**Department of Health and Human Services**
**DEPARTMENTAL APPEALS BOARD**
**Appellate Division**

Targazyme, Inc.
Docket No. A-18-101
Decision No. 2939
April 29, 2019

# FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Targazyme, Inc. (Targazyme) appealed a June 1, 2018 decision by the National Institutes of Health Appeals Board (NIH) pursuant to the first-level appeal process at 42 C.F.R. Part 50, subpart D. NIH upheld a determination by the National Cancer Institute (NCI), which had disallowed $180,468.40 in costs charged by Targazyme to its Small Business Innovation Research award, and withheld support for a then-pending non-competing continuation award, on the basis that Targazyme failed to comply with specific terms and conditions of its award. NIH concluded, in sum, that Targazyme failed to provide evidence that it had requested prior written approval to use grant funding for costs incurred more than 90 days before the beginning date of the initial budget period of a new award ("early expenditures"). Because this violated grants policy as well as the terms and conditions of the grant award, NIH concurred with NCI's findings to disallow $128,906 in direct costs and $51,562.40 in associated facilities and administration costs. NIH Dec. at 4. Moreover, NIH upheld multiple other findings which collectively showed a material failure to comply with grant requirements. *Id.* at 6-9, 12.

For the reasons discussed below, we find no basis to disturb the NIH Decision. Targazyme raises several contentions in support of its Notice of Appeal. However, with one immaterial exception, Targazyme failed to support its contentions with evidence. Therefore, we affirm the NIH Decision.

## Applicable legal authorities

A grant award is a type of federal financial assistance that provides support or stimulation to accomplish a public purpose. 45 C.F.R. §§ 5.2 (definitions of "Federal award" and "Federal financial assistance"), 75.201; 31 U.S.C. §§ 6301-08. Research grant awards made by the NIH, or one of its institutes, such as NCI, are subject to general terms and

conditions depending on the type of grantee and other factors, as well as any special terms and conditions in the notice of award. NIH issues a Grants Policy Statement (NIH GPS) to consolidate requirements into a single document.[1] NIH GPS at ii; *see also* 45 C.F.R. § 75.400. The version applicable here is the statement issued March 31, 2015.[2]

A recipient's financial management system must identify and provide for the accurate, current, and complete disclosure of the financial results of each Federal award or program. *Id.* § 75.302(b)(2). The system must also have records that identify adequately the source and application of funds for federally-funded activities; provide for effective control over, and accountability for, all funds, property, and other assets; have written procedures to implement the requirements of § 75.305 of the regulations; and have written procedures for determining the allowability of costs in accordance with Subpart E of the regulations and the terms and conditions of the Federal award. *See* 45 C.F.R. § 75.302(b)(3)-(7).

The approved budget for the Federal award must be related to performance for program evaluation purposes whenever appropriate. *Id.* § 75.308(a). Recipients are required to report deviations from budget or project scope or objective, and to request prior approvals from HHS awarding agencies for budget and program plan revisions, in accordance with section 75.308. *Id.* § 75.308(b). For non-construction Federal awards, recipients must request prior approvals from HHS awarding agencies for program or budget-related reasons such as: change in the scope or the objective of the project, program, or key person specified in the application; disengagement from the project by the approved project director or principal investigator; inclusion of costs that require prior approval under the regulations; transfer of funds budgeted for participant support costs; unauthorized subawarding, transferring or contracting out of any work under a Federal award; and if the need arises for additional Federal funds to complete the project. *Id.* § 75.308(c).

A Federal award recipient must retain financial records, supporting documents, and all other records pertinent to an award for a specified period. *Id.* § 75.361. HHS awarding agencies or any of their duly authorized representatives "have the right of access to any documents, papers, or other records of the [award recipient] which are pertinent to the

[1] NIH fiscal years run from October 1 through September 30. The NIH GPS applies to grant awards with budget periods beginning within the same fiscal year. For example, an award made in January 2019 would adhere to the requirements contained in the October 2018 Grants Policy Statement. The budget periods relevant to this appeal are September 1, 2015 through August 31, 2016 and September 1, 2016 through August 31, 2017. NIH Dec. at 1. Therefore, the March 31, 2015 version of the NIH GPS is applicable here.

[2] The March 31, 2015 NIH GPS is archived on the NIH website and is available at https://archives.nih.gov/asites/grants/05-21-2015/grants/policy/nihgps/nihgps.pdf.

Federal award . . . ." *Id.* § 75.364(a). HHS may also make site visits as needed to monitor award performance. *Id.* §§ 75.342(e), 75.352(e)(2). All commercial organizations are required to comply with the cost principles in the uniform administrative requirements.

As a prerequisite to NIH approval of a non-competing continuation award, a grantee must submit an annual progress report. NIH GPS at IIA-52, IIA-127. The NIH GPS warns, however, that the Grants Management Officer may "require additional information to evaluate the project for continued funding" and may use the cash transaction reports submitted to the Payment Management System to monitor the grant, reviewing patterns of cash expenditures, including accelerated or delayed drawdowns, to assess whether programmatic or financial management problems exist. *See id.* at IIA-128-32. Elsewhere, the NIH GPS informs grantees that NIH "expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations." *Id.* at IIA-62. The NIH GPS explains that "[e]xpenditure patterns are of particular concern because they may indicate a deficiency in the grantee's financial management system or internal controls" and "[a]ccelerated or delayed expenditures may result in a grantee's inability to complete the approved project within the approved budget and period of performance." *Id.* In these situations, the Grants Management Officer "may seek additional information from the grantee and may make any necessary and appropriate adjustments." *Id.*

Where an award recipient "fails to comply with . . . terms and conditions" of its award, the awarding agency may "take one or more" enforcement actions, including terminating the award, withholding further awards for a project, or disallowing "all or part of the cost of the activity or action not in compliance." 45 C.F.R. §§ 75.371, 75.372; 75.375; *see also* NIH GPS § 8.5.2, at IIA-140.

Elsewhere, the NIH GPS states that "Part II includes administrative and other remedies the Federal government may use if a recipient deliberately withholds information or submits fraudulent information or does not comply with applicable requirements." NIH GPS at I-66. It then lists other authorized civil or criminal actions and states that "NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 45 CFR 75." *Id.* at I-67. Part II also distinguishes enforcement actions from recovery of "funds in the recipient's account that exceed the final amount determined to be allowable." *Id.* at IIA-141.

The Board provides independent review on appeal of certain final written decisions by various HHS components concerning direct, discretionary project grants or cooperative agreements. 45 C.F.R. Part 16. Appealable decisions include: 1) a decision to terminate an award for failure to comply with its terms and conditions; and 2) a decision to deny a

noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award. *Id.*, App. A, ¶ C(a)(2)-(3). Before the Board takes an appeal, the appellant must exhaust any available preliminary appeal process required by regulation, such as the process described in 42 C.F.R. Part 50 (subpart D) for Public Health Service programs. 45 C.F.R. § 16.3(c).

The Board's Appellate Division Practice Manual[3] provides that, in disallowance cases, the respondent (here, NIH) has the burden to articulate clearly the basis of the disallowance and to include in the disallowance letter enough detail to enable the appellant to understand the issues and the respondent's position. *See* 45 C.F.R. § 75.374. If the respondent carries that burden, then the grantee that appeals a disallowance has the burden of identifying, documenting, and justifying its claimed costs and hence establishing its defense to the respondent's disallowance. *Kids Central, Inc.*, DAB No. 2897, at 3 (2018). Thus, in the kind of cases that come before the Board under 45 C.F.R. Part 16, the appellant always bears a general burden of proof. In grant cases, "a grantee always bears the burden to demonstrate that it has operated its federally funded program in compliance with the terms and conditions of its grant and the applicable regulations." *Norwalk Econ. Opportunity Now, Inc.*, DAB No. 2002, at 7 (2005). Further, the Board may proceed to decision in cases governed by Part 16 at the close of the briefing process described in section 16.8, without further opportunity for developing the record. Consequently, an appeal file should be as complete a documentary record as possible. A party should submit all documents that would assist the Board in making findings on disputed issues, as well as documents that provide necessary background information.

**Factual and procedural background**[4]

In August 2016, NCI issued two grant award notices to Targazyme for periods comprising September 1, 2015 through August 31, 2016 (1 R44 CA 192601-01A1 (revised)) and September 1, 2016 through August 31, 2017 (5 R44 CA 192601-02). NIH Dec. at 1-2. On December 12, 2016, the NIH Office of Management Assessment, the NIH office responsible for review of allegations of waste, fraud and abuse, conducted a site visit on Targazyme. *Id*. at 3. Based on the concerns raised by that visit, on April 7, 2017, NCI requested Targazyme provide accounting records reflecting how Targazyme (and all subgrantees) spent funds awarded in grant years 1 and 2, and documenting that the expenditures complied with certain grant program requirements. *Id.*

[3] The Appellate Division Practice Manual may be accessed here: https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-board/practice-manual/index.html.

[4] The summary in this section is drawn from the June 1, 2018 NIH Appeals Board Decision and is not intended to replace, modify, or supplement any findings of fact.

On April 17, 2017, Targazyme responded by submitting certain spreadsheets, which NCI found did not document how grant funds were expended. *Id*. Moreover, NCI found, designated early expenditures of $185,022 were for costs incurred more than 90 days prior to the start of the initial budget period (September 1, 2015), but Targazyme had not requested required prior NCI approval. *Id*. NCI offered to consider the costs retrospectively if Targazyme also provided a "written statement providing a sound scientific rationale for why the costs were necessary to support the conduct of the specific scientific aims of the grant more than 90 days prior to the beginning of the initial budget period for the award." *Id*. Targazyme submitted invoices for the expenditures included in the spreadsheet; however, NCI found, Targazyme failed to submit a statement of sound scientific rationale to support the early expenditures. *Id*. NCI found nonresponsive the rationale Targazyme offered, relating to manufacturing challenges, pre-award termination of a relationship with a vendor, and higher than expected costs. *Id*. Therefore, NCI disallowed the charged costs and withheld support for a non-competing continuation award based on Targazyme's failure to comply with other grant terms and conditions. *Id*., at 1, 12.

Targazyme appealed NCI's adverse determination to NIH. On appeal, NIH upheld NCI's disallowance and decision not to make a non-competing continuation award. NIH Dec. at 1. Regarding the disallowance, NIH concluded that Targazyme neither requested written prior approval for pre-award costs incurred more than 90 days before the initial budget period nor produced a written statement of a sound scientific rationale for the necessity of pre-award costs when NCI offered to consider retrospective approval. *Id*. at 4. NIH also concluded that "Targazyme provided no evidence that they had accounting records that supported charges to the NCI grant, as required by NIH grants policy and the terms and conditions of grant award." *Id*. at 7. NIH concurred with NCI's conclusion that Targazyme failed to show that it maintained a positive time and effort reporting system, because "Targazyme's methodology involving goals and objectives does not capture daily after-the-fact reporting of hours expended on individual projects or indirect activities nor does it record both hours worked and hours absent, as required by NIH grants policy and the terms and conditions of the award." *Id*. at 8.

NIH further concluded that Targazyme provided no evidence of a formal written agreement with the "consortium participants," despite Targazyme having paid them from grant funds.[5] *See id*. at 9. Specifically, NIH found that the email between Targazyme and a collaborator did not serve as a formal written consortium agreement because it did not contain elements required by the terms and conditions of the award. *Id.* Moreover,

[5] NIH reviewed the notices of award (of which the NIH Grants Policy Statement was a term and condition); progress reports; NCI's letters to Targazyme, dated April 7 and June 27, 2017; Targazyme's letters to NCI, dated April 17 and July 7, 2017 (with email relating to a subaward to one research institution and a letter of commitment from a separate research institution). NIH Dec. at 1-2.

NIH concluded, the collaborators/consortium investigators stated in their e-mail to Targazyme that they lacked the authority to enter into a subcontract. *Id*. NIH also agreed with NCI's conclusion that Dr. J. F. was ineligible to serve as Targazyme's principal investigator under the program because Dr. J. F. was an independent contractor and not a Targazyme employee. *Id.* at 12. NIH did not uphold NCI's specific determination that Targazyme had drawn down all available funds prior to the budget period end date, in violation of the terms and conditions of the award. *See id*. at 10-11. NIH concluded that "NCI's specific term of award included in the Targazyme Notice of Award may have caused some confusion with respect to the grants policy requirement." *Id*. Nonetheless, NIH concluded that NCI appropriately disallowed costs and withheld support for the non-competing continuation award under the NIH GPS § 8.5.2, due to material noncompliance with the terms and conditions of the award. *Id*. at 12.

## Discussion

### 1. *Targazyme failed to submit supporting documentation with its appeal; therefore, insufficient evidence in the administrative record supports Targazyme's arguments.*

On appeal to the Board, Targazyme argues that events beyond its control caused a shortage of the drug necessary for the clinical trials it was to conduct. Notice of Appeal at 1.[6] Consequently, Targazyme reallocated another supply of the drug slated for other clinical trials and "expensed those costs to the [instant] award." *Id*. Targazyme contends that it submitted accounting evidence to NIH supporting the propriety of its expenditures, and states that it should be allowed to explain "confusion in the presentation" of the expenditures. *Id*. at 2. Next, Targazyme contends that submitting monthly goals and objectives and hiring a new finance and human resources director constitute evidence that Targazyme has "monthly positive time and effort reporting that tracks our employees' activities, including those activities related to the grant." *Id*. Targazyme answers the charge that it failed to provide evidence of policies governing subawards by stating that it did not enter into subawards with the two collaborators which were to host the clinical trials for year two of the grant due to the aforementioned lack of available drug. *Id*. at 4. Regarding the NIH's finding that Targazyme's invoices showed payments to the two collaborators without subaward agreements, Targazyme responded that it had "reported transactions in Year 2 [of the grant] that were for Year 1 work based on the time that they were invoiced." *Id*. Therefore, Targazyme states, Targazyme "did not disburse any funds regarding Year 2 work." *Id.* Finally, Targazyme argues that the fact that its principal investigator was a contract "1099 employee" did not make her ineligible to act

[6] Targazyme's Notice of Appeal is not paginated. We identify the pages by their sequential order.

as principal investigator for the clinical trials. *Id*. Targazyme contends that it documented the principal investigator's employment status in a letter which explained that she had no other employment that would preclude her working at least 50 percent of her time for Targazyme. *Id*.

The Board has reviewed the NCI's disallowance (as summarized in NIH's decision) and concludes that it articulated clearly the basis of the disallowance and included in the disallowance letter enough detail to enable Targazyme to understand the issues and the respondent's position. NIH found that the documentation Targazyme provided did not support the claimed costs with adequate accounting records. NIH Dec. at 7. In addition, NIH concluded that Targazyme failed to provide supporting documentation to show that it maintained a time-and-effort reporting system, as required by the NIH GPS. *Id*. at 8. NIH also upheld the NCI's findings that Targazyme improperly made payments to collaborators and that Dr. J. F. was ineligible to serve as principal investigator on the grant. *Id*. at 9, 12. Therefore, we conclude that NIH has met its initial burden to clearly articulate the basis for the disallowance and the decision to withhold support for a non-competing continuation award. Below we explain why Targazyme failed to meet its burden to provide evidence rebutting the basis for those decisions.

a) Targazyme failed to submit the appellant's brief and the appellant's appeal file as Board procedures require.

The Board issued a letter on July 16, 2018, which acknowledged receipt and outlined the Board's procedures for Targazyme to pursue its appeal (Ack. Ltr). In that letter, we notified NIH to send notice to Targazyme and to the Board "stating the name, address and telephone number of its representative." Ack. Ltr. at 2. NIH submitted its notice of representative on August 9, 2018. Targazyme was required to "provide the same information to the Board and to [NIH] if someone other than the person who signed the notice of appeal will be its representative," which Targazyme did by letter dated September 14, 2018. *Id*. Within 30 days after receiving the acknowledgment letter, Targazyme should have submitted a brief ("a written statement of its arguments concerning why the appealed decision is wrong") and an appeal file ("copies of any documents on which its arguments are based"). *Id*. (referring to 45 C.F.R. § 16.8(a) and additional instructions contained in the Acknowledgment Letter). The letter next directed NIH to submit its brief and supplement the appeal file within 30 days after receiving the appellant's brief and appeal file. *Id*. (referring to 45 C.F.R. § 16.8(b)).

The Acknowledgement Letter also explained that the Board is distinct from the decision-making agency (here, NIH). Ack. Ltr. at 2 ("The Board is separate from the part of HHS which issued the decision being appealed."). The Board has for consideration only the information that the parties present; therefore, the Appellate Division Practice Manual

advises appellants that the appeal file should "include all documents that would assist the Board in making findings on disputed issues, as well as documents which provide necessary background information." ("What kinds of documents have to be filed in an appeal governed by 45 C.F.R. Part 16?")

Upon Targazyme's request and without objection from NIH, the Board twice granted Targazyme extensions of time in which to file its brief and appeal file. The first extension, granted on September 20, 2018, gave Targazyme until October 15, 2018 to submit its appellant's brief and appeal file. The reasons Targazyme gave for the first extension was that its mail had been misplaced and that its small staff was occupied addressing concerns of an investor. *See* Targazyme Letter dated September 14, 2018. The second extension, granted on October 12, 2018, extended the deadline to October 31, 2018. For that extension Targazyme again cited its small staff as the cause. *See* Targazyme letter dated October 9, 2018. However, rather than submit a brief and appeal file, Targazyme submitted a two-page letter on October 31, 2018, which its representative characterized as "further comments and updates" in addition to "the June 29, 2018 brief." Targazyme did not submit an appeal file with its October 31, 2018 letter, or seek leave to submit it at any later date. In the letter, Targazyme characterized the notice of appeal to the Board as its brief; however, we have considered and reject Targazyme's arguments, as explained below. We also considered the attachments to Targazyme's appeal notice in lieu of an appeal file (NIH Dec.; Dr. J. F. letter, dated October 18, 2017) and conclude that they contain no accounting or source documentation supporting any of Targazyme's disallowed costs.

b) Targazyme submitted virtually no supporting evidence to this Board, despite citing in its appeal various documents apparently sent to the NIH.

Because Targazyme failed to submit the evidence considered by NIH, the Board cannot review most of the evidence which Targazyme contends supports its arguments in favor of reversing NIH's disallowance and non-support determinations.[7] The only evidence before the Board is Dr. J. F.'s letter to NIH dated October 18, 2017, pertaining to Dr. J.F.'s eligibility to serve as principal investigator based on Dr. J. F.'s employment status with Targazyme. NIH considered this evidence and found that it shows that Dr. J. F. was a contractor, and therefore ineligible to serve as Targazyme's principal investigator under the award. *See* NIH Dec. at 12. However, we do not reach this issue, because even if

[7] We note that NIH filed no brief in response to Targazyme's appeal. Given Targazyme's failure to file its brief and appeal file even after two extensions, we do not find that NIH was on notice that its opportunity to file a responsive brief was triggered. In any case, as we have explained, the NIH decision addressed most of the arguments made again by Targazyme in its appeal, and Targazyme submitted no supporting documentation on appeal. Therefore, we find no need for any further submissions.

Targazyme prevailed on this point (which we do not conclude), we would still uphold the instant disallowance and withholding based on Targazyme's failure to rebut other findings of material noncompliance. *See* 45 C.F.R. §§ 75.371, 75.372; 75.375; NIH GPS Part II, Section 8.5.2, at IIA-140.

**2. *Targazyme's arguments provide no other basis for reversing the NIH Decision.***

Although Targazyme offers explanations for why it was non-compliant with the terms and conditions of its award, it does not argue or offer evidence to show that it was materially in compliance with the award terms and conditions. Targazyme does not argue that NIH erred in determining that Targazyme's material non-compliance constitutes a sufficient basis for the enforcement actions NIH has taken. Targazyme's argument that the lack of available drug for clinical trials constituted a sound, scientific rationale for charged pre-award costs is unsubstantiated by any supporting evidence to establish that it had provided that rationale in writing to NCI. The question before NIH was whether lack of sufficient drug inventory with which to conduct clinical trials constituted a sound scientific rationale for pre-award costs charged to the grant more than 90 days prior to the beginning date of the initial budget period of the new award. The question before us is whether evidence in the record shows that Targazyme submitted a request in writing for early expenditures in which it provided a sound scientific rationale for charging those costs to the grant. As discussed above, there is no evidence of such a writing, and Targazyme does not contend that it submitted one to NIH. We conclude that Targazyme has not shown that it properly obtained approval for the pre-award costs and that Targazyme was therefore materially non-compliant on this issue.

The Part 16 regulations provide that "one of the objectives of administrative dispute resolution is to provide a decision as fast as possible consistent with fairness[.]" 45 C.F.R. § 16.15(a). Targazyme failed to meet the Board's deadline for submitting an appellant's brief or an appeal file. "If the appellant fails to meet any filing or procedural deadlines, appeal file or brief submission requirements, or other requirements established by the Board, the Board may dismiss the appeal, may issue an order requiring the party to show cause why the appeal should not be dismissed, or may take other action the Board considers appropriate." 45 C.F.R. § 16.15(b).

No purpose would be served by issuing an order to show cause why the Board should not dismiss the appeal. Moreover, further delay would be contrary to administrative economy. Consequently, the Board has concluded that the appropriate course of action is to issue a decision unfavorable to Targazyme on the merits.

**Conclusion**

Targazyme has failed to provide evidence supporting a basis for its request to reverse NIH's Decision to disallow costs and withhold support for a pending non-competing continuation award. Therefore, we uphold NIH's Decision.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Christopher S. Randolph
Presiding Board Member