UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. GLENN A. CHIN, Defendant.	Court No.: 14-cr-10363-RGS-2

GOVERNMENT'S SENTENCING MEMORANDUM AND MEMORANDUM IN SUPPORT OF THE GOVERNMENT'S MOTIONS FOR FORFEITURE AND RESTITUTION

The United States of America hereby submits this memorandum in aid of the re-sentencing of defendant Glenn A. Chin ("Chin") and in support of the Government's Motions for Forfeiture and Restitution.

In October 2017, following a 5-week trial, a jury unanimously found Chin guilty of directing the fraudulent clean room operations of New England Compounding Center ("NECC"), which, at Chin's direction, dispensed hundreds of thousands of substandard and dangerous drugs manufactured in filthy conditions for use on unsuspecting patients throughout the nation. The crimes committed by Chin and his codefendants led to an unprecedented public health crisis. More than 100 victims died after receiving tainted drugs made by Chin himself, and hundreds more were injured and continue to suffer today. Following his trial, in which the jury found him guilty on all 77 counts, this Court sentenced Chin to a period of incarceration of 96 months, entered an order of forfeiture in the amount of $175,000, and entered an order of restitution in an amount to be determined. Chin appealed two of his convictions, his sentence, and the orders of forfeiture and restitution. The Government also appealed, challenging the calculation of Chin's guidelines sentencing range, as well as the orders of forfeiture and restitution. The First Circuit affirmed

Chin's convictions; vacated his sentence, forfeiture order, and restitution order; and remanded the matter for further proceedings consistent with the order. *United States v. Chin*, 965 F.3d 41 (1st Cir. 2020). Specifically, the First Circuit held, among other things, that contrary to this Court's rulings, additional sentencing enhancements could apply to Chin's sentencing guidelines range, that Chin's forfeiture amount should not be reduced by his tax liability or any Eighth Amendment considerations, and that the patients who were injected with NECC's contaminated methylprednisolone acetate ("MPA") may be considered victims of Chin's fraud.

Taking account of the applicable enhancements to Chin's sentencing guidelines range and the factors set forth in 18 U.S.C. § 3553, the Government recommends that the Court sentence Chin to 210 months. The Government also requests that the Court enter an order of forfeiture in the amount of $473,584 and, finally, an order of restitution in the amount of $82 million, with joint and several liability with Chin's RICO-coconspirator Barry Cadden ("Cadden").

PROCEDURAL BACKGROUND

On October 25, 2017, a jury convicted Chin on 77 counts of racketeering in violation of 18 U.S.C. § 1962(c), racketeering conspiracy in violation of 18 U.S.C. § 1962(d), mail fraud in violation of 18 U.S.C. § 1314, introducing adulterated drugs into interstate commerce in violation of 21 U.S.C. §§ 351(a)(2)(A), 331(a) and 333(a)(1), and introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 352(a)(2), 331(a) and 333(a)(2). Doc. 1277. Chin filed a post-verdict motion for judgment of acquittal on November 22, 2017. Docs. 1354-55. On January 31, 2019, this Court sentenced Chin to 96 months of imprisonment and two years of supervised release. Doc. 1412.

After briefing and a hearing on forfeiture and restitution, this Court entered a forfeiture money judgment in the amount of $175,000.00. Docs. 1400, 1452. On March 18, 2018, the Court

granted the Government's request for an order of restitution, but held in abeyance a determination of the amount of restitution owed. Doc. 1455. The Court entered an amended order of judgment on March 27, 2018 to reflect the order of forfeiture, which both the Government and Chin appealed. Docs. 1458, 1462, 1470. *See generally Chin*, 965 F.3d 41. This Court subsequently denied Chin's post-verdict motion for judgment of acquittal, finding the motion moot in light of the pendency of the First Circuit appeal. Doc. 1486. Chin appealed that order as well. Doc. 1499.

On July 9, 2020, the First Circuit entered an order on the consolidated appeals. *Chin*, 965 F.3d 41. The First Circuit rejected Chin's challenges to his convictions, but found errors in the calculation of his sentence, in the restitution order, and in the amount of his forfeiture obligation, and entered an order of remand for further proceedings consistent with the First Circuit's opinion. *Id.* The First Circuit's mandate was entered pursuant to Federal Rule of Appellate Procedure 41(a) on July 30, 2020. *Id.*

CHIN'S CRIMINAL CONDUCT

Chin's convictions were based on overwhelming evidence demonstrating that Chin conspired with Cadden and others at NECC to fraudulently produce and sell substandard drugs that were marketed as safe and were anything but. These drugs were contaminated, they were improperly tested or not tested at all, they were super- or sub-potent, and they were manufactured using expired ingredients. The drugs were manufactured in "clean rooms" that were filled with mold and bacteria that Chin and others knew were on the floor and surfaces, on their gloved fingertips while making and filling drugs, and in the air all around them. Chin was not only a knowing and willful participant in NECC's fraudulent activities, he directed them. He oversaw the clean room staff in both clean rooms and all of NECC's sterile drug manufacturing activities. He directed the mislabeling of lot numbers and the altering of expiration dates. He gave

instructions to his staff to falsify cleaning logs and ignored environmental monitoring results that warned of the increasing danger. When federal and state investigators arrived at NECC during the outbreak, he lied to them about the sterilization of the MPA and the supposed quarantine of untested drugs. And he directed technicians to hide cracks in the clean room floor with trash barrels. All as regulators raced against time to determine the source of the outbreak that was harming patients across the country, and stop it.

Because of Chin's own misconduct, drugs manufactured by NECC were contaminated and highly dangerous. When the drugs he made were injected into patients, more than 100 died. Almost 700 others were harmed. Every one of those patients was a victim of Chin's crimes. The Court should impose a sentence that reflects the full scope of Chin's conduct and accounts for the vast harm visited upon his victims.

SENTENCING RECOMMENDATION

The Court previously calculated Chin's total offense level to be 28. The Court calculated Chin's offense level as follows:

	Offense Level
Mail Fraud racketeering base offense level (§2B1.1(a)(1))	7
- Total fraud loss $550,000 - $1,500,000 (§2B1.1(b)(1)(H))	+14
- Involved 10 or more victims and committed through mass marketing (§2B1.1(b)(2))	+2
Offense Level for Grouped Mail Fraud Acts / Counts	**23**
- Organizer or leader of criminal activity (§3B1.1(a))	+3
- Abuse of a Position of Trust (USSG §3B1.3)	+2
Total Adjusted Offense Level	**28**

That total offense level, combined with Chin's lack of previous criminal history, led the Court to determine Chin's sentencing guidelines range to be 78 to 97 months. [1] The Court sentenced Chin to 96 months incarceration—near the top-end of this range. In sentencing Chin at the top-end of the guidelines range, the Court adopted the same reasoning and rationale for a high-end guidelines sentence it had expressed at Cadden's sentencing (*see* Chin Sentencing Transcript (Jan. 31, 2018) 15:7-10), that is, that the "persistence of the misrepresentations in this case [were] aggravated" and that Cadden and Chin's fraud "led to something far worse" than "financial devastation." Cadden Sentencing Transcript (June 26, 2017) 120:20-121:7.

On appeal, the First Circuit found the Court erred in refusing to include three sentencing enhancements: (1) a two-level enhancement because Chin's "offense involved . . . the conscious or reckless risk of death or serious bodily injury" pursuant to USSG § 2B1.1(b)(16); (2) a "vulnerable victim" enhancement pursuant to USSG § 3A1.1(b); and (3) a four-level enhancement because Chin "was as an organizer or leader of a criminal activity that involved five or more participants or was otherwise extensive" pursuant to USSG § 3B1.1(a). Accordingly, the First Circuit vacated Chin's sentence and remanded the case with instructions to this Court to determine whether these three enhancements are applicable to Chin's case, and to resentence him under a properly calculated sentencing guidelines range. The government submits now, as it did before, that the three enhancements apply.

[1] In its presentence report, the Probation Department calculated Chin's total offense level to be 37, with a base offense level of 7 (USSG §2B1.1(a)(1)), a 22 level enhancement based upon a loss amount between $25 million and $65 million (USSG § 2B1.1(b)(1)(L), a two-level enhancement because the offense involved 10 or more victims (USSG §2B1.1(b)(2)(A)(i)), a two-level enhancement because Chin abused his position of trust as a licensed pharmacist (USSG §3B1.3), and a four-level enhancement because Chin was an organizer or leader of criminal activity involving five or more participants (USSG §3B1.1A).

Conscious or Reckless Risk of Death or Serious Bodily Injury Enhancement

At Chin's previous sentencing, this Court declined to apply a two-level enhancement because Chin's "offense involved . . . the conscious or reckless risk of death or serious bodily injury." USSG § 2B1.1(b)(16). The Court based this decision on its erroneous conclusion that the enhancement could apply only if Chin had committed a criminal offense that, "by its nature, involved the conscious or reckless risk of death or serious bodily injury" and its further error that, with respect to Chin's fraud offenses, the "victims that were identified were the clinics and the hospitals who purchased the drugs, not the patients who were actually put at risk." *Chin*, 965 F.3 at 52 (internal quotation marks omitted). In reversing this decision, the First Circuit held that this Court erred by focusing too narrowly on the offense of conviction—rather than, as required in sentencing, on the full scope of Chin's relevant conduct. On remand, the First Circuit instructed this Court to evaluate not only the specific offense of conviction, but all "'relevant conduct' for which the Guidelines hold [Chin] accountable," including "'all acts and omissions' that Chin 'committed, aided, abetted, counseled, commanded, induced, procured, or willfully caused . . . that occurred during the commission of the offense of conviction.'" *Id.* at 22 (citing USSG § 1B1.3(a)(1)(A)) (emphasis added). As the First Circuit further explained:

> Chin's participation in a scheme to distribute medications that are subject to USP-797 – including high-risk sterile ones like MPA – but that are not compounded in compliance with it despite representations to the contrary could potentially constitute "relevant conduct" that "involved . . . the conscious or reckless risk of death or serious bodily injury." Thus it was legal error for the District Court to conclude such a finding could not trigger the enhancement simply because the patients who might inject those medications were not themselves defrauded and only NECC's direct customers were.

Chin, 965 F.3d at 53 (citing USSG § 2B1.1(b)(16)).

In addition, the First Circuit also clarified the appropriate *mens rea* requirement (as it did in its opinion in *United States v. Cadden*, 965 F.3d 1, 33-34 (1st Cir. 2020)) for determining

whether an enhancement under USSG § 2B1.1(b)(16) applies. The First Circuit explained that the two-level enhancement applies so long as Chin acted "in spite of either a conscious or reckless risk." *Chin*, 965 F. 3d at 53 (citing USSG § 2B1.1(b)(16)(A)) (emphasis added by the First Circuit). Accordingly, this Court's statement at Chin's sentencing that Chin did not act with "a reckless and knowing disregard of a reasonable certainty of causing death or great bodily harm" does not foreclose application of this enhancement under the "reckless" prong of USSG § 2B1.1(b)(16).

Applying the appropriate *mens rea* for this enhancement and accounting for the full scope of Chin's relevant conduct, it is readily apparent that the two-level enhancement applies. As an initial matter, NECC was a "high-risk compounder" by its very name and nature because Chin and the pharmacists he directed in NECC's clean rooms made supposedly sterile drugs using nonsterile ingredients. By assuming responsibility for the sterilization of drugs sold for the purpose of being injected into highly sensitive areas of patients' bodies, this drug-making operation was *per se* high-risk to patients, and Chin knew it. The evidence presented at trial showed overwhelmingly that Chin also knew he was violating many critical requirements of USP-797 in the ways that he and those under his supervision were compounding drugs. Chin himself committed and directed others to commit several separate and distinct violations of USP-797: improper sterilization, improper testing, mislabeling of drugs, improper cleaning and disinfecting, falsifying cleaning records and log formula worksheets, and ignoring environmental monitoring results. Moreover, the evidence demonstrated that Chin took numerous steps to conceal his fraudulent practices from customers and regulators, including mislabeling drugs, falsifying documents, and lying to regulators, as well as directing NECC's pharmacy technicians to do the same.

Improper Sterilization

First, Chin knew that NECC was selling MPA and other drugs that he had not properly sterilized. USP-797 states that to achieve sterility, drugs sterilized in an autoclave should be exposed to steam at 121ºC under pressure of one atmosphere for a period of 20 to 60 minutes. Exh. 41 (34 USP 797, at 346). NECC's own MPA formula instructions, which Chin signed each time he made a batch, required the MPA to be sterilized for a period of 20 minutes within the autoclave. Exh. 444, at 10. FDA Investigator Stacey Degarmo testified she reviewed NECC's records and found that the three contaminated lots were each only sterilized for a period of 15 minutes. Trial Tr. at 137-139 (Oct. 6, 2017). Considering the 11-minute time-lag of the autoclave, Chin was actually only sterilizing the MPA for "as little as four minutes." Trial Tr. at 144 (Oct. 6, 2017).

On October 3, 2012, during the FDA's inspection of NECC to discover the source of the nationwide fungal meningitis outbreak, Degarmo interviewed Chin about the MPA sterilization time. In the interview, Chin *falsely* told her that when NECC purchased a new autoclave in April 2011, he began sterilizing the MPA for 15 minutes rather than 20, and that the 15-minute cycle was the default time listed in the then new autoclave's operating manual. Trial Tr. at 137-38 (Oct. 6, 2017). Degarmo reviewed NECC's sterilization records and found, in fact, that Chin had used a 15-minute sterilization cycle for several years prior to 2011, when NECC purchased the new autoclave. Trial Tr. at 138-39 (Oct. 6, 2017). Degarmo also retrieved the operating manual for the new autoclave and determined that its default time was 27-minutes rather than the 15 minutes Chin falsely claimed. Trial Tr. at 140 (Oct. 6, 2017).

Chin also knew that NECC had not verified the process for sterilizing the MPA it was selling. USP-797 and NECC's own standard operating procedure ("SOP") required verification

of the autoclave sterilization process through the use of a biological indicator. Exh. 41 (34 USP 797, at 346); Exh. 52, at 133. Chin told Degarmo that he was not using a biological indicator to verify the sterilization of the MPA, but that NECC had purchased some the prior week. Trial Tr. at 154-155 (Oct. 6, 2017). Annette Robinson, NECC's head of quality control, testified that following the outbreak, Cadden and Chin came to her and told her to order biological indicators, and that they "should have been using them all along." Trial Tr. at 73 (Oct. 5, 2017).

Further, Chin also told Degarmo that he had never validated the autoclave load pattern or used any temperature probes to ensure that the drug reached the correct sterilization temperature, despite USP-797's requirement to do so. Exh. 41 (34 USP 797, at 346).

Improper Testing

Second, Chin knew that NECC was selling MPA and other supposedly sterile drugs that had been improperly tested. Specifically, Chin knew he was not following USP-797 standards and NECC's own SOPs regarding sterility testing of the MPA. USP Expert Eric Kastango testified that to comply with USP-71, Chin should have tested a total of 80 vials from each lot of MPA. Trial Tr. at 108-09 (Oct. 17, 2017). Instead, Chin only tested a single 5ml vial for the entire lot. During his interview with Degarmo, Chin confirmed that they were not complying with the testing requirements set forth in the USP and NECC's own SOPs. Trial Tr. at 4-6 (Oct. 10, 2017).

In addition, Chin was not even waiting for test results prior to shipping the MPA and other drugs to customers. Degarmo testified that during her inspection of NECC during the outbreak, Chin *falsely* told her that drugs were quarantined pending the receipt of test results. Trial Tr. at 4, 8 (Oct. 10, 2017). Upon reviewing NECC's records, however, Degarmo discovered thirteen shipments of the contaminated MPA that were shipped prior to the receipt of test results. Trial Tr. at 8 (Oct. 10, 2017).

NECC's former pharmacy technicians testified during the trial that Chin routinely instructed them to ship drugs prior to completion of testing. *See, e.g.*, Trial Tr. at 139 (Sept. 26, 2017) (Cory Fletcher) (testifying that Chin instructed him to fill vials of MPA from a lot that had just been made and had not yet been tested); Trial Tr. at 105 (Sept. 22, 2017) (Joe Connolly) ("Q: And so was that stock drug able to be tested before it was put into the final? A: It was not."); Trial Tr. at 50 (Sept. 25, 2017) (Nick Booth) ("Q: Who instructed you to do this, to use drugs that hadn't been tested yet? A: Initially, it was Glenn. Then it just became a thing.").

Emails admitted into evidence corroborated the testimony of the pharmacy technicians about this fraudulent practice and offered further proof that Chin and others knew they were not properly testing the drugs and that this posed a serious risk. *See, e.g.*, Exhs. 192 (email from Chin to Sharon Carter admitting that acetylcysteine, a purportedly sterile drug, was not being tested for sterility); 682 (email exchanged between Chin and Alla Stepanets discussing the shipment of 200 vials of bupivacaine without testing); 199 (email from Cadden to Chin and Christopher Leary stating, "I have no way of explaining to a client that we shipped before we had full sterility data"); 203 (email from Cadden to Carter admitting NECC was not doing end-product testing); 662 (email from Cadden to Chin describing lack of testing as "a disaster waiting to happen"). The shipment of drugs without proper (or any) testing was a critical component of Chin's and his co-defendants' fraud—it allowed them to ship drugs as soon as they made them, which they knowingly did repeatedly as they ramped up production in spite of the risk to the health of patients who would be injected with them.

Mislabeling of Drugs

Third, to mask the fact that the clean room staff was sending out untested drugs, Chin instructed NECC pharmacy technicians to mislabel untested drugs with the lot numbers of older

lots for which NECC had test results, a practice that Chin referred to as "botching lots." Trial Tr. at 2 (Sept. 26, 2017). Former pharmacy technician Owen Finnegan explained the practice as "[s]o basically if we had enough to fill 400 vials and they needed 500 to be shipped out that day, 400 would be the tested lot, and 100 of them would be labeled the tested lot even though they were the newer lot that we had not received testing back for yet." Trial Tr. at 167 (Sept. 25, 2017). To aid this fraudulent practice, Finnegan testified that bags of unlabeled finished vials were kept inside the clean room and were used to fill orders themselves, and that Chin would direct him to label the vials with the lot number of whatever lot had last been tested. Trial Tr. at 13-14 (Sept. 26, 2017). Similarly, Cory Fletcher testified about a specific instance involving MPA on August 13, 2012, when he requested labels from staff outside the clean room for the 06292012@26 MPA lot in order to mislabel vials actually filled with the 08102012@51 lot, for which they had not yet received test results. Trial Tr. at 138-39 (Sept. 26, 2017). Of course, neither lot was properly tested and both were contaminated, a combination that proved to be deadly.

Additional emails admitted into evidence corroborated this fraudulent and highly dangerous mislabeling practice. *See, e.g.,* Exhs. 204 (directing Chin to "make as many lots as you like 'internally' but only label vials with lot # of tested lots to cover our ass"); 206 (directing Chin to relabel old lot with new lot number).

Expired Drugs

Fourth, throughout the trial in this case, there was extensive evidence of Chin's fraudulent use of expired drugs at NECC, including the use of the long-expired methotrexate powder. NECC purchased the 1kg bottle of methotrexate drug powder from Spectrum Chemical in 2005. The bottle bore the lot number "UD0026" and contained an expiration date of "1/23/2007." Trial Tr. at 94, 98 (Oct. 3, 2017); Exh. 62. Tom Tyner, the Vice President of Quality at Spectrum Chemical,

testified that a bottle of methotrexate that exceeds its expiration date should be disposed of, not used to make drugs. Trial Tr. at 100 (Oct. 3, 2017). USP-797 specifically prohibits the use of expired ingredients in the compounding of drugs. Exh. 41 (34 USP 797, at 339). Despite the expiration date and the prohibition against using it, NECC used the powder to make drugs, often used for chemotherapy, for unknowing customers. Cory Fletcher testified that the bottle of methotrexate powder (Exhibit 62) was "the only bottle we had" and that he was instructed by Chin to use it to fill drug orders. Trial Tr. at 142 (Sept. 26, 2017); *see also*, Exh. 154 (email from Chin to Cadden describing expired methotrexate: "[w]hen I say old I mean OLD, it expired in 2007 according to the sticker").

To mask the use of the expired ingredient, Chin instructed Fletcher to *falsify* the expiration dates in the Compounder software system and thus on NECC's log formula worksheets so the methotrexate powder would appear to be in-date to anyone reviewing the paperwork. Trial Tr. at 147 (Sept. 26, 2017). The finished drug products NECC shipped to customers were labeled with beyond use dates of six months after the drugs were compounded—dates that, unbeknownst to the customers, were not even close to accurate. Trial Tr. at 149-50 (Sept. 26, 2017). In an email, Chin explained that it was his practice in making methotrexate with this old active pharmaceutical ingredient to under-dilute it to try to account for the fact that the ingredient was old and presumably subpotent; Chin "guessed" that the final drug product he made was "90-95% potent." Exh. 154. This obviously fraudulent and highly dangerous drug-making practice was emblematic of Chin's knowing disregard for the risk his practices posed to patients' health and safety.

Improper Cleaning

Fifth, there was overwhelming evidence that Chin ignored, and directed others to ignore, cleaning of the clean room. Throughout the summer of 2012, when production increased, Chin

instructed the clean room staff to forego cleaning in favor of faster drug production. Nick Booth, one of the designated cleaners inside the clean room, testified that he informed Chin that because of his production responsibilities, he could not complete his cleaning assignments. Booth testified that Chin's response was that he "wanted us to focus on getting the drug out. That was the main concern at the time." Trial Tr. at 36 (Sept. 25, 2017). As a result, cleaning inside the clean room —a critical aspect of safe drug production practices—was ignored.

Nevertheless, though NECC's cleaning logs always documented that the cleaning was complete, there was overwhelming evidence at trial that these logs were regularly falsified at Chin's direction. NECC pharmacy technicians Connolly, Booth, Finnegan, and Fletcher all testified that Chin directed them and other technicians to fill out the cleaning logs for cleaning tasks they did not do. Trial Tr. at 72 (Sept. 22, 2017); at 39 (Sept. 25, 2017); at 30 (Sept. 26, 2017); at 16 (Sept. 27, 2017). Connolly explained that Chin instructed the pharmacy technicians "to go through and just scatter our initials around to make it look like it was contemporaneous...[s]o if any regulators came in or anything, they would see – it would look legitimate." Trial Tr. at 72-73 (Sept. 22, 2017). *See also* Trial Tr. at 125-130 (October 4, 2017) (Annette Robinson testifying that clean room logs were regularly not contemporaneously filled out).

Environmental Contamination

Sixth, Chin also knew that in 2012, NECC's lack of cleaning led to gross contamination inside the clean room in which he was compounding the MPA. Specifically, NECC recorded action- or alert-level environmental monitoring hits for mold and bacteria during thirty-seven out of thirty-eight weeks prior to the shutdown in October 2012. Robinson testified that there were repeated mold hits inside the clean room, and she emailed them to Chin because "[m]old is bad." Trial Tr. at 169 (Oct. 4, 2017). Cadden informed Chin that "we have another fungal bloom on

June-28th…." Exh. 231. They ignored it. Instead, the very next day, June 29, 2012, Chin compounded the second fatal contaminated MPA lot, 06292012@26. Nineteen patients died after being injected at Michigan Pain Specialists with the contaminated MPA Chin made on that day.

The emails admitted into evidence also demonstrate that Chin, Cadden, and others were fully aware of the insanitary conditions in which NECC was producing its purportedly sterile drugs. *See, e.g.*, Exhs. 232 (email from Cadden to Chin, Leary, and Gene Svirskiy stating "we had another fungal bloom last month"); 235 (email from Cadden to Svirskiy and Chin discussing oil bubbling up in clean room 2); 234 (email from Cadden stating that Svirskiy "has an actual oil leak in the floor by the wall" inside clean room 2). In one particularly memorable exchange, Chin and Cadden discussed the substantial amount of hair and insects discovered inside the clean room. *See* Exh. 229 (email exchange between Chin and Cadden describing the clean room staff as "hairy zoo animals"). In response to Cadden, Chin wrote, "[t]he cleaners actually told me this month that the anteroom is actually cleaner than inside the clean room." *Id.*

Despite these repeated alert- and action-level environmental monitoring hits and findings of mold, bacteria, insects, and hair within the clean room, Chin did not take any remedial action to eliminate the contamination, as was required by USP-797 and NECC's own SOPs. Specifically, USP-797 states in two different sections that "[h]ighly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving [compounded sterile preparations] and must be immediately remedied…." Exh. 41 (34 USP 797 at 350). USP-797 highlights the particular danger of finding fungi inside the clean room because "microorganisms or mold or fungus in an injectable medication[], when injected, can harm or kill somebody." Trial Tr. at 65 (Oct. 17, 2017). Dr. Almaris Alonso-Claudio from the FDA testified that she reviewed NECC's environmental monitoring results and found a

"high level of contamination [] inside that clean room." Trial Tr. at 139-40 (Oct. 10, 2017). In fact, even after stopping production and thoroughly cleaning the room to the point that it smelled of bleach, the FDA still recovered bacteria and mold from inside NECC's clean room during its outbreak inspection. Trial Tr. at 135-36 (Oct. 10, 2017).

In short, there was overwhelming evidence that Chin routinely flouted USP-797 and NECC's own SOPs and directed others to do the same when manufacturing drugs at NECC. The shortfalls were systemic and multi-layered. Chin was well aware that these drugs would ultimately be injected into patients and that a lack of sterility posed grave risks of death or serious bodily injury to them. He did it anyway. While he harmed hundreds, he put tens of thousands at risk of harm including death. At the time the outbreak was discovered to be caused by NECC's MPA, there were 17,361 vials of the three contaminated lots in clinics across the country. This is more than sufficient to demonstrate that Chin's actions "involved a reckless risk of death or serious bodily injury." USSG § 2B1.1(b)(16). *See, e.g.*, *United States v. Moran*, 778 F.3d 942, 978 (11th Cir. 2015) (affirming application of two-level increase for defendant who committed health care fraud by placing drug addicts in substandard facility); *United States v. Mateos*, 623 F.3d 1350, 1371 (11th Cir. 2010) (affirming application of § 2B1.1(b)(15) to sentencing of defendant, a licensed nurse, who gave unnecessary injections to HIV-positive patients, none of whom were actually harmed, because "any injection always carries some risk of infection or other complications, and that risk is especially high when the patients have HIV and weakened immune systems"); *United States v. Awad*, 551 F.3d 930, 940 (9th Cir. 2009) (affirming application of the enhancement in a health care fraud sentencing where the defendant failed to supervise respiratory treatments given to patients as required due to the risk of adverse side effects, even though no patient reported any such effects); *United States v. Prigmore*, 1996 WL 464030, at *10 (2d. Cir.

2005) (finding the enhancement applies to the defendants' deliberate violations of FDA regulations regarding heart catheters despite no patients being harmed); *United States v. Laughlin*, 26 F.3d 1523, 1530 (10th Cir. 1994) (finding enhancement applies where defendant performed unnecessary surgical procedures as part of a fraudulent double-billing scheme that resulted in victim's hospitalization). The two-level enhancement under USSG § 2B1.1(b)(16)) applies to Chin's guidelines sentencing range.

Vulnerable Victim Enhancement

This Court previously declined to apply the "vulnerable victim" enhancement under USSG §§ 3A1.1(b)(1) and 3A1.1(b)(2) because it concluded that "the harmed patients were not 'victims' within the meaning" of that enhancement. *Chin*, 965 F.3d at 54. The First Circuit rejected that conclusion. Instead, the First Circuit explained, to "come within the guidelines' definition of 'victim,' 'one need not be a victim of the charged offense so long as one is a victim of the defendant's other relevant conduct." *Id.* (citations omitted). The First Circuit further explained:

> [t]he "relevant conduct" that the Guidelines hold Chin accountable for engaging in includes … any action he took during the commission of mail fraud. If, for instance, Chin failed to comply with appropriate safety procedures in compounding the fatal lots of MPA, the patients who died from being injected with those lots could potentially be "victims" of his offense.

Id. at 26.

The commentary to the Sentencing Guidelines provides a pertinent example in which the enhancement would apply: patients in "a fraud case, in which the defendant marketed an ineffective cancer cure." USSG § 3A1.1, cmt. n.2. Similarly, in *United States v. Sidhu*, 130 F.3d 644, 655 (5th Cir. 1997), the defendant was convicted of mail fraud and other offenses relating to the submission of false claims for medical services. The Fifth Circuit held in that case that patients

involved in the scheme—who were prescribed and became addicted to prescribed narcotics—qualified as "vulnerable victims" under USSG § 3A1.1(b)(1).

The patients hurt by the crimes of Chin (and Cadden) fit squarely within this rubric. By reason of their pain and/or debilitated health conditions, they sought epidural steroid injections at medical centers and pain clinics for back and joint pain. In many cases, these injections were the victims' last hope for avoiding serious back surgeries and alleviating chronic pain. They were given NECC's contaminated drugs without any choice or say of their own, and had no way to detect or prevent the fungal contamination. What the patients knew was that their doctors recommended these drugs to relieve their pain. And the doctors believed what NECC sold them: That NECC scrupulously adhered to USP-797, the protocols that were explicitly intended to prevent harm and death to patients injected with high-risk sterile compounds. What neither patient nor doctor knew, nor could possibly have known, is that NECC's representations regarding the safety of its drugs were lies told to increase NECC's profits, regardless of the risk to patients. So doctors injected patients with MPA compounded at NECC, both trusting NECC and trusting that NECC's drugs would alleviate, rather than cause harm. But this trust was tragically misplaced. NECC's representations were lies and, under Chin's supervision, NECC flouted USP-797 and endangered patient lives. And instead of relieving their pain, NECC's drugs dramatically increased it. And in more than 100 cases, their trust cost them their lives. As one victim, William Thomas, expressed in his victim impact statement, "I expected to be treated, get better, go home and recover. As always in my life I was prepared to work hard every day to get well, do everything the doctors said to do and never ever miss my meds. In a few months I'd be well! No Doubt! How wrong I was on every expectation! To this day I am sick all day every day." Similarly, the niece of another victim, Alice Machowiak explained, "Alice trusted the medical community

explicitly. She always had faith that her doctors were doing the best for her …. [Chin] could have done what is right … However, [he] chose to go against every principle of sterility."

The drugs were shipped to 76 facilities in 23 states, and used on thousands of unsuspecting, trusting, vulnerable patients. Rather than being safe and efficacious—as promised—the drugs made by Chin and at his direction sickened approximately 800 patients, and killed more than 100. These patients were victims of Chin's fraudulent criminal behavior, and they were highly vulnerable and dependent on a health care system that ultimately was unable to protect them from the pharmacists' fraud. *See United States v. Stella*, 591 F.3d 23, 29-30 (1st Cir. 2009) ("[P]atients put at risk" by defendant's tampering with medications "were vulnerable by reason of their illness and the need for medication."). Accordingly, the four-level enhancement for a large number of vulnerable victims should be applied under USSG §§ 3A1.1(b)(1) and 3A1.1(b)(2).

Enhancement for Being an Organizer or Leader of the Criminal Activity

At Chin's prior sentencing, the government argued that Chin was "an organizer or leader of a criminal activity that involved five or more participants" and that, accordingly, his offense level should be increased by four levels pursuant to USSG § 3B1.1(a). This Court determined that Chin was instead "a supervisor or manager," not an "organizer or leader," of such activity, and that his offense level should be increased by only three points pursuant to USSG § 3B1.1(b).

The First Circuit held that this Court erred in two respects in its analysis of this enhancement. First, the First Circuit found that by stating "[t]he organizer and leader of the enterprise was Barry Cadden," this Court appeared to have improperly foreclosed the possibility that "'[t]here can . . . be more than one person who qualifies as a leader or organizer of a criminal association or conspiracy.'" *Chin*, 965 F.3d at 55 (quoting USSG § 3B1.1 cmt. n.4). Second, the First Circuit found that this Court appeared to improperly rely on Chin's title at NECC—

"supervisory pharmacist"—to conclude that the three-point "supervisor or manager" enhancement was applicable. As the First Circuit has stated, "'titles such as "kingpin" or "boss" are not controlling.'" *Id.* at 26-27 (citing *United States v. Benítez-Beltrán*, 892 F.3d 462, 469 (1st Cir. 2018)).

The evidence at trial demonstrated overwhelmingly that Chin exercised considerable authority and discretion over the fraudulent clean room operations of NECC, and that he personally directed both pharmacists and pharmacy technicians to engage in criminal misconduct. Specifically, Chin knew that NECC was selling MPA and other drugs that were improperly sterilized. *See supra* pp. 8-9. Chin directed NECC clean room employees to ship drugs prior to the completion of testing. *See supra* pp. 9-10. Chin directed NECC clean room employees to mislabel untested drugs with the lot numbers of older lots for which NECC had test results to trick customers into thinking the drugs were safe. *See supra* pp. 11. Chin directed NECC clean room employees to use expired ingredients to manufacture drugs and to falsify NECC's records to hide the use of expired chemicals. *See supra* pp 11-12. Chin directed NECC clean room employees to disregard clean room cleaning and SOPs to speed up drug production and then instructed those employees to falsify cleaning records to hide his misconduct. *See supra* pp. 13-16.

Taken together, this evidence shows that Chin did not merely participate in and supervise NECC's fraudulent practices—but acted with considerable autonomy and discretion in directing NECC clean room pharmacists and pharmacy technicians to engage in criminal activity. In short, he was a "leader" and "organizer"—not a mere "supervisor" of NECC's criminal misconduct. Accordingly, Chin's total offense level should be increased by four levels under USSG § 3B1.1(a).

The Re-Calculated Sentencing Guidelines Range, the Section 3553 Factors, and the Government's Recommended Sentence

Applying (i) the two-level enhancement because Chin acted with "the conscious or reckless risk of death or serious bodily injury," USSG § 2B1.1(b)(16), (ii) the four-level enhancement because Chin "knew or should have known that a victim of the offense was a vulnerable victim" and "the offense involved a large number of [such] vulnerable victims," USSG §§ 3A1.1(b)(1) and 3A1.1(b)(2), and (iii) the four-level enhancement as "an organizer and leader of the criminal activity," USSG § 3B1.1(a), takes Chin's total offense level from the Court's previously-calculated level of 28 to a total offense level of 35. The revised calculation is as follows:

	Offense Level
Mail Fraud racketeering base offense level (§2B1.1(a)(1)	7
- Total fraud loss > $550,000 - $1,500,000 (§2B1.1(b)(1)(f))	+14
- Involved 10 or more victims and committed through mass marketing (§2B1.1(b)(2))	+2
- Conscious or reckless risk of death or bodily injury (§2B1.1(b)(16))	+2
Offense Level for Grouped Mail Fraud Acts / Counts	**25**
- Organizer or leader of criminal activity (§3B1.1(a))	+4
- Abuse of a Position of Trust (USSG §3B1.3)	+2
- Large Number of Vulnerable Victims (§3A1.1(b)(1) & (2))	+4
Total Adjusted Offense Level	**35**

As a result, Chin's sentencing guidelines range is increased from the previously calculated range of 78 to 97 months to a range of 168 to 210 months.

The Government submits that this revised range more appropriately reflects the gravity of Chin's offenses and the profound and widespread harm he caused to approximately 800 patients across the country. As it did at Chin's first sentencing, this Court should sentence Chin to the high

end of the applicable guidelines range, 210 months. In making this recommendation, the Government does not urge rote adherence to the guidelines. To the contrary, the Government submits that the revised guidelines range more adequately accounts for the breadth of Chin's conduct. Specifically, the properly calculated guidelines range reflects that Chin should be held to account for—and punished for—the full scope of his harms, including (i) his reckless disregard for the safety of the patients across the country receiving drugs compounded by him and at his direction; (ii) the terrible harm—including death and grave injuries—inflicted on approximately 800 vulnerable patients; and (iii) the full significance of Chin's role in directing the sustained criminal activity that pervaded NECC.[2]

Application of the Section 3553(a) factors likewise supports this sentence. The "nature and circumstances of the offense," 18 U.S.C. § 3553(a)(1), include that Chin worked at NECC, compounding supposedly sterile drugs that would be injected into vulnerable patients. Rather than adhere to USP-797 and NECC's own SOPs, Chin dispensed tens of thousands of vials of drugs manufactured in filthy, hazardous conditions. These drugs were ultimately used on unsuspecting patients who trusted them, harming approximately 800 patients and killing more than 100. Only a sentence at the top of the revised guidelines range will adequately "reflect the seriousness of the offense," "promote respect for the law," and "provide just punishment for the offense," 18 U.S.C. § 3553(a)(2)(A). Chin caused so much harm to so many, and failed over a sustained period of time to stop his conduct or reverse course despite the warning signs of the increasing danger, such

[2] As this Court stated at Cadden's sentencing, "[i]f [the guidelines] range appears reasonable, the judge is to impose a sentence accordingly, but he or she retains the discretion to depart upwards or downwards from the Guidelines. However, that discretion is to be exercised only where the Guidelines fail to adequately address the magnitude of a called-for adjustment or perhaps overstate its significance." Cadden Sentencing Transcript (June 26, 2017) at 113. In this case, the revised guidelines range does not overstate the significance of Chin's crimes and the harm he caused to hundreds of people.

as the concerns raised by pharmacy technicians under his direction, the dramatic increase in drug production and the corner-cutting that made it possible, the escalating environmental monitoring hits for mold and bacteria, and the three nonsterile results received in the summer of 2012 for lots of the antibiotics Bacitracin and Polymyxin Bacitracin. These were all warning signs of the severe danger that was increasingly present and looming large, but that the defendant chose to ignore. A sentence at the top end of the revised sentencing guidelines range more adequately captures the gravity and context of Chin's offenses and takes into consideration the harm and devastation he caused.

CHIN'S FORFEITURE OBLIGATION

Due to his racketeering and racketeering conspiracy convictions, Chin is required to forfeit "any property constituting, or derived from, any proceeds which [he] obtained, directly or indirectly, from racketeering activity." 18 U.S.C. § 1963(a)(3). This Court has previously concluded Chin earned $473,584 from March 2010 through October 2012—the period during which, according to this Court, NECC was operating as a criminal enterprise. *Chin*, 965 F.3d at 56.

Rather than order Chin to forfeit this full amount, however, this Court limited the amount of forfeiture to $175,000 based on (1) its assertion that Chin had never "obtained" the portion of his salary that was paid as taxes to the United States Treasury, and (2) out of concern that an order of forfeiture in the full amount of Chin's salary would be an unconstitutional "excessive fine" under the Eighth Amendment to the United States Constitution.

On appeal, the First Circuit found neither of these considerations meritorious and "directed [this Court] to enter a forfeiture order in the full amount sought by the government" —$473,584.

See Chin, 965 F.3d at 58. The Government requests that the Court enter that forfeiture order as directed by the First Circuit.

RESTITUTION OWED BY CHIN

The Mandatory Victim Restitution Act of 1996 ("MVRA") makes restitution mandatory for crimes involving fraud or deceit. 18 U.S.C. 3663A(c)(1)(A)(ii). Here, the jury convicted Chin of all 77 counts with which he was charged, including racketeering, racketeering conspiracy, mail fraud, and violations of the FDCA; 48 of the counts of which Chin was convicted involved "fraud or deceit." As such, restitution to Chin's victims is mandatory pursuant to the MVRA. 18 U.S.C. § 3663A(c)(1)(A)(ii).

In a preliminary order, this Court found that the only "victims" entitled to restitution were the medical facilities that purchased drugs from NECC (Doc. 1455 at 7), but deferred calculation of the amount of restitution until the completion of the trials of Chin's co-defendants.

The Government appealed that order and the Court's narrow definition of the "victims" eligible for compensation under the MVRA, which resulted in the exclusion of the hundreds of patients who were actually harmed by the tainted drugs compounded at NECC. As it did with respect to the enhancements for conscious or serious risk of bodily injury and vulnerable victims, the First Circuit disagreed with the Court's conclusion that patients were, as a matter of law, not "victims" within the scope of the MVRA. The First Circuit explained:

> [t]he restitution analysis focuses on the causal relationship "between the conduct and the loss," not between the nature of the statutory offense and the loss….This approach to the "victim" analysis tracks the language of the statute, as it focuses on whether the victim was "harmed as a result of the commission of an offense," or "by the defendant's criminal conduct in the course of [a] scheme, conspiracy, or pattern [of criminal activity]."

Chin, 965 F.3d at 59-60 (citations omitted) (First Circuit's emphases). "When an offense 'involves as an element a scheme, a conspiracy, or pattern of criminal activity,' like Chin's mail fraud and

racketeering-related convictions … 'any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern' is a victim." *Id.* at 59 (citing 18 U.S.C. § 3663A(a)(2)).

On remand, the tasks for this Court are therefore, first, to identify Chin's victims—those who were "directly and proximately harmed" (18 U.S.C. § 3663A(a)(2)) by Chin's criminal conduct—and then to determine the amount that is owed to those victims.

The Government submits that the evidence at trial demonstrated that the patients who were killed or injured by nonsterile and substandard drugs manufactured by Chin and under his direction are victims, along with hospitals and insurers, of Chin's criminal offense, and that the record amply supports an order of restitution—joint and several with Cadden—in the amount of $82 million to those victims.

Patients Harmed by Chin's Fraudulent Drugs Qualify as Victims under the MVRA.

The MVRA defines a "victim" as:

> a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered including, in the case of an offense that involves as an element a scheme, conspiracy, or pattern of criminal activity, any person directly harmed by the defendant's criminal conduct in the course of the scheme, conspiracy, or pattern.

18 U.S.C. § 3663A(a)(2). The First Circuit has explained that this statutory language means that "the government must show not only [1] that a particular loss would not have occurred but for the conduct underlying the offense of conviction, but also [2] that the causal connection between the conduct and the loss is not too attenuated (either factually or temporally)." *United States v. Cutter*, 313 F.3d 1, 7 (1st Cir. 2002) (quoting *United States v. Vaknin*, 112 F.3d 579, 590 (1st Cir. 1997)). "Put otherwise," the second prong of this test asks "was the harm foreseeable?" *Chin*, 965 F.3d at 60.

The patients harmed by Chin's fraudulent drugs clearly fall within the MVRA's definition of a "victim." It is indisputable that the patients identified in the fungal meningitis outbreak would not have been harmed but for Chin's criminal conduct in manufacturing the contaminated MPA. The patients were harmed and killed because Chin made, and directed others to make, drugs that should have been sterile and properly tested, but were not. Thus, the question is whether it was foreseeable that a sterile compounding pharmacist who fraudulently makes injectable drugs that are improperly sterilized, improperly tested, shipped prior to the receipt of test results, made in a clean room that is not cleaned, and where environmental monitoring shows the repeated presence of mold and bacteria, could harm patients that receive those injections. The Government submits that the answer to the question is unequivocally and obviously yes. Indeed, this is precisely the reason why the Massachusetts Board of Registration in Pharmacy requires pharmacists to follow USP-797. As the Chapter states *in the very first sentence on the very first page*, "[t]he objective of this chapter is to describe conditions and practices *to prevent harm, including death, to patients that could result from…microbial contamination*…." Exh. 41 at 336 (emphasis added). Chin knew that if he did not follow the rules, patients would be harmed. He said it himself to pharmacy technicians he supervised. *See, e.g.,* Trial Tr. (Sept. 25, 2017) at 126-127, 133-134. Chin knew he was not working as an accountant or a landscaper; he was a sterile compounding pharmacist manufacturing massive quantities of supposedly sterile injectable drugs that were being injected into patients' bodies. Nevertheless, he chose not to do it safely or properly, and, along with Cadden, ran a fraudulent criminal enterprise that produced contaminated and fatal injectable steroids. It was entirely foreseeable that Chin's criminal actions would lead to patients being harmed. And they did. 793 patients, over 100 of whom died.

Accordingly, the Government submits that the patients harmed by NECC's contaminated drugs are clearly victims entitled to restitution, as required by the MVRA.

Restitution Calculation

Because the patients harmed as a result of Chin's criminal conduct meet the definition of "victim" under the MVRA, they are entitled to mandatory restitution pursuant to the statute. Specifically, the MVRA states that "when sentencing a defendant convicted of an offense [committed by fraud or deceit], the court *shall order*…that the defendant make restitution to the victim of the offense, or, if the victim is deceased, to the victim's estate." 18 U.S.C. § 3663A(a)(1) (emphasis added). 379 patients harmed in the outbreak submitted detailed restitution requests, as did certain medical facilities that purchased the drugs and insurance plans that paid for patients' treatment.

The Government contracted with Thomas A. Barocci and Joshua Anderson of TAB Consulting to evaluate and analyze the restitution claims submitted by the patient victims in this case. The accompanying TAB Report (Exhibit A hereto) details their considered economic analysis of the victims' requests.[3] The expert declaration at the beginning of the report outlines

[3] Dr. Barocci submitted his initial analysis in a report dated September 25, 2017 in *United States v. Cadden*, 14-cr-10363-RGS-1. Dr. Barocci submitted an updated report on January 25, 2018 in this case, reflecting (1) an analysis of economic losses to victims who sent in data after the initial report; and (2) an analysis of additional data provided by certain victims included in the first report. The version of the summary table of the TAB Report submitted herewith under seal (Exhibit C to the TAB Report) corrects two typographical errors with respect to the restitution losses claimed by Victims 1051 and 1337; the out of pocket expenses for each of those victims should say "$0." The correct figure ($0) was, however, used in calculating the restitution owed to each of those victims—as reflected in the victims' restitution worksheet (Exhibit D to the TAB Report)—and therefore these two typographical errors do not alter the total amount of restitution sought by the government. This version also corrects a calculation error with respect to Victim 1095, whose losses were undercounted by $3,095, resulting in an increase in the total amount of restitution sought by the government by $3,095. This version of the TAB Report encompasses the full set of known victims who are seeking restitution in the NECC matters.

the methodology used in evaluating and analyzing the various restitution claims. The TAB Report conservatively calculates a total restitution amount of $80.1 million for the 379 patient victims. *See* Exhibit A.

The TAB Report is well-supported. The restitution calculations were performed by Thomas Barocci, who holds a Ph.D. in the field of economics and has authored hundreds of similar economic analyses over the past 40 years. Dr. Barocci, the owner of TAB Consulting, personally reviewed the data and information for each individual prior to the economic analysis being performed, and reviewed it again following completion of the analysis. While calculation of future medical expenses or lost income must involve certain economic assumptions, the assumptions that were required to complete the analyses for each victim were documented and explained in the TAB Report. In sum, the TAB Report uses garden-variety economic analyses well-established in federal law, and routinely used in federal courts throughout the nation. Indeed, Dr. Barocci and Joshua Anderson of TAB Consulting performed a similar economic analysis in *United States v. Tsarnaev*, 13-cr-10200-GAO, which was adopted in its entirety by Judge O'Toole in fashioning the restitution order in that case. The comprehensive economic analysis set forth in the TAB Report is substantially more than "a modicum of reliable evidence [] required to establish a restitution award." *United States v. Mahone*, 453 F.3d 68, 74 (1st Cir. 2006)). Accordingly, this Court should order that Chin pay restitution to the individual patients of $80.1 million as identified in the TAB Report.

In addition, two clinics that purchased NECC's fraudulent drugs and two insurance plans that paid for patients' treatment submitted restitution requests totaling approximately $1.9 million. *See* Exhibit B, filed under seal. With respect to the clinics' restitution claims, the restitution award should account for the fact that the clinics endured substantial out-of-pocket losses as a result of

Chin's fraudulent scheme beyond the cost of NECC's substandard drugs—including the cost of the unreimbursed care of patients infected by NECC's contaminated drugs, expenses associated with the anti-fungal medication that was used to treat patients, the cost of an infectious disease specialist to treat the patients, the expenses of clinic staff to respond to the outbreak, and attorneys' fees incurred by the clinic as part of the investigation and prosecution of Chin.

Pursuant to the MVRA, the Court should order Chin to pay restitution to the patient victims, medical facilities that purchased the tainted drugs, and insurance companies that paid the patients' claims, in a total amount of $82 million. The Government requests that the Court order that any restitution payments be made first to the individual patient victims, and that the clinics and insurance plans receive restitution payments only after the patient victims have been fully compensated.

CONCLUSION

WHEREFORE, for the reasons set forth above, the Government respectfully requests the Court:

(I) Sentence Glenn A. Chin to a term of incarceration of 210 months;

(II) Enter a forfeiture order in the amount of $473,584; and

(III) Enter an order of restitution in the amount of $82 million, owed jointly and severally with Barry J. Cadden, with the individual patient victims to be paid before the insurance plans and clinics.

Respectfully submitted,

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Dated: April 30, 2021

Certificate of Service

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to counsel for the defendant, who are registered participants as identified on the Notice of Electronic Filing (NEF).

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Christopher Looney
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Dated: April 30, 2021