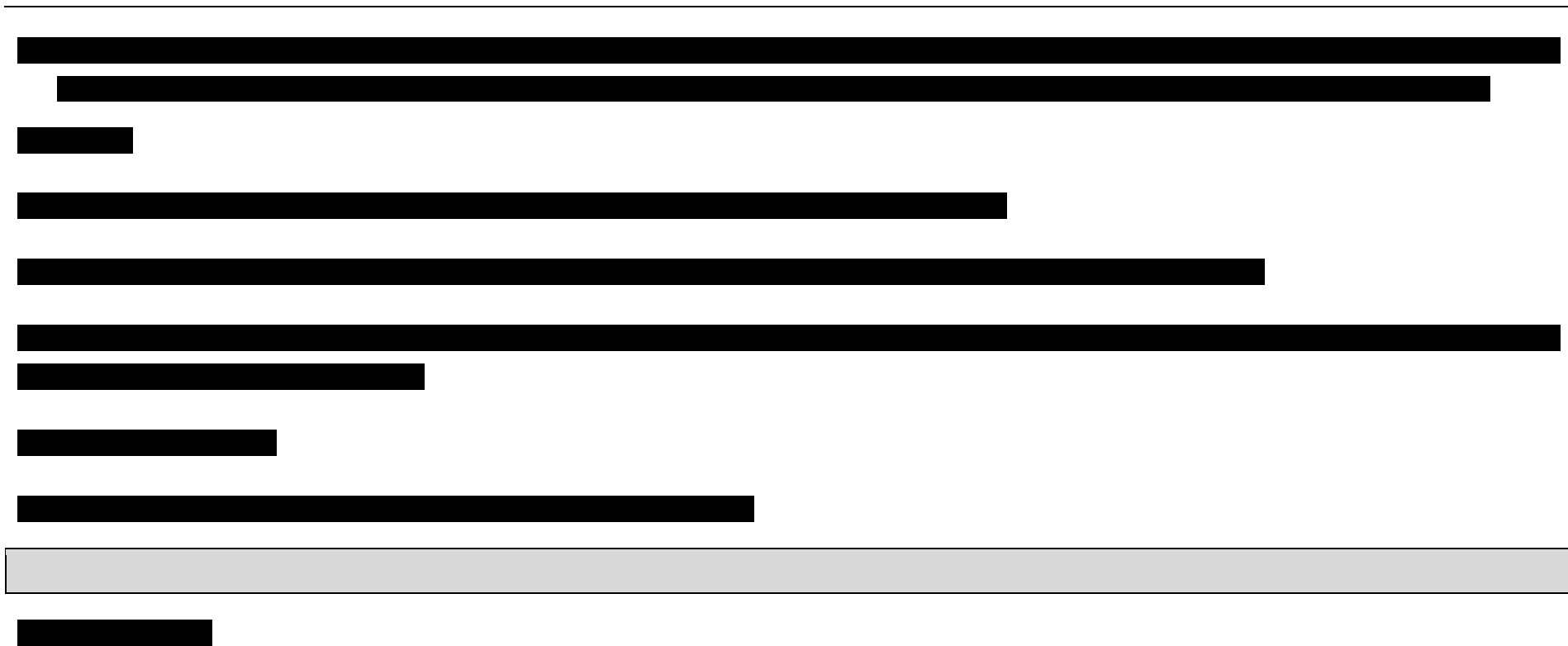
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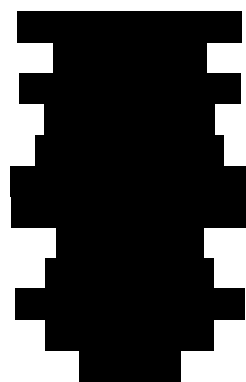
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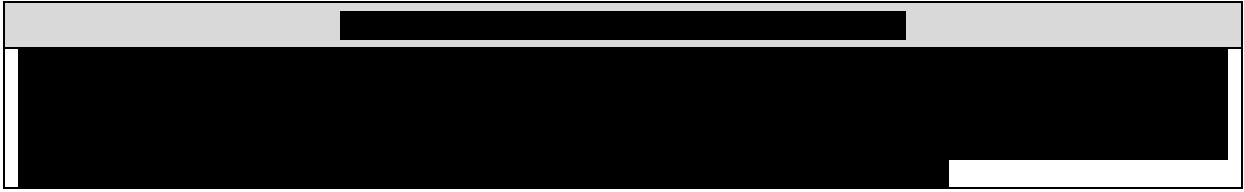






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## 19.2. Skala oceny stopnia nasilenia zapalenia i zwłóknienia w wątrobie

**Tabela 417.**  
**Ocena stopnia nasilenia zapalenia w wątrobie - indeks HAI wg. Ishak**

Kategoria	Zmiany zapalne	Stopnie oceny
A	Martwica kęśowa	0-4
B	Martwica przęsłowa	0-6
C	Aktywność zapalna wewnątrz zrazików	0-4
D	Intensywność nacieku zapalnego w przestrzeniach wrotnych	0-4
<b>Łącznie</b>		<b>0-18</b>

Źródło: opracowanie własne na podstawie *Ishak* [35]

**Tabela 418.**  
**Ocena stopnia nasilenia zwłóknienia w wątrobie według skali Ishak**

Stadium	Charakterystyka objawów
0	Brak zwłóknień
1	Rozwinięte zwłóknienia w kilku przestrzeniach wrotnych z lub bez krótkich przegród
2	Rozwinięte zwłóknienia w większości przestrzeni wrotnych z lub bez krótkich przegród
3	Rozwinięte zwłóknienia w większości przestrzeni wrotnych ze sporadycznymi mostkami wrotno-wrotnymi (P-P)
4	Rozwinięte zwłóknienia w większości przestrzeni wrotnych z wyraźnymi mostkami wrotno-wrotnymi (P-P), jak również wrotno-centralnymi (P-C)
5	Wyraźne mostki wrotno-wrotne (P-P), jak również wrotno-centralne (P-C) ze sporadycznymi guzkami (niepełna marskość)
6	Marskość (prawdopodobna lub pewna)

Źródło: opracowanie własne na podstawie *Ishak* [35]

### 19.3. Skale oceny jakości badań

**Tabela 419.**  
**Ocena jakości danych wg skali Jadad**

Pytanie	Odpowiedź Tak/Nie	Punktacja 1/0
Czy badanie opisano jako randomizowane?		
Czy badanie opisano jako podwójnie zaślepienie?		
Czy podano informacje o utracie pacjentów z badania i okresu obserwacji?		
Czy dodać 1 punkt za podany opis randomizacji i właściwą metodę?		
Czy dodać 1 punkt za podany opis zaślepienia i właściwą metodę?		
Czy odjąć 1 punkt za niewłaściwą metodę randomizacji?		
Czy odjąć 1 punkt za niewłaściwą metodę zaślepienia?		
<b>SUMA PUNKTÓW</b>		

**Tabela 420.**  
**Ocena jakości danych wg skali NICE**

Pytanie	Odpowiedź Tak/Nie	Punktacja 1/0
1. Czy badanie było prowadzone w więcej niż jednym ośrodku?		
2. Czy hipoteza badawcza/cel badania jest jasno opisany?		
3. Czy kryteria włączenia i wykluczenia pacjentów są sprecyzowane?		
4. Czy zostały jasno zdefiniowane punkty końcowe?		
5. Czy dane były poprawnie analizowane?		
6. Czy w opisie badania znajduje się stwierdzenie, że pacjenci byli włączani kolejno?		
7. Czy opisano jasno wyniki badania?		

Pytanie	Odpowiedź Tak/Nie	Punktacja 1/0
8. Czy wyniki przedstawiono w podziale na podgrupy pacjentów (np. wg stopnia zaawansowania choroby, charakterystyk pacjentów, innych czynników)?		
<b>SUMA PUNKTÓW</b>		

**Tabela 421.**
**Kwestionariusz Newcastle-Ottawa Scale (NOS) do oceny badań nierandomizowanych**
**SKALA OCENY JAKOŚCI BADAŃ NEWCASTLE-OTTAWA – BADANIA KOHORTOWE**

Uwaga: badanie może otrzymać najwyżej jedną gwiazdkę za każdy numerowany element skali w kategoriach "Dobór próby" i "Punkt końcowy". W kategorii „Porównywalność” można przyznać najwyżej dwie gwiazdki.

**Dobór próby**

 1) Reprezentatywność kohorty narażonej

- w pełni reprezentatywna w odniesieniu do przeciętnego \_\_\_\_\_ (proszę wypisać) w danej społeczności \*
- w pewnym stopniu reprezentatywna w odniesieniu do przeciętnego \_\_\_\_\_ w danej społeczności \*
- określona grupa użytkowników (np. pielęgniarki, wolontariusze)
- nie określono metody doboru kohorty

 2) Dobór kohorty bez narażenia

- z tej samej co narażona kohorta \*
- z innego środowiska (z innej populacji)
- nie określono metody doboru kohorty bez narażenia

 3) Stwierdzenie narażenia

- dane pewne (np. dokumentacja zabiegu chirurgicznego) \*
- ustrukturyzowany wywiad \*
- raportowane przez chorego w formie pisemnej
- nie określono

 4) Wykazano, że badany punkt końcowy nie występował na początku badania

- tak \*
- nie

**Porównywalność**

 1) Porównywalność kohort na podstawie planu badania lub analizy

- w badaniu uwzględniono \_\_\_\_\_ (proszę wybrać najbardziej istotny czynnik) \*
- w badaniu uwzględniono dodatkowy czynnik (to kryterium można zmodyfikować tak, aby dotyczyło innego istotnego czynnika) \*

**Punkt końcowy**

 1) Ocena wystąpienia punktu końcowego

- niezależna ocena z zaślepieniem \*
- odwołanie do dokumentacji \*
- raportowane przez chorego
- nie określono

 2) Czy okres obserwacji był odpowiednio długi, aby wystąpił punkt końcowy?

- tak (proszę wybrać odpowiedni okres obserwacji dla badanego punktu końcowego) \*

b) nie
3) <u>Poprawność obserwacji kohort</u>
a) pełna obserwacja – znane losy wszystkich chorych *
b) małe prawdopodobieństwo błędu systematycznego na skutek utraty chorych z okresu obserwacji – niewielka liczba utraconych chorych - > ____ % ukończyło obserwację (proszę wybrać odpowiedni odsetek) lub odniesiono się losów chorych utraconych *
c) < ____% ukończyło obserwację (proszę wybrać odpowiedni odsetek) i brak odniesienia do losów chorych utraconych
d) nie określono

**Tabela 422.**
**Kryteria oceny jakości danych wg wytycznych GRADE**

Rodzaj badania:
<ul style="list-style-type: none"> <li>– badanie z randomizacją = jakość wysoka</li> <li>– badanie obserwacyjne = jakość niska</li> <li>– jakiegokolwiek inne dane = jakość bardzo niska</li> </ul>
Czynniki obniżające jakość danych:
<ul style="list-style-type: none"> <li>– poważne (–1) albo bardzo poważne (–2) ograniczenie jakości badania</li> <li>– ważna niezgodność wyników (–1)</li> <li>– umiarkowana (–1) lub duża (–2) niepewność co do możliwości odniesienia danych</li> <li>– nieprecyzyjne oszacowanie efektów lub zbyt mała liczba danych (–1)</li> <li>– duże prawdopodobieństwo, że część badań na dany temat nie została opublikowana (–1)</li> </ul>
Czynniki zwiększające jakość danych:
<ul style="list-style-type: none"> <li>– silny związek pomiędzy interwencją a punktem końcowym – statystycznie istotne ryzyko względne &gt;2 (albo &lt;0,5) oszacowane na podstawie zgodnych wyników <math>\geq 2</math> badań obserwacyjnych, bez prawdopodobnych czynników zakłócających mogących zmniejszyć zaobserwowany efekt (+1)</li> <li>– bardzo silny związek pomiędzy interwencją a punktem końcowym – statystycznie istotne ryzyko względne &gt;5 (albo &lt;0,2) na podstawie danych bezpośrednich, bez poważnych zastrzeżeń co do ich wiarygodności (+2)</li> <li>– wykazanie zależności efektu od dawki (+1)</li> <li>– wszystkie prawdopodobne, ale niewzięte pod uwagę czynniki zakłócające najprawdopodobniej zmniejszyły zaobserwowany efekt (+1)</li> </ul>

**Tabela 423.**
**Klasyfikacja doniesień naukowych odnoszących się do terapii<sup>1</sup>**

Typ badania	Rodzaj badania	Opis podtypu
Przegląd systematyczny RCT	IA	Metaanaliza na podstawie wyników przeglądu systematycznego RCT;
	IB	Systematyczny przegląd RCT bez metaanalizy;
Badanie eksperymentalne	IIA	Poprawnie zaprojektowana kontrolowana próba kliniczna z randomizacją <sup>2</sup> ;
	IIB	Poprawnie zaprojektowana kontrolowana próba kliniczna z pseudorandomizacją;

Typ badania	Rodzaj badania	Opis podtypu
	<b>IIC</b>	Poprawnie zaprojektowana kontrolowana próba kliniczna bez randomizacji <sup>3</sup> ;
<b>Badanie obserwacyjne z grupą kontrolną</b>	<b>IIIA</b>	Przegląd systematyczny badań obserwacyjnych;
	<b>IIIB</b>	Poprawnie zaprojektowane prospektywne badanie kohortowe z równoczesową grupą kontrolną;
	<b>IIIC</b>	Poprawnie zaprojektowane prospektywne badanie kohortowe z historyczną grupą kontrolną;
	<b>IIID</b>	Poprawnie zaprojektowane retrospektywne badanie kohortowe z równoczesową grupą kontrolną;
	<b>IIIE</b>	Poprawnie zaprojektowane badanie kliniczno-kontrolne (retrospektywne);
<b>Badanie opisowe</b>	<b>IVA</b>	Seria przypadków - badanie pretest/posttest <sup>4</sup> ;
	<b>IVB</b>	Seria przypadków - badanie posttest <sup>5</sup> ;
	<b>IVC</b>	Inne badanie grupy pacjentów;
	<b>IVD</b>	Opis przypadku;
<b>Opinia ekspertów</b>	<b>V</b>	Opinia ekspertów w oparciu o doświadczenie kliniczne, badania opisowe oraz raporty panelów ekspertów;

<sup>1</sup> Modyfikacja własna na podstawie: *Undertaking systemic reviews of research on effectiveness: CRD guidelines for those carrying out or commissioning reviews*. CRD report #4, University of York, York 1996.

<sup>2</sup> Kontrolowana próba kliniczna z randomizacją, ang. *randomised controlled trial*, RCT.

<sup>3</sup> Kontrolowana próba kliniczna, ang. *clinical controlled trial*, CCT.

<sup>4</sup> Badanie typu pretest/posttest – badanie opisowe ze zbieraniem danych przed zastosowaniem ocenianego postępowania i po nim.

<sup>5</sup> Badanie typu posttest – badanie opisowe ze zbieraniem danych tylko po zastosowaniu ocenianego postępowania.

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## 19.4. Badania wykluczone na podstawie pełnych tekstów

### 19.4.1. I część przeglądu systematycznego

Tabela 425.  
 Powody wykluczenia badań na podstawie ich pełnych tekstów (przeгляд systematyczny – część I)

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#### 19.4.2. II część przeglądu systematycznego

Tabela 426.

Powody wykluczenia badań na podstawie ich pełnych tekstów (przeгляд systematyczny – część II)

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## 19.5. Zakończone (nieopublikowane), trwające lub planowane badania kliniczne

Tabela 427

Zakończone (nieopublikowane), trwające lub planowane badania kliniczne dla deferazyroksu w populacji docelowej

Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
Deferasirox Treatment and Labile Plasma Iron in Iron Overloaded Patients Who Have Undergone Allogeneic Hematopoietic Stem Cell Transplantation	NCT01159067	Przedwcześnie zakończone	City of Hope Medical Center	Jednoramiennie, otwarte	Ocena bezpieczeństwa i tolerancji deferazyroksu u chorych po przeszczepieniu krwiotwórczych komórek macierzystych u chorych z obciążeniem żelazem. Dodatkowo analizowano wpływ niskiej dawki DSX na labilną pulę żelaza.	Lipiec 2010	Sierpień 2011
Open-Label Single-Arm Pilot Study of Deferasirox (Exjade®) in Adult Allogeneic Hematopoietic Stem Cell Transplant Recipients With Transfusional Iron Overload	NCT00602446	Przedwcześnie zakończone	Masonic Cancer Center, University of Minnesota	Jednoramiennie, otwarte	Ocena skuteczności i bezpieczeństwa DSX w leczeniu chorych z obciążeniem żelazem po przeszczepieniu komórek macierzystych dawcy.	Sierpień 2007	Grudzień 2009
A One-year, Open-label, Single Arm, Multi-center Trial Evaluating the Efficacy and Safety of Oral ICL670 (20 mg/kg/d) in Patients Three to Six Months After Allogeneic Hematopoietic Cell Transplantation in Whom Iron Overload is Present	NCT00654589	Zakończone, nieopublikowane	Novartis Pharmaceuticals	Jednoramiennie, otwarte	Ocena skuteczności i bezpieczeństwa terapii chelatującej z zastosowaniem DSX u chorych z objawami przeciążenia żelazem powstałego po allogenicznym przeszczepieniu komórek macierzystych.	Luty 2008	Kwiecień 2011

Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
A Phase II, Multi-center, Single-arm, Prospective Study to Evaluate the Safety and Efficacy of Deferasirox in Beta-thalassemia Major Patients After Hematopoietic Stem Cell Transplantation	NCT01610297	Przed rekrutacją chorych	Novartis Pharmaceuticals	Jednoramiennie, otwarte	Ocena skuteczności i bezpieczeństwa DSX w leczeniu przeciążenia żelazem w okresie po przeszczepieniu u chorych z talasemią beta major	Czerwiec 2012	Lipiec 2014
Open-Label Single-Arm Pilot Study of Deferasirox (Exjade®) in Adult Allogeneic Hematopoietic Stem Cell Transplant Recipients With Transfusional Iron Overload	NCT01335035	Zakończone, nieopublikowane	Novartis Pharmaceuticals	Jednoramiennie, otwarte	Badanie zaprojektowane w celu oceny skuteczności i bezpieczeństwa DSX w leczeniu chorych z obciążeniem żelazem w czasie od 6 do 18 miesięcy po allogenicznym przeszczepieniu komórek macierzystych. Celem badania była ocena średniej zmiany poziomu ferrytyny w surowicy po 52 tygodniach leczenia DSX .	Grudzień 2008	Maj 2011

Źródło: opracowanie własne

Data ostatniego wyszukiwania: 22.01.2013 r.



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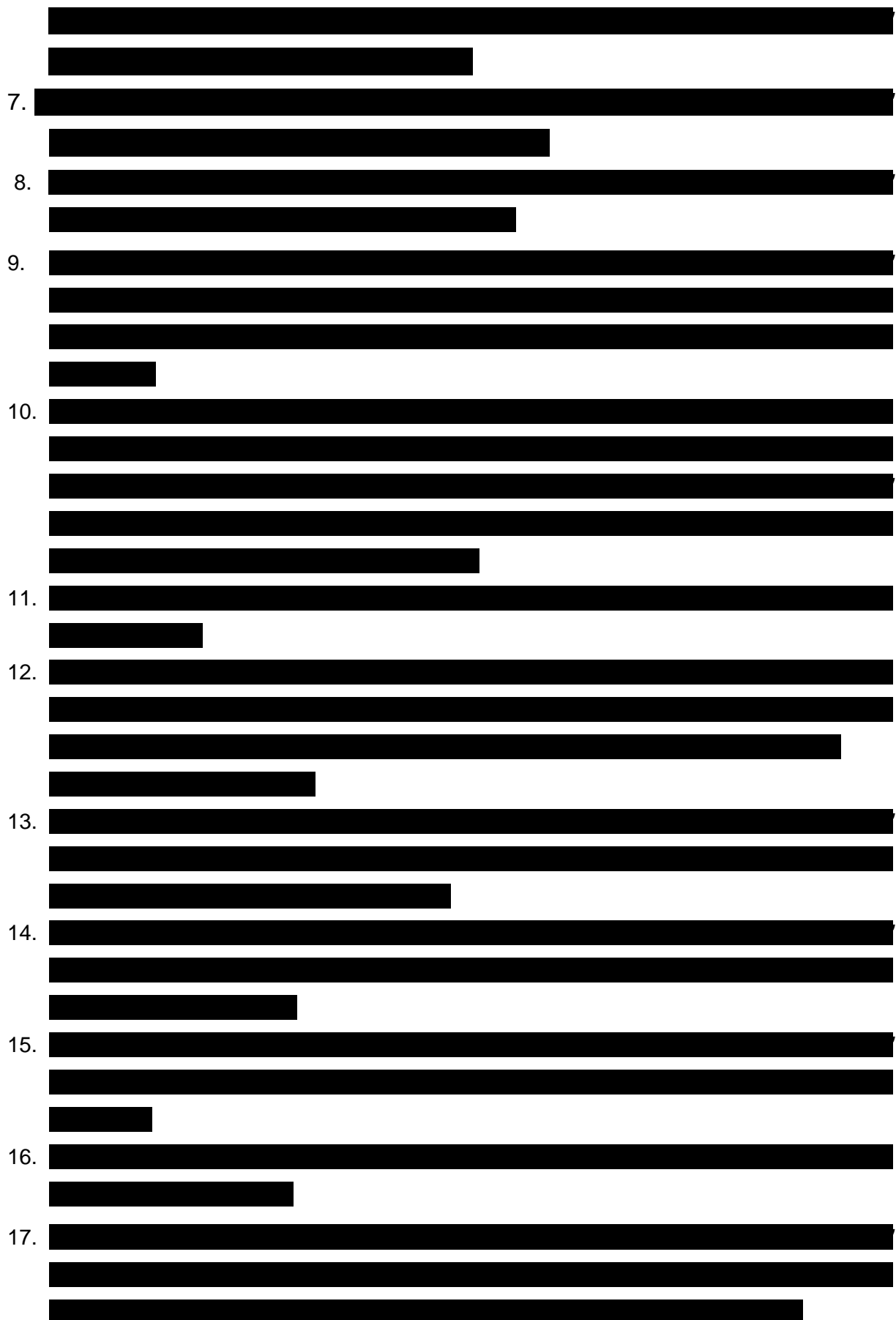
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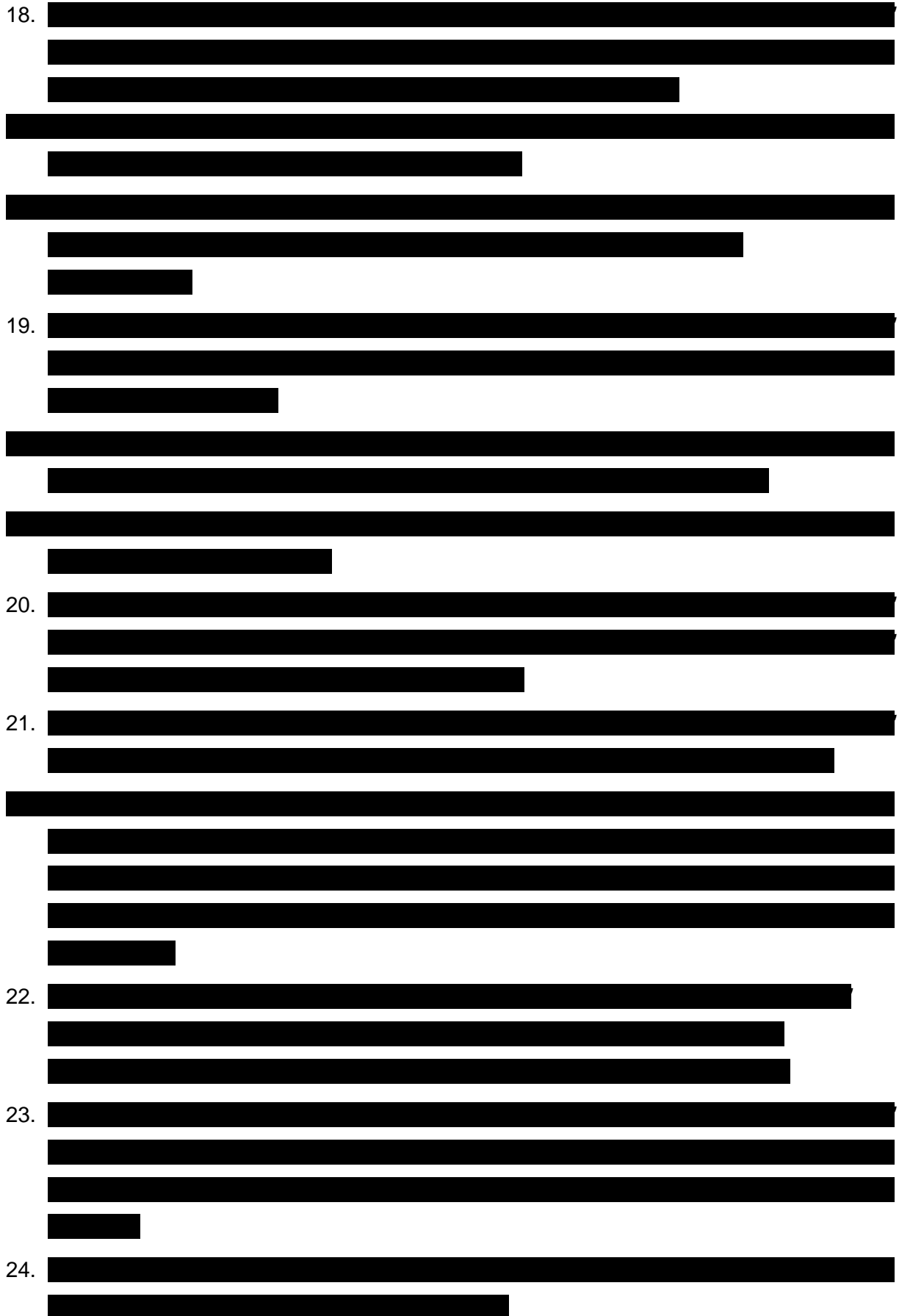
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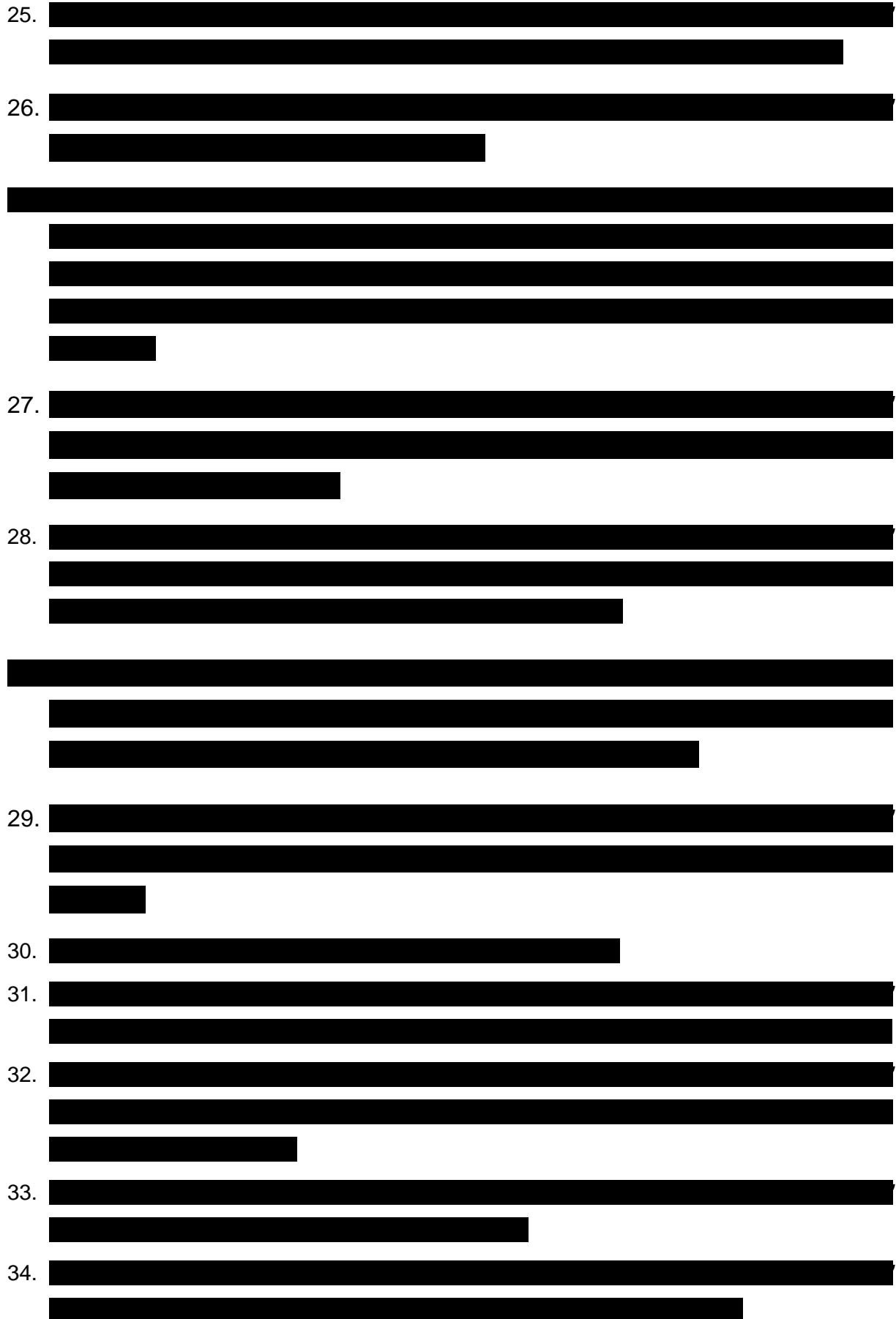
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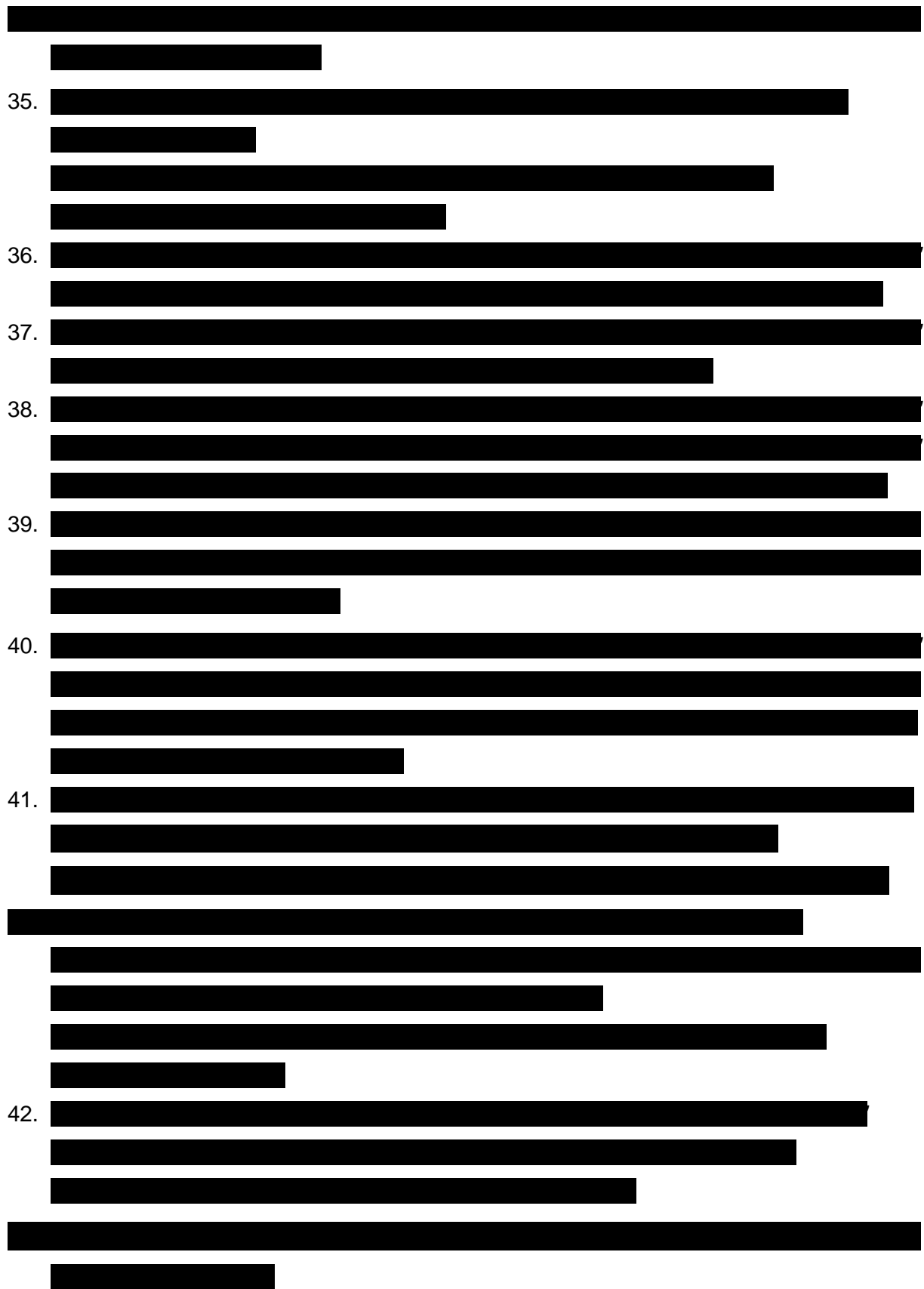
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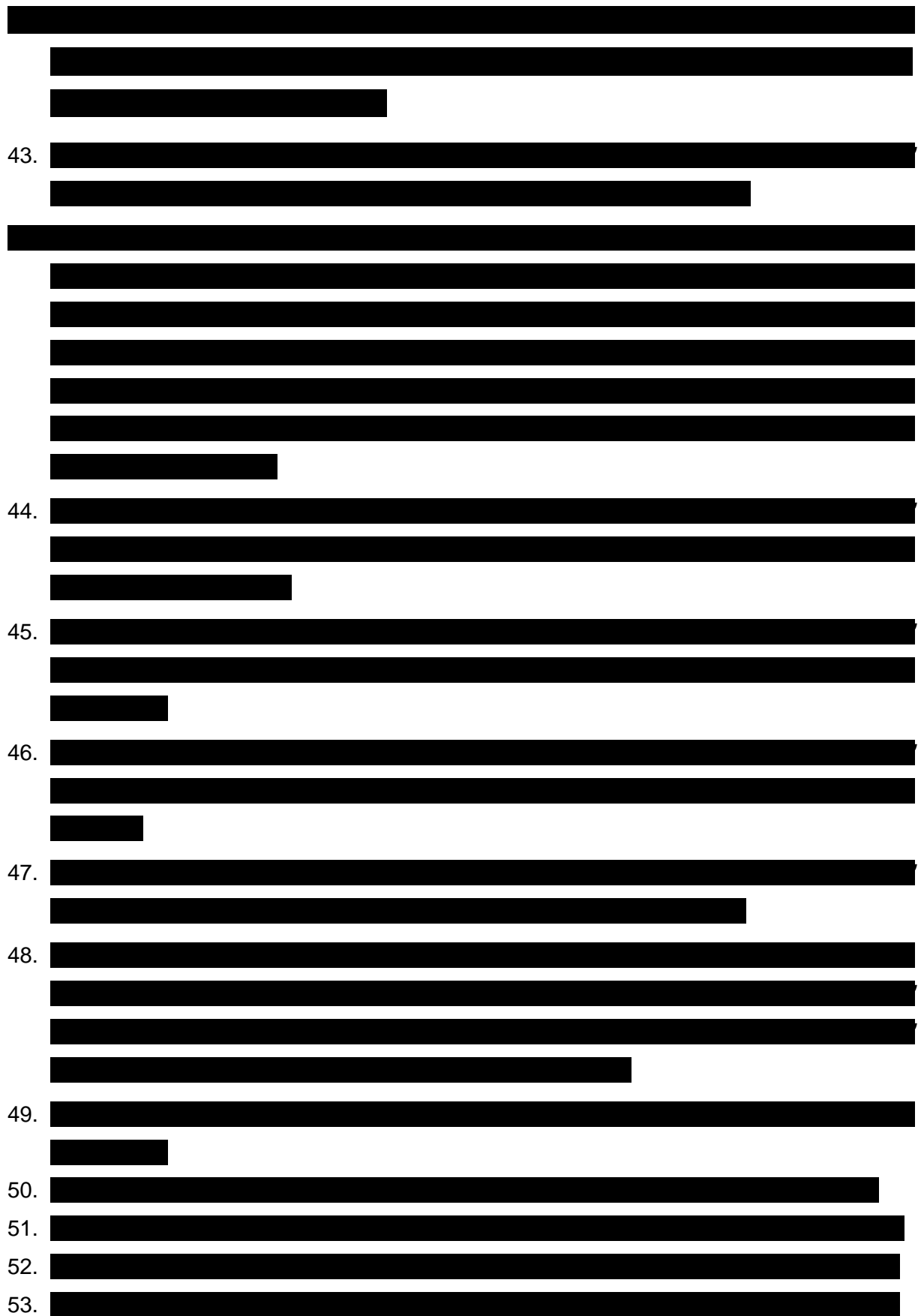


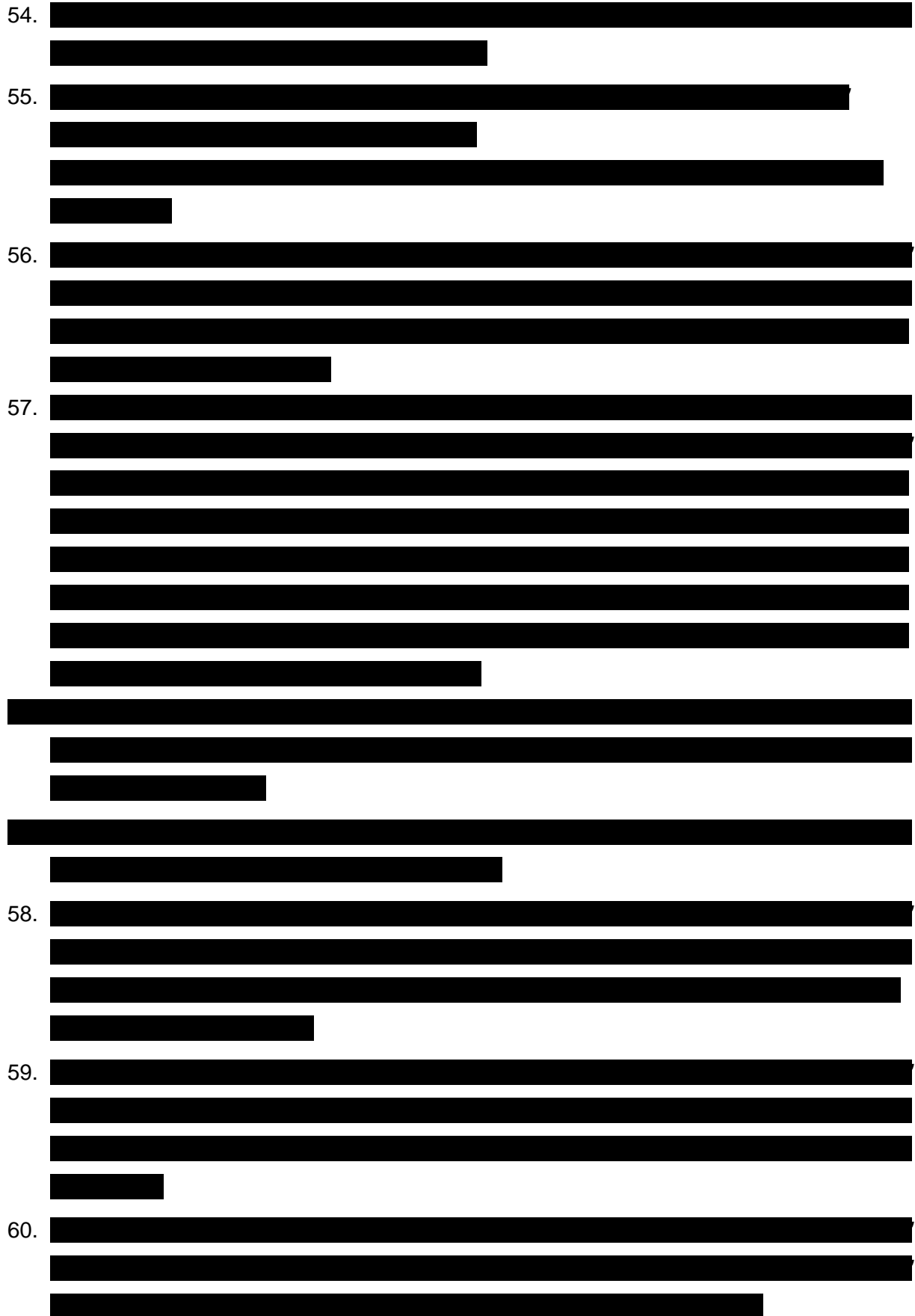


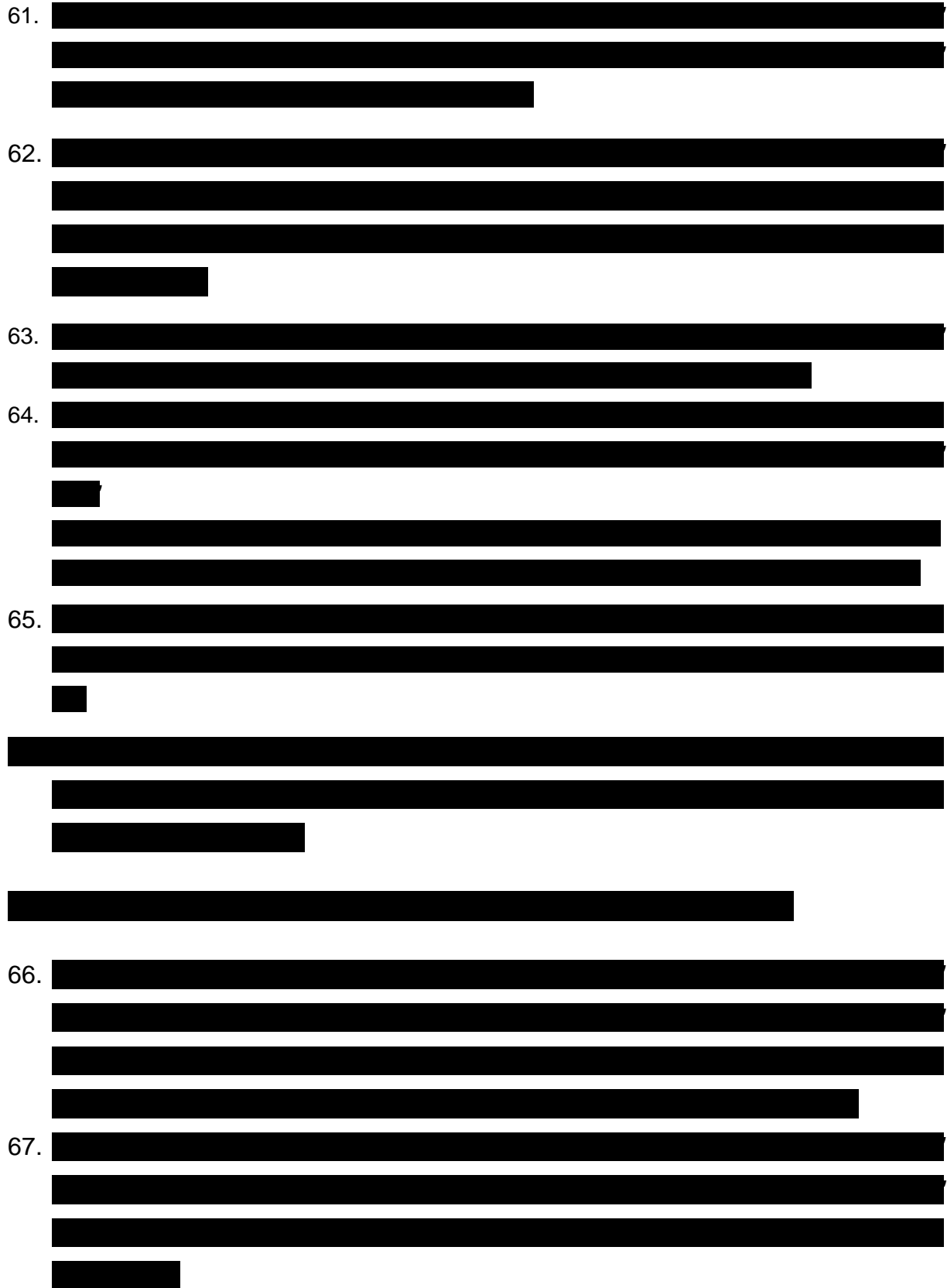


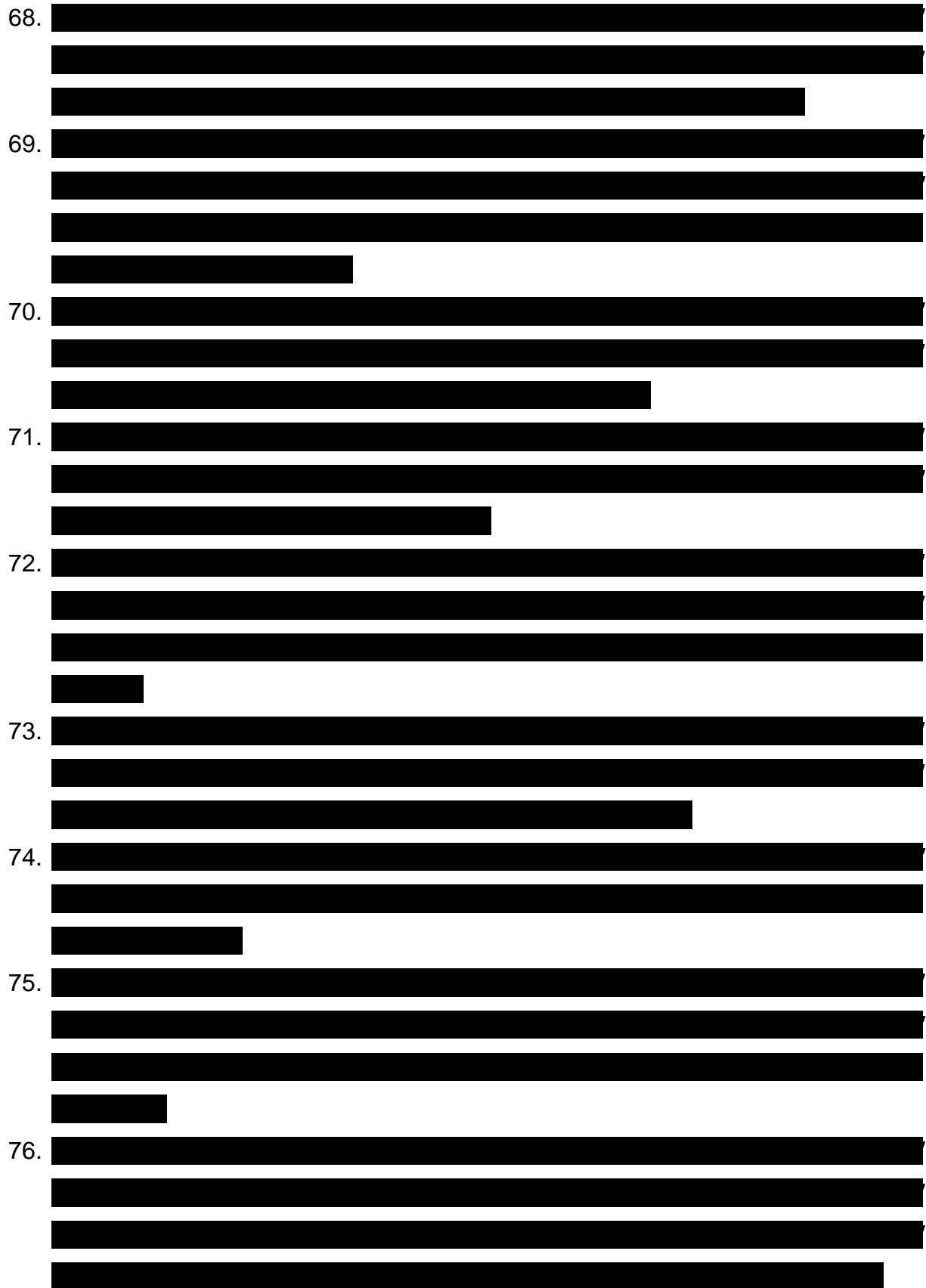


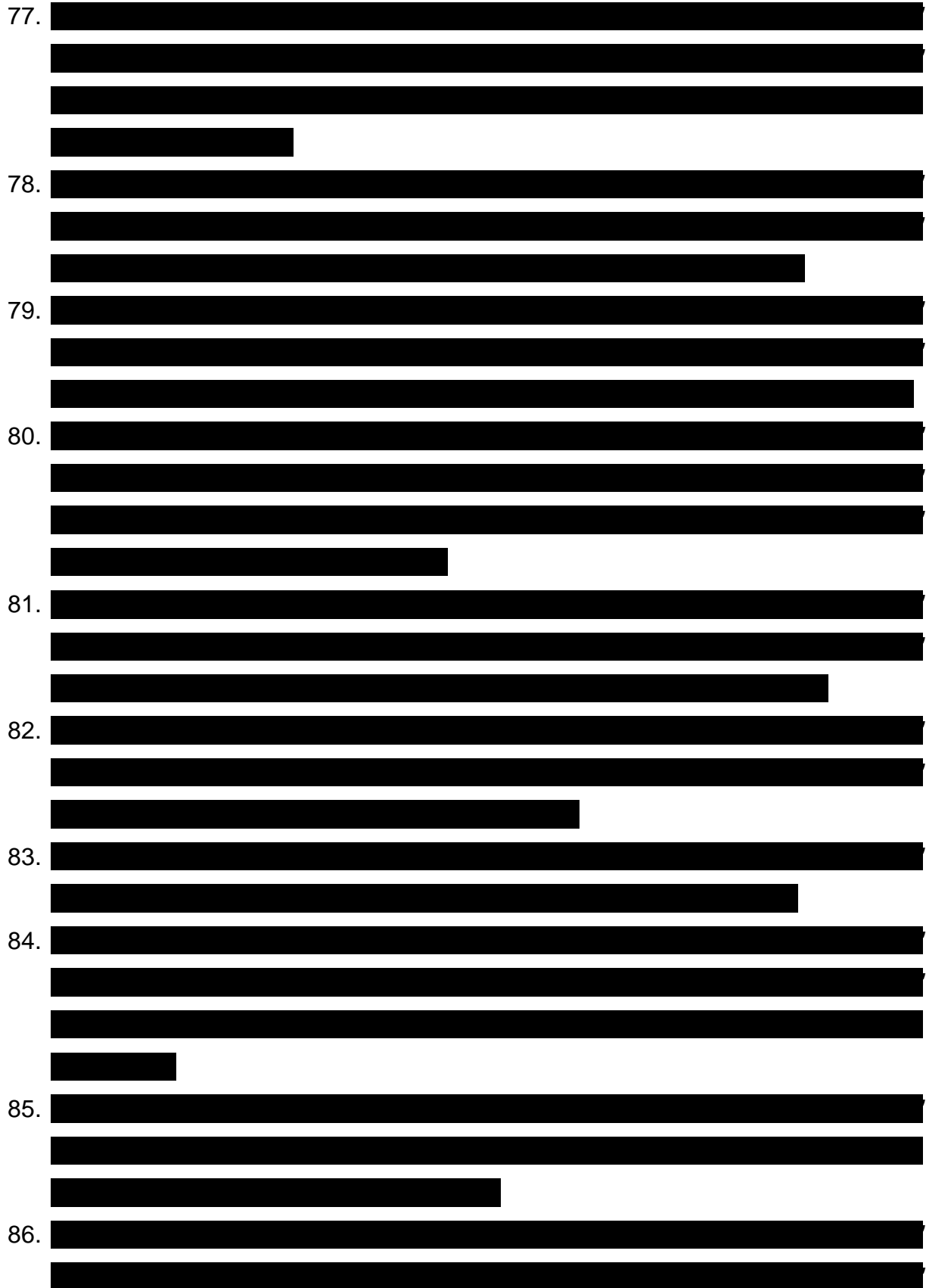




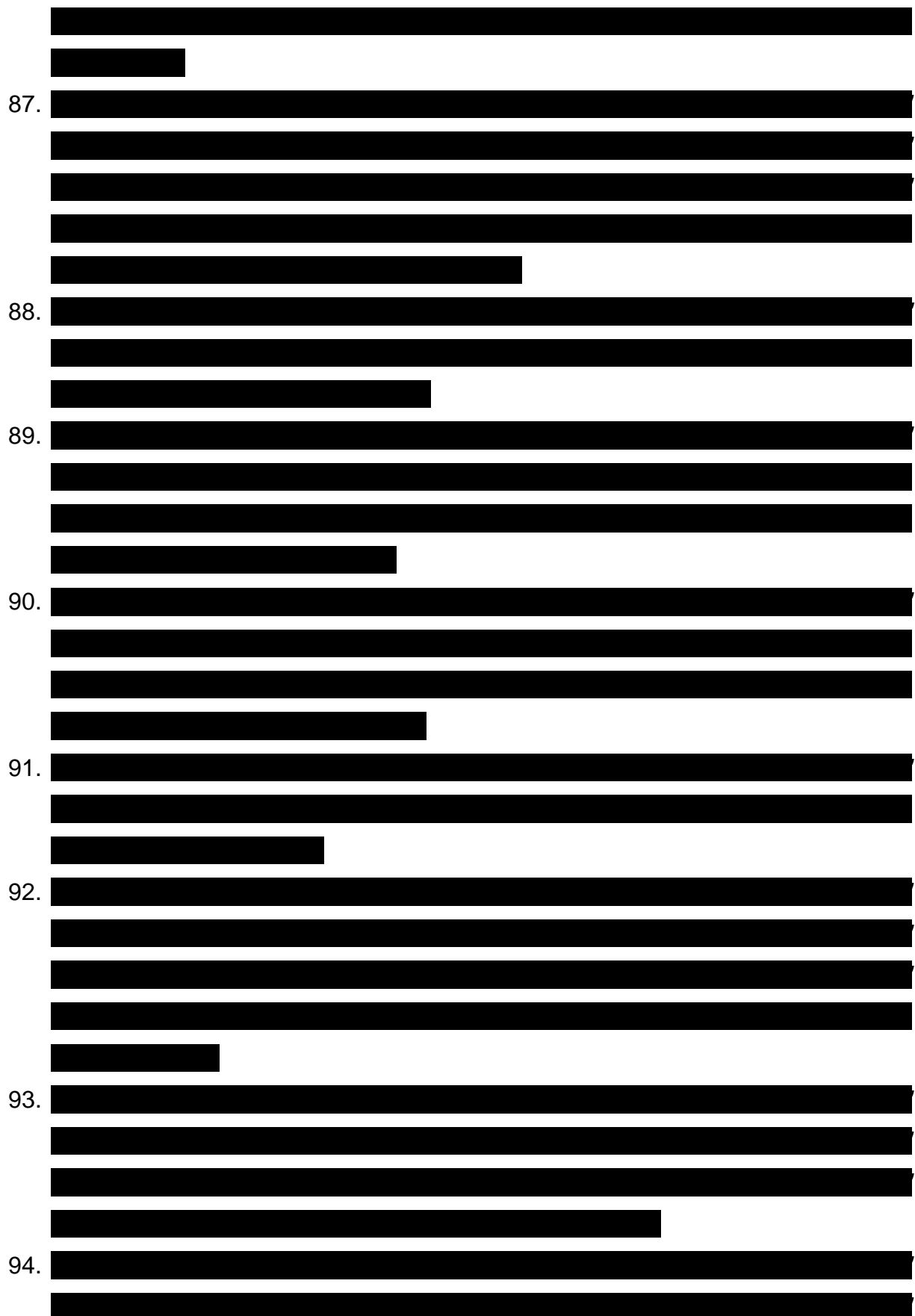


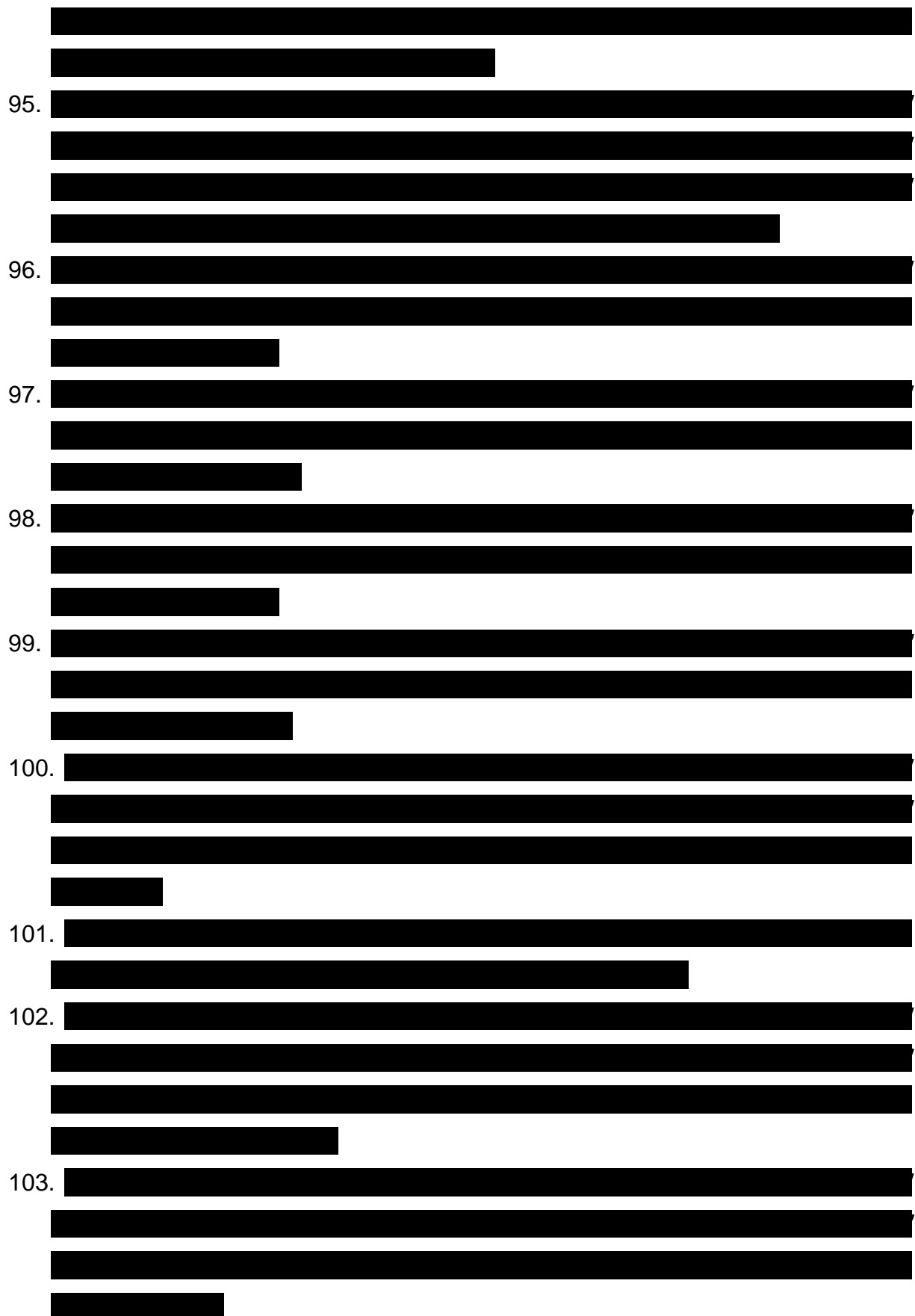


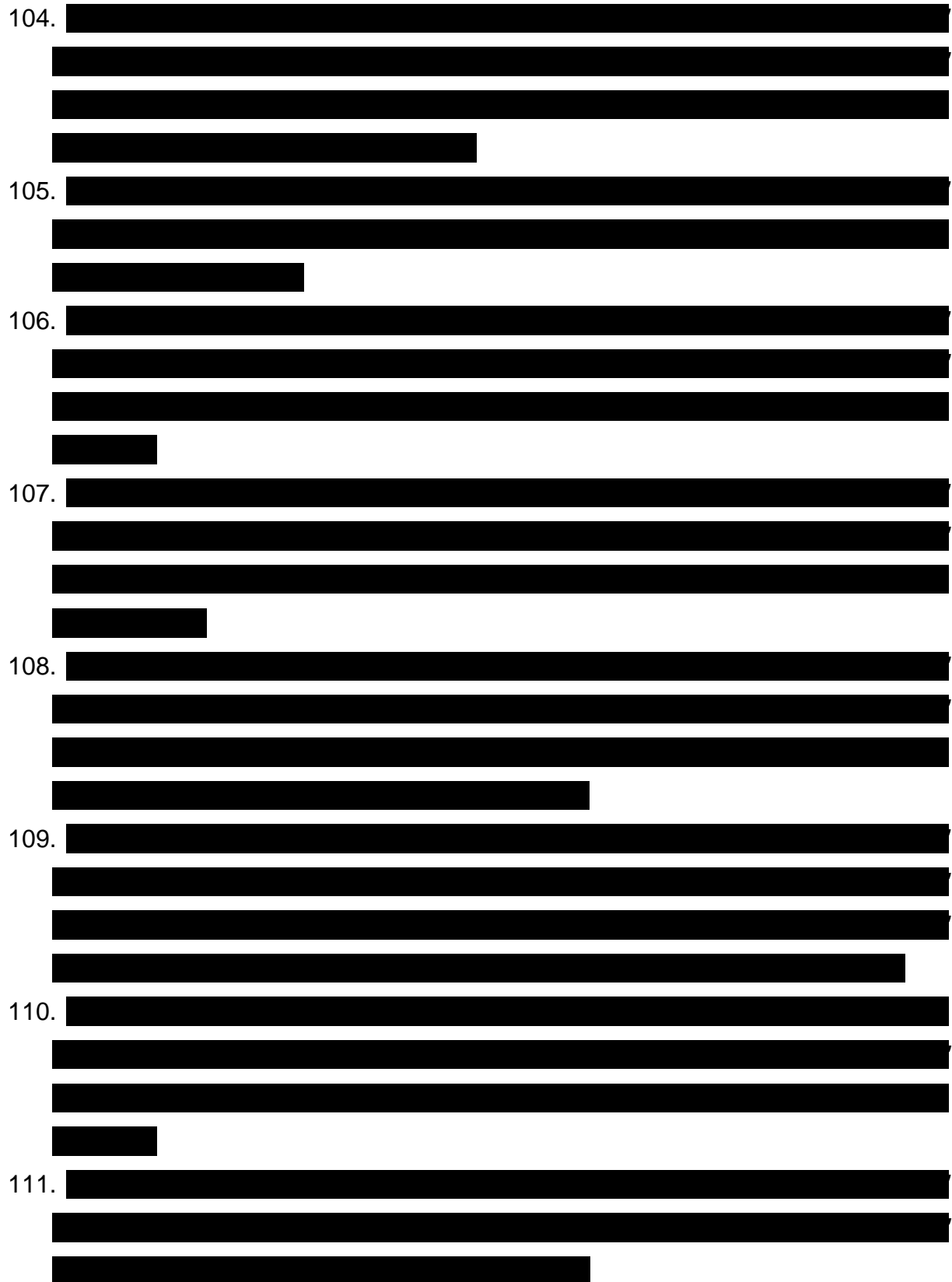












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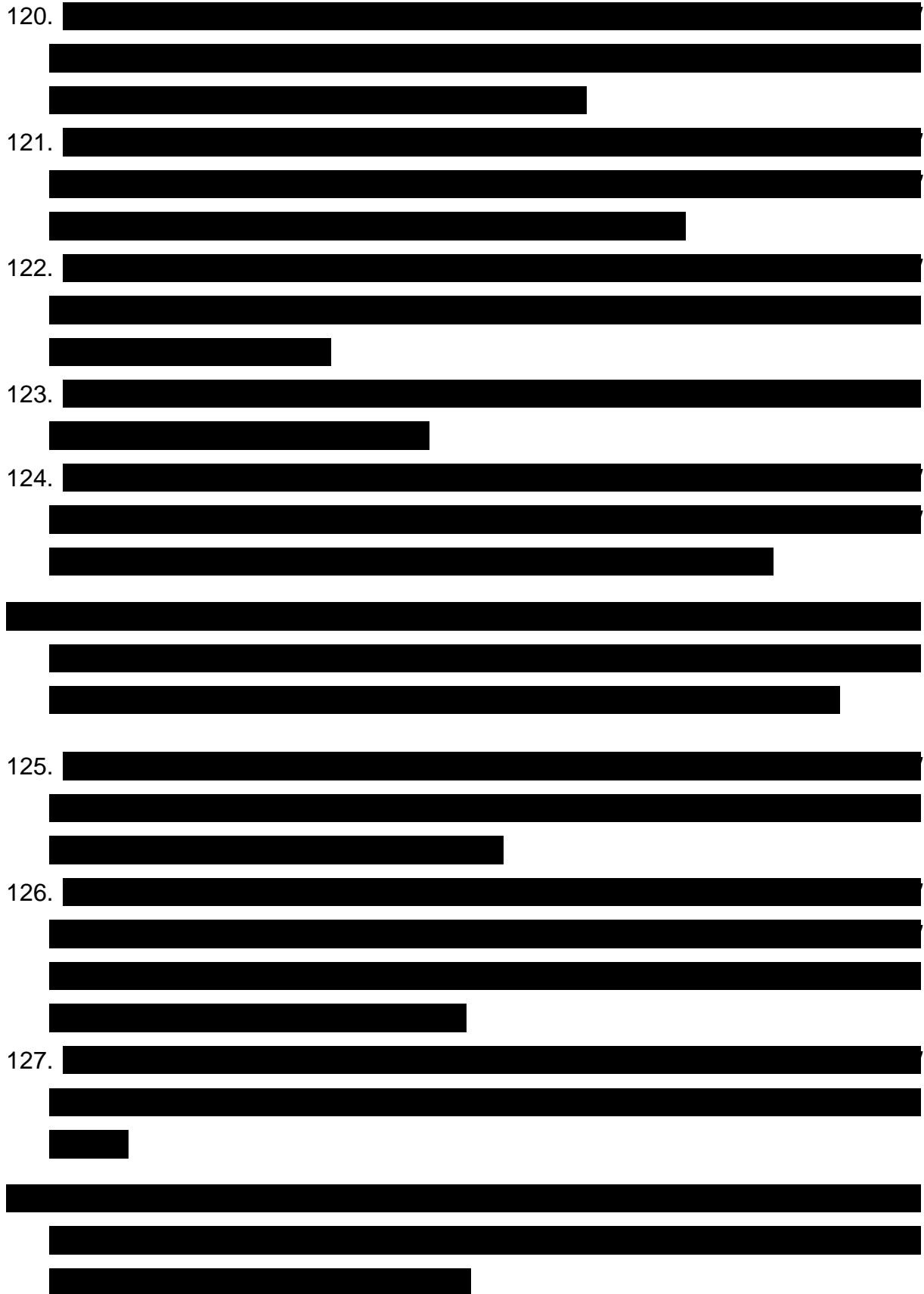
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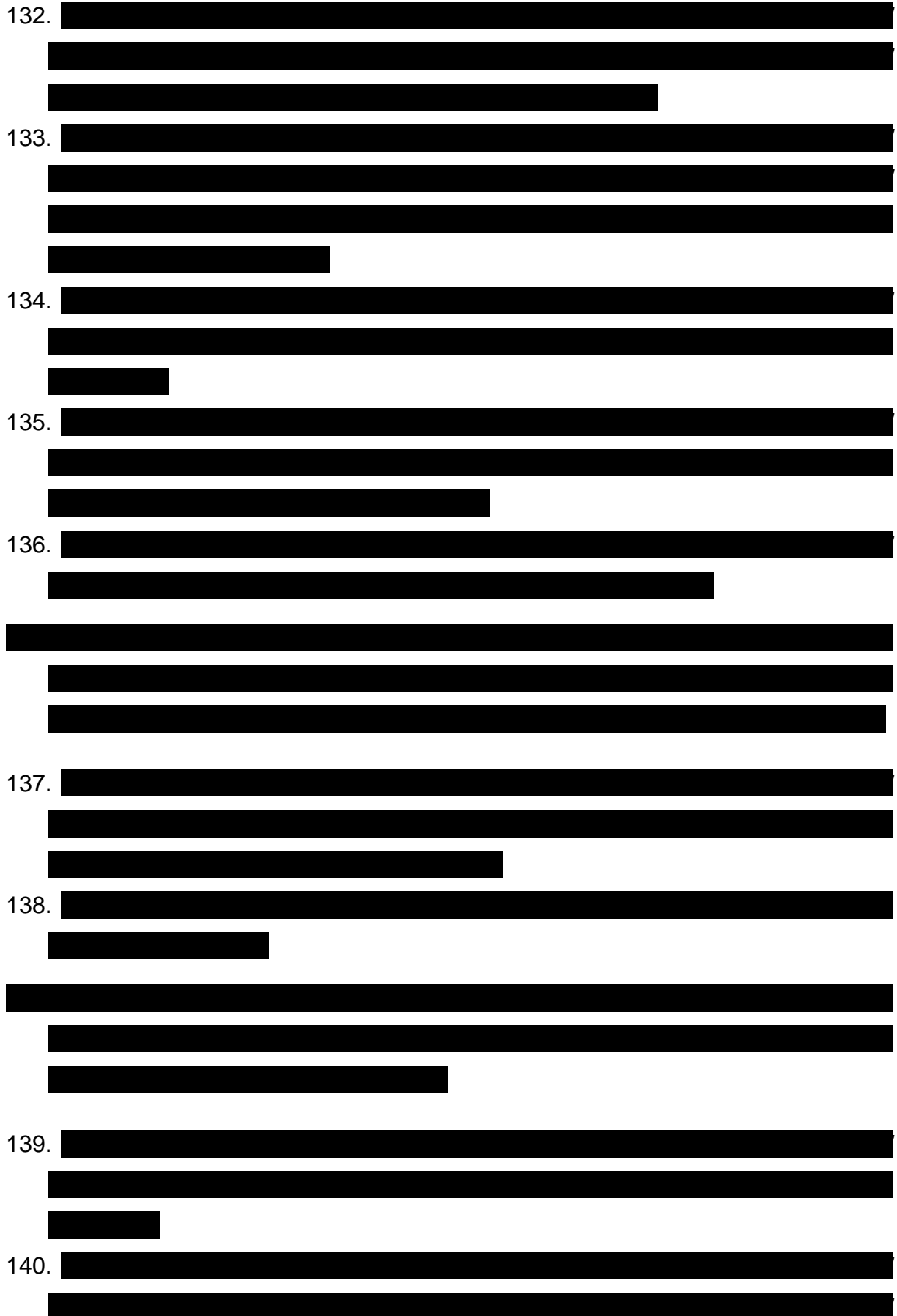
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