

OFFICES OF THE COUNTY EXECUTIVE

Douglas M. Duncan County Executive

Bruce Romer Chief Administrative Officer

August 28, 2003

Derick P. Berlage, Esquire Chairman Montgomery County Planning Board Maryland-National Capital Park and Planning Commission 8787 Georgia Avenue Silver Spring, Maryland 20910

Re: Request for Waiver from Requirements of Subdivision Regulations

Dear Chairman Berlage:

The purpose of this letter is to request a waiver, pursuant to Section 50-38 of the Subdivision Regulations, to facilitate the timely implementation of an important economic development project for Montgomery County, specifically, the Silver Spring Ovarian Cancer Laboratory Project by United Therapeutics Corporation. United Therapeutics is a publicly traded biotechnology company headquartered in Silver Spring that is desirous of expanding operations in the CBD rather than elsewhere, but is subject to time constraints imposed by the U.S. Food and Drug Administration ("FDA"). Without the proposed waiver, the County risks losing the Project to another state.

The Site

The Applicant, Montgomery County (the "County"), owns certain property located at the southeast corner of Cameron and Spring Streets in Silver Spring, Maryland. A portion of this property is improved with Montgomery County Parking Garage No. 21 and the balance of the property is currently used for surface parking as Lot No. 21. The portion of the property comprising Lot No. 21, containing approximately 0.92± acres, is the subject of this waiver request (the "County Property"). (See drawing attached as Exhibit "A.")



The Project

The County is pleased to advise that it is proposing to enter into a long-term lease to Unither Pharmaceuticals, Inc. ("UPI") for the County Property. The Lease will include an option for UPI to purchase the County Property. The purpose of the Lease is to provide a site for the Silver Spring Ovarian Cancer Laboratory Project (the "Project"). UPI is a wholly-owned subsidiary of United Therapeutics Corporation. ("UTC" or "Company"). UTC is a publicly traded biotechnology company with its headquarters at 1110 Spring Street in Silver Spring; UPI is the subsidiary that will own and operate the Laboratory. The proposal for the Lease is obviously subject to formal County approval for disposition of the County Property and the Planning Board's approval of the subject waivers.

UTC needs to have the Laboratory operational as part of the validation process by FDA for the new drug, OvaRex[®], to be used for treatment of ovarian cancer (see below). UTC wishes to develop the Project in Silver Spring. The County strongly believes that retaining the Project in the County is critical to the implementation of the County's long-term economic development plans for Silver Spring and for the biotech industry.

The Economic Development Element

The proposed Project serves two important County purposes. First, the Project continues support and focus on the biotechnology industry as a part of the County's overall strategic economic development program. Retaining and nurturing biotechnology enterprises is an established County objective. Second, while the biotechnology industry in the County has often focused on the I-270 Corridor and the Shady Grove Life Sciences Center, UTC presents a unique opportunity of a new venue for such companies in Silver Spring.

UTC is already located in Silver Spring, wishes to remain in Silver Spring, and wishes to expand in Silver Spring. Although it has offices elsewhere in the United States and Europe, UTC wants the Project to be in Silver Spring. However, because of an unexpected problem in securing the vacancy of the existing buildings on the site originally planned for the Project, UTC could be compelled to locate the Laboratory Project in Massachusetts (where it has been pursuing a backup site alternative).

The County has been advised by UTC that the Laboratory Project is an important part, but only a part, of the Company's long term expansion plans for Silver Spring. These plans include future expansion of the headquarters building on Spring Street (under the optional method of development). Thus, this Project supports both the County's focus on economic development, particularly biotechnology, and on retention and expansion of businesses in the Silver Spring CBD. These efforts are consistent with the 1993 General Plan revision and the County's pending Strategic Plan for Economic Development.

The Waiver Request

This letter requests that the Planning Board grant a waiver of two elements of the Subdivision Regulations, pursuant to its authority under Section 50-38(a)(1) of the Montgomery County Code. These waivers are needed in order to expedite the construction approvals necessary for the construction of the Silver Spring Ovarian Cancer Laboratory Project.

Montgomery County respectfully requests that the Planning Board grant: (1) a waiver exempting the Project from the requirements of filing and obtaining approval of a preliminary plan of subdivision before recording a plat for the County Property, and (2) a waiver from the requirement that a building permit not be approved unless a proposed structure will be located on a recorded lot (with the condition that a plat for the County Property must be recorded prior to occupancy of the Project). Specifically, the County seeks a waiver from the following provisions of the Subdivision Regulations:

- 1. Section 50-20, which provides that a building permit must not be approved for construction of a structure unless the structure will be located "on a lot or parcel of land which is shown on a plat;"
- 2. Section 50-23 and Section 50-34, which provide general procedures that must be followed in the submission and approval of subdivision plans as a prerequisite for recording a plat;
- 3. Section 50-35(1), which provides that a preliminary plan must "substantially conform to the applicable master plan, sector plan...including maps and text unless the Planning Board finds that events have occurred to render the relevant...plan recommendations no longer appropriate;" and
- 4. Section 50-37(b), which requires that a record plat comply with an approved preliminary plan.

As more fully set forth below, this waiver request is necessitated by the unusual circumstances of the County Property and the practical difficulties associated with the need to develop the Project on an expedited basis and thereby support Montgomery County's economic development goals for Silver Spring.

Background of the County Property

The County Property is part of an aggregation of recorded lots and deeded parcels owned by the County in this block. Lot No. 21 occupies part of a deeded parcel acquired by the County in 1954 by deed recorded in Liber 1963, folio 475. Garage No. 21 is located on the remainder of the County's property in the block and is constructed on lots, parts of lots, unrecorded parcels and parts of unrecorded parcels. (See Exhibits "B-1" and "B-2," attached.)

County Parking Garage No. 21 was constructed across the lot lines established by a 1938 plat that created several lots along Colesville Road. The other part of the Garage sits on unrecorded parcels. None of the deeded parcels appear to have been platted and the lots recorded in 1938 were never assembled and replatted. The County Property, used for surface parking as Lot No. 21, is on part of an unrecorded parcel, the residue from the Garage construction. As a result, the land that will be the subject of the Lease with UPI has never received preliminary plan or record plat approval.

The Company, the Proposed Project and Timing

A. <u>The Company.</u>

UTC was founded in 1996 as a biotechnology company focused on life-saving therapeutics. The Company is active in the three therapeutic areas of cardiovascular medicine, infectious disease and oncology, with four therapeutic platforms--prostacyclin analogs, anti-viral iminosugars, arginine formulations and telemedicine.

Most of the Company's resources are presently focused on the treatment of pulmonary hypertension, peripheral vascular disease and metastatic cancer. The Company's second principal focus is the development of specific compounds for the treatment of hepatitis B and C. The Company also devotes resources to the further development of life-saving applications of arginine, especially in coronary artery disease research, and of telecardiology, principally for cardiac arrhythmia. The theme of United Therapeutics is "medicines for life" because all of the therapeutics are geared to life-threatening conditions. The Company established its world headquarters at 1110 Spring Street in Silver Spring in 1998.

UTC is attached and devoted to its roots in Silver Spring. From a small, inconspicuous building, almost visible from the Planning Board's offices, the reach of the Company stretches across national boundaries. UTC's goal is to expand its current operation in Silver Spring to include this new laboratory facility for its ovarian cancer program, even though the laboratory could be created more easily and at considerably less cost in another state.

B. The Project.

The Silver Spring Ovarian Cancer Laboratory Project is a state-of-the-art biotech laboratory facility for the therapy called OvaRex[®], which is used to treat ovarian cancer. Ovarian cancer is the fifth most frequent cause of cancer death in women and the leading cause of gynecologic cancer in the United States. The American Cancer Society projects 25,400 new cases of ovarian cancer in the United States in 2003 that will result in 14,300 deaths. In terms of treatment, although most patients initially respond to chemotherapy, the subsequent relapse rate is approximately 85%. Within two years of surgery, tumors usually recur and once the patient relapses, there is no cure. Today, the long-term survival of patients with such advanced, recurrent disease is typically less that 10%.

The Silver Spring Ovarian Cancer Laboratory Project will consist of a series of sophisticated antibody labs that will include processing steps for: cell culture, purification, and bulk filling. Support areas will include: testing laboratories, media and buffer preparation, raw material receiving, warehousing, isolation and release rooms. At the completion of this phase of the antibody processing, bulk substance will be shipped to a contract manufacturer to produce and label final product for commercial sale. The Laboratory will also include associated laboratories, administrative and office functions and storage.

C. Project Timing.

Unfortunately, no therapy other than OvaRex® exists to treat advanced ovarian cancer patients in the period following completion of chemotherapy and prior to disease relapse. As a result of this unmet medical need, the OvaRex® development program received Fast Track Designation from the FDA and two Phase III pivotal clinical trials are currently enrolling patients. (These are the largest trials ever in ovarian cancer following chemotherapy.) Before OvaRex® can be approved, there must be in place an FDA inspected and validated facility related to development of the drug. In order to comply with these extremely rigorous regulations, construction, installation of equipment and processing associated with OvaRex® at a commercial scale must be repeatedly demonstrated before the FDA will even review the clinical trial results. The Silver Spring Ovarian Cancer Laboratory Project is therefore a critical path item which must be completed in order for OvaRex® to receive FDA approval, providing this life-saving therapy from Silver Spring to patients worldwide.

Standards for Waiver Under Section 50-38

Under the standards of Section 50-38 of the Subdivision Regulations, the Planning Board may grant waivers that meet the following criteria.

"(a) Authority of Board
"The Board may grant a waiver from the requirements of this
Chapter upon a determination that practical difficulties or unusual
circumstances exist that prevent full compliance with the
requirements from being achieved, and that the waiver is: 1) the
minimum necessary to provide relief from the requirements; 2) not
inconsistent with the purposes and objectives of the General Plan;
and 3) not adverse to the public interest."

In order for the Silver Spring Ovarian Cancer Laboratory Project to be built in accordance with the usual requirements of the Subdivision Regulations, the County Property that is the subject of the Lease normally must be platted prior to the issuance of a building permit. However, given the fast track time schedule of the Project, the time necessary for the procedural requirements of preliminary plan approval and time for recording a plat prior to the issuance of a building permit will jeopardize County retention of the Project. Accordingly, Montgomery County requests that the Planning Board waive the requirements of the Subdivision Regulations that require preliminary plan approval in advance of plat approval, as well as those that require that a record plat be approved and recorded prior to the issuance of a building permit. For the reasons set forth below, the County believes that this waiver is the minimum necessary to overcome the unusual circumstances of the Property and the practical difficulties involved in the Company's efforts to develop the Project on an expedited basis.

Granting the waivers will allow construction of the Project to be commenced while the record plat is being processed. The County would agree to a condition that a certificate of use and occupancy not be issued until the plat has been recorded. Such a condition would accommodate the expedited schedule for construction commencement and ensure that the Project remains in Montgomery County. This proposal will also guarantee that the building is not occupied until physical site requirements, such as necessary dedications, have been satisfied and the ultimate configuration of the Property is validated with a recorded plat.

A. Practical Difficulties or Unusual Circumstances.

For over nine months, UTC has been diligently seeking to develop the Project on an existing property created along Spring Street, adjacent to its headquarters. The Laboratory would have been built on the site of two existing buildings at 1104 and 1106 Spring Street that were purchased for this purpose. (In fact, while negotiating with the tenants, and in expectation of vacating those buildings, UTC had already designed the building and processed the building permit application for construction of the laboratory on the 1104/1106 site.) However, one remaining tenant (under a lease predating UTC's ownership) is unwilling to vacate one of the existing buildings, thereby preventing demolition and construction of the Project. UTC cannot wait for the lease term to expire, because it must have the Laboratory operating to meet the time parameters established by FDA. Rather than have UTC acquire and refit an existing building in Massachusetts, Lot No. 21 is being made available. However, Lot. No. 21 is not a record lot and therefore, the ability to build in the required time frame would be impossible. The County has made Lot No. 21 available because of the practical difficulty that has occurred in trying to vacate the original planned building site. The unplatted character of Lot No. 21 is a very unusual circumstance, considering that it is the residue of a parcel on which a structure (the County Garage) is already located.

This confluence of facts presents a practical difficulty and a unique circumstance of hardship to both UTC and Montgomery County. The Company, from the outset, sought to develop the Project in Silver Spring, consistent with the County's goals for revitalization, as well as retention of existing businesses in Silver Spring. Nevertheless, the inability to use UTC's private site (due to the tenant occupancy issue) and the unsubdivided (unbuildable) character of the County Property, present an unusual practical difficulty and a substantial, unusual circumstance.

B. Minimum Necessary to Provide Relief from the Requirements.

The proposed waivers are the minimum necessary to provide relief. The waiver is simply needed to expedite the ability to authorize and commence the Project so that it can occur in Montgomery County.

The Project will be a standard method of development. The Lot No. 21 property will be platted eventually. The plat will be prepared and recorded before occupancy of the Project. The plat will provide for dedication of the required share of additional right-of-way for each of Cameron and Spring Streets, in accordance with the CBD Sector Plan.

The traffic effect of the Project has been evaluated by Planning Board Staff and determined to be below 50 trips, thus removing consideration of Local Area Review. Staff has also required that construction provide the standard Silver Spring Streetscape in the right-of-way along the frontages of Cameron and Spring Streets.

There is, therefore, no adverse effect by allowing these waivers.

C. Not Inconsistent with the Purposes and Objectives of the General Plan.

The waivers requested will allow the Silver Spring Ovarian Cancer Laboratory Project to be developed in Silver Spring and will thereby advance the purposes and objectives of the General Plan as to economic development, business retention and business expansion/revitalization in Silver Spring.

The 1993 General Plan Refinement ("1993 General Plan" or the "Plan") recognizes "economic activity" as a separate and independent goal of the General Plan for the first time. The Plan identifies Montgomery County as a "world class center" for business and technology (Plan, p.60), and emphasizes that existing businesses should be "retained and enhanced" (Plan, p. 60). UTC is an existing County business seeking to enlarge its roots in the County and in Silver Spring. The 1993 General Plan identifies corporate headquarters and biotechnology research as businesses "the County should particularly encourage" (Plan, p. 60). UTC is the County's only known biotechnology company in Silver Spring, thus being a targeted business type that is also in a targeted business area.

In the strategies for implementation of the economic goals, the 1993 General Plan states that Montgomery County should be "promoted as a world class center" for "research, development and technology" (Plan, p. 63) and that land use decisions should "support the County's economic development objectives of retaining and attracting headquarters . . . [and] biotechnology research . . . (Plan, p. 63). The 1993 General Plan encourages "flexibility in land use . . . to accommodate . . . developing technologies." (Plan, p. 63). The Plan also proposes that the development review process be continually assessed "to determine ways to streamline the process and to encourage economic growth within the Urban Ring" (which includes Silver Spring). (Plan, p. 68.)

Granting the requested waivers for the Laboratory Project will advance the economic goals of the 1993 General Plan, as well as encourage that activity in Silver Spring, thereby fostering the ongoing rebirth in this area. UTC has a national reputation as being on the "cutting edge" of biotechnology. UTC's drug, Remodulin, is one of only two drugs being successfully commercially produced by "home-grown" Montgomery County companies (the other is Synagis by Medimmune, another monoclonal antibody). UTC identifies Silver Spring as the home for its world headquarters.

The proposed waiver will allow the expansion of this existing biotechnology company, thus advancing the 1993 General Plan's objective to "encourage new and existing businesses that complement the County's strengths..." (Plan, p. 63) as well as the strategy of "retaining and attracting" headquarters and biotechnology research (Plan, p. 63). Biotechnology has been a major focus of the County's economic development efforts, successfully exemplified by the companies in the I-270 Corridor, Shady Grove Life Sciences Center and elsewhere, making the most of the County's unique resource, the NIH. For these reasons, Montgomery County believes that granting the waiver will be consistent with the 1993 General Plan and will not be adverse to public interest.

D. Not adverse to the Public Interest.

While fulfilling the public interest through implementation of the 1993 General Plan, this Application also presents the need to balance different County policies in achieving that public interest.

The Approved and Adopted 2000 Silver Spring CBD Sector Plan (the "CBD Plan"), which is a guide to the development of the CBD, has as one of its recommendations that the County "create housing incentives in the CBD by converting publicly owned surface parking lots to housing." (CBD Plan, p. 112.) Among the parcels referenced in that recommendation is "Parking Lot No. 21 at the corner of Cameron and Spring Streets." No time frame is suggested for implementing the recommendation. In addition, the County Property is identified in the Sector Plan as a potential site for an urban library (CBD Plan, p. 120), although discussion with Planning Board Staff indicates this is not a "finalist" site. At the same time, the Plan itself recognizes that

"Achieving the Silver Spring Sector Plan recommendations will require the coordinated efforts of a variety of participants . . .

"Landowners, developers and investors are key players in revitalization . . .

"Local business owners must be alert to changes in national, regional and local markets, and must be active in promoting their services and products to existing and new customers...

"Some forces in revitalization are beyond local control--national and local economies, market competition, politics, and demographic changes . . .

"Revitalization strategies in Silver Spring must reflect the reality that these factors and must be flexible enough to accommodate changes in the marketplace." (CBD Plan, p. 147.)

As market forces change, an important step will be to reevaluate periodically the plans, proposed development, land uses, zoning and plan approval processes. Additionally, in looking at the commercial portion of the Silver Spring downtown, the Sector Plan recognizes that office uses "should build on the CBD's existing basic business activity. From large headquarters to independent proprietors, Silver Spring should offer opportunities for new construction and renovation of existing space, supported by business services and regional transportation links." (CBD Plan, p. 18.) The proposed UTC Project represents just such an opportunity.

The proposed Project will also satisfy recommendations contained in the CBD Plan. The CBD Plan recognizes that a "commercial downtown" should build on the CBD's existing base of business activity. UTC is an existing company seeking to expand within the CBD. While the CBD Plan proposes that County agencies explore the possibility of using surface parking lots within the CBD for housing, implicit in that recommendation is the fact that the County may find a more appropriate use for those surface parking lots. This is such an instance. In fact, the County, through its Department of Economic Development, has determined that the use proposed by UTC is vital to the implementation of the County's economic development plans for Silver Spring, a consideration in the CBD Plan, but also an important independent element of the 1993 General Plan and the policies for revitalization of Silver Spring. The race for successful revitalization cannot be reliably carried on the back of only one horse.

The County Executive has approved the Strategic Plan for Economic Development for Montgomery County. That Plan notes that "the County's long-term economic and fiscal advantage lies in promoting employment growth" (p. 20).

In discussing the goal of a business climate that supports economic development, the Plan notes: "attracting and retaining existing companies requires a business and regulatory environment that is predictable, responsive and acts in a timely fashion to changing corporate needs." (p. 26). Implementation mechanisms for this goal include: "incorporat[ing] the goals of the County's Strategic Plan for Economic Development into County economic, land use, education and infrastructure policies," and to "continue efforts to expedite permit review time and simplify the ability of a land or building owner to receive necessary approvals . . ." (p. 27).

In considering the goal of promoting leadership in biosciences and healthcare, the Plan seeks to make the State of Maryland and the Mid-Atlantic Region the number one location for life sciences activity. This is to be achieved by advancing "public policies that will lead to the establishment of more laboratories and manufacturing space of technology companies" and to "foster the climate for technology entrepreneurship, growth and expansion (p. 30). Part of this is achieved by providing "nurturing support to the means of established County businesses by facilitating access to capital and business opportunities" (p. 35). The Project itself and the proposed waivers are consistent with these directions.

The CBD Plan recommendation must be balanced against other, sometimes conflicting, County policies. Those other County policies, as well as elements of the CBD Plan itself, support the appropriateness of using the resource of Lot No. 21 for the purpose of the Project and for the enhancement of the public interest of the County as a whole. The comprehensive and holistic view of the CBD Plan, when joined with the circumstances of the Company and the CBD, as measured by the changed events of today, demonstrates that if the proposal does not satisfy the requirements of Section 50-35(l), then the proposal will be appropriate for waiver.

Summary

The proposed use will allow an existing biotechnology company to expand its capabilities, will bring jobs to the CBD, and may be the catalyst for additional biotechnology successes in Silver Spring. Certainly, the Project will be another reason for UTC to pursue its planned optional method headquarters expansion in Silver Spring. The County believes that the Project is a tremendous opportunity for the economic development and growth of Silver Spring and the County. This opportunity and benefit fosters the public interest and outweighs what could result from the possible use of Lot No. 21 for residential purposes at some uncertain time in the future.

For the forgoing reasons, the County requests the waivers be granted.

Thank you for your consideration of this request.

Sincerely,

Bruce Romer

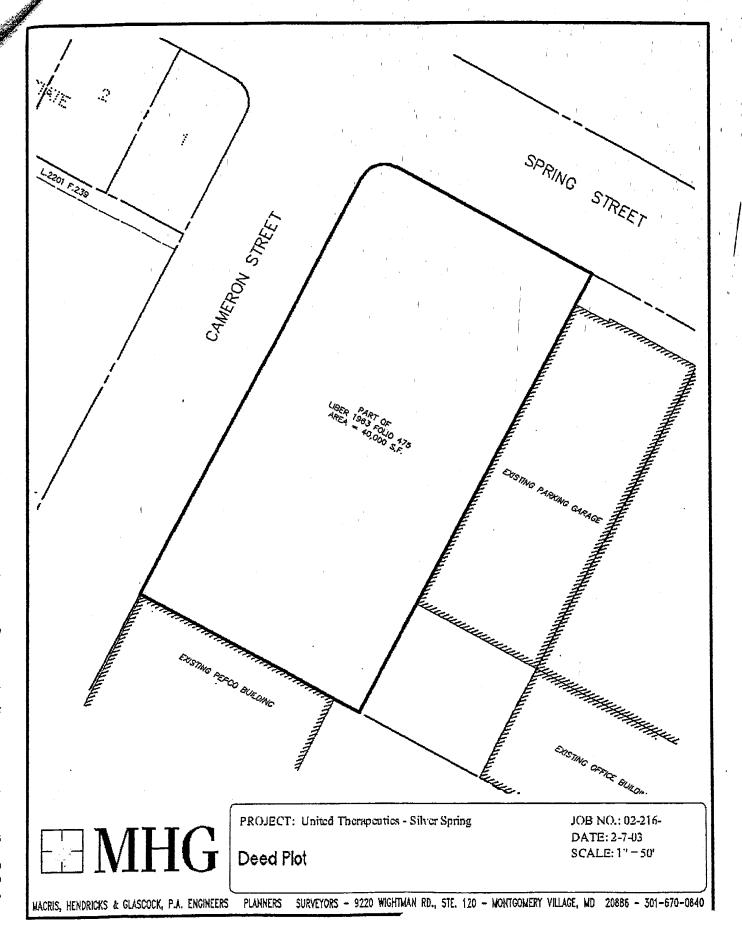
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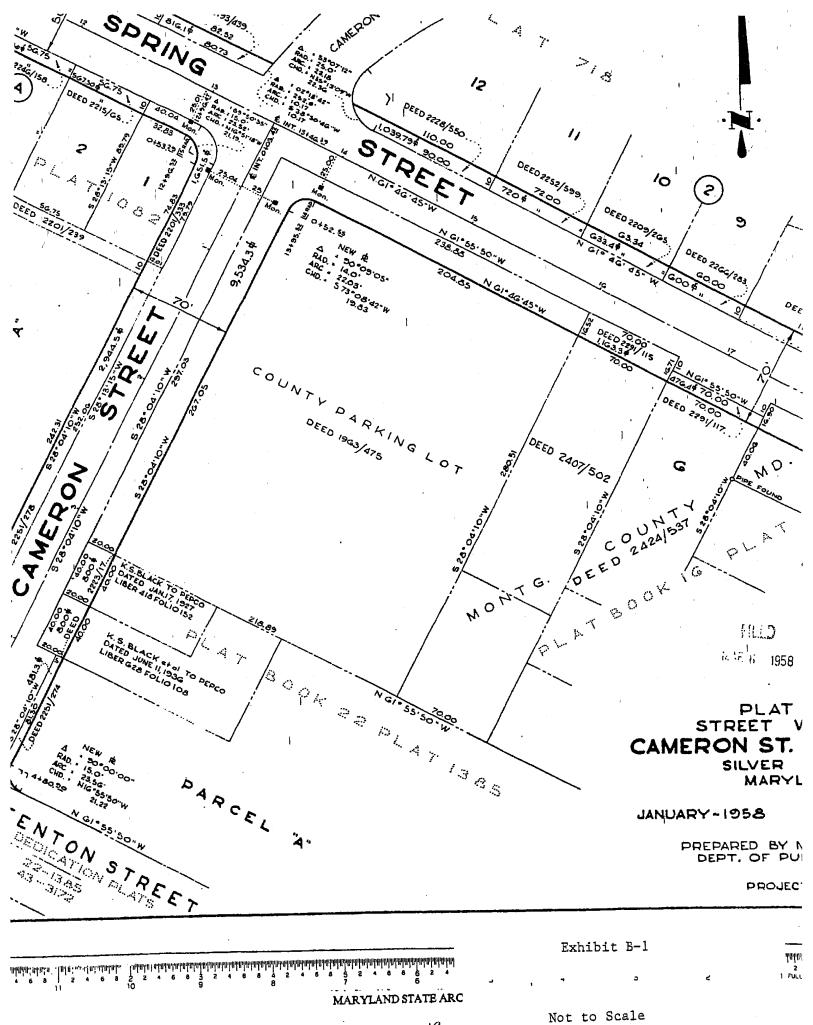
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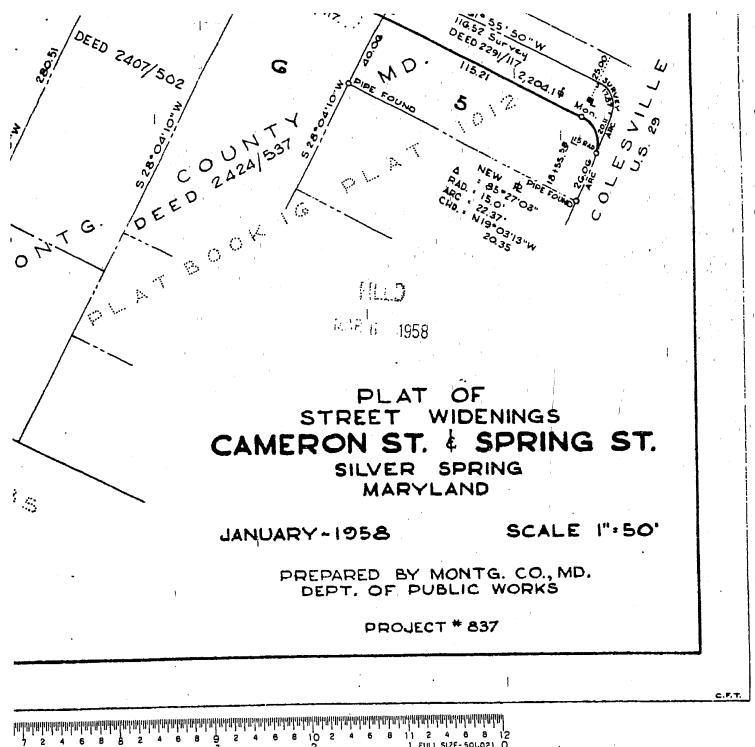
cc: David W. Edgerley
Marc Hansen

Al Genetti

William Kominers







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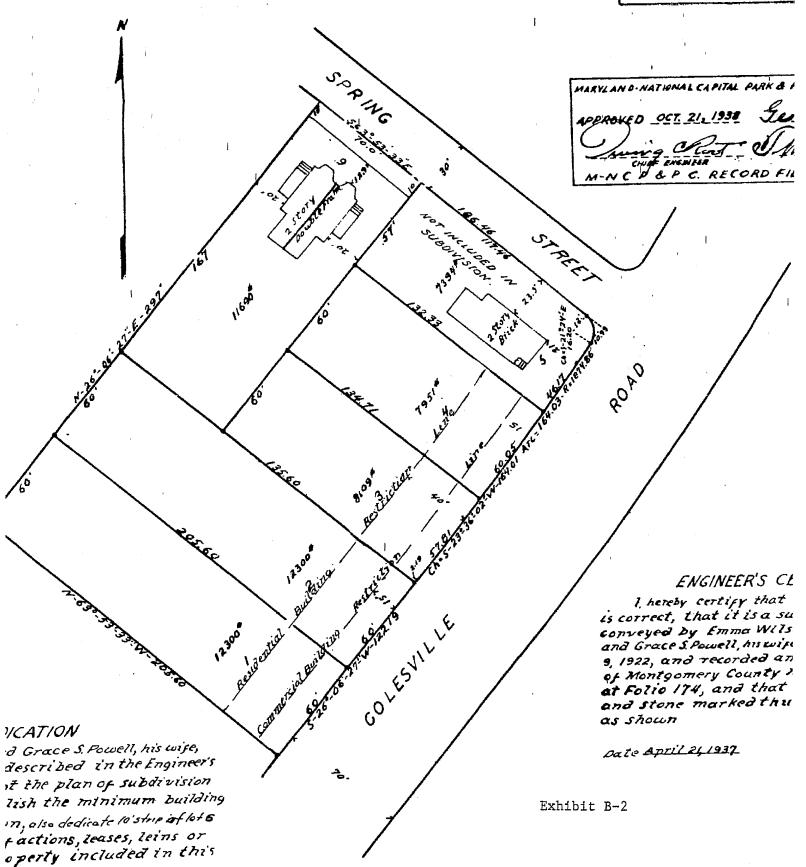
PLAT No. 1012

MASHINGTON SUBURBAN SANITA.

APPROVED OCT. 24,19

AS TO SUITABILITY FOR WATER.

SHIERE



51.84.35.36.08.W.184.01

FILED NOV 7-1938

ENGINEER'S CERTIFICATE

I, hereby certify that the plat shown hereon is correct, that it is a subdivision of the land conveyed by Emma Wilson to Edwin C. Powell and Grace S. Powell, his wife, by beed dated October 9, 1922, and recorded among the land records of Montgomery County Marytand in Liber 322 at Folio 174, and that pipe marked thus e, and stone marked thus have been placed as shown

Date April 21, 1937

H.C. Frolsom

PLAT

OF

SUBDIVISION

OF

E.C.POWELL'S PROPERTY,

SILVER SPRING

MONTGOMERY COUNTY MARYL AND
Scale 1:40 Ft.

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September 11, 2003

MEMORANDUM

TO:

Joe Davis, Chief

Development Review Division

FROM:

Glenn Kreger, Silver Spring/Takoma Park Team Leader

Community-Based Planning Division

SUBJECT:

Waiver of Preliminary Plan Requirements for Parking Lot 21

I understand that the County proposes to transfer Parking Lot 21 at Spring Street/Cameron Street to United Therapeutics to assist them in relocating their current facility within the Silver Spring Central Business District (CBD). Furthermore, a waiver of the normal preliminary plan requirements has been requested to expedite this project. The master plan guidance contained in this memorandum is intended to assist the Planning Board in evaluating the waiver request. Please note that the disposition of the public parking lot is also subject to Mandatory Referral. As of this date, we have not received an application for Mandatory Referral review.

Community-Based Planning finds that the proposed use of Lot 21 by United Therapeutics is generally consistent with the relevant recommendations in the *February 2000 Approved and Adopted Silver Spring CBD Sector Plan*. The relevant Sector Plan guidance is the following:

A. Sector Plan Themes

- 1. Transit Oriented Downtown: The proposed project encourages employment within walking distance of the Transit Center.
- Commercial Downtown: The proposed project would enable the CBD to retain an important commercial enterprise.
- 3. Residential Downtown: The Silver Spring CBD Sector Plan encourages the conversion of publicly owned parking lots to housing. Parking Lot 21 was specifically identified in the Sector Plan as a potential site for new housing (pp. 112-113). While we continue to support this goal, we also acknowledge that Lot 21 was only one of several sites identified in the Sector Plan as potential housing sites. Other public properties, including the parking lot behind MRO continue to be available as potential housing locations.

- 4. Civic Downtown: Parking Lot 21 was considered as a potential site for relocation of the Silver Spring library; however, it was not selected as a preferred site. Other locations have been identified for the major civic components of the Silver Spring revitalization (e.g., the new fire station, civic building and court house).
- 5. Green Downtown: We presume that any redevelopment on Lot 21 will satisfy the Public Use Space requirements in either the Standard or Optional Method of Development, whichever is utilized. (Note: We strongly encourage that any Standard Method proposal be designed in a way that does not preclude future expansion under the Optional Method of Development.)
- 6. Pedestrian Friendly Downtown: I understand that the applicant will streetscape the frontage of the property along both Spring Street and Cameron Street in accordance with the Streetscape Guidelines.

B. Transportation Facilities

1. Parking

The Silver Spring CBD Sector Plan encourages the County to undertake a comprehensive assessment of parking needs in the CBD with an eye toward ensuring that parking be located to serve businesses and residences conveniently and to encourage transit use. (p. 108) It also states that "the conversion of publicly-owned parking lots should be preceded by analysis of parking needs and supply." (p. 112) We understand that the County has reviewed Lot 21 and determined it to be surplus to the current parking needs in the immediate area. However, the County has yet to undertake a comprehensive study that looks at current and future needs given the ongoing redevelopment in the CBD. We recommend that the Planning Board take this opportunity to encourage the County to undertake the comprehensive parking needs analysis as soon as possible.

2. Roads

The master planned rights-of-way on both Spring Street and Cameron Street must be provided as noted in the September 9 memorandum from Transportation Planning.

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cc: John Carter