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August 11, 2023

Mr. Van Mitchell, Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: COMAR 14.01.03 Public Information Act Proposal

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board) proposed regulations regarding the Public Information Act (COMAR 14.01.03).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

The Board – in direct contradiction with the statute – grants itself the authority to determine which information is confidential, trade-secret, or proprietary information.

BIO has serious concerns regarding the impact that these proposed regulations (COMAR 14.01.03) and related regulations (COMAR 14.01.01.04) would have on manufacturers and their confidential, trade-secret, and proprietary information. In particular, we are extremely concerned about the Board establishing new regulations for sharing information with the public that might otherwise be

confidential, trade-secret, or proprietary. In establishing these processes, the Board is making distinctions where they — by statute — have no right authority.

According to the statute, 21-2C-10, “all information and data obtained by the Board under the subtitle, that is not otherwise publicly available: (1) is considered to be a trade secret and confidential and proprietary information; and (2) Is not subject to disclosure under the Public Information Act.” The statute indicates the protection of confidential, proprietary information is of the utmost importance. The protection of this information guarantees the innovative healthcare ecosystem can thrive.

Regulations the board has already promulgated, COMAR 14.01.01.04, state that the “Board may also determine that information it has received is confidential, trade-secret, or proprietary.” As we have noted in previous comments, we believe this is inconsistent with the plain reading of the statute, particularly given that information that would be deemed “otherwise publicly available” would be subject to the Public Information Act, as indicated under statute and the proposed regulations, COMAR 14.01.03. We believe the statute is clear and BIO’s longstanding concerns regarding existing regulations and the protection of confidential, proprietary, and trade secret information are only heightened by these new regulations.

The statute does not grant the Board authority to determine whether information is confidential, and thus, protected. That authority rests with those submitting data to the Board and the person certifying that information is designated as protected information. If data is not otherwise publicly available, then its status under the statute is unambiguously protected information and the Board should recognize it as so. We are extremely concerned that this fundamental issue has not been addressed in the rules, yet the Board has proceeded with establishing rules for Public Information Act requests. We urge the Board to reconsider its approach and ensure its regulations — both proposed and already enacted — are in harmony with the established statute.

BIO appreciates the opportunity to provide feedback to the Maryland PDAB through these proposed rules for comment. We look forward to continuing to work with the Board to ensure Marylanders can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact me at 202-962-9200 or at jgeisser@bio.org.

xxxxx
Jack Geisser

Senior Director, Healthcare
Policy, Medicaid, and State
Initiatives