



VIA EDGAR

April 19, 2023

Ms. Jeanne Baker  
Mr. Terence O'Brien  
Division of Corporation Finance  
Office of Industrial Applications and Services  
U.S. Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

**Re: BECTON DICKINSON & CO**  
**Form 10-K filed November 22, 2022**  
**File No. 001-04802**

Dear Ms. Baker and Mr. O'Brien:

Becton, Dickinson and Company (the "Company" or "we," "our," or "us") is writing this letter in response to the comment letter (the "Comment Letter") of the Staff of the Securities and Exchange Commission (the "Staff" of the "Commission") dated March 21, 2023, relating to the Company's Form 10-K for the fiscal year ended September 30, 2022 (the "2022 Form 10-K").

For your convenience, we have reproduced the Staff's comment preceding our response below. Please let us know if you have any questions or if we can provide additional information or otherwise be of assistance in expediting the review process.

Form 10-K for the Fiscal Year Ended September 30, 2022

Management's Discussion and Analysis

Critical Accounting Policy – Contingencies, page 45

*1. As of September 30, 2022, you are defending approximately 31,445 product liability claims involving your line of hernia repair devices. You have accruals of \$2.1 billion and \$2.5 billion as of September 30, 2022 and 2021, and recorded pre-tax charges of approximately \$21 million, \$361 million, and \$378 million during 2022, 2021 and 2020, respectively. While you disclose a list of "additional information obtained during fiscal years 2022, 2021 and 2021," you do not provide the specific factors that impacted your accrual. For example, your claims significantly increased from 25,030 product liability claims as of September 31, 2021, but your accrual decreased and your pre-tax charge in 2022 was significantly less than in 2021. Given the significance of the recorded liability and your cautionary disclosures that you could incur material charges in excess of*

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currently established accruals, please provide a fuller description of your critical accounting estimates that considers key judgments made in applying ASC 450 and more specifically explains the volatility of the assumptions and changes in the recorded liability.

For example:

- Explain why your estimates and assumptions bear risk of change. To this end, consider disclosing the information you evaluate as part of your legal review and the approach you apply to develop your estimates. Address the potential impact on your accrual of changes in significant qualitative factors and material underlying quantitative assumptions, including changes in the number of estimated new claim filings, the time period over which claims may be asserted, average settlements per claim, average costs per claim, and stage of litigation. Include quantification where possible;
- Explain the specific reasons for changes in estimates that materially impact the financial statements. Clarify whether your accrual and related charges have been impacted by claims related to your line of inferior vena cava filter products and/or pelvic mesh products;
- Address the impact the three bellwether trials you discuss in Note 6 had on your accrual, with particular emphasis on the \$4.8 million verdict in August 2022;
- Please quantify the extent of your insurance coverage and disclose and discuss the impact of any insurance proceeds on your results of operations; and
- Explain the basis for the significant assumptions you use in any sensitivity analysis you provide and address how the assumptions compare with both your historical experience and the broader approach you use to estimate your accrual.

**Response:**

In response to the Staff's comment, the Company respectfully advises the Staff that, in accordance with Accounting Standards Codification 450 ("ASC 450"), it establishes accruals for future losses which are both probable and reasonably estimable. As noted in Note 6 Commitments and Contingencies of the 2022 Form 10-K, on page 74, the Company considers the following information (the "accrual support information") to estimate its product liability accrual:

*...including, but not limited to: the nature, quantity, and quality of unfiled and filed claims; the continued rate of claims being filed in certain product liability matters; the status of certain settlement discussions with plaintiffs' counsel; the allegations and documentation supporting or refuting such allegations; publicly available information regarding similar medical device mass tort settlements; historical information regarding other product liability settlements involving the Company; and the stage of litigation.*

The Company also disclosed the following on page 72 of the 2022 Form 10-K regarding the consideration of the information described above for purposes of adjusting its product liability accruals:

*In most product liability litigations like those described above, plaintiffs allege a wide variety of claims, ranging from allegations of serious injury caused by the products to*

*efforts to obtain compensation notwithstanding the absence of any injury. In many of these cases, the Company has not yet received and reviewed complete information regarding the plaintiffs and their medical conditions and, consequently, is unable to fully evaluate the claims. The Company expects that it will receive and review additional information regarding any remaining unsettled product liability matters.*

The Company respectfully acknowledges and addresses the Staff's more specific questions and comments regarding its product liability accruals and related disclosures in the discussion below.

#### Changes in Estimates

The Company's product liability accrual is estimated with the assistance of outside counsel and a third-party actuarial specialist. The estimated accrual is derived from quantitative and qualitative assumptions and information relating to the status of claims, including historical claims experience, the number of filed claims, estimates of the number of unfiled claims, the quality of filed and unfiled claims, the stage of the litigation, and the Company's legal strategy. As per our excerpted disclosure above, the information the Company has available to estimate this liability is incomplete and estimating probable losses from litigation matters is inherently difficult. As such, our assumptions and the Company's product liability accrual are subject to change as new information regarding claims and other data become available. The Company adjusts its product liability accrual as it receives and reviews additional information regarding outstanding unsettled product liability matters. For example, the decrease in the Company's product liability accrual as of September 30, 2022 as compared with September 30, 2021 largely reflected the impact of settlements paid during fiscal year 2022, in addition to the various impacts associated with other accrual support information as described above. Notably, the estimated accrual as of September 30, 2022 reflected the determination that the quality of the hernia repair device claims has diminished over time. As noted by the Staff, the number of outstanding claims relating to our hernia repair devices as of September 30, 2022 compared with September 30, 2021 increased and this increase reflects new claims that were filed in 2022 as well as unfiled claims that the Company was made aware of in 2022. However, these additional claims did not impact our overall product liability accrual as of September 30, 2022 because the underlying actuarial estimate of our liability includes and already accounts for unfiled claims. As further discussed in greater detail below, filings of new claims relating to the pelvic mesh device and IVC filter matters did not materially impact our product liability accrual as of September 30, 2022.

The Company provided quantitative context regarding ongoing claim activity in Note 6 Commitments and Contingencies of the 2022 Form 10-K, on page 71, by disclosing the outstanding number of hernia repair device claims as of the reporting date. For the reasons discussed below, the Company does not believe that detailed disclosure regarding pelvic mesh and IVC filter product liability matters is useful for investors given the late stage of the litigation for such matters. In response to the Staff's request to quantify information such as the time over which claims may be asserted, average settlements per claim and the average costs per claim, the Company respectfully advises the Staff that, as per our disclosure excerpted above, product liability accruals can represent projected product liability claims in different litigation environments

and with different fact patterns. Given the nonhomogeneous nature of product liability claim populations, the Company respectfully submits that specific information regarding claim activity would not be useful to investors as such information may not necessarily be indicative of the Company's ultimate liability under a mass tort matter.

Impact of Pelvic Mesh and IVC Filter Product Liability Matters on the Product Liability Accrual

In Note 5 Commitments and Contingencies of the Company's Form 10-K for the Year Ended September 30, 2021, on pages 68 and 69, we disclosed the following regarding outstanding product liability claims relating to pelvic mesh devices and IVC filters:

*As of September 30, 2021, the Company is defending approximately 405 product liability claims involving the Company's line of pelvic mesh devices.*

*As of September 30, 2021, the Company is defending approximately 275 product liability claims involving the Company's line of inferior vena cava ("IVC") filters (collectively, the "Filter Product Claims").*

In Note 6 Commitments and Contingencies of the Company's 2022 Form 10-K, the Company adjusted its disclosures relating to pelvic mesh devices and IVC filter products to reflect the diminution of the risks posed by these mass torts. Not only has there been significant progress with settlements, but new filings of both pelvic mesh device and IVC filter product claims have slowed, such that in fiscal year 2022, there were less than approximately 35 and 10 new filings, respectively, indicating that these matters are near the end of their lifecycle. Further, we respectfully advise the Staff that the recorded liability associated with pelvic mesh devices and IVC filter products is no longer material to the overall financial position of the Company when taken as a whole. Accordingly, the Company does not believe that more detailed disclosure regarding these cases would be useful for investors.

Impact of Bellwether Trials on Product Liability Accrual

In response to the Staff's comment, the Company respectfully submits that it believes its current disclosure in Note 6 Commitments and Contingencies of the 2022 Form 10-K, on page 75, appropriately and adequately reports the status and outcomes of the bellwether trials:

*From time to time, the Company engages in resolution discussions with plaintiffs' law firms regarding certain of the Hernia Product Claims, but the Company also intends to vigorously defend Hernia Product Claims that do not settle, including through litigation.*

- *The first bellwether trial in the hernia MDL resulted in a complete defense verdict in favor of the Company in September 2021.*
- *The second hernia MDL bellwether resulted in a \$255 thousand verdict in April 2022.*
- *The first bellwether trial in RI resulted in a \$4.8 million verdict in August 2022, which the Company plans to appeal.*

Trials involving our product liability claims have resulted in both favorable and unfavorable judgments for the Company. The outcome in any one trial, including the trials specifically

disclosed as per above, is not representative or indicative of potential outcomes of all cases or claims involving the subject product. We further respectfully advise the Staff that our product liability accruals are estimated in accordance with ASC 450 and as such, our product liability accrual reflects product liabilities for which a future loss has been determined to be probable and estimable. Accordingly, our product liability accrual as of September 30, 2022 reflected the matters noted above.

Insurance Coverage and Related Impact on Results of Operations

The Company respectfully advises the Staff that it does not maintain or has limited insurance coverage and as such, the Company's insurance liability coverage, as well as the cost relating to such insurance, is not material to the Company's operating results or financial condition. In Item 1A Risk factors, page 20 of our 2022 Form 10-K, we disclose the following regarding our insurance coverage, specifically with regards to product liability insurance.

*Also, for certain product liability claims or lawsuits, BD does not maintain or has limited remaining insurance coverage, and we may not be able to obtain additional insurance on acceptable terms or at all that will provide adequate protection against potential liabilities.*

Based upon the immaterial impact of product liability insurance on our operating results or financial condition, we believe our existing disclosure regarding such coverage is appropriate.

Significant Assumptions Underlying Sensitivity Analysis Performed

In the Critical Accounting Policies – Contingencies section within Management's Discussion and Analysis of Financial Condition and Results of Operations of our 2022 Form 10-K, on page 46, we disclose the following as it relates to our process in estimating accruals for certain mass tort litigation:

*When appropriate, the accrual is developed with the consultation of outside counsel and, as in the case of certain mass tort litigation, the expertise of an actuarial specialist regarding the nature, timing and extent of each matter. The accruals may change in the future due to new developments in each matter or changes in our litigation strategy.*

As discussed above, the Company engages a third-party actuarial specialist to assist in estimating the overall liability of certain mass tort litigation, which includes the hernia repair device mass tort litigation. In developing the actuarial assessment, we, outside counsel and the actuary consider quantitative and qualitative data including, but not limited to, the number of filed claims and the claims filing rate, advertising spend, historical settlement amounts (to the extent relevant based upon the quality of settled claims), stage of litigation, and the Company's legal strategy.

For purposes of providing the Staff additional insight regarding the Company's internal controls relating to product liability matters, the actuarial analysis is updated on an annual basis at a minimum, or more often as needed. To determine if an interim actuarial analysis is required at each quarter-end, the Company examines the actual experience during the quarter, which includes, among other items, actual new claim filings and settlement activity. The Company

compares such information to the assumptions and estimates included within the results of the actuarial study, so as to determine if there have been any changes to facts and circumstances that could have a significant impact to our product liability accruals. In addition, our quarterly assessment also includes consideration of any changes to the overall legal landscape and/or our legal strategy.

Enhancement of Disclosures in Future Filings

To further enhance our disclosures in future filings, we hereby advise the Staff that going forward, we will expand our disclosure to include language similar to the underlined, added text in the extract from pages 72 and 74 of the 2022 Form 10-K below. We believe that this expanded disclosure will help investors better understand the inherent uncertainty and volatility that underlies these estimations.

From time to time, the Company engages in resolution discussions with plaintiffs' law firms regarding certain of the Hernia Product Claims, but the Company also intends to vigorously defend Hernia Product Claims that do not settle, including through litigation. The outcome in any one trial is not representative of potential outcomes of all cases or claims related to our product liability claims.

The Company considers the following information when estimating its product liability accruals, including but not limited to: the nature, quantity, and quality of unfiled and filed claims; the continued rate of claims being filed in certain product liability matters; the status of certain settlement discussions with plaintiffs' counsel; the allegations and documentation supporting or refuting such allegations; publicly available information regarding similar medical device mass tort settlements; historical information regarding other product liability settlements involving the Company; and the stage of litigation. Because the information that is currently available regarding product liability matters is often limited, there is inherent uncertainty and volatility relating to the Company's estimate of product liability. As additional information becomes available, the Company records adjustments to its product liability accruals as required. During fiscal years 2022, 2021, and 2020, the Company recorded pre-tax charges to Other operating expense, net, of approximately \$21 million, \$361 million, and \$378 million, respectively, related to certain of the product liability matters discussed above under the heading "Product Liability Matters," including the related legal defense costs.

2. Please provide herein, or elsewhere in MD&A, a roll forward of your outstanding hernia repair device claims, including the number of claims pending at each balance sheet date, the number of claims filed each period presented, the number of claims dismissed, settled, or otherwise resolved for each period, and the average settlement amount per claim. See Question 3 to SAB Topic 5Y. To the extent material, address this comment as it relates to your line of pelvic mesh products and inferior vena cava filter products.

**Response:**

In response to the Staff's comment, the Company respectfully submits that in developing our disclosures, we considered Question 3 to SAB Topic 5Y with respect to the Product Liability Matters, as well as the requirements of Item 101 (Description of Business), Item 103 (Legal Proceedings), and Item 303 (Management's discussion and analysis of financial condition and results of operations) of Regulation S-K. The interpretive response to Question 3 to SAB Topic 5Y states that "[d]isclosures [regarding loss contingencies] should be sufficiently specific to enable a reader to understand the scope of the contingencies affecting the registrant." Further, in addition to certain specific disclosure items, Item 303 of Regulation S-K requires that registrants provide "information that the registrant believes to be necessary to an understanding of its financial condition, changes in financial condition and results of operations." Finally, the specific disclosure items of Regulation S-K are all subject to a materiality threshold. In light of these disclosure requirements, contingency-related disclosures should provide investors with material information that is sufficiently specific to understand the scope of an entity's contingencies and the potential impact that future losses may have on the entity's operating results and financial condition.

Based upon our consideration of these disclosure requirements, the Company believes that it has provided disclosure which complies with the requirements referenced above. For example, in Note 6 Commitments and Contingencies of the 2022 Form 10-K, we included the number of claims in the hernia repair device mass tort litigation as of the balance sheet date, a description of various proceedings related to these matters, the results of the hernia repair device bellwether trials, and the adjustments recorded to our product liability accrual based upon our review of the accrual support information. We believe that our disclosure is appropriate based on the nature and stage of the hernia repair device mass tort litigation and encompasses the material information that is necessary to understand the scope of the related contingencies and its potential impact on our financial condition and results of operations.

With regard to the Staff's request for a roll forward of our outstanding hernia repair device claims, we note that Question 3 to SAB Topic 5Y cites this disclosure example as being relevant for a contingency which involves a large number of relatively small individual claims of a similar type, such as personal injury from exposure to asbestos. We respectfully advise the Staff that the quality of the claims filed by plaintiffs' attorneys in the hernia repair device mass tort litigation varies by claimant. Further, the value of each individual claim may differ due to many factors, including the quality of each underlying claim and the hernia repair device used, as the products subject to various claims are different. Given the nonhomogeneous nature and population of the hernia repair device claims, information regarding claims filed or resolved during the period is not

indicative of the Company's ultimate liability and therefore the Company respectfully submits is not material to an understanding of the related contingencies. Therefore, the Company respectfully submits that providing a roll forward to include the number of claims filed for each period presented and the number of claims dismissed, settled, or otherwise resolved for each period does not provide sufficient context to investors. Based upon these considerations, we believe our existing disclosures provide investors with the best estimate and description of the Company's estimated liability and material factors that may impact that exposure.

As discussed above, due to the wide variety of the facts associated with each case and the nonhomogeneous population of hernia repair device claims, providing an average settlement amount would also not provide helpful information to an investor as such information is generally not indicative of the Company's ultimate liability. Additionally, we respectfully advise the Staff that we consider the settlement data to be proprietary information and this data is also confidential as per the contractual terms of settlement arrangements.

With respect to our consideration of your request relative to our pelvic mesh products and IVC filter products, we respectfully advise the Staff that such product liability matters are not material to the Company's operating results or financial condition, as more fully discussed above in our response to comment 1 in the Comment Letter.

#### Financial Statements

##### Note 6 Contingencies, page 71

1. *To the extent material, please disclose how you account for your liability insurance.*

#### **Response:**

In response to the Staff's comment, we respectfully advise the Staff that the Company either does not maintain or has limited insurance coverage. As such, the Company's liability coverage, as well as the cost relating to this insurance, is not material to the Company's operating results or financial condition. The Company has included disclosure to this effect in Item 1A. Risk Factors of our 2022 Form 10-K, on page 20:

*Also, for certain product liability claims or lawsuits, BD does not maintain or has limited remaining insurance coverage, and we may not be able to obtain additional insurance on acceptable terms or at all that will provide adequate protection against potential liabilities.*

In the Critical Accounting Policies section of Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of our 2022 Form 10-K, on page 46 we additionally provide the disclosure below:

*We record expected recoveries from product liability insurance carriers or other parties when realization of recovery is deemed probable.*



We respectfully advise the Staff that in accordance with ASC 450, all our contingent liabilities are estimated independently from any possible claim for recovery. Based upon the immaterial impact of liability insurance on our operating results or financial condition, we believe our existing disclosure regarding insurance coverage is appropriate.

\* \* \*

In connection with our response to the Staff's comment, we acknowledge that the Company and our management are responsible for the accuracy and adequacy of our disclosures, notwithstanding any review, comments, action or absence of action by the Staff.

Please do not hesitate to call me at (201) 847-6314 with any questions you may have with respect to the foregoing.

Very truly yours,

BECTON, DICKINSON AND COMPANY

By: /s/ Thomas J. Spoerel

Name: Thomas J. Spoerel

Title: Senior Vice President,  
Controller & Chief Accounting Officer

cc: Christopher J. DelOrefice, Executive Vice President and Chief Financial Officer  
Michelle Quinn, Executive Vice President and General Counsel  
Gary DeFazio, Senior Vice President and Corporate Secretary