Personal Note: Defects in a previous memo submitted to the Land Use Committee led me to dig deeper into the biosafety issue. I found that Somerville lacks a regulatory framework adequate to the coming wave of biotech lab leasing. Hence this memo as an alert. I am not a credentialed expert but I have drawn upon a few knowledgeable people in my circle of family, friends and neighbors,

October 2, 2021

TO: SOMERVILLE MAYOR AND CITY COUNCIL
FROM: LEE AUSPITZ, [redacted]

RE: SOMERVILLE BIOSAFETY FRAMEWORK

Summary:

High rental rates for biotechnology laboratory space (@ $80-$100 per square-foot) are fueling a splllover of biotech real estate investment from Cambridge and Boston into Somerville. To prepare for leasing, the City's regulatory framework for biotech tenants needs to be updated, activated, broadened and refined to cover the full variety of biotech laboratory activity. The experience of Cambridge suggests that a rigorous regulatory regime can serve to promote biotech growth while protecting public health. As developers have already announced plans for over three million square feet of lab/office space in Somerville, the City should act promptly. With intrinsic advantages of location, transportation links, workforce skills and tech-savvy economic development, Somerville does not need an overly vague or permissive regulatory regime to attract suitable tenants. Both Somerville's zoning provisions for lab buildings and its 1994 biotechnology ordinance will benefit from an upgrade.

Background

Since the early 1980s both the World Health Organization (WHO) and the US Center for Disease Control and Prevention (CDC) have worked continuously on detailed manuals setting out safety guidelines for biotechnology laboratories. The CDC and WHO manuals now in their 6th and 5th editions respectively, employ a four-tiered approach to BioSafety Levels (BSLs 1-4). The aim is to reduce the well-documented potential for the spread of lab-associated infections (LAIs). At highest risk is Bio Safety Level 4, which deals with potentially lethal materials in self-sequestered facilities. There are only about a dozen such labs in the US, one of which is under the aegis of Boston University. Level 4 labs are currently banned in Cambridge and Somerville. Labs in the BSL 3 to 4 range also pose toxic risks. They are therefore closely monitored in Cambridge, a "world capital" of biotech, with annually renewable public health permits, fines for violations levied daily, and provision for closure on short notice for compliance failures.

Somerville is no stranger to such issues. In January 1981 the City received a pioneering application for a commercial recombinant DNA lab in an industrial building on the Somerville side of Beacon Street. The Mayor and Board of Alderman were initially receptive to the lab, but after a stormy public meeting the City deferred action, pending a report from a broadly based committee of residents and experts. Though the applIcant withdrew, the committee completed its report, which led to the City's adoption later in 1981 of an ordinance focused on recombinant DNA. The City's determination to regulate what then seemed to be a potentially hazardous activity was strengthened by an unrelated event. In April 1981 Somerville fell victim to the worst chemical spill in the history of Massachusetts: the leakage of hazardous fumes from a supposedly sealed tank car in a city-based freight yard. The spill,

which required the temporary evacuation of thousands of Somerville residents, served as a reminder that mishaps happen.

In 1994 the City updated its biotech ordinance with a few general phrases to include biotechnology research beyond recombinant DNA. The enforcement provisions, though rigorous, remained limited to recombinant DNA. There has been no change in the ordinance since 1994, no record of its enforcement body after 2001, and indeed, no minutes to suggest that it has ever met.

Meanwhile, at the federal and international levels forty years of continuous upgrading of CDC/WHO lab safety guidelines have greatly allayed public concerns about lab-associated infections. At BSL levels 1 and 2, experts now consider the risks to be negligible when CDC /WHO guidelines are followed. At BSL 3 and 4, more regulations are considered appropriate, including regular inspections by municipal boards of health and outright banning of highest risk labs in densely populated areas. Whether or not the origins of Covid 19 are ultimately traced to negligent lab practices, the pandemic experience will keep biosafety and biotech issues in the public eye for many years.

Areas of deficiency

1. **Somerville's 1994 Biotechnology Ordinance** (Chapter 6, Article IV, link attached) is seriously out of date: though intended to broaden the focus of the 1981 ordinance, its enforcement provisions retain the City's original preoccupation with recombinant DNA research. The ordinance cites NIH guidelines on rDNA but fails to cite what has become the more inclusive standard: CDC's lab safety manual: the so-called "BMBL" ---*Biosafety in Microbiological and Biomedical Laboratories*, now in its sixth edition (link attached below). The BMBL addresses the full range of lab activity and lays out minimum practices for the four biosafety risk levels. Though not a regulatory document as such, the BMBL manual is given the force of law in Cambridge and Boston, where it is incorporated by reference into the governing Biosafety Regulations (links attached). The Somerville ordinance of 1994 is lacking in comparable coverage and specificity.

2. **The Somerville Biotech Safety Committee**, which is charged by City Ordinance with public health enforcement of labs, appears to have been defunct for at least twenty years. A public records search revealed no minutes and no activity after 2001, presumably because no rDNA lab applications have been submitted. Even if the Committee were active, its rigorously detailed enforcement authority under the 1994 ordinance extends only to recombinant DNA research. Somerville, like Cambridge, prohibits the very highest risk labs (BSL 4) but, unlike Cambridge, Somerville is silent on high risk labs in the BSL 3 to 4 range.

3. Somerville also lacks special provision, for **humane treatment of laboratory animals**. One does not have to be an animal rights advocate to appreciate that careful handling of animals is essential to prevent lab-associated infections in humans. Cambridge has an elaborate ordinance which, in effect, extends the obligations attached to federal grants-in-aid to private biotech labs. [Link to Cambridge ordinance attached below]

4. **The table of Permitted Uses in Somerville's Zoning Code** (Section 9.1.1) has no breakout category to distinguish biotech labs from the general run of "R & D or Laboratory" uses. As a result, anything below Level 4 calling itself a "lab" can be erected by right—i.e. without special permits-- across the whole span of commercial, mid-rise and high-rise real estate. This undifferentiated approach generates anomalies within the Zoning Code. For example, the absence of any category or sub-category for biotech

contrasts sharply with the Code's five (5) sub-categories under Cannabis Establishments; the required special permitting (SP)for Health Services (doctors, dentists, physical therapists, etc), as well as for three sub-categories of Animal-related Services (veterinary, kennels and pet stores) has the effect of giving the housing of lab animals ("vivariums") a free regulatory ride as compared with establishments serving human beings and their pets. More importantly, the failure to break out biotech from computer, green and other clean labs deprives the City of the ability to recognize standardized risk levels within the biotech lab category or to customize lab safety requirements to neighborhood character.

5. Understandably, in the absence of problematic cases **Somerville's neighborhood planning and participation process** has not yet addressed concerns over inappropriate lab tenants. Now that a biotech wave is imminent, however, neighborhood planning should reflect the differences between high-rise lab buildings sited on large Master Plan, privately assembled and City-purchased tracts, on the one hand, and insertion of smaller lab spaces into urban infill locations, on the other. More on this in the next section.

These deficiencies are all easy to correct. With the first high-rise lab building nearing completion in Boynton Yards, prompt attention is advisable before leasing begins. **In a high turnover election year, it would be a service to the incoming Mayor and City Council, if current city leaders would begin the process before January 2022.** Biotech is an area where a clear regulatory regime is a precondition to smooth economic development.

The Somerville Infill Difference

Somerville is well-positioned to profit from the biotech building boom. It houses a young, educated workforce, has good public transit links, is located near major universities and research facilities, and it likes to think of itself as receptive to innovative ideas. Somerville does not have to compromise on safety to attract lab tenants. As the most densely populated city in New England, it will inevitably host some lab facilities in close proximity to pre-existing residences. This is Somerville's point of difference from lab real estate development in Kendall Square and suburban locations.

Two models are emerging in Somerville: a pre-planned high-rise model, and a more problematic urban infill model. The preponderance of Somerville lab space will be housed in high-rise buildings on larger tracts assembled by public or private purchasers on previously under-utilized land. In the high-rise model separate residential apartment buildings are pre-planned or pre-zoned as part of a mixed-use pattern. Typically, there are no pre-existing residential abutters for lab developers to worry about.

In the urban infill model, by contrast, smaller scale, mid-rise lab/office buildings may be inserted into settings directly abutting pre-existing residences, or within very close proximity to them. The infill model poses abutter issues that have been muted (though not wholly absent) in Cambridge, where commercial biotech spread from industrial tracts. Somerville's infill opportunities require a more differentiated approach to land use regulation.

It is worth noting that the incidence of failure in early stage biotech is high and that failing businesses tend to cut corners on their way down. Smaller Infill opportunities are more likely to attract transient, non-incubator tenants. Many will either fail or outgrow their original space. All this makes a differentiated regulatory framework for biotech especially useful in infill cases.

Measures to Consider

From the foregoing analysis, the following measures seem appropriate:

1. Public Health

A. Update the Somerville Biotech Ordinance of 1994, using the Cambridge template as a time-tested , lab-friendly starting point. The main improvements to be found in the Cambridge ordinances are

-- a scientifically grounded definition of biotech that includes the whole range of lab activity, not just recombinant DNA

--incorporation by reference of comprehensive federal safety guidelines as found in the most recent BMBL edition and elsewhere

-- requirement for annual re-permitting of BSL-3 labs whether self-standing or in lab incubators, with license fees to cover the administrative costs

-- explicit standards for lab animals

-- using a risk-level approach to replace an outdated subject-matter focus on rDNA

B. Administrative considerations

--share administrative burdens by requiring landlords to write into leases specific reference to BMBL and other relevant guidelines

-- require a safety report from an institutional point of contact in leased BSL-3 labs as part of annual re-permitting

-- consider outsourcing inspections until the volume of work justifies adding full-time staff

2. Land Use

A. Break out biotech as a separate category under "Office: *Research and Development or Laboratory"* in the *Table of Permitted Uses* in section 9.1.1 of the Zoning Code (pages 415ff) with the following risk-based sub-categories

-- BSL 4 to be marked N (Not Permitted) across all land use categories

-- BSL 3 to be marked SP (Special Permit Required) where now marked P*

-- BSL 1-2 to be marked P (Permitted) where already marked P – i.e. no change

*Alternatively, one could restrict BSL-3 special permitting to neighborhoods where such labs are within a predefined proximity (x feet) to pre-existing residences

B. Neighborhood considerations

-- Some neighborhoods may wish to ban BSL-3 labs when abutting or within a set distance of pre-existing residences (though as a business matter, such location would be unlikely in competition with the suburbs)

-- Some neighborhoods may wish to discourage animal experimentation regardless of risk level

-- Master Plan neighborhoods may wish to bypass additional special permitting

Conclusion

In recent years Somerville has been at the forefront of many health and tech issues. It would be in keeping with its innovative spirit to have a regulatory framework in place in anticipation of the coming wave of biotech leasing. This memo is submitted as an alert, in the hope that City leaders will improve upon its analysis and suggestions.

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Links

For convenience of reference here are links to the documents mentioned:

1.CDC/WHO Guidelines

CDC's most recent "BMBL" *(Biosafety in Microbiological and Biomedical Laboratories, 6h edition, 2020): https://www.cdc.gov/labs/BMBL.html*

An earlier WHO manual underlines that the four-level risk approach is international and longstanding: *https://www.who.int/publications/i/item/9241546506*

2. Municipal Ordinances

Somerville 1994 Biotechnology Ordinance
https://library.municode.com/ma/somerville/codes/code_of_ordinances?nodeId=PTIICOOR_CH6HE_ARTIVBIRE

Somerville Zoning Ordinance (see pages 415ff for "Use Provisions")
https://3pb8cv933tuz26rfz3u13x17-wpengine.netdna-ssl.com/wp-content/uploads/sites/2/2019/12/20191212-Adopted-SomervilleZoningOrdinance.pdf

Cambridge 2009 Biosafety Regulation
https://www.cambridgepublichealth.org/Cambridge_Biosafety_Regulation_2009.pdf

Cambridge Lab Animal Ordinance
https://www.cambridgepublichealth.org/services/regulatory-activities/lab-animals/lab-animal-ordinance.php#6.12.020

Boston 2006/2019 Biosafety Regulation (amended in 2021 to strike rDNA focus)
https://bphc.org/boardofhealth/regulations/Documents/Biological%20Laboratory%20Regulation%20As%20Amended%20January%2016%202019.pdf