

BioTechnology Committee to Rewrite R&D Regulations

By Lynne Cook Polcari

Belmont's new Biotechnology Advisory Committee, a subcommittee of the Board of Health, has been working hard since March to create new biotechnology regulations for the town. Belmont currently has only minimal regulations, and the Board of Health believes that immediate action is necessary to prepare for the Research and Development Park scheduled to be built on the McLean land. The board's goal is to have up-to-date regulations in place before industry moves into the new facilities.

Under the zoning passed in July 1999, a 150,000-square-foot Research and Development complex is to be built, by developer Belmont ValueRealty. In addition, McLean Hospital has retained the right to convert 200,000 square feet of its existing space into medical research and development facilities. If regulations are on the books before space is leased, companies will be told the town's standards and can then judge whether they are willing to comply with them.

The Biotechnology Committee is considering a broad adoption of the guidelines set down by the National Institute of Health (NIH). Standards will be tightened where necessary. The committee is also reviewing stricter regulations adopted by other towns, particularly Lexington. Even companies normally exempt from NIH regulations must meet Lexington's standards, which are independent of federal guidelines.

One topic the group has discussed at length is the levels of biotechnology research that should be permitted in Belmont. The National Institute of Health currently classifies research as Biosafety levels 1, 2, 3, and 4. Levels 1 and 2 are considered safe and pose few safety concerns to the surrounding community if properly regulated and executed. Level 3 may have adverse effects, because it can permit work on airborne pathogens such as tuberculosis and influenza. Biosafety Level 4 work involves research on such extremely dangerous pathogens as Ebola, research that is generally considered inappropriate in a densely populated community like Belmont.

The group believes that Level 4 probably should be banned outright, but it is debating whether to allow Level 3 research, through a special permit process. Some members feel that instances of Level 3 research could be beneficial. For example, a lab that has made an important breakthrough and needs to do Level 3 work to continue its research could remain in Belmont if it received a special permit.

Other members of the committee are concerned that a special permit process may create a loophole that the town will constantly have to examine and assess. One member noted that the town would always be defending itself against industry lawyers trying to justify their clients' research. An outright ban of Level 3 would close the loophole and free the town from the expensive and time-consuming evaluation of the merits of different types of research.

Enforcement of the new regulations is another area of concern. One member pointed out that the NIH guidelines are only guidelines, and that it is up to each community to enforce the regulations. Technically, scientists can do whatever they want in their labs, unless they agree to the public spirit of the regulations. Without a mechanism for oversight and enforcement, there is no guarantee that the regulations will be followed. One remedy is to require that all companies have an Institutional Biosafety Committee (IBC) to oversee recombinant DNA research, with a focus on biological safety. Belmont could require that the IBC have at least two members who are not affiliated with the institution but who represent the community-at-large and have background in science or public health. This will give the community direct knowledge of the research being conducted at the institution.

At the invitation of the Board of Health, McLean Hospital made a presentation to the Biotechnology Committee of its current facilities. Pete Paskevich, Vice-President/Director of Research

Administration at McLean Hospital, and Andrew Braun, Research and Biosafety Officer from Massachusetts General Hospital, met with the committee on May 31.

McLean Hospital currently conducts Biosafety Levels 1 and 2 research on the Belmont campus in two research buildings containing over 50 labs. The hospital has a lab capable of handling Biosafety Level 3 work, but it is currently not in use. McLean reported that it follows the standards set by the NIH and inspects its own labs annually. The Institutional Biosafety Committee (IBC) that oversees McLean's recombinant DNA projects is in charge of all Harvard affiliate research, with the exception of that being done at Dana Farber. That committee visits the McLean campus approximately once every three years.

In addition, McLean reported that it has an animal lab currently containing 150 primates. The hospital provides annual reports to the NIH and to the U. S. Department of Agriculture and also conducts its own regular inspections of the primate center.

The Biotechnology Committee has agreed not to make decisions on the ethical issues connected with animal or biotechnology research; rather, it will limit its focus to the health and safety of the community. It is possible that when animal research is conducted, the Board of Health could be responsible for ensuring the appropriate treatment of the animals, and the Town would bear at least some of the cost of this enforcement. The Board of Health is addressing this issue separately.

The board's charge to the Biotechnology Committee does not include industries other than biotechnology. The new McLean by-law, however, puts no restrictions on the type of research that can be conducted in the new Research and Development complex. It explicitly permits research in biology, chemistry, electronics, engineering, geology, medicine, pharmaceuticals, physics, and computer research and technology. Each of these poses some risk to citizen health and safety. The Biotechnology Committee and the Board of Health recognize the need for appropriate regulations, but feel it is important to stay focused on first creating biotechnology regulations. Once this is done, it is hoped that this group of citizens will agree to have its charge broadened and consider updating Belmont's hazardous material regulations.

The Board of Health is fortunate to have many talented and experienced citizens to work on the Biotechnology Advisory Committee. Co-chairpersons are Linda B. Wolfe and Michael S. Baram. Ms. Wolfe is the director of Environmental Health and Safety at the Whitehead Institute and has been involved with similar citizens' efforts in Randolph and Cambridge. Mr. Baram is an attorney and professor of law and the director of the Center of Law and Technology at Boston University School of Law. He is also a professor of health law at Boston University.

Other committee members are Christine Blazynski, director of Science Content at Webivore Knowledge Systems, LLC; Stephen P. Hale, a scientist at Phylos, Inc., in Lexington; Mariana Nacht, a molecular biologist at Genzyme Corporation; and James MacIsaac, a Belmont police officer who previously worked in the biotech field.

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Summary: *Spurred by the new research and development activity on the McLean land, Belmont's Board of Health is updating safety regulations designed to prevent industrial accidents.*