

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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| LENA LASHER, | : | |
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| Plaintiff, | : | |
| | : | |
| v. | : | Civil Action No. 17-1746 (ABJ) |
| | : | |
| DEPARTMENT OF HEALTH AND | : | |
| HUMAN SERVICES, <i>et al.</i> , | : | |
| | : | |
| Defendants. | : | |

MEMORANDUM OPINION

Plaintiff Lena Lasher (“Lasher”) has brought this action under 42 U.S.C. § 405(g) challenging the decision of the Secretary of Health and Human Services (“DHHS”) to exclude her from participation in federal health care programs for a period of 10 years.¹ This matter is before the Court on the Defendants’ Motion to Dismiss or, in the Alternative, for Summary Judgment. [Dkt. 14.] For the reasons discussed below, the Court will grant the motion. In light of Lasher’s conviction of multiple counts involving fraud in health care related federal programs, the sentence she received, and all of the factors considered by the agency, her exclusion for the ten year period was reasonable, supported by substantial evidence, and consistent with the applicable law. Lasher’s efforts to challenge her underlying conviction in this proceeding are misplaced, and none of the constitutional violations she has alleged provide a basis to alter the agency’s decision.

¹ Because Lasher appeals an administrative decision, this action proceeds against the Secretary of DHHS. *See* 42 U.S.C. § 1320a-7(f)(1). The Court will dismiss the Departmental Appeals Board, Christopher S. Randolph, Susan S. Yim, Sheila Ann Hegy and U.S. Department of Justice as party defendants.

I. BACKGROUND

A. Exclusion from Federal Health Care Programs

There are “certain bases upon which individuals . . . must[] be excluded from participation in Medicare, Medicaid and all other Federal health care programs.” 42 C.F.R. § 1001.1(a). One such basis is an individual’s conviction of a program-related offense:

The Secretary shall exclude . . . from participation in any Federal health care program . . . [a]ny individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program . . . operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

42 U.S.C. § 1320a-7(a)(3); *see* 42 C.F.R. § 1001.101. An individual is deemed “convicted of a criminal offense . . . when a judgment of conviction has been entered against [her] by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged.” 42 U.S.C. § 1320a-7(i)(1).

This exclusion authority is delegated to DHHS’ Inspector General (“IG”). *See* 48 Fed. Reg. 21662 (May 13, 1983). The IG issues a notice of exclusion which specifies the period of exclusion and its effective date. *See* 42 U.S.C. § 1320a-7(c), (f)(1).

The mandatory exclusion period lasts a minimum of five years. 42 U.S.C. § 1320a-7(c)(3)(B); 42 C.F.R. § 1001.102(a). However, if aggravating factors are found, the IG may extend the mandatory exclusion period. *See* 42 C.F.R. § 1001.102(b). Aggravating factors include “acts that resulted in conviction . . . committed over a period of one year or more,” 42 C.F.R. § 1001.102(b)(2), and a sentence including incarceration, 42 C.F.R. § 1001.102(b)(5). If

aggravating factors are found to exist, the IG may consider “mitigating factors . . . as a basis for reducing the period of exclusion to no less than 5 years.” 42 C.F.R. § 1001.102(c). For example, the IG may consider a sentencing court’s “determin[ation] that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual’s culpability,” 42 C.F.R. § 1001.102(c)(2), as a mitigating factor. An individual who has been excluded may apply for termination of the exclusion. *See* 42 U.S.C. § 1320a-7(g).

An individual whom the IG has excluded may request a hearing before an administrative law judge (“ALJ”) of the Civil Remedies Division (“CRD”) of DHHS’ Departmental Appeals Board (“DAB”), *see* 42 U.S.C. § 1320a-7(f)(1); 42 C.F.R. § 1005.2(a), “on the issues of whether: (i) [t]he basis for the imposition of the sanction exists, and (ii) [t]he length of exclusion is unreasonable.” 42 C.F.R. § 1001.2007(a)(1). The parties to this proceeding are the petitioner and the IG. 42 C.F.R. § 1005.2(b). A hearing request must be submitted to the DAB in writing, 42 C.F.R. § 1005.2(c), and it shall “contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner . . . disagrees, and the basis for . . . her contention that the specific issues or findings and conclusions were incorrect.” 42 C.F.R. § 1005.2(d).

Generally, the parties may conduct discovery, enter into stipulations of facts or law, introduce evidence, present and cross-examine witnesses, and make oral arguments to the ALJ. *See* 42 C.F.R. § 1005.3. In discharging his or her duties to “conduct a fair and impartial hearing, avoid delay, maintain order and assure that a record of the proceeding is made,” 42 C.F.R. § 1005.4(a), the ALJ may, among other things, “[r]eceive, rule on, exclude or limit evidence,” 42 C.F.R. § 1005.4(b)(10), and “[c]onduct any conference . . . or hearing in person or, upon agreement of the parties, by telephone.” 42 C.F.R. § 1005.4(b)(13). Ordinarily, witness testimony is given

orally. 42 C.F.R. § 1001.16(a). However, the ALJ may admit non-expert testimony “in the form of a written statement.” 42 C.F.R. § 1005.16(b).

The ALJ conducts at least one prehearing conference, 42 C.F.R. § 1005.6(a), during which stipulations, witnesses, scheduling, discovery and other matters are discussed. *See* 42 C.F.R. § 1005.6(b). After the prehearing conference, the ALJ “issue[s] and order containing the matters [the parties have] agreed upon” and any matters the ALJ had ordered during the prehearing conference. 42 C.F.R. § 1005.6(c).

The ALJ may issue a decision based on the written record “if the parties do not identify any proposed witnesses, do not offer the written direct testimony of any witnesses when ordered to do so, or do not request an opportunity to cross-examine a witness whose written direct testimony has been offered.” Administrative Record (“A.R.”) at 45 (CRD Proc. 19(d)). “The ALJ will issue an initial decision based only on the record, which will contain findings of fact and conclusions of law.” 42 C.F.R. § 1005.20(a).

The petitioner may appeal the ALJ’s initial decision to DAB’s Appellate Division. 42 C.F.R. § 1005.21(a). Along with the notice of appeal, the petitioner must submit “a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.” 42 C.F.R. § 1005.21(c). “DAB will not consider any issue not raised in the parties’ briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.” 42 C.F.R. § 1005.21(e). Nor may the DAB revisit an underlying criminal conviction:

When the exclusion is based on the existence of a criminal conviction . . . by Federal, State or local court, a determination by another Government agency, or any other prior determination where the facts were adjudicated and a final decision was made, the basis for the underlying conviction . . . is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal.

42 C.F.R. § 1001.2007(d). “The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record,” and the standard of review on a disputed issue of law is “whether the initial decision is erroneous.” 42 C.F.R. § 1005.21(h). DAB issues its decision on appeal to the parties along with a notice “describing the right of any petitioner or respondent who is found liable to seek judicial review.” 42 C.F.R. § 1005.21(i); *see* 42 U.S.C. § 1320a-7(f).

B. Lasher’s Criminal Convictions²

According to a Superseding Indictment issued on April 2, 2015 by a grand jury in the United States District Court for the Southern District of New York (“SDNY”), Lasher, a

² The Second Circuit, which affirmed Lasher’s criminal convictions, described her criminal history as follows:

Defendant-Appellant Lena Lasher was the supervising pharmacist at two Pennsylvania pharmacies that filled thousands of prescriptions for addictive painkillers issued over the Internet by doctors who had never met or consulted with their patients. In filling hundreds of prescriptions daily, Lasher and her employees, among other things, poured pills into vials without counting them, re-dispensed returned medication to new customers without properly inspecting the pills, and altered the instructions on pharmacy labels such that they did not correspond to what any physician had ordered.

On September 10, 2015, following a ten-day trial, Lasher was found guilty by a jury of conspiracy to misbrand drugs held for sale in violation of 18 U.S.C. § 371 (Count I); introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) and 18 U.S.C. § 2 (Count II); conspiracy to commit mail and wire fraud in violation of 18 U.S.C. § 1349 (Count III); and mail and wire fraud in violation of 18 U.S.C. §§ 1341, 1343, and 2 (Counts IV and V). She was then sentenced principally to three years’ imprisonment.

United States v. Lasher, 661 F. App’x 25, 26 (2d Cir. 2016), *cert. denied*, 197 S. Ct. 2254 (2017).

pharmacist, participated in an internet drug distribution scheme from 2010 through November 2012. Defs.’ Statement of Material Facts To Which There Is No Genuine Dispute (“Defs.’ Facts”) ¶ 1; A.R. at 712-24. A jury convicted Lasher of five offenses: conspiracy to misbrand prescription drugs, misbranding drugs, conspiracy to commit mail and wire fraud, mail fraud, and wire fraud. Defs.’ Facts ¶ 2; A.R. at 726-27. SDNY imposed a three-year prison sentence on each count to be served concurrently. Defs.’ Facts ¶ 2; A.R. at 728. The court also ordered a two-year term of supervised release upon Lasher’s release from imprisonment. A.R. at 729.

C. Lasher’s Proceedings Before DHHS’ Departmental Appeals Board

On March 31, 2016, the IG sent Lasher a notice of his decision to exclude her from participating in Medicare, Medicaid, and all other federal health care programs:

This is to notify you that you are being excluded from participation in any capacity in the Medicare, Medicaid, and **all** Federal health care programs for a minimum period of 10 years This exclusion is due to your felony conviction as defined in [42 U.S.C. § 1320a-7(i)] in the United States District Court for the Southern District of New York, of a criminal offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or with respect to or any act or omission in a health care program . . . operated or financed by any Federal, State, or local Government agency.

A.R. at 18 (emphasis in original); *see* Defs.’ Facts ¶ 3.³ The IG explained that the exclusion period would exceed five years because Lasher’s criminal acts “were committed over a period of one year or more,” A.R. at 18, and “[t]he sentence imposed by the court included incarceration.” A.R. at

³ The March 31, 2016 notice stated in error that the underlying acts were committed from about 2000 through November 2012. A.R. at 18. The acts actually were committed from about 2010 through November 2012, and the IG issued an amended notice of exclusion on July 25, 2016. A.R. at 668.

19. On May 25, 2016, Lasher, through counsel, submitted a written request for a hearing before an ALJ. A.R. at 16. While Lasher did “not dispute that the [IG] has a basis for the [imposition] of a sanction, [she did] dispute the length of the exclusion[.]” A.R. at 16.

The ALJ conducted the prehearing conference by telephone on July 20, 2016, A.R. at 54, and issued her Order and Schedule for Filing Briefs and Documentary Evidence on the following day. *See generally* A.R. at 54-60. Among other requirements, the ALJ instructed the parties to file short-form briefs, A.R. at 56, preprinted versions of which accompanied her order, *see* A.R. at 61-65 (petitioner), 66-70 (IG). If the parties were to offer witness testimony, the ALJ ordered them to “do so in the form of written direct testimony.” A.R. at 57 (emphasis removed). The ALJ then limited the hearing to the cross-examination of witnesses whose direct testimony had been submitted in writing. A.R. at 57. In addition, the ALJ “strongly caution[ed]” the parties to be “fully cognizant that written direct testimony [would] not be accepted for the purpose of being a collateral attack on any underlying conviction[.]” A.R. at 57.

The IG submitted his informal brief and supporting documents on August 24, 2016. *See generally* A.R. at 71-81. He argued that Lasher’s “role in a substantial internet pharmacy scheme,” A.R. at 72, and her subsequent criminal conviction, A.R. at 73, supported his exclusion decision. The IG further argued that Lasher’s 10-year exclusion was reasonable based on two aggravating factors: SDNY imposed a three-year term of incarceration and Lasher’s conduct occurred over a period of more than one year. *See* AR at 74-78.

On September 28, 2016, the ALJ granted the motion of Lasher’s counsel to withdraw from representation and extended the deadline for Lasher’s short-form brief and supporting exhibits to October 28, 2016. A.R. at 92. On October 20, 2016, Lasher submitted her brief and supporting documents. *See generally* A.R. at 98-112, 548-663. She conceded her conviction of a felony for

which exclusion is required, *see* A.R. at 98, and asserted that the length of her exclusion was unreasonable. *See* A.R. at 112.⁴ Neither party submitted written direct testimony or a request for an in-person hearing. Defs.’ Facts ¶¶ 6, 8. However, on November 10, 2016, after Lasher’s filing deadline had passed, Lasher submitted another brief which did request an in-person hearing. Defs.’ Facts ¶ 8; *see* AR at 119-63, 137. The ALJ did not accept this second brief or Lasher’s “rebuttal” to the IG’s reply brief because Lasher did not seek leave to file them. A.R. at 3.

The singular theme of Lasher’s submissions was her purported innocence. Her brief began with an assertion that she “was wrongly convicted.” A.R. at 98. Generally, Lasher denied any wrongdoing on her part, and she claimed to have complied with all applicable laws and regulations. *See, e.g.*, A.R. at 98, 102. She blamed her codefendants for all illegal acts, *see, e.g.*, A.R. at 108, and claimed that their wrongful conduct had been improperly attributed to her. Lasher also faulted the presiding judge’s unfavorable rulings on evidentiary questions, *see, e.g.*, A.R. at 99, 104, and the prosecutors’ allegedly misleading statements. *See, e.g.*, A.R. at 100, 108.

On January 30, 2017, the ALJ issued the decision on behalf of the Civil Remedies Division. *See generally* A.R. at 1-10. She concluded “that the IG [had] a basis for excluding [Lasher] because she was convicted of five felony offenses, to include conspiracy to commit wire and mail fraud, mail fraud, and wire fraud while engaged as a pharmacist in a scheme to illegally dispense drugs.” A.R. at 1. “Being that [Lasher] was found guilty of five offenses related to her role in a scheme to illegally dispense drugs, to include conspiracy to commit fraud and the actual commission of fraud, her convictions [were] undoubtedly related to fraud” and these offenses were

⁴ The preprinted Informal Brief of Petitioner asked whether Lasher had been “convicted of a felony that was committed after August 21, 1996.” A.R. at 61. Lasher responded, “Yes but I was wrongly convicted.” A.R. at 98. Lasher provided the same response, A.R. at 98, when asked whether she had been “convicted of an offense for which exclusion is required,” A.R. 62.

“in connection with’ the delivery of a health care item or service” for purposes of 42 U.S.C. § 1320a-7(a)(3). A.R. at 7. Notwithstanding Lasher’s strong belief that she was wrongly convicted, the ALJ had no authority to entertain a collateral attack on her criminal convictions. *See* A.R. at 8 (citing 42 C.F.R. § 1001.2007(d)). Further, the ALJ “affirm[ed] the 10-year exclusion period because the IG has proven two aggravating factors, and there are no mitigating factors present.” A.R. at 1. In light of the two aggravating factors, the ALJ concluded that the length of the exclusion period was not unreasonable. A.R. at 10.

Undaunted, in February 2017, Lasher appealed the ALJ’s decision to the DAB’s Appellate Division. *See generally* A.R. 221-48. Lasher maintained that she had been wrongly convicted, *see* A.R. at 221, and she requested a hearing in order to present “expert witness [testimony] to corroborate [her own] testimony and that of the video recordings” which she claimed would show that she did not label, store, destroy or count pills improperly. A.R. at 221; Defs.’ Facts ¶ 11. The IG opposed the appeal, arguing that the ALJ’s decision was supported by substantial evidence in the record. *See* A.R. at 249-57; Defs.’ Facts ¶ 11. And the IG reiterated that “[n]either the ALJ nor the [BAD] may consider evidence which would only be relevant to a prohibited collateral attack on [Lasher’s] underlying conviction.” A.R. at 254 (citing 42 C.F.R. § 1001.2007(d) (additional citations omitted)).

Lasher submitted a second brief to the BAD on April 3, 2017, arguing that the IG violated rights protected under the Fourth, Fifth and Sixth Amendments to the United States Constitution by refusing to allow a collateral attack on her conviction. *See* A.R. at 276. Further, she argued that she should be allowed to submit evidence of her innocence, that the ALJ wrongfully denied her an in-person hearing, and that her trial counsel was ineffective. *See generally* A.R. at 276-78, 286, 288. Not surprisingly, the IG noted that Lasher’s “arguments and exhibits failed to rebut the

substantial evidence and law that support her ten-year exclusion, and instead proposed to raise prohibited collateral attacks.” Defs.’ Facts ¶ 13; *see* A.R. at 254, 515.

On June 28, 2017, the Appellate Division affirmed the ALJ’s decision, *see generally* A.R. at 537-43, finding that Lasher “has not identified any basis for reversing the ALJ Decision,” A.R. at 538. Lasher’s “attempts to show that she was wrongly convicted are collateral attacks on the validity of her criminal conviction on which the exclusion was based . . . are expressly forbidden by regulation,” A.R. at 538, and the ALJ did not err by refusing to consider Lasher’s constitutional claims, A.R. at 539.

II. DISCUSSION⁵

Lasher, who describes herself as “an Asian female of Vietnamese descent,” Compl. ¶ 5; Objection to Defs.’ Mot. to Dismiss or, in the Alternative, for Summ. J. (“Pl.’s Opp’n”) at 2 (page numbers designated by ECF, contends that she “was . . . excluded because of her race, national origin, and sex,” Compl. ¶ 2; and that rights protected under the Fifth and Sixth Amendments to the United States Constitution were violated during both the criminal proceedings and the administrative proceedings regarding her exclusion from federal health care programs. *See id.*; Pl.’s Opp’n at 1, 3. She complains that although “others (white males) . . . testified at [her] trial that they committed . . . crime[s,]” Compl. ¶ 2, only she was punished, *see id.* Once again, Lasher faults the IG for having based his exclusion decision solely on a criminal conviction “wrongfully achieved” through perjured testimony and suppression of exculpatory evidence, *id.* ¶ 5; *see, e.g.*, Pl.’s Opp’n at 1, 3-4. She dismisses the ALJ’s decision as “essentially only rubber-stamping a

⁵ Although the Court granted Lasher leave to supplement, ECF No. 22, her opposition to Defendants’ motion, ECF No. 19, the Court does not rely on the supplement in reaching its decision, which is based on the complaint, ECF No. 1, the parties’ briefs, ECF Nos. 14, 19, and 21, and the Administrative Record, ECF Nos. 24-27.

wrongful conviction,” Pl.’s Opp’n at 3, and asserts that the IG punished her because she exercised her constitutional right to a jury trial. *See* Compl. ¶ 2; Pl.’s Opp’n at 27. Finally, Lasher asks that this Court review and reverse the exclusion decision and award her monetary damages. Compl. (Prayer for Relief) ¶¶ 2-3, 5.

“As exclusions from participation in federal health care programs are subject to the same judicial review as decisions regarding social security benefits, *see* 42 U.S.C. § 1320a-7(f)(1), the standard of review derives from 42 U.S.C. § 405(g), the statute governing decisions of the Commissioner of Social Security.” *Aswad v. Hargan*, No. 2:16-CV-1367, 2018 WL 704370, at *2 (D.N.M. Feb. 2, 2018). The Court may ask “only whether the Secretary’s . . . decision was ‘based on substantial evidence in the record and correctly applies the relevant legal standards.’” *Friedman v. Leavitt*, No. 08-CV-0586, 2008 WL 11389031, at *9 (D.D.C. Dec. 6, 2008) (quoting *Rossello v. Astrue*, 529 F.3d 1181, 1184 (D.C. Cir. 2008) (additional citation omitted)).

The application of that standard to this record makes short work of the resolution of Defendants’ motion. The fact of Lasher’s conviction for crimes related to fraud in connection with the delivery of a health care item or service is undisputed. Notwithstanding Lasher’s insistence that she did no wrong, the Court’s role “is to review the validity of the exclusion,” not the underlying criminal conviction, *Travers v. Sullivan*, 801 F. Supp. 394, 403 (E.D. Wash. 1992), *aff’d sub nom. Travers v. Shalala*, 20 F.3d 993 (9th Cir. 1994). Lasher’s sole argument – that she was wrongfully convicted – is the one matter that neither BAD nor this Court may entertain. *See Ellicott v. Leavitt*, No. 107-CV-088, 2008 WL 4809610, at *4 (S.D. Ga. Nov. 4, 2008) (citing 42 C.F.R. § 1001.2007(d)) (“Indeed, any argument or evidence that tends to undermine or mitigate against the criminal conviction is not properly presented in an appeal from a § 1128(a)(1) exclusion.”); *Anderson v. Thompson*, 311 F. Supp. 2d 1121, 1126 (D. Kan. 2004) (finding that

arguments “parrot[ing] those [the petitioner] made on direct appeal of his conviction” for violations of the Medicare Anti-Kickback Statute were “nothing more than a veiled collateral attack on his conviction, which is improper and beyond the scope of judicial review”). In this case, there is ample evidence in the record to support the IG’s mandatory exclusion decision.

Similarly, the record fully supports extension of the exclusion period from five to 10 years. There is no dispute that Lasher’s criminal conduct took place over more than one year and that SDNY imposed a prison sentence. These two facts qualify as aggravating factors, *see* 42 C.F.R. § 1001.102(b), and absent evidence in the record of a mitigating factors, *see* 42 C.F.R. § 1001.102(c), support the conclusion that the 10-year exclusion period is not unreasonable.

Lasher is no more successful with respect to her constitutional claims. Lasher cannot credibly claim a violation of procedural due process, “[t]he fundamental requirement” of which “is the opportunity to be heard at a meaningful time and in a meaningful manner.” *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (internal quotation marks and citations omitted). It is apparent that the relevant statute and regulations provide for notice of the IG’s decision prior to the exclusion’s effective date, a hearing before an ALJ, an opportunity to present and cross-examine witnesses, appeal of the ALJ’s decision to BAD’s Appellate Division, and judicial review in federal district court. It is also apparent that Lasher availed herself of the administrative process at both the ALJ and the appellate level, even though her request for in-person hearing before the ALJ was denied because it was filed after the deadline for making such a request had passed. The ALJ’s pre-hearing order set forth filing deadlines and clear instructions for submission of written direct testimony, as well as the ALJ’s warning that, if an in-person hearing were necessary, its sole purpose would have been for cross-examination of the witnesses whose direct testimony the parties had submitted previously in writing. As neither party submitted witness testimony in writing,

Lasher cannot claim a due process violation arising from the ALJ's refusal to conduct an in-person hearing. Nor did the ALJ or DAB err by declining to consider evidence which Lasher sought to introduce for the stated purpose of undermining the validity of her conviction. An administrative hearing under 42 U.S.C. § 1320a-7(f) "does not necessitate an evidentiary hearing concerning the underlying conviction." *Travers*, 801 F. Supp. at 403. The Court is satisfied that the procedures Lasher was afforded for challenging the IG's exclusion decision comported with due process.

Lasher's claims of discrimination and violation of her right to equal protection are unavailing. There is no support in the record for Lasher's assertion that the decisions of the IG, ALJ, or the DAB were based in any way on Lasher's race, gender or national origin. Lasher herself concedes that the IG had a valid basis for excluding her, and her criminal conviction was "the triggering event" for the IG's imposition of a mandatory exclusion. *Travers*, 20 F.3d at 998.

III. CONCLUSION

The Court concludes that there is substantial evidence in the record to support defendant's decision to exclude Lasher from participation in federal health care programs for a 10-year period based on her criminal conviction, and that defendant correctly applied the relevant legal standards. Accordingly, will Court grants defendants' motion, and a separate Order will issue.

DATE: March 27, 2019

/s/
AMY BERMAN JACKSON
United States District Judge