In the Matter of Treatment Solutions of New Jersey, Inc. Application for Alternative Treatment Center Permits, Northern, Central and Southern Regions	NEW JERSEY DEPARTMENT OF HEALTH Division of Medicinal Marijuana Application Nos. N0023; C0017 and S0018 CIVIL ACTION

BRIEF IN SUPPORT OF MOTION FOR STAY OF ALTERNATIVE TREATMENT CENTER APPLICATION APPROVALS FROM JULY 2018 REQUEST FOR APPLICATIONS

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PRELIMINARY STATEMENT

On January 30, 2019, Treatment Solutions of New Jersey, Inc. ("TSONJ") filed three appeals[1] from the December 17, 2018 Department of Health ("DOH") approvals of six Alternative Treatment Center ("ATC") permit applications to proceed in the permitting process ("the Approvals"). TSONJ respectfully requests that DOH stay the Approvals pending resolution of TSONJ's appeals.

The Approvals, which permit six applications to proceed in the permitting process, is the culmination of an invalid Request for Applications ("RFA") and a flawed evaluation process. The validity of the RFA was compromised when the DOH applied a new rule to the application process absent proper rulemaking procedures. The evaluation process was flawed because the selection committee inconsistently and arbitrarily scored the applications.

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[1] The three appeals are captioned as follows: In the Matter of Treatment Solutions of New Jersey, Inc. Application for Alternative Treatment Center Permit Northern Region, Dkt. No. A-002263-18; In the Matter of Treatment Solutions of New Jersey, Inc. Application for Alternative Treatment Center Permit Central Region, Dkt. No. A-002265-18; and In the Matter of Treatment Solutions of New Jersey, Inc. Application for Alternative Treatment Center Permit Southern Region, Dkt. No. A-002266-18.

As set forth in more detail below, TSONJ satisfies the requirements for a stay: (1) it will suffer imminent irreparable harm without injunctive relief; (2) the balance of equities and hardships favor the entry of a stay to maintain the status quo; (3) it can demonstrate that it is likely to succeed on the merits of its appeals; and (4) the public's interest will not be harmed and, indeed, will be advanced by a permitting process that is in accordance with the existing statute and regulations and not arbitrary or flawed.

PROCEDURAL HISTORY AND STATEMENT OF FACTS

The New Jersey Compassionate Use Medical Marijuana Act ("the Act"), N.J.S.A. 24:6I-1, et seq., enacted in 2010, charges DOH as the regulatory enforcement agency to ensure the availability of a sufficient number of ATCs throughout the State, pursuant to need, including at least two each in the northern, central and southern regions of the State. N.J.S.A. 24:6I-7. The Act directs DOH to issue the permits for the first two ATCs in each region to non-profit entities. Id. Thereafter, the number of non-profit and for-profit permits available is contingent on DOH determining whether there are a sufficient number of ATCs

to meet the needs of the registered qualifying patients in the State. N.J.S.A. 24:6I-12.

The ATC Permitting Process

The ATC permitting process is heavily regulated. The regulations, N.J.S.A. 8:64-1, et seq., ("the Regulations"), implemented pursuant to the Act in compliance with the Administrative Procedure Act, N.J.S.A. 52:14B-4, require a permit applicant to provide a plethora of information related to the entity seeking the permit. N.J.A.C. 8:64-6.2; N.J.A.C. 8:64-7.1. The regulations declare that no permit application can be considered responsive and successful if the applicant fails to "address all applicable criteria and measures" or "provide requested information." N.J.A.C. 8:64-6.2. Pursuant to N.J.A.C. 8:64-6.2, ATC permit applications are evaluated by a selection committee on the following general criteria:

1. Submission of mandatory organizational information;
2. Documented involvement of a New Jersey acute care general hospital in the ATC's organization;
3. Ability to meet overall health needs of qualified patients and safety of the public;
4. Community support and participation; and
5. Ability to provide appropriate research data.

N.J.A.C. 8:64-7.1(b) further specifies that applicants shall submit to DOH the application form required by N.J.A.C. 8:64-6.5, and all forms and other documentation

required by DOH, which shall include, "the legal name of the corporation, a copy of the articles of incorporation and by-laws," and "evidence that the corporation is in good standing with the New Jersey Treasurer."

Proposed Rule Amendments

In June 2018, pursuant to its enabling statute, N.J.S.A. 24:6I-16, DOH introduced Proposed Rule Readoption with Amendments for N.J.A.C. 8:64 et seq. ("Proposed Rule Amendments"). (See Exhibit E attached to the Certification of Alan S. Naar (hereinafter "Naar Cert.") submitted herewith).[2] The Proposed Rule Amendments address the permit application procedures and requirements for ATCs enumerated in N.J.A.C. 8:64-7. Id. at TSONJ62[3]. Specifically, one of the Proposed Rule Amendments seeks to revise the required information provision at 7.1(b) so that "corporation" would be replaced with "business entity" and "articles of incorporation and bylaws" would be replaced by "the entity's organizational documents." Id.

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[2] A complete version of Proposed Rule Readoption with Amendments for N.J.A.C. 8:64 et seq. is available at *NJ Health Medicinal Marijuana Program, Program Rules*, https://nj.gov/health/legal/documents/notice-of-rule-proposal/8_64.pdf (last accessed February 6, 2019).

[3] "TSONJ#" refers to the page numbers affixed to the exhibits attached to the Certification of Alan S. Naar submitted herewith.

Pursuant to proper rulemaking procedures codified at N.J.S.A. 52:14B-5.1(C)(2), filing the Proposed Rule Amendments automatically extended the December 31, 2018 expiration date of the current rules by 180 days to June 17, 2019. The Proposed Rule Amendments have not yet been approved. 50 N.J.R. 2566, Register Index of Rule Proposals and Adoptions.

By spring 2018, five non-profit ATCs were operating and the sixth was scheduled to open in June 2018. In March 2018, DOH recommended five additional medical conditions to the list of conditions available for treatment with medicinal marijuana. See Department of Health, E06 Final Report, available at https://www.nj.gov/health/medicalmarijuana/documents/E06Report_Final.pdf (last accessed February 5, 2019). As a result of the increase to the qualified patient population, DOH determined that six additional ATCs were necessary to meet the needs of qualified patients. (Naar Cert., Ex. B).

The RFA

On July 16, 2018, DOH announced that it would issue its first RFA for six new ATC permits (two in each of the three defined geographical regions of the state) available to both non-profit and for-profit entities. N.J.S.A.

24:6I-5; Naar Cert., Ex. B. The RFA applied to all applications, but each applicant was required to submit a separate application for each regional permit sought. Id. at TSONJ26. The application form was released on August 1, 2018 and the submission deadline was August 31, 2018. Id. at TSONJ28.

The RFA generally advised that "application materials submitted by each applicant shall include full and complete written responses to each of the criteria specified in this announcement, as well as completion and submission of all mandatory information." Id. at TSONJ27. The RFA also provided that for Mandatory Organizational Information, "[a]ll applicants must submit the following information" and that "[f]ailure to submit any of the information may result in automatic disqualification from the selection process. Id. The RFA outlined "mandatory documentation" as being "noted on the application form" and included "[t]he legal name of the corporation, a copy of the articles of incorporation and by-laws, evidence that the corporation is in good standing with the New Jersey Department of Treasury and a certificate certified under the seal of the New Jersey State Treasurer as to the legal status of the business entity." Id. The application

instructions again pronounced the aforementioned application completeness requirements. (Naar Cert., Ex. C).

The Regulations

The Regulations further delineate that the required documentation provided by an applicant shall include "the legal name of the corporation, a copy of the articles of incorporation and by-laws, [and] evidence that the corporation is in good standing with the New Jersey Secretary of State . . . ." N.J.A.C. 8:64-7.1. In fact, the regulations expressly require that "[t]he applicant's failure to . . . provide requested information . . . in the application process shall result in the application being considered non-responsive and shall be considered an unsuccessful application pursuant to N.J.A.C. 8:64-6.4." N.J.A.C. 8:64-6.2.

Scoring of Applications

The RFA announced that the application evaluation criteria and respective weighting would be based on a 1000-point scale. (Naar Cert., Ex. B at TSONJ30). The RFA disclosed how many points were allocated to each criterion and each related question; however, no information was provided in the RFA or by DOH as to how the criteria would be scored or the methodology by which an applicant would

earn all available points (or some, but less than all available points) for each question. Id. A selection committee, comprised of six evaluators, is required to "evaluate and score each application based on the quality of the applicant's submission, and its conformity to the notice of request for applications. N.J.A.C. 8:64-6.4; See also Naar Cert., Ex. A at TSONJ5. Yet, again, no information was provided in the RFA or by DOH as to how the evaluators would score the "quality" of a submission or its "conformity" to the notice of request for applications. (Naar Cert., Ex. B). Nor was any criteria listed or scoring rubric provided to make certain that each evaluator would consistently apply the same standards across the board. Id.

FAQs

During the RFA question and answer period, DOH issued its responses by publishing two documents presented as FAQs or Frequently Asked Questions. (Naar Cert., Ex. D). In response to an inquiry of whether the ATC entity must be a "corporation, or can it be a limited liability company (LLC)?," DOH stated that the "form of entity . . . required for ATCs" was "at the discretion of the applicant." Id. at TSONJ47. In the same FAQs, DOH also reiterated that the

"RFA process [was] based on the rules currently in effect" in its response to a question about inconsistencies between the proposed and current rules. Id. at TSONJ45. However, in anticipation of the adoption of the Proposed Rule Amendments, the RFA also advised that DOH would issue additional RFAs in Fall 2018 and in Winter 2019 under the Proposed Rule Amendments. (Naar Cert., Ex. B at TSONJ26).

TSONJ

On August 31, 2018, TSONJ, a corporation incorporated in the State of New Jersey, submitted a complete and responsive application for an ATC permit in each of the three available regions in accordance with the statute, regulations, RFA and application instructions. (Naar Cert., Ex. A). On December 17, 2018 TSONJ received DOH's final agency decisions denying each of its regional applications for an ATC permit. Id. at TSONJ05; TSONJ13; TSONJ21. At the same time, DOH issued its final agency decision, selecting two applications for each of the Northern, Central and Southern regions--all of which were limited liability companies. Id.

Although TSONJ earned the highest scores of all corporation applicants for each region, it was not approved to continue the permitting process for any region having

received an 873.6666666666663 composite score for its Northern and Central region applications, and an 877.5 composite score for its Southern region application. Id. Moreover, TSONJ received arbitrarily inconsistent scores for individual evaluative questions within each criterion set. (Naar Cert., Ex. H). In some cases, one evaluator awarded TSONJ no points for a question, while another evaluator awarded all of the available allocated points to TSONJ's response to the same question. Id.

On January 30, 2019, TSONJ filed notices of appeal from DOH's denial of each of its regional permit applications. (Naar Cert., Ex. A). TSONJ filed a motion to consolidate its three appeals on the same date. (Naar Cert., Ex. I).[4]

This application for a stay of the Approvals follows.

ARGUMENT

DOH SHOULD STAY THE APPROVALS AND ANY FURTHER APPROVAL PROCESS RELATED TO THE RFA TO PRESERVE THE STATUS QUO PENDING RESOLUTION OF TSONJ'S APPEALS.

An agency decision may be stayed pending appeal, R. 2:5-4, upon the movant's showing of good cause as

[4] TSONJ has become aware that other applicants have filed appeals of the Approvals as well as a stay motion.

prescribed by the standard announced in Crowe v. DeGioia, 90 N.J. 126 (1982). In Crowe, the Supreme Court set forth the following standard for obtaining injunctive relief: (1) irreparable harm will be suffered if the requested relief is not granted; (2) the balance of equities demonstrate movant will suffer greater hardship if the requested relief is not granted than the non-movant will if the relief is granted; (3) the movant has demonstrated a likelihood of success on the merits and the law at issue is well-settled; and (4) it is in the public interest to grant the requested relief. Crowe v. DeGioia, 90 N.J. 126, 132-34 (1982). See also Dolan v. DeCaprio, 16 N.J. 599, 614 (1954); Beckman v. New Jersey Voice, Inc., 302 N.J. Super. 169, 175 (App. Div. 1996). "[T]he power to impose restraints pending the disposition of a claim on its merits is flexible; it should be exercised 'whenever necessary to subserve the ends of justice,' and 'justice is not served if the subject-matter of the litigation is destroyed or substantially impaired during the pendency of the suit.'" Waste Mgmt. of N.J., Inc. v. Morris Cty. Mun. Utils. Auth., 433 N.J. Super. 445, 453 (App. Div. 2013) (quoting Christiansen v. Local 680 of Milk Drivers, 127 N.J. Eq. 215, 219-20 (E. & A. 1940)).

The less rigid approach for granting injunctive relief, "permits preserving the status quo even if the claim appears doubtful when a balancing of the relative hardships substantially favors the movant, or the irreparable injury to be suffered by the movant in the absence of the injunction would be imminent and grave, or the subject matter of the suit would be impaired or destroyed." Waste Mgmt., 433 N.J. Super. at 454.

Here, justice would be served by a stay because TSONJ's right to participate in a proper permit application process would be substantially impaired, if not destroyed, absent a stay during the pendency of its appeals. Without a stay, and judicial interpretation and decision on the issues before the Appellate Court, a victory before the Appellate Court will be rendered nugatory since permits will be issued and businesses will be established and operating-- to the irreparable detriment of TSONJ and the public. Balancing the relative hardships substantially favors TSONJ, and the irreparable injury TSONJ will suffer by not being selected for an ATC because of an improper and flawed permitting process is imminent and grave.

Per the RFA, DOH expects the approved applicants to "move expeditiously to become operational." (Naar Cert.,

Ex. D at TSONJ44). Indeed, the approved applicants are expected to continue developing their business locations for further DOH review throughout the continuing permitting process. A stay pending TSONJ's appeals can preserve the market conditions until the improper and flawed permitting process is corrected on appeal.

A. TSONJ will suffer irreparable harm absent a stay of the Approvals because the relief sought is not monetarily quantifiable.

"Harm is generally considered irreparable in equity if it cannot be redressed adequately by monetary damages." Crowe v. DeGioia, 90 N.J. at 132-33. Permits to operate an ATC are limited and are only established based on DOH's evaluation of the patient market. DOH's 2018 evaluation found the need for just six more ATCs. At present, no additional RFAs have been published. Market conditions for medicinal marijuana--from community tolerance to regulatory restraints--are dubious and fast-changing. As such, TSONJ's opportunity to compete for an ATC permit in the future is uncertain and, at best, speculative.

The July 2018 RFA was unique, as it was the first opportunity for for-profit entities to secure an ATC permit. Even if there is another RFA, that does not

address the competitive advantage of holding a license from an earlier RFA, securing an operating location and establishing a market in advance of competition--economic advantages that cannot be quantified and redressed by money damages. By virtue of the permitting process, the approved applicants will continue to develop a business, enter the marketplace and forever change the landscape upon which the July 2018 RFA was based. Accordingly, the harm that TSONJ will suffer cannot be redressed adequately by money damages and would be irreparable.

B. The balance of the equities demonstrate TSONJ will suffer greater hardship than the approved applicants if the stay is not granted.

A stay "serves as an equitable policing measure to prevent the parties from harming one another during the litigation" and "to keep the parties, while the suit goes on, as far as possible in the respective positions they occupied when the suit began." Hamilton Watch Co. v. Benrus Watch Co., Inc., 206 F.2d 738 (2d Cir. 1953). Here, a stay is necessary to keep the parties in their respective positions pending resolution of the appeals that go to the very heart of the approval process. Indeed, the principal conditions the RFA relied on are

altered every day the permitting process is allowed to continue. Each approved applicant will continue to build its business in anticipation of obtaining a full operating license. TSONJ will suffer greater hardship if a stay is not granted than the successful applicants will suffer if a stay is granted because it will maintain the status quo while the issues raised in TSONJ's appeals are resolved and a valid approval process that is not arbitrary is achieved. If the Approvals are upheld on appeal, the successful applicants will be able to continue the process to obtain a final permit. On the other hand, TSONJ will have been irreparably harmed and its ability to compete in the future speculative at best.

From the outset, approved applicants were advised that they must demonstrate control of the proposed ATC site within 30 days of the selection notice. (Naar Cert., Ex. B at TSONJ30). The approved applicants presently enjoy the benefit of developing their respective businesses with DOH approval. DOH approval has enhanced each approved applicant's opportunity to purchase, lease, or otherwise secure property for its ATC by projecting a likelihood of financial stability. Meanwhile, if TSONJ continues to develop its business and respective property investments,

it must do so at a much greater economic risk since it lacks the same economic security and financial stability that an approval provides. Furthermore, the means of access to medicinal marijuana are broadening with additional medical conditions being added to the list of treatable conditions, but the geographical opportunities for a successful ATC are shrinking. As more municipalities ban dispensaries from their zoning plans, the hardships TSONJ faces in pursuing this market intensify. See Payton Guion, N.J. is still waiting on legal weed as nearly 60 towns have banned it. See the full list., NJ.com (January 16, 2019, 10:50 am), https://www.nj.com/expo/news/erry-2018/12/64cb95fd7e1151/nj-is-moving-toward-legal-weed.html.

The hardships TSONJ faces if the Approvals are not stayed substantially outweigh the hardships the approved applicants might face during the stay. For that reason alone, the stay should be granted.

C. TSONJ has a reasonable likelihood of success on the merits of its appeals and the law is well-settled.

1. DOH violated its statutory mandate to comply with the APA when implementing its rules.

DOH issued its RFA and application instructions with explicit directions that responses to the requested mandatory information was required, which included the "name of a corporation." Nonetheless, through the question and answer segment of the RFA process, DOH unilaterally altered the statutory and regulatory requirements by stating that applicants had "discretion to determine the form of entity" (Naar Cert., Ex. D at TSONJ47). That was not permitted under the existing regulations. See N.J.S.A. 24:6I-7(b). By deleting the requirement for a "corporation" in the Proposed Rule Amendments, DOH demonstrates that it could not lawfully amend the existing rules without following proper rulemaking. Pursuant to N.J.S.A. 24:6I-16, the "Commissioner shall promulgate rules and regulations" pursuant to the "Administrative Procedure Act."

Given the plain language of the regulation requiring the "name of a corporation" and the "articles of incorporation," DOH materially violated its obligation to engage in formal rulemaking per the Administrative Procedure Act in implementing a rule change via its informal FAQ process in violation of N.J.S.A. 24:6I-16.

2. **The approved applications are inherently non-responsive and DOH contravened its regulations by considering applications of limited liability companies.**

The enabling statute and regulations require DOH to comply with its regulations in evaluating ATC permit applications. The requirement for ATC applicants to provide the name of a corporation was specified in the RFA on multiple occasions, consistent with the DOH regulations, and thus was a material requirement. Additionally, DOH assured applicants that the rules in effect at the time of the application filing would control. Therefore, the name of a corporation was an absolute requirement for applicants to proceed in the application process. By failing to adhere to N.J.A.C. 8:64-6.2, DOH departed from the statutorily and regulatorily mandated application process. Applications from limited liability companies should have been deemed nonresponsive. N.J.S.A. 24:6I-7(b); N.J.A.C. 8:64-6.2 and N.J.A.C. 8:64-6.4. DOH could not waive that material requirement absent proper rulemaking - which was not followed by DOH. As a result, a stay should be granted until this foundational and fundamental issue is resolved on appeal.

3. **The DOH failed to score the applications on the 1000-point scale in a consistent and non-arbitrary fashion.**

DOH also failed to provide any scoring methodology in the RFA. Although, the scored portion of the application allocated a variety of points to evaluative questions related to a particular criterion, DOH did not disclose how the total points for each question were earned or not earned or how they would be consistently applied by different evaluators. Thus, TSONJ could have established that its answer to a question was complete and provided everything that was requested, yet suffer a small or large deduction of points by a particular evaluator for an arbitrary reason or for no reason at all. And this, in fact, occurred, when one or more of the other evaluators awarded TSONJ's answer the top score allowed[5]. (Naar Cert.,

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[5] For example, TSONJ's response to Criterion 1, Measure 4, Question 1d, (10 points): "Estimate of the time needed to produce first full crop of medicinal marijuana, including projected size of that crop, and reasoning for estimates," received 0 points from one evaluator and all 10 points from 4 other evaluators; TSONJ's response to Criterion 1, Measure 5, Question 5d (25 points): "Record of past business taxes paid to federal, state and local governments" received 0 points from one evaluator, 20 points from three evaluators, and 25 points from another evaluator; TSONJ's response to Criterion 2, Measure 3, Question b (25 points): "Any certifications or designations establishing the business is women-owned, minority-owned,

Ex. H). There is no indication anywhere of any scoring methodology that the evaluators were supposed to use. In fact, by virtue of the blatant inconsistencies in scoring, it appears that there was no methodology. As a matter of law, an ambiguity in a material term of a RFA (such as here regarding the lack of any scoring methodology to be used by multiple evaluators) must render void both the RFA and any award thereunder. L. Pucillo & Sons, Inc. v. Mayor and Council of Borough of New Milford, 73 N.J. 349, 355 (1977).

Considering that the scoring is the only differential between the approved and denied applications, DOH was required to disclose, and failed to disclose, the requirements for a successful answer to each evaluative question and, at the very least, the criteria that were to be employed by the different evaluators. It is deeply troubling that one evaluator could and did deem a response worthy of all the points allocated to the question and another evaluator could and did deem the response devoid of any merit. The scoring methodology, if any, employed by the individual evaluators proved to be arbitrary and inconsistent. As such, DOH's scoring of TSONJ's

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or veteran-owned" received 0 points from two evaluators and all 25 points from another evaluator.

applications was arbitrary, capricious, unreasonable, and was unsupported by evidence in the record.

D. The public interest will be furthered by a stay of the Approvals.

The foundation of the ATC permitting process is to make certain that patients have reasonable access to properly approved facilities. However, there is a strong public interest in a regulatory enforcement agency adhering to the strict requirements of its own regulatory structure. Indeed, courts recognize that when the public interest is implicated, the court may exercise its equitable power "much farther . . . to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved." Waste Mgmt., 433 N.J. Super. at 454.

DOH's permitting process must be administered pursuant to the statutory and regulatory restrictions that protect the public's health and safety and the integrity of the highly regulated industry of medicinal marijuana and its licensing process. Similar to the rationale for restrictions in licensing for the liquor industry, the restrictions for medicinal marijuana justify staying the

Approvals to ensure DOH has lawfully administered the strict requirements of the ATC permitting process. See Canada Dry Ginger Ale, Inc. v. F & A Distrib. Co., 28 N.J. 444, 454 (1958).

The court often "place[s] great weight on the interpretation of legislation by the administrative agency to whom its enforcement is entrusted;" however that is afforded where the agency's interpretation "is not plainly unreasonable." In re Adamar of New Jersey, 401 N.J. Super. 247, 265 (2008)(citing Metromedia, Inc. v. Dir. Div. of Taxation, 97 N.J. 313, 327 (1984)). However, DOH did not "interpret" the Regulations, for what it might be entitled to deference. Rather it subverted the ATC permitting process by engaging in improper rulemaking. As the record here shows, DOH's actions in the RFA and application process unreasonably subvert the charges of its enabling statute and regulatory foundation. Despite acknowledging that proper rulemaking was required for the material change to the "name of a corporation" requirement by proposing that change in the Proposed Rule Amendments, DOH unlawfully allowed non-corporation entities to apply and proceed with the permitting process.

Comparable to the strict statutory and regulatory requirements of the casino licensing process, the strict statutory and regulatory requirements for licensing ATCs preserves the public's confidence and trust in the credibility and integrity of the regulatory process. Thus, a stay of the Approvals is in the public's best interest until DOH strictly and non-arbitrarily enforces the statutory and regulatory ATC permitting requirements.

CONCLUSION

For the aforementioned reasons, TSONJ respectfully requests that DOH stay the Approvals and any further approval process related to the RFA to preserve the status quo pending disposition of TSONJ's pending appeals.

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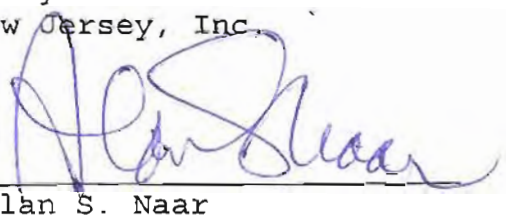
By: 
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Dated: February 6, 2019