

December 9, 2021

Via Electronic Mail

The Honorable Gabe Albornoz, President
Montgomery County Council
Stella B. Werner Council Office Building
100 Maryland Avenue, 4th Floor
Rockville, Maryland 20850

Re: Biohealth Priority Campus ("BPC") Plans
Zoning Text Amendment 21-09 & Subdivision Regulation Amendment 21-02

Dear Council President Albornoz and Members of Council:

On behalf of United Therapeutics Corporation ("United Therapeutics"), this letter supplements my oral remarks to the Montgomery County Council on November 30, 2021, concerning Zoning Text Amendment 21-09, Office & Professional – Biohealth Priority Campus (the "ZTA") and Subdivision Regulation Amendment 21-02, Administrative Subdivision – Biohealth Priority Campus (the "SRA") (together, the "Amendments").

As I explained at the time of hearing, United Therapeutics fully supports the proposed Amendments. The Amendments will be particularly beneficial for biotechnology companies that are pursuing development opportunities in Montgomery County's urbanized areas, including in our home in Silver Spring. They also provide an exciting opportunity for the County to replicate and repurpose the same general processes that it has already approved for Signature Business Headquarters ("SBH") development to accommodate biotechnology opportunities, fulfilling the promise of that yet-to-be utilized SBH process as an economic development tool.

As you know, the biopharma industry often requires highly specialized facilities in order to turn ideas into FDA-approved therapies. Constructing these specialized facilities requires a strategy to align the process by which a facility is designed, permitted and built with the R&D and product development cycle. The goal of this coordinated effort is to understand the timing for making the capital investments necessary to ensure that FDA-approved, operational facilities exist when needed.

The longer the timing required to deliver facilities, the earlier in the product cycle these large capital investment decisions must be made; and, the earlier in the product cycle, the greater the risk and uncertainty around the ultimate viability of the product that the planned facility will be supporting. Because fewer than 10 percent of R&D initiatives actually result in FDA-approved products, a swift and efficient land use entitlement process allows this risk to be mitigated and, therefore, is critical for site selection.

While we find that the time required to design, construct, and obtain necessary FDA approvals for new facilities to be relatively consistent from project to project, the time required to obtain land use entitlements varies substantially by jurisdiction, resulting in very real competitive advantages and disadvantages. Historically, the entitlement process in Montgomery County has been longer and more complicated than those of other biotech hubs that we have analyzed. However the Amendments, if approved, will effectively change that narrative and put Montgomery County on equal or better footing with its competitors. The Amendments will simplify and accelerate the processes by which United Therapeutics can build its mission-critical facilities, which in turn allows

us to more quickly and efficiently bring innovative, life-saving therapies to the patients who desperately need them.

Even though United Therapeutics supports the Amendments, we remain concerned that some of the specific revisions that the Montgomery County Planning Board and the Montgomery County Planning Department have proposed are not compatible with the primary strategic objective of Amendments (*i.e.*, streamlining development review for certain biotechnology projects). At the same time, we support certain concepts that the Planning Board has raised in their letter of November 29, 2021. We would like to note the following for your consideration:

1. Concept Plan submissions and other pre-application requirements that prolong the time required for development review should be avoided.

We oppose the idea of requiring a formal Concept Plan submittal in advance of a BPC Plan submission. This or any other additional step would only serve to add time back into the development review process. Further, we note that such pre-application measures are not required for SBH Plan reviews. Adding time back into the development review schedule only undermines the streamlining that the ZTA is otherwise seeking to achieve.

2. The Amendments should allow for potential extensions from applicable BPC Plan post-approval compliance and validity deadlines, if circumstances warrant.

We support including extensions in the Amendments to allow Applicants to request additional time, if needed, to meet required deadlines for subsequent regulatory processes and approvals (such as Certified Site Plan submittal and approval and building permit application submittal and issuance). We believe including authorization for these extensions to be particularly important for biotechnology uses, given that the industry is particularly affected by rapid developments and innovations, as well as unexpected roadblocks in research. Many potential factors can affect a project's ability to advance to building permit.

3. The Amendments should designate the Planning Department as the lead agency for BPC Plans and require reviewing agencies to accept and abide by lead agency determinations.

To ensure timely reviews and provide a mechanism for conflicting views to be resolved, we support the idea of naming the Planning Department as the lead agency in the BPC Plan process, and thereby allowing it to make decisions for other agencies, if needed. However, it is critical that the agencies then abide by those decisions in implementing the BPC Plan. Any lead agency provisions that are added to the Amendments should make clear that reviewing agencies must be bound by such determinations for subsequent reviews and permits.¹

4. The Amendments should clarify that applicable overlay zones are included as part of the underlying zoning, but are subject to the hearing and review schedule required for BPC Plans.

At the time of Planning Board review, the Planning Department proposed revisions to ensure that applicable overlay zones are considered part of the underlying zoning of a property that establishes the standards and procedures for the review of a BPC Plan. We agree that overlay zone requirements, if applicable, should carry forward to BPC Plans to the same extent as the base zone. However, the standards

¹ To the extent that the Planning Department has concerns with accommodating the review schedules of other regulatory agencies, we note that those agencies should be engaged now and educated about the proposed Amendments. The creation of this process is an opportunity for all participants in the development review process to row together to reach the same goal. Not because it is compelled by law, but because it is good for the County and the State, and good for business in the County. This is an opportunity for those agencies – not otherwise subject to County control – to work cooperatively with the County (as they always profess to do) and revise their own procedures to voluntarily cut review times to conform to the standards set by the Amendments, so as to allow full participation in the BPC Plan process and to sign on as full and strong advocates for the County's economic development priorities.

and procedures for those overlay zones should, in turn, be expressly subject to the hearing and review schedule required for BPC Plans. We encourage the Council to include this clarification in the Amendments in order to ensure that the revision proposed by the Planning Department remains consistent with the County's objectives for the Amendments (*i.e.*, creating a streamlined development review option for qualifying biotechnology projects).

5. *The Council should ensure that adequate financial resources are available to the Planning Department and to reviewing agencies, as needs arise, in order to ensure successful implementation of the Amendments.*

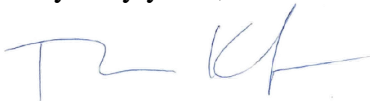
We understand the Planning Board's position that the Amendments may require additional financial resources to be made available to the Planning Department and other County reviewing agencies, so that the required regulatory reviews are able to be completed in the expedited timeframes. To this end, we support the Planning Board's request that sufficient financial resources be made available to the Planning Department and other reviewing agencies, as need arises, to ensure the successful administration of the proposed BPC Plan process.

As an aside, to the extent that the Planning Department has expressed reservations about its ability to complete the expedited development review process in the timeframes proposed, we are confident that the provision of additional resources will dispel any such concerns. Wouldn't a terrific outcome of the Amendments be for the County to have so many BPC Plan applications submitted for projects that we were concerned with being able to complete reviews in the required timeframes? This would represent a concrete measure of economic development success.

For convenience, we are also attaching to this letter a copy of our previous written testimony to the Planning Board dated November 17, 2021 (Exhibit A). This prior testimony includes detailed comments about our concerns with the revisions that were initially proposed by the Planning Department and discussed with the Planning Board at the time of their hearing on November 18, 2021.

We thank you for your consideration of these issues and appreciate the opportunity to participate in this amendment process. Please do not hesitate to let us know if you have any additional questions or if we can provide additional information.

Very truly yours,



Thomas Kaufman, Senior Director of Corporate Real Estate
United Therapeutics Corporation

w/ Enclosures

cc: The Honorable Evan Glass
The Honorable Andrew Friedson
The Honorable Tom Hucker
The Honorable Will Jawando
The Honorable Sidney Katz
The Honorable Nancy Navarro
The Honorable Craig Rice
The Honorable Hans Reimer
Livhu Ndou, Esquire

Exhibit A

**ZONING TEXT AMENDMENT 21-09, OFFICE & PROFESSIONAL – BIOHEALTH PRIORITY
CAMPUS & SUBDIVISION REGULATION AMENDMENT 21-02, ADMINISTRATIVE
SUBDIVISION – BIOHEALTH PRIORITY CAMPUS**

Testimony of Thomas Kaufman on Behalf of United Therapeutics Corporation

November 17, 2021

Good afternoon. For the record, I am Thomas Kaufman, Senior Director of Corporate Real Estate at United Therapeutics Corporation. This testimony supplements the oral remarks that I will deliver to the Montgomery County Planning Board on November 18, 2021, concerning proposed Zoning Text Amendment 21-09, Office & Professional – Biohealth Priority Campus (the "ZTA") and proposed Subdivision Regulation Amendment 21-02, Administrative Subdivision – Biohealth Priority Campus (the "SRA") (together, the "Amendments").

United Therapeutics fully supports the proposed Amendments and we are pleased that the Montgomery County Planning Department has recommended the Planning Board support them with only minor amendments. We believe that the Amendments will be particularly helpful for biotechnology companies like United Therapeutics that are pursuing development opportunities in Montgomery County's urbanized areas, including in our home in Silver Spring. Furthermore, we believe the Amendments provide an exciting opportunity for the County to replicate and repurpose the same processes that it has already approved for Signature Business Headquarters ("SBH") development to accommodate biotechnology opportunities. In doing so, the Amendments provide a unique opportunity to fulfill the promise of that unutilized SBH process as an economic development tool.

At the same time, United Therapeutics is concerned that certain of the Planning Department's proposed revisions are inconsistent with the primary strategic objective of the Amendments to streamline the development review process for certain biotechnology projects. Our particular concerns include the following:

I. Definition of Biohealth Priority Campus (ZTA Staff Report, Page 7)

The Planning Department proposes to revise the definition of the Biohealth Priority Campus ("BPC") so as to limit the applicability of the use to only those properties that are located within Red Policy Areas, or those that "abut" or "confront" Red Policy Area properties (as the Zoning Ordinance defines those terms). We understand that these changes are intended, in part, to address concerns that the use of the phrase "adjacent to" in the current ZTA is potentially vague.

United Therapeutics is concerned that restricting the potential locations for BPC uses as Planning Department Staff proposes may inadvertently disqualify some of United Therapeutics' real property holdings from being included in a future BPC Plan for our Silver Spring campus. More specifically, United Therapeutics is aware that certain of our properties are separated physically from Red Policy Area locations by rights-of-way that are greater than 80' and, therefore, would not be deemed "confronting" under applicable Zoning Ordinance definitions if Staff's proposed revision were included in the ZTA. Spring Street, for example, has a 100' right of way. Therefore, properties on the north side of Spring Street would not be considered "confronting" with this revision, nor would other separate parcels behind those fronting on Spring Street.

To prevent this outcome while addressing Staff's concerns with vagueness, we suggest the following clarification:

- b. *is located (1) on a property within, [[or adjacent to]] abutting, or confronting property located within a red policy area [[, within an opportunity zone, or within ½ mile of a planned or existing Bus Rapid Transit route]], or (2) on or abutting a property that is directly across a public road right of way greater than 80' from a property within a red policy area that is zoned CR, or (3) within an opportunity zone, or (4) within ½ mile of a planned or existing Bus Rapid Transit route].²*

² The Planning Department's proposed revisions are shown in red font, and our proposed revisions are shown in blue.

II. Use Standards – Height (ZTA Staff Report, Page 8)

The Planning Department proposes revisions to clarify that mapped building heights are maximums that cannot be flexibly interpreted to accommodate reallocated densities within a BPC Plan. We do not object to this clarification per se. However, we note that the Zoning Ordinance allows increases above mapped building heights in several instances, such as for the various permitted height encroachments for certain rooftop elements in Section 4.1.7.C.3. For this reason, we believe that any revision in the ZTA to limit building height as mapped, should include additional language to clarify that building heights may not exceed the maximum mapped height "except where permitted in accordance with other applicable Zoning Ordinance provisions, including any height increases allowed by this Chapter."

III. Application Requirements – Concept Plan (ZTA Staff Report, Page 9)

The Planning Department proposes to require a Concept Plan submittal in advance of any BPC Plan application. However, United Therapeutics is concerned that requiring such advance submittals and reviews will directly undermine the efficacy of the ZTA as a tool for streamlined development approvals. We understand that the Concept Plan process typically adds ± 2 to 3 months to the overall development review process, excluding the necessary lead time for preparing the Concept Plan application materials. (The additional proposed revision requiring a Traffic Impact Study or Statement at Concept Plan would only serve to prolong the time before filing is allowed).

Furthermore, the Concept Plan process is advisory in nature and non-binding. There is no assurance that sufficiently detailed responses will be elicited from participating reviewing agencies. For that reason, the Concept Plan process does not serve to prevent contrary guidance by the agencies at the time of subsequent application reviews and, therefore, often does not advance a clear benefit for applicants that cannot be otherwise obtained through preliminary consultations and outreach to Department Staffs (which is not precluded and typically occurs in the normal course of preparing for application submittal).

Adding $\pm 60 - 90$ days, at minimum, back into the development review process erases the potential time that would be saved by utilizing the BPC Plan process and that the ZTA seeks to achieve. In addition, Concept Plan submittals are not mandatory for SBH applications. Why add such a requirement for BPC Plans when it is not needed for SBH Plans? We fail to see the need for this revision and oppose the introduction of this added requirement.

IV. Findings for Approval (ZTA Staff Report, Pages 11-12)

The Planning Department recommends creating an additional finding for Planning Board approval of BPC Plans – proposed Finding (f) (7.3.6.E.2.f) – to address compatibility review with existing and proposed future development per recommendations in the Master Plan and requirements of the Zoning Code. This recommendation proposes to add an additional criterion for review that is not applicable to SBH applications. Why add this for BPC Plans?

To the extent that Staff is concerned with ensuring compliance with applicable Master Plan recommendations and Zoning Ordinance requirements concerning compatibility, we note that other provisions of the ZTA already address these issues. More specifically, Master Plan conformance is addressed through Finding (e), which requires the Planning Board to find that the BPC Plan "substantially conforms with the intent of the applicable master plan and any guidelines approved by the Planning Board that implement the applicable plan". (Section 7.3.6.E.2.e in the ZTA, and similar language in Section 7.3.5.E.2.e in the SBH legislation.) Similarly, proposed Finding (b) requires the Planning Board to find that the BPC Plan "satisfies the applicable use and development standards and general requirements of this Chapter." (Section 7.3.6.E.2.b in the ZTA; Section 7.3.5.E.2.b in the SBH legislation.)

Because the ZTA already addresses these issues, proposed Finding (f) is redundant and we do not support this change.

V. Decision – Requirement for Certified Site Plan Submission Within 35 Days (ZTA Staff Report, Page 12)

The Planning Department recommends that BPC Plan applicants be required to submit BPC Plans for certification within 35 days of Planning Board approval. However, we note that the Planning Board has discretion to impose conditions of approval on BPC Plans that must be completed prior to certification. In some instances, these conditions cannot be addressed in the timeframe of one month (for example, where easements or agreements with County agencies or utilities are to be negotiated and recorded). As a result, this requirement simply would be unworkable. Notably, the Zoning Ordinance does not include a comparable timing requirement for the certification of SBH plans.

To the extent that Staff are concerned that plans for an approved BPC will not be submitted for certification in a timely manner, we note that the ZTA already requires BPC plans to be certified by the Planning Director within 24 months of the mailing date of any Planning Board approval resolution. We believe that this durational limitation is sufficient to ensure the timely certification of BPC Plans and, because it may not otherwise be possible for a BPC applicant to address required conditions of approval within a 35 day timeframe as described above, we oppose revising the ZTA in this manner.

VI. Decision – Duration of Approval (ZTA Staff Report, Page 13)

Finally, Planning Department Staff propose revisions to clarify that a BPC plan approval will be revoked in the event that an applicant fails to comply with certain prescribed deadlines for building permit application and building permit issuance. If these proposed clarifications are included in the ZTA, we respectfully suggest that provisions should also be added to clarify that the Planning Board may extend the two-year building permit filing and issuance requirement for the approved BPC plan. We note that such extensions may be particularly important for biotechnology development, given that the industry is non-linear in nature and many potential factors could affect a project's ability to advance to building permit. The ability to obtain permits may also be impacted by other circumstances beyond the applicant's control, such as situations where other governmental approvals are required but cannot be completed in the prescribed timeframes.

We thank you for your consideration of these issues and look forward to discussing the Amendments with you in more detail at the time of hearing. In the meantime, please do not hesitate to let us know if you have any questions.