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U.S. Citizenship  
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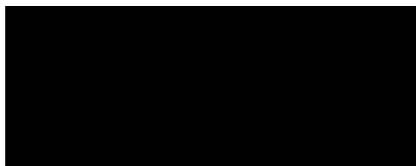
Office: NEBRASKA SERVICE CENTER

Date: SEP 26 2008

IN RE: Petitioner: [REDACTED]  
Beneficiary: [REDACTED]

PETITION: Immigrant Petition for Alien Worker as a Member of the Professions Holding an Advanced Degree or an Alien of Exceptional Ability Pursuant to Section 203(b)(2) of the Immigration and Nationality Act, 8 U.S.C. § 1153(b)(2)

ON BEHALF OF PETITIONER:



INSTRUCTIONS:

This is the decision of the Administrative Appeals Office in your case. All documents have been returned to the office that originally decided your case. Any further inquiry must be made to that office.

  
Robert P. Wiemann, Chief  
Administrative Appeals Office

**DISCUSSION:** The Director, Nebraska Service Center, denied the employment-based immigrant visa petition. The matter is now before the Administrative Appeals Office on appeal. The appeal will be dismissed.

The petitioner seeks classification pursuant to section 203(b)(2) of the Immigration and Nationality Act (the Act), 8 U.S.C. § 1153(b)(2), as a member of the professions holding an advanced degree. The petitioner seeks employment as a software engineer at Prutech Solutions, Inc., Iselin, New Jersey, a firm that provides contract services to various pharmaceutical companies. The petitioner asserts that an exemption from the requirement of a job offer, and thus of a labor certification, is in the national interest of the United States. The director found that the petitioner qualifies for classification as a member of the professions holding an advanced degree, but that the petitioner has not established that an exemption from the requirement of a job offer would be in the national interest of the United States.

Section 203(b) of the Act states, in pertinent part:

(2) Aliens Who Are Members of the Professions Holding Advanced Degrees or Aliens of Exceptional Ability. --

(A) In General. -- Visas shall be made available . . . to qualified immigrants who are members of the professions holding advanced degrees or their equivalent or who because of their exceptional ability in the sciences, arts, or business, will substantially benefit prospectively the national economy, cultural or educational interests, or welfare of the United States, and whose services in the sciences, arts, professions, or business are sought by an employer in the United States.

(B) Waiver of Job Offer.

(i) . . . the Attorney General may, when the Attorney General deems it to be in the national interest, waive the requirements of subparagraph (A) that an alien's services in the sciences, arts, professions, or business be sought by an employer in the United States.

The director did not dispute that the petitioner qualifies as a member of the professions holding an advanced degree. The sole issue in contention is whether the petitioner has established that a waiver of the job offer requirement, and thus a labor certification, is in the national interest.

Neither the statute nor the pertinent regulations define the term "national interest." Additionally, Congress did not provide a specific definition of "in the national interest." The Committee on the Judiciary merely noted in its report to the Senate that the committee had "focused on national interest by increasing the number and proportion of visas for immigrants who would benefit the United States economically and otherwise. . . ." S. Rep. No. 55, 101st Cong., 1st Sess., 11 (1989).

Supplementary information to regulations implementing the Immigration Act of 1990 (IMMACT), published at 56 Fed. Reg. 60897, 60900 (November 29, 1991), states:

The Service [now Citizenship and Immigration Services] believes it appropriate to leave the application of this test as flexible as possible, although clearly an alien seeking to meet the [national interest] standard must make a showing significantly above that necessary to prove the “prospective national benefit” [required of aliens seeking to qualify as “exceptional.”] The burden will rest with the alien to establish that exemption from, or waiver of, the job offer will be in the national interest. Each case is to be judged on its own merits.

*Matter of New York State Dept. of Transportation*, 22 I&N Dec. 215 (Commr. 1998), has set forth several factors which must be considered when evaluating a request for a national interest waiver. First, it must be shown that the alien seeks employment in an area of substantial intrinsic merit. Next, it must be shown that the proposed benefit will be national in scope. Finally, the petitioner seeking the waiver must establish that the alien will serve the national interest to a substantially greater degree than would an available U.S. worker having the same minimum qualifications.

It must be noted that, while the national interest waiver hinges on prospective national benefit, it clearly must be established that the alien’s past record justifies projections of future benefit to the national interest. The petitioner’s subjective assurance that the alien will, in the future, serve the national interest cannot suffice to establish prospective national benefit. The inclusion of the term “prospective” is used here to require future contributions by the alien, rather than to facilitate the entry of an alien with no demonstrable prior achievements, and whose benefit to the national interest would thus be entirely speculative.

We also note that the regulation at 8 C.F.R. § 204.5(k)(2) defines “exceptional ability” as “a degree of expertise significantly above that ordinarily encountered” in a given area of endeavor. By statute, aliens of exceptional ability are generally subject to the job offer/labor certification requirement; they are not exempt by virtue of their exceptional ability. Therefore, whether a given alien seeks classification as an alien of exceptional ability, or as a member of the professions holding an advanced degree, that alien cannot qualify for a waiver just by demonstrating a degree of expertise significantly above that ordinarily encountered in his or her field of expertise.

In a statement accompanying the initial filing, counsel asserted that the petitioner qualifies for the waiver by virtue of his “extensive research experience in the nationally crucial fields of Pharmaceutical and Clinical Studies.” The petitioner’s initial submission included several witness letters, examples of which we shall discuss here.

Four of the six letters are from staff members of Alkermes, Inc., Cambridge, Massachusetts, which is one of the petitioner’s client companies. [REDACTED] Manager of Statistical Programming at Alkermes, described the petitioner’s work with that company:

[The petitioner] currently serves as a Senior Statistical Programmer. His position involves dealing with the most complex Clinical data and reporting issues imaginable. In his current position, [the petitioner’s] responsibilities have included Statistical Programming for important Phase III clinical studies. . . .

[The petitioner] has several specialized skills . . . [that] encompass both clinical and computer programming work. In my years of experience, I have seldom known a Clinical Statistical Programmer with all of these skills. . . . Further, [the petitioner] has published several important papers in international journals and given presentations at national meetings.

██████████, a Senior Biostatistician at Alkermes, praised the petitioner's work and stated: "As further testament to his exceptional standing in his field, [the petitioner] has been a member of the DIA, which is a prestigious association that requires outstanding achievements of its members." The DIA to which ██████████ referred is the Drug Information Association; the record contains a copy of the petitioner's membership certificate from that organization. The record contains nothing from the DIA to support ██████████'s assertion that membership is contingent on "outstanding achievements." Going on record without supporting documentary evidence is not sufficient for purposes of meeting the burden of proof in these proceedings. *Matter of Soffici*, 22 I&N Dec. 158, 165 (Comm. 1998) (citing *Matter of Treasure Craft of California*, 14 I&N Dec. 190 (Reg. Comm. 1972)).

The witness letters from Alkermes are dated late August and early September 2005. Subsequent submissions demonstrate that the petitioner left Alkermes later in September 2005.

The fifth letter is from ██████████ Vice President of ICON Clinical Research, who stated:

[The petitioner] worked in our New York, NY office as a key resource supporting electronic document submissions for New Drug Applications (NDA) to the Food and Drug Administration. . . .

[The petitioner's] work involves developing prototypes. These prototypes provide a mechanism to aid in efficient processing of the clinical data. This effort will reduce the time it takes to prepare and review New Drug Applications (NDA), ultimately reducing the time and cost of bringing a new drug to patients sooner. [The petitioner] is one of the pioneering researchers in this clinical research area. His work is instrumental both in the rapid analysis of clinical trial data and in presenting the data clearly for review by Food and Drug Administration officers. . . .

It is rare, if not virtually impossible to find an individual with so many unique and useful skills to conduct this research. It because of this wide array of skills that [the petitioner's] contributions to his field of research have been significantly greater than that of his peers.

The only witness who claims no close connection to the petitioner is ██████████ Senior Biostatistician at the National Cancer Institute of Canada, who stated:

For the past five years, [the petitioner] has been continuously participating in important clinical research in the pharmaceutical industries. [The petitioner] has worked for several US pharmaceutical companies (UCB Pharma, ICON Clinical Research Organization for Pfizer

Inc., Alkermes), where he has experienced the variety of statistical analysis and data management issues in different phases of clinical trials. . . .

In his current position at Alkermes, Cambridge, MA, he is responsible for . . . a study of using Vivitrex (naltrexone long-acting injection) in alcohol dependent patients to control alcohol dependence. . . . [The petitioner] played key roles in providing input to statistical methods for evaluating long-term safety of Vivitrex, monitoring Adverse Events, performing descriptive statistics to summarize changes in laboratory parameters, and generating summaries of social functions and drinking behaviors. [The petitioner] also developed techniques for validating SAS based statistical systems and validated the data sets of Integrated Summary of Efficacy and Integrated Summary of Safety (ISS/ISE), electronic submission and CDISC implementation. He is responsible for preparing datasets, and generating tables, figures and listings, too. In this study, his contribution was extraordinary.

. . . [The petitioner] has strong experience in applying statistical methods in clinical research practice. . . .

[The petitioner] has published (independent or co-authored) several articles in the leading peer-reviewed journals. . . . He has also presented in various seminars/symposia. This publication and presentation record is quite unusual for and separates [the petitioner] from his peers.

The witnesses praised the petitioner's skills and credited him with significant contributions toward specific projects, but they did not indicate how, if at all, the petitioner has influenced the way others in his field perform their work. Published articles and conference presentations are a means by which the petitioner has the potential to influence others, but the record does not establish the impact of the petitioner's work in those areas. The petitioner's articles and presentations, published and presented between 1986 and 1995, reflect the petitioner's credentials in chemistry but do not appear to relate directly to his subsequent statistical work for pharmaceutical companies.

Regarding the petitioner's present work, there is no indication that the petitioner is responsible for actually developing the drugs being tested in the clinical trials. The above letters do not explain how it benefits the nation (rather than just the employers) to have the petitioner, rather than another competent software engineer, work on these projects.

On August 17, 2006, the director issued a request for evidence, instructing the petitioner to submit documentation to establish the national scope of the petitioner's work and the degree of the petitioner's influence on his field. In response, the petitioner submitted 39 new exhibits, 32 of which are published articles or other documents concerning various clinical trials on which the petitioner had worked. The petitioner also submitted a statement from counsel, but counsel did not explain how any of these exhibits show that it was in the national interest for the petitioner, rather than another qualified worker, to participate in these trials. Counsel discussed the various individual drugs, but there is no indication that the petitioner's work affected the properties of the drugs themselves. Counsel stated that the petitioner's "work has allowed

safe medications to be used for the benefit of the American people,” but the record contains nothing to show that the petitioner’s absence would have prevented the drugs from being made available.

The remaining seven exhibits are further witness letters. Five of the witnesses are on the staff of MGI Pharma, Baltimore, Maryland, the petitioner’s client since September 2005. These witnesses discussed the importance of clinical trials, and asserted that the petitioner is highly skilled in the computer techniques used for design of clinical trial protocols, as well as subsequent data analysis. The witnesses described the importance of various clinical trials in which the petitioner has participated, but they did not clearly state how the outcomes of these trials would have differed with a different qualified professional in the petitioner’s place.

Assistant Professor at Johns Hopkins University School of Medicine, praised the petitioner’s “research achievements in the areas of Radio Analytical methods,” as did Guthikonda of Merck Research Laboratories. The petitioner conducted that research more than a decade ago and there is no evidence that such work has any direct relevance to his current work writing computer programs for pharmaceutical companies. It may be the case that few in the petitioner’s current field have comparable training and experience, but apparently this is because the petitioner’s current field does not require such expertise.

The director denied the petition on May 4, 2007, stating that the petitioner had not shown that the necessary skills for his position could not be articulated on an application for labor certification. The director also found that the petitioner had failed to establish that his work is national in scope. On appeal, counsel argues that the petitioner “has impacted the lives of the American people through his successful work” on clinical trials for various drugs. Counsel then describes several of these drugs. Because the petitioner did not develop these drugs, it would be unrealistic to credit him for their beneficial effects.

Counsel rightly observes that the pharmaceutical industry possesses national scope, but it does not follow that every worker in that industry can claim that his or her work is likewise national in scope. As the record amply shows, clinical trials are a standard and required step in the introduction of every new drug. Once these drugs were developed without the petitioner’s evident involvement, it was a foregone conclusion that the companies would either conduct clinical trials or abandon the projects. The petitioner’s work affects neither the development of the drugs, nor their effects, nor their ultimate distribution. The petitioner’s work, rather, appears to be essentially a matter of internal logistics within a particular company.

Counsel argues that, while the petitioner’s basic skills can be listed on a labor certification, “what cannot be listed upon any piece of paper is his creativity, his innovativeness and his ability to achieve results where others could not.” Counsel cites no specific instance of the petitioner’s “ability to achieve results where others could not.” The petitioner has claimed involvement in trials for several new drugs, but has not shown how the involvement of a different software engineer in his place would have been contrary to the national interest.

Counsel emphasizes passages from several witness letters. These letters are not without value as evidence, but we must view them in the context of the record rather than in isolation. The objective, documentary

evidence of record simply does not support counsel's contention that the petitioner has established "widespread impact" in his field. The petition appears to rest, in large part, on the overall importance of the pharmaceutical industry, and on the observation that the petitioner produced several published articles several years before he began performing his present work as a software engineer for pharmaceutical companies.

As is clear from a plain reading of the statute, it was not the intent of Congress that every person qualified to engage in a profession in the United States should be exempt from the requirement of a job offer based on national interest. Likewise, it does not appear to have been the intent of Congress to grant national interest waivers on the basis of the overall importance of a given profession, rather than on the merits of the individual alien. On the basis of the evidence submitted, the petitioner has not established that a waiver of the requirement of an approved labor certification will be in the national interest of the United States.

The burden of proof in these proceedings rests solely with the petitioner. Section 291 of the Act, 8 U.S.C. § 1361. The petitioner has not sustained that burden.

This denial is without prejudice to the filing of a new petition by a United States employer accompanied by a labor certification issued by the Department of Labor, appropriate supporting evidence and fee.

**ORDER:** The appeal is dismissed.