IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

TEAMSTERS LOCAL 443 HEALTH SERVICES & INSURANCE PLAN, ST. PAUL ELECTRICAL CONSTRUCTION PENSION PLAN, ST. PAUL ELECTRICAL CONSTRUCTION WORKERS SUPPLEMENTAL PENSION PLAN (2014 RESTATEMENT), RETIREMENT MEDICAL FUNDING PLAN FOR THE ST. PAUL ELECTRICAL WORKERS, AND SAN ANTONIO FIRE & POLICE PENSION FUND,	)	
Plaintiffs,	)	
v.	)	C.A. No. 2019-0816-SG
JOHN G. CHOU, STEVEN H. COLLIS, RICHARD W. GOCHNAUER, LON R. GREENBERG, TIM G. GUTTMAN, JANE E. HENNEY, M.D., KATHLEEN W. HYLE, MICHAEL J. LONG, AND HENRY W. MCGEE,	)	
Defendants,	)	
-and-	)	
AMERISOURCEBERGEN CORPORATION,	)	
Nominal Defendant.	)	

MEMORANDUM OPINION

Date Submitted: May 27, 2020
Date Decided: August 24, 2020

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GLASSCOCK, Vice Chancellor

It has become among the hoariest of Chancery clichés for an opinion to note that a derivative claim against a company's directors, on the grounds that they have failed to comply with oversight duties under *Caremark*,[1] is among the most difficult of claims in this Court to plead successfully. As with many a cliché, there is truth in the notion. In order to survive a motion to dismiss under Rule 23.1, a plaintiff must raise an inference that demand on the board to undertake the action would have been futile.[2] Typically, in the *Caremark* context, this requires a pleading of specific facts from which the Court may infer a substantial likelihood of liability on the part of a majority of the board on whom demand would have been made. Such a pleading must allege with particularity facts which imply that the directors utterly failed to provide a corporate reporting system to permit board-level review of compliance with law, or that the directors were provided sufficient notice of corporate non-compliance with law such that their failure to remediate amounts to bad faith. This is a formidable burden.

The facts of *Caremark* claims, on the other hand, often invoke judicial sympathies. Frequently, the facts of the case involve corporate misconduct that has led to material suffering among customers, or to the public at large. A judge in the *Caremark* context must be careful to remember the issues before her. At issue is *not*

[1] *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996).
[2] Or that demand was made and wrongfully refused.

whether specific or society-wide victims may themselves receive a remedy for corporate misconduct. Instead, the issue is whether the corporation, whose directors have allegedly allowed it to commit bad acts, should *itself* recover damages that ultimately inure to the benefit of the corporate owners, its stockholders. This unusual posture raises the question of whether *Caremark* liability is merely a branch of fiduciary liability designed to make the beneficiaries of that duty whole for breach, or whether it should be seen also as a blunt but useful tool to encourage good corporate citizenship. That question is for academic discussion, not judicial resolution; again, a judge in equity must be mindful that it is the corporation, not that corporation's victims, to whom any recovery will flow.

It is of little wonder that *Caremark* liability is rarely imposed, as it is fortunately rare that directors, otherwise unconflicted, should nonetheless take actions knowingly inimical to the corporate interest, such as ignoring a known duty to act to prevent the corporation from violating positive law. I find, however—at least at this pleading stage where I must accept the allegations of the complaint along with reasonable plaintiff-friendly inferences—that the Plaintiffs here have pled such a case.

The Plaintiffs are stockholders in AmerisourceBergen Corporation ("ABC" or, the "Company"). ABC acquired Medical Initiatives, Inc. d/b/a Oncology Supply Pharmacy Services ("Pharmacy") as an indirect wholly-owned subsidiary in 2001 as

part of a larger merger. Pharmacy, per the complaint, was run as a criminal organization. Pharmacy was not, in fact, a state-licensed pharmacy, although it operated in a way that made it appear as such to avoid Food and Drug Administration ("FDA") oversight. Pharmacy's business was to buy single-dose sterile vials of oncology drugs, put those drugs into syringes, and sell the syringes for injection into a cancer patient's body. As acquired by Pharmacy, these single-dose vials had been intentionally overfilled by the manufacturer to account for human error in filling syringes and to permit the medical provider to discharge a small amount before injection to avoid air bubbles, but still have a full dose. Instead of discarding this overfill, which was not intended for patient use, Pharmacy illegally "pooled" the overfill and used it to fill additional syringes. This process was unsterile and led to the contamination of the drugs so pooled.

Having thus created extra product, ABC both pocketed the extra revenue, and undercut the competition by providing kickbacks to buyers to increase market share. The operation used sham prescriptions to make it appear that Pharmacy was, in fact, a pharmacy, and thus shielded from FDA oversight. When the pooled drugs were so grossly contaminated that particulates were visible to the naked eye, Pharmacy filtered out these "floaters" and sold the drug, nonetheless.

Ultimately, the criminal activities at Pharmacy and other associated ABC subsidiaries were uncovered, and significant corporate criminal and civil penalties ensued.

The question is whether, in allowing these conditions to obtain at Pharmacy and its associated entities, the ABC directors failed their duty to oversee operations, in bad faith. The Defendants have moved to dismiss under Rules 23.1 and 12 (b)(6). According to the Defendants, the egregiousness of the allegations is undercut by the small part of the total ABC business represented by the Pharmacy operations. It is true that directors are not omniscient, that their eyes cannot be on every sparrow, and that not every failure of oversight is the result of bad faith. Here, however, ABC operated a criminal enterprise. The directors ignored such red flags as did exist, and, in addition, permitted a woefully inadequate reporting system with respect to the business line in which Pharmacy operated. At this pleading stage, assuming as true the well-pled allegations and drawing reasonable inferences helpful to the Plaintiffs, I find that the complaint states a claim for *Caremark* liability, and that the likelihood of that liability is such that demand is excused. A close look at the facts supporting that conclusion, and my reasoning, follow.

I. BACKGROUND[3]

I turn first to the scope of the record on this Motion to Dismiss. The final order in the Plaintiffs' underlying 8 *Del. C.* § 220 action to obtain ABC's books and records required that within five business days of the completion of production ABC's counsel certify that "[w]ith the exception of any documents included on the privilege log, to the best of my knowledge after reasonable investigation, the Company's production is complete with respect to every category of documents that the Company is required to produce."[4] "Given this stipulation, if [ABC] failed to produce a document that it would reasonably be expected to possess if a particular event had occurred, then the [P]laintiff[s] [are] entitled to a reasonable inference that the event did not occur."[5] The final order in the Section 220 action also deems all books and records produced pursuant to the Plaintiffs' demand to be incorporated by reference in any plenary complaint filed by the Plaintiffs in any subsequent

[3] I draw the facts from the well-pled allegations of the Plaintiffs' Verified Stockholder Derivative Complaint, D.I. 1 (the "Complaint" or "Compl."), the exhibits attached thereto, documents incorporated by reference or integral to the pleading, and judicially noticeable facts. *See In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *2 (Del. Ch. Oct. 1, 2019) (setting forth Delaware's judicial notice doctrine). ABC has produced documents to the Plaintiffs in response to a demand for books and records by the Plaintiffs under 8 *Del. C.* § 220 in the case captioned *In re AmerisourceBergen Corporation Section 220 Litigation*, Consol., C.A. No., 2018-0209-SG. *See* Compl., ¶¶ 37–39. I follow the Plaintiffs' convention in citing to documents included in the Section 220 production, but not attached as exhibits to the Complaint, by using the Bates numbers, which begin with "ABC-220 CONSOLIDATED." Specific page numbers are cited as ABC-220 CONSOLIDATED [Bates number of first page of document], at [last four digits of Bates number of cited page].

[4] Compl., Ex. 1, ¶ 2.

[5] *Hughes v. Hu*, 2020 WL 1987029, at *2 (Del. Ch. Apr. 27, 2020) (citing *Morrison v. Berry*, 191 A.3d 268, 275 n.20 (Del. 2018)).

litigation relating to the Section 220 action.[6] Consequently, I may consider any documents incorporated by reference "in their entirety rather than rely only [on] the portions 'cherry picked' by the [Plaintiffs]."[7]

A. The Parties and Relevant Entities

1. ABC and its Direct and Indirect Subsidiaries

Nominal Defendant ABC is a publicly-traded Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.[8] ABC is a pharmaceutical sourcing and distribution company and was formed in 2001 following a merger between Bergen Brunswig Corporation ("Bergen Brunswig") and AmeriSource Health Corporation ("AmeriSource Health").[9] In the time period pertinent to this Action, ABC's pharmaceutical distribution segment consisted of two operating segments: AmerisourceBergen Drug Corporation (which is not pertinent here) and AmerisourceBergen Specialty Group ("Specialty").[10]

Specialty, based in Frisco, Texas, is the parent entity for a group of companies serving the specialty pharmaceuticals market, including the areas of biotechnology, blood-plasma, and oncology.[11] Specialty and its subsidiaries provide

[6] Compl, Ex. 1, ¶ 3.
[7] *Clovis*, 2019 WL 4850188, at *2 n.8 (Del. Ch. Oct. 1, 2019) (citing *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 797 (Del. Ch. 2016), *abrogated on other grounds*, 214 A.3d 933 (Del. Aug. 7, 2019)).
[8] Compl., ¶ 17.
[9] *Id*.
[10] *Id*. ¶ 18.
[11] *Id*. ¶ 20.

pharmaceutical distribution and related services directly to physicians and to institutional healthcare providers, including hospitals.[12] One of the companies operated by Specialty is ASD Specialty Healthcare, LLC d/b/a Oncology Supply ("Oncology").[13] Oncology is located in Dothan, Alabama and has been distributing chemotherapy and supportive care products to independent oncology practices throughout the United States for over thirty-five years.[14]

Oncology operated its subsidiary, Pharmacy.[15] Pharmacy is a Florida corporation and was acquired by ABC following the 2001 merger between Bergen Brunswig and AmeriSource Health.[16] Pharmacy operated out of Oncology's facility in Dothan, Alabama between 2001 and 2014.[17] Pharmacy's sole function was to create pre-filled syringes of oncology drugs for sale and distribution to healthcare providers—this was known as the Pre-Filled Syringe Program, which is the focus of this Action.[18] ABC closed Pharmacy's business on January 31, 2014.[19]

[12] *Id*.
[13] *Id*. ¶ 21. Oncology is an "unincorporated subsidiary" of Specialty. *Id*.
[14] *Id*.
[15] *Id*. ¶ 22.
[16] *Id*.
[17] *Id*.
[18] *Id*.
[19] *Id*.

Oncology Group was one of Specialty's eight business units, and at all relevant times included Oncology, Pharmacy, and ION (a group purchasing organization).[20]

2. Director and Officer Defendants

Defendant Steven H. Collis is ABC's Chairman, President, and Chief Executive Officer, and is Chair of ABC's Executive Committee.[21] Collis has been a member of ABC's Board of Directors (the "Board") since 2011 and has served as the Board's Chairman since March 2016.[22] Collis founded the Specialty Group at AmeriSource Health in 1994 (which later became Specialty) and has held various positions at ABC and its subsidiaries and predecessors.[23] Collis was President of Pharmacy from 1999 until its closure in 2014.[24]

Defendant Richard W. Gochnauer has been a director of ABC since September 2008.[25] Gochnauer currently serves as Chair of the Finance Committee.[26] Gochnauer was a member of the Audit and Corporate Responsibility Committee (the "Audit Committee") from 2011 to 2012.[27]

[20] *Id*. ¶ 116, n.54.
[21] *Id*. ¶ 24.
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] *Id*. ¶ 25.
[26] *Id*.
[27] *Id*.

Defendant Lon R. Greenberg has been a director of ABC since May 2013.[28] Greenberg has been a member of the Audit Committee since 2013, and is currently its Chair.[29]

Defendant Jane E. Henney, M.D., has been a director of ABC since January 2002, and has been the Lead Independent Director since March 2016.[30] Henney was a member of the Audit Committee from 2004 to 2010.[31]

Defendant Kathleen W. Hyle has been a director of ABC since May 2010.[32] Hyle was a member of the Audit Committee from 2010 to 2017 and its Chair from 2011 to 2016.[33]

Defendant Michael J. Long has been a director of ABC since May 2006.[34] Long was a member of the Audit Committee from 2011 to 2017.[35]

Defendant Henry W. McGee has been a director of ABC since November 2004.[36] McGee has a member of the Audit Committee since 2018, and was previously a member of the Audit Committee from 2009 to 2015.[37]

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[28] *Id*. ¶ 26.
[29] *Id*.
[30] *Id*. ¶ 28.
[31] *Id*.
[32] *Id*. ¶ 29.
[33] *Id*.
[34] *Id*. ¶ 30.
[35] *Id*.
[36] *Id*. ¶ 31.
[37] *Id*.

Defendant John G. Chou has been the Executive Vice President of ABC since August 2011 and ABC's Chief Legal and Business Officer since June 2017.[38] Chou has worked at ABC since 2002 and has previously held several other positions with the Company.[39] Chou was the General Counsel of Pharmacy from at least 2008 to 2014 and a member of the Board of Directors of Pharmacy from at least 2008 to 2018.[40]

Defendant Tim G. Guttman was a senior executive at ABC from 2008 to 2018.[41] Guttman was a Vice President and Director of Pharmacy from 2012 to 2018.[42]

3. Non-Party Directors

Non-party Ornella Barra has been a director of ABC since January 2015.[43]

Non-party D. Mark Duncan has been a director of ABC since September 2015.[44]

[38] *Id*. ¶ 32.
[39] *Id*.
[40] *Id*.
[41] *Id*. ¶ 33.
[42] *Id*.
[43] *Id*. ¶ 34.
[44] *Id*. ¶ 35.

4. Plaintiffs

Plaintiff Teamsters Local 443 Health Services & Insurance Plan ("Teamsters") was a stockholder of ABC during the time period relevant to the Complaint and has been a stockholder of ABC continuously since that time.[45]

Plaintiffs St. Paul Electrical Construction Pension Plan, St. Paul Electrical Construction Workers Supplemental Pension Plan (2014 Restatement), and Retirement Medical Funding Plan for the St. Paul Electrical Workers (together, "St. Paul") own and have continuously owned shares of ABC since December 2009.[46]

Plaintiff San Antonio Fire & Police Pension Fund ("San Antonio," and, together with Teamsters and St. Paul, the "Plaintiffs") owns and has continuously owned shares of ABC since prior to August 1, 2008.

B. The Pre-Filled Syringe Program

Pharmacy operated the Pre-Filled Syringe Program out of Oncology's facility in Dothan, Alabama.[47] The Pre-Filled Syringe Program consisted of the creation, packaging, and shipping of pre-filled syringes to oncology practices treating immunocompromised patients.[48] The Pre-Filled Syringe Program shipped pre-filled syringes to oncology centers, medical practices, and physicians.[49]

[45] *Id*. ¶ 14.
[46] *Id*. ¶ 15.
[47] *Id*. ¶ 42.
[48] *Id*. ¶ 41.
[49] *Id*. ¶ 44.

Pharmacy created the pre-filled syringes by removing FDA-approved drug products from their original glass vials and repackaging them into single-dose plastic syringes.[50] When Pharmacy would remove the desired dosage of oncology drug from its original glass vial a small amount of drug product would be left over—this is known as "overfill."[51] When packaging drug products, manufacturers intentionally include overfill to help with accurate dosage, as it accounts for human error in filling syringes and permits the medical provider to avoid dangerous air bubbles.[52] Overfill is not intended for patient use.[53] Pharmacy would extract the overfill from FDA-compliant vials and combine the contents from multiple vials—this is known as "pooling."[54] The pooled excess drug product was repackaged into new syringes.[55] By pooling overfill, the Pre-Filled Syringe Program was able to create more doses than it bought from the original drug manufacturers.[56]

In 2006, the Board approved a capital expenditure plan to expand Oncology's Dothan, Alabama facility that housed the Pre-Filled Syringe Program.[57] The Pre-Filled Syringe Program sold more than 1 million pre-filled syringes annually after

[50] *Id*.
[51] *Id*.
[52] *Id*. ¶ 45.
[53] *Id*.
[54] *Id*.
[55] *Id*.
[56] *Id*.
[57] *Id*. ¶ 42.

the expansion and at the height of its operation generated more than $14 million in profit for ABC each year.[58]

In operating the Pre-Filled Syringe Program, neither Oncology nor Pharmacy were registered with the FDA as a drug manufacturer or repackager.[59] Additionally, neither entity obtained valid prescriptions, performed checks for harmful potential drug interactions, or saw or counseled patients.[60] Oncology and Pharmacy did not maintain records of medication history, diagnosis, laboratory data or other pertinent information for the patients to whom pre-filled syringes were administered.[61] Neither Oncology nor Pharmacy had sufficient information to identify the patients to whom the pre-filled syringes were ultimately administered.[62] Oncology and Pharmacy routinely provided pre-filled syringes to oncology practices without receiving prescriptions signed by practitioners for specific patients.[63]

Oncology and Pharmacy frequently assigned the name of a single individual—as the receiving "patient"—to an entire batch of pre-filled syringes and often filled orders that had been submitted with a single person's name but in amounts far in excess of what could be plausibly or safely administered to one

[58] *Id*.
[59] *Id*. ¶ 52.
[60] *Id*. ¶ 54.
[61] *Id*.
[62] *Id*. ¶ 55.
[63] *Id*.

patient.[64] In many cases, the individual assigned to receive a batch of pre-filled syringes was known to be an employee at an oncology practice (such as a nurse or office manager)—sometimes the named individual was a former patient of the customer practice, either because the individual had passed away or was otherwise no longer receiving treatment.[65]

Pharmacy prepared the pre-filled syringes in an unclean and unsterile environment.[66] The FDA-approved vials from which Pharmacy transferred the oncology drugs into the syringes were designated for single use, yet Pharmacy's technicians frequently re-entered vials multiple times after the vials were decapped.[67] Pharmacy's process for creating pre-filled syringes resulted in some syringes containing particulate or foreign matter—Pharmacy's employees internally referred to such particulate or matter as "floaters."[68] Floaters were identified in pre-filled syringes before at least 2007, and from 2007 to 2013 Pharmacy tracked the number of pre-filled syringes that contained floaters.[69] Between 2007 and 2013, more than 32,000 pre-filled syringes were identified as containing floaters.[70]

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[64] *Id*. ¶ 56.
[65] *Id*.
[66] *Id*. ¶ 58.
[67] *Id*.
[68] *Id*. ¶ 59.
[69] *Id*.
[70] *Id*. The Plaintiffs illustrate this amount by stating that more than 100 pre-filled syringes each week contained floaters. *Id*. Stated otherwise, because Pharmacy sold at least 1,000,000 pre-filled syringes each year after the Oncology facility expansion (in 2006), and an average of approximately 5,333 syringes per year from 2007–2013 contained floaters, an average of at least

Most of the pre-filled syringes containing floaters were made from vials of a drug called Procrit®, which is used to treat chemotherapy-induced anemia, among other conditions.[71] The FDA-approved label for Procrit® stated: "drug products should be inspected visually for particulate matter and discoloration prior to administration. *Do not use any vials exhibiting particulate matter or discoloration*."[72] Vials or syringes of Procrit® containing particulate were required by the FDA to be destroyed.[73] Pharmacy, however, did not destroy vials or syringes containing floaters, and instead used its own process to "filter out" the visible particulate before placing the drug in the pre-filled syringes.[74]

Pharmacy did not take steps to determine the cause, composition, or sterility of floaters identified in pre-filled syringes.[75] Nor did Pharmacy identify what may have caused particulate matter to enter the pre-filled syringes or test the particulate extracted from the pre-filled syringes to determine whether any sub-visible remnants or contaminants remained in the syringes or posed a risk to patients.[76] No assessment was made to determine (i) whether Pharmacy's filtration process impacted the sterility, stability, or purity of the injectable drug content or (ii) the frequency of pre-

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0.5% of the pre-filled syringes from 2007–2013 were identified as containing floaters. *Id*. ¶¶ 42, 59. This contaminated medicine was destined to be injected into cancer patients.

[71] *Id*. ¶ 60.

[72] *Id*. (italics in original).

[73] *Id*. ¶ 61.

[74] *Id*.

[75] *Id*. ¶ 62.

[76] *Id*.

filled syringes sold to health care providers in which particulate was present but not visible.[77]

Out of more than nine million pre-filled syringes created by Pharmacy, only eighty-two were submitted to an outside laboratory for sterility testing.[78] Such testing occurred on three occasions: once each in 2009, 2011, and 2012.[79] On two of the three occasions (2009 and 2011), several pre-filled syringes tested positive for bacteria, but Pharmacy did not conduct follow up tests to confirm the source of the bacteria nor did Pharmacy alert outside parties—including the healthcare providers who purchased pre-filled syringes from the batches that tested positive for bacteria—of the results.[80]

Additionally, rather than using a consistent and objective process to ensure each pre-filled syringe contained the correct amount of injectable drug product, when filling syringes, Pharmacy technicians "eyeballed" the volume using the visible line on the syringe indicating the ordered dosage amount.[81] Some Pharmacy technicians drew drug product into the syringe just below the line whereas others filled the syringe up to the line—these practices changed and/or varied among Pharmacy technicians over the history of the Pre-Filled Syringe Program.[82]

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[77] *Id*.
[78] *Id*. ¶ 63.
[79] *Id*.
[80] *Id*.
[81] *Id*. ¶ 65.
[82] *Id*.

Pharmacy had an "incentive program" whereby Pharmacy technicians who produced more syringes using overfill received higher bonuses; this created a financial incentive to use less drug product in each syringe, and thereby preserve more overfill.[83]

Pharmacy technicians pooled drug product in a so-called "cleanroom."[84] On multiple occasions the air flow hoods in the cleanroom tested positive for bacteria in excess of acceptable levels.[85] Pharmacy had the air hoods cleaned following the positive tests, but did not conduct follow-up sampling to determine if the bacterial contamination had been removed by the cleaning.[86] Additionally, the air in the cleanrooms tested positive for fungal contamination and/or bacterial contamination in excess of acceptable levels on multiple occasions, but Pharmacy did not cease operations during cleaning or conduct any immediate follow-up sampling.[87] Pharmacy did not alert health care providers who received the pre-filled syringes of the positive tests.[88] Additionally, Pharmacy staff routinely entered cleanrooms "without wearing any gowns or other protective clothing, and wore exposed jewelry, makeup, nail polish and street clothing," while preparing pre-filled syringes.[89] Non-

[83] *Id*. ¶ 66.
[84] *Id*. ¶ 67.
[85] *Id*.
[86] *Id*.
[87] *Id*. ¶ 68.
[88] *Id*.
[89] *Id*. ¶ 69 (internal quotation marks omitted).

sterile items were also left in the cleanrooms, including open Band-Aids, iPods and exposed earbuds, skin lotion, aloe gel, chewing gum, lip balm, and non-sterile mops.[90]

C. Criminal Guilty Plea and Civil Settlement Relating to the Pre-Filled Syringe Program

1. The Criminal Information

On September 11, 2017, the United States Department of Justice ("DOJ") filed a Criminal Information against Specialty resulting from allegations related to the Pre-Filled Syringe Program (the "Criminal Information").[91] The Criminal Information charged Specialty with the introduction of misbranded drugs into interstate commerce under the Food and Drug Commission Act ("FDCA") under 21 U.S.C. §§ 331(a), 333(a)(1), 352(o), and 360, and 18 U.S.C. §§ 2, 3551 *et seq*.[92]

The Criminal Information noted that it is illegal to introduce an unapproved new drug into interstate commerce unless an approved new drug application ("NDA"), biologics license application ("BLA") or similar application is in effect for the drug.[93] The Criminal Information alleged that "commercial repackaging of FDA-approved sterile injectable drugs or biologics from their original containers

[90] *Id*.
[91] *Id*. ¶ 72.
[92] *Id*.
[93] *Id*. ¶ 46; Compl., Ex. 3 ("Criminal Information"), ¶ 10. The similar applications, as identified in the Criminal Information, are an abbreviated new drug application or an investigational new drug application. Criminal Information, ¶ 10.

(i.e. glass vials) into syringes, using a process that contradicted the instructions for the approved drug" was not exempt from filing an NDA or BLA "and in any event doing so without obtaining patient specific prescriptions for such repackaged products required filing a new NDA or BLA."[94] The Criminal Information alleged that Specialty "unlawfully introduced unapproved new drugs into interstate commerce via its [Pre-Filled Syringe] Program, which engaged in the removal of FDA-approved drug product from glass vials and the repackaging of that product into plastic syringes."[95]

The Criminal Information also noted that any entity engaged in the "manufacture, preparation, propagation, compounding or processing" of a drug must register with the FDA.[96] The requirement to register with the FDA "applied to entities engaged in 'repacking' or 'otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.'"[97] If a drug was manufactured, prepared, propagated, compounded, or processed in an establishment in any state not duly registered with the FDA it was deemed misbranded under the

[94] Criminal Information, ¶ 13.
[95] *Id*. ¶ 69.
[96] *Id*. ¶ 15.
[97] *Id*.

FDCA, but an entity operating as a pharmacy may have qualified for certain exemptions, including by conformity with local laws regulating the practice of pharmacy and medicine.[98] The Criminal Information alleged that Specialty did not register Pharmacy as a repackager or manufacturer with the FDA, in an attempt to avoid the FDA's regulatory oversight and instead Specialty portrayed Pharmacy as a state-regulated pharmacy operated in compliance with local state law.[99] Per the Criminal Information however, Pharmacy "did not function in accordance with local state laws, and functioned solely to repackage drug product from vials to [pre-filled syringes] on a massive commercial scale."[100]

The Criminal Information alleged that the business model for the Pre-Filled Syringe Program was "known to and approved at the highest levels of [Specialty] and ABC."[101] Furthermore, in addition to charging Specialty with the introduction of misbranded drugs into interstate commerce, the Criminal Information also included a criminal forfeiture allegation.[102] The Criminal Information served as the first disclosure to ABC's stockholders of the alleged misconduct that occurred at Pharmacy.[103]

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[98] *Id*. ¶ 16.
[99] *Id*. ¶ 66.
[100] *Id*.
[101] *Id*. ¶ 25.
[102] Compl., ¶ 72.
[103] *Id*. ¶ 74.

2. The Criminal Guilty Plea

On September 27, 2017 Specialty pleaded guilty to violating the FDCA.[104] In the plea agreement, Specialty admitted that in operating the Pre-Filled Syringe Program, Pharmacy's staff "opened sterile vials, pooled the drug product from the vials, and then transferred the drug product into smaller [pre-filled syringes]."[105] Specialty also admitted that Pharmacy "often dispensed [pre-filled syringes] in response to order forms that were not prescriptions signed by practitioners," and "often filled orders that had been submitted with a single patient name, and/or assigned a single individual's name to an order of [pre-filled syringes], in excess of plausible and/or safe use of the drug product contained in the syringes."[106]

Specialty admitted that it did not register Pharmacy with the FDA as required by the FDCA, and that Pharmacy did not qualify for an exemption to the registration requirement for pharmacies that maintained establishments in conformance with applicable local laws regulating the practice of pharmacy.[107] To fully comply with Alabama pharmacy law, Pharmacy was required to maintain the medication history, diagnosis, laboratory data, and other pertinent information for the patients to whom pre-filled syringes were administered.[108] Finally, Specialty admitted to have

[104] *Id*. ¶ 75; *see* Compl., Ex. 4 ("Plea Agreement").
[105] Plea Agreement, ¶ 6.
[106] *Id*. ¶ 8.
[107] *Id*. ¶¶ 9–10.
[108] *Id*. ¶ 10.

"introduced, or caused the introduction of, misbranded drugs into interstate commerce, as such drugs were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with the FDA . . . ."[109]

Pursuant to its guilty plea, Specialty paid $260 million to the DOJ, consisting of a $208 million criminal fine and a criminal money forfeiture of $52 million ABC had obtained from unlawful sales of pre-filled syringes in violation of the FDCA.[110]

3. Civil Settlement

On November 21, 2017, ABC announced via an SEC filing that Specialty had reached an agreement in principle with the United States Attorney's Office for the Eastern District of New York to resolve civil claims under the False Claims Act for $625 million.[111] The filing stated:

> Since fiscal 2012, [ABC and Specialty] have been responding to subpoenas from the U.S. Attorney's Office for the Eastern District of New York ("USAO-EDNY") requesting production of documents and information relating to the pre-filled syringe program of [Pharmacy] . . . , [Specialty's] oncology distribution center, its group purchasing organization for oncologists, and intercompany transfers of certain oncology products. [Pharmacy] voluntarily ceased operations in early 2014. [ABC] has produced documents and witnesses, and has engaged in [an] ongoing dialogue with the USAO-EDNY, since 2012.[112]

An accompanying press release stated:

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[109] *Id.* ¶ 11.
[110] Compl., ¶ 79.
[111] *Id.* ¶ 80.
[112] *Id.*

> The United States contends that ABC sought to profit from the excess drug product or "overfill" contained within the original FDA-approved sterile vials for these cancer supportive injectable drugs by establishing a pre-filled syringe program through a subsidiary that it claimed was a pharmacy. The United States alleged that the "pharmacy" **was in reality** a repackaging operation that created and shipped millions of pre-filled syringes to oncology practices for administration to cancer-stricken patients. As part of this operation, ABC purchased original vials from their respective manufacturers, broke their sterility, pooled the contents, and repackaged the drugs into pre-filled syringes.[113]

The press release also noted that it was alleged that ABC "never submitted any safety, stability, or sterility data to the FDA to show that its operation ensured the safety and efficacy of the repackaged drug products," and that it was alleged that the pre-filled syringes were "prepared in non-sterile conditions, contaminated with bacteria and other unknown particles, and lacked the required quality and purity."[114]

The allegations specific to the False Claims Act were that by harvesting overfill, ABC was able to bill multiple healthcare providers for the same vial of drug, causing excess billing of federal health care programs, and that the Pre-Filled Syringe Program made it possible for ABC to provide drugs at a discount, enabling ABC to increase its market share.[115] The discounts were in the form of general pharmacy credits provided to customers, constituting "illegal kickbacks"—customers would be billed for the full price of a drug and then a "general credit"

[113] Compl., Ex. 6, at 1 (emphasis in original).
[114] *Id*.
[115] Compl., ¶ 82.

would be issued to customers' accounts, resulting in the submission of false claims to federal programs.[116]

D. ABC's Procedures for Oversight of Regulatory Compliance

According to ABC's Corporate Governance Principles, the Board is charged with providing "independent risk oversight with a focus on the most significant risks facing [ABC], including strategic, operational, and reputational risks."[117] The Board has five standing committees: the Audit Committee, the Compensation and Succession Planning Committee, the Finance Committee, the Governance and Nominating Committee, and the Executive Committee.[118] The Board has "delegated specific risk oversight responsibility" to all Committees other than the Executive Committee.[119] In addition to other specific responsibilities, the Board "asses[es] major risks facing [ABC] and review[s] options for their mitigation," and "ensur[es] processes are in place for maintaining the integrity of [ABC]," including "the integrity of compliance with law and ethics."[120]

Under the Audit Committee's Charter, the Audit Committee is charged with "assist[ing] the [Board] with oversight of [ABC's] compliance with legal and regulatory requirements and performance of [ABC's] internal audit function and

[116] *Id*.
[117] *Id*. ¶ 85; ABC-220 CONSOLIDATED R001754, at 1754.
[118] Compl., ¶ 85.
[119] *Id*.; ABC-220 CONSOLIDATED R001754, at 1754.
[120] ABC-220 CONSOLIDATED R001754, at 1754–55.

independent auditor."[121] The Audit Committee also "obtain[s] reports from management and [ABC's] senior internal auditor that [ABC] is in conformity with applicable legal requirements and [ABC's] Code of Ethics and Business Conduct."[122] ABC's Code of Ethics and Business Conduct states that ABC is "committed to the belief that, as a principle of sound management, all business dealings shall be conducted with the highest level of business ethics, honesty and integrity"—all directors, officers, and employees are "expected to . . . comply with all federal, state, and local laws, regulations and rules . . . ."[123] The Audit Committee is responsible for reporting regularly to the Board.[124]

During the relevant time period, the Board did not set aside a portion of Board meetings devoted to drug safety and compliance.[125] Aside from the Audit Committee's responsibility to assist the Board with oversight of compliance with legal and regulatory requirements, the Audit Committee was responsible to obtain reports from management and the senior internal auditor regarding ABC's compliance with legal and regulatory requirements.[126] The Audit Committee was not otherwise required to deliver written materials to the Board.[127]

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[121] Compl., ¶ 87; ABC-220 CONSOLIDATED R002236, at 2240.
[122] Compl., ¶ 87; ABC-220 CONSOLIDATED R002236, at 2240.
[123] Compl., ¶ 87 n.35; ABC-220 CONSOLIDATED R001803, at 1804.
[124] ABC-220 CONSOLIDATED R002236, at 2241.
[125] Compl., ¶ 88.
[126] *Id*.
[127] *Id*.

According to a document entitled "Corporate Compliance Program," ABC also established (or contemplated establishment of) an Office of Compliance to "oversee ABC's Compliance Program on an enterprise-wide basis."[128] A Chief Compliance Officer and a Chief Compliance Counsel were responsible for the Compliance Program.[129] The Plaintiffs' Verified Stockholder Derivative Complaint (the "Complaint") alleges that this document was a draft and was never completed, approved, or enacted.[130]

Additionally, ABC's Corporate Security and Regulatory Affairs ("Corporate Security") unit provides "regulatory compliance and security assistance to all operating units through the utilization of on-site audits[,] proactive/targeted visits, training seminars and investigations."[131] However, Corporate Security has no Board-level reporting obligations.[132]

No reports regarding ABC's compliance with applicable legal requirements were submitted to or obtained by the Audit Committee regarding Pharmacy or the Pre-Filled Syringe Program until after the Pre-Filled Syringe Program was shut down.[133] Additionally, neither the Board nor the Audit Committee ever received an

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[128] ABC-220 CONSOLIDATED R008943, at 8945.
[129] *Id*.
[130] Compl., ¶ 124 n. 58. As support, Plaintiffs point out that the document was one of several attachments to an email and that the file was titled as a "DRAFT." Pls.' Answering Br. in Opp'n to Defs.' Mot. to Dismiss, D.I. 16 ("Pls.' Answ. Br."), at 19 n.19.
[131] ABC-220 CONSOLIDATED R001763, at 1763.
[132] Compl., ¶ 107 n. 49.
[133] *Id*. ¶ 89.

update regarding compliance at Pharmacy or in connection with the Pre-Filled Syringe Program.[134]

E. The Board's Monitoring of Specialty, Oncology, Pharmacy, and the Pre-Filled Syringe Program

1. Expansion of the Oncology Facility

On May 11, 2006, ABC's then-CEO David R. Yost introduced a capital expenditure request to the Board to expand the Oncology facility in Dothan, Alabama where the Pre-Filled Syringe Program operated.[135] The majority of the expansion was dedicated to the facility whose sole business was to fill and distribute pre-filled syringes.[136] The capital expenditure request—which detailed the rationale for undertaking the project—did not address any compliance or safety issue or any expansion of compliance policies or procedures corresponding to the expansion of the facility.[137] The Board did not consider or discuss the regulatory and compliance issues implicated by the expansion at that time.[138] The Board approved the capital expenditure request to expand the Oncology facility.[139]

[134] *Id.*
[135] *Id.* ¶ 91.
[136] *Id.*
[137] *Id.* ¶ 92.
[138] *Id.* ¶ 94.
[139] *Id.* ¶ 91.

2. The Davis Polk Report

In 2007, Defendant Chou, acting on behalf of ABC, engaged Davis Polk & Wardwell ("Davis Polk") to "undertake an assessment of the adequacy of [ABC's] Compliance Program, to recommend improvements and to report the results of the assessment to the Audit Committee" (the "Davis Polk Report").[140]

Davis Polk notified the Audit Committee of deficiencies in ABC's compliance program. The areas for improvement in the Davis Polk Report included: (1) greater accountability for compliance violations; (2) better organizational optics around compliance function; (3) greater integration of Specialty from compliance standpoint; (4) additional centralization of compliance and security decision-making; and (5) better documentation and tracking of compliance and ethics processes.[141]

Important implications of Davis Polk's findings were that Specialty was not integrated into ABC's compliance and reporting function, and that oversight responsibilities were being left to officers and directors of the various ABC subsidiaries.[142]

[140] *Id*. ¶ 97.
[141] *Id*. ¶¶ 98–101; ABC-220 CONSOLIDATED R000001, at 0001–02.
[142] Compl., ¶¶ 99, 102.

In the aftermath of the Davis Polk Report the Board and the Audit Committee did not follow through on Davis Polk's recommendations.[143] Indeed, Pharmacy and Oncology were kept out of ABC's compliance programs for the entire period of the Pre-Filled Syringe Program's existence.[144]

With regard to greater integration of Specialty into ABC's compliance program and additional centralization of compliance authority, ABC's Chief Compliance Officer ("CCO") Debra Swartz described to the Audit Committee "efforts that [had] been implemented to increase oversight of [Specialty's] compliance activities by [Corporate Security]."[145] But there is no report to the Audit Committee detailing these efforts, and the Audit Committee never asked Swartz what such efforts were or whether they had been implemented.[146] Neither the Audit Committee nor the Board received a single report from Corporate Security concerning Specialty.[147]

Additionally, Swartz told the Audit Committee at the meeting where the Davis Polk Report was presented that she "had presented a preliminary response to the Davis Polk assessment and recommendations at the November 7, 2008 meeting and that she would now present a more fulsome [sic] response and action plan" to the

[143] *Id*. ¶ 104.
[144] *Id*. ¶ 105.
[145] *Id*. ¶ 107; ABC-220 CONSOLIDATED R000001, at 0002.
[146] Compl., ¶ 107.
[147] *Id*.

Audit Committee.[148] However, neither the "preliminary response" nor the "more fulsome response and action plan" were ever documented by Swartz or the Board.[149] Swartz also proposed that she would serve as Secretary of ABC's Ethics Committee so that the Audit Committee would have transparency into ABC's compliance activities.[150] The Audit Committee never received an update from the Ethics Committee nor does it appear that the Ethics Committee reported to the Board.[151]

Swartz had also informed the Audit Committee in response to the Davis Polk Report that an "electronic matter management system" would "enable [ABC] to track matters from opening to signoff."[152] However, the Audit Committee never heard or received a report from the system following Swartz's comments.[153] Swartz "presented a proposed penalty matrix . . . intended to provide for greater consistency of disciplinary action," and informed the Audit Committee that the matrix would be implemented around November 2008.[154] No documentation of the matrix or other reforms were presented to the Audit Committee or the Board.[155]

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[148] *Id.* ¶ 108; ABC-220 CONSOLIDATED R000001, at 0001. The November 2008 date is presumably an error, because the Audit Committee meeting was held in February 2008.
[149] Compl., ¶ 108.
[150] *Id.* ¶ 109.
[151] *Id.*
[152] *Id.* ¶ 111; ABC-220 CONSOLIDATED R000001, at 0001.
[153] Compl., ¶ 111.
[154] *Id.* ¶ 112; ABC-220 CONSOLIDATED R000001, at 0002.
[155] Compl., ¶ 112.

The Audit Committee never received any reports specifically concerning compliance at Pharmacy or in connection with the Pre-Filled Syringe Program.[156] The Board did not receive any updates or progress reports on ABC's reporting controls following the Davis Polk Report or any time thereafter.[157] Additionally, ABC had no committee specifically designated to oversee compliance with FDA rules and regulations.[158]

3. Mullen's Concerns and *Qui Tam* Action

Michael Mullen was an executive at Specialty beginning in 2003 and was appointed to ABC's Corporate Ethics Committee.[159] In September 2009, Mullen was promoted to COO of Specialty where he was responsible for Specialty's eight business units including the Oncology Group (which included Oncology and Pharmacy).[160]

By January 2010, Mullen had identified significant issues across all of Specialty's business units, including serious issues with Specialty's oncology business model that created regulatory exposure.[161] Mullen prepared six strategic initiatives to address Specialty's issues, which he summarized in a PowerPoint

[156] *Id.* ¶ 110.
[157] *Id.*
[158] *Id.* ¶ 113.
[159] *Id.* ¶ 114. Mullen was Specialty's CFO from May 2003 to September 2008 and in September 2008 was appointed President, Distribution Services at Specialty. *Id.*
[160] *Id.* ¶¶ 115–16.
[161] *Id.* ¶ 117.

presentation.[162] Mullen provided the presentation to Defendant Collis (and possibly ABC's then-CEO Yost), and presented the initiatives at a senior management retreat held in January 2010.[163] In the months after the retreat, Mullen repeated his concerns about Specialty's oncology business model to Collis and Yost, and in one such conversation Yost noted there were aspects of the Oncology Group's business—which operated under Specialty's umbrella—that he "would not want to see on the front page of the Wall Street Journal."[164]

Mullen met with Yost on March 23, 2010 regarding the Oncology Group, and was adamant that serious issues needed to be addressed.[165] Mullen's concerns encompassed a number of areas including business, competitiveness, and regulatory exposure.[166] Mullen provided Yost with another PowerPoint presentation detailing his concerns with the Oncology Group—Yost did not inform the Board of this information or provide the PowerPoint to the Board.[167]

After months of raising concerns about Specialty's oncology business and lobbying for ABC to address the compliance issues at Specialty, Mullen was terminated on April 8, 2010, in a meeting with Yost, June Berry (then ABC's head

[162] *Id.* ¶ 118.
[163] *Id.*
[164] *Id.*
[165] *Id.* ¶ 119.
[166] *Id.*
[167] *Id.*

of Human Resources), and Defendant Chou.[168] Management never told the Board about Mullen's compliance concerns or firing.[169] Likewise, Mullen's concerns were not documented, and the Board's Compensation Committee was not informed of (nor did it discuss) Mullen's departure even though it was required to "[a]pprove or recommend employment agreements and severance agreements for the CEO and other executive officers."[170] Shortly after Mullen was terminated he contacted Defendant Chou and later met with ABC's in-house counsel, Rob Stone, in May 2010.[171] At that meeting, Mullen provided Stone "extremely detailed written documentation" regarding "a long-standing, and very profitable Specialty oncology business group practice involving overfill and numerous oncology drugs."[172]

Several email exchanges from July 2010 indicate that Chou and others made inquiries into the Pre-Filled Syringe Program after Mullen's termination, but none of them were relayed to the Board.[173] On July 23, 2010 Rob Stone forwarded an email chain regarding overfill provisions in a proposed draft rule to the Medicare Physician Fee Schedule to Chou, CCO Swartz, and others—the forwarded chain includes a comment from a Senior Vice President at ABC that states: "Based on my understanding of how we managed PFS at OS, I 'think' we are fine . . . but I wanted

[168] *Id.* ¶ 122.
[169] *Id.* ¶ 123.
[170] *Id.* ¶ 124.
[171] *Id.* ¶ 125.
[172] *Id.*
[173] *Id.* ¶ 128.

to alert you all to this provision as it may be wise to have an external/expert legal review update an opinion on this issue."[174] An earlier email in the same chain from an employee of an ABC subsidiary states: "[Center for Medicare and Medicaid Services] recognizes that, in some cases, manufacturers intentionally include overfill (an amount over what's indicated on the FDA approved table) to ensure the patient will get the full dose. In the context of [Average Sales Price] calculation and drug payment, CMS proposes to clarify its regulations to clearly state that the unused overfill amount should not be harvested and billed incrementally. That is, the intentional overfill is 'free' product."[175] An email dated July 26, 2010, from Vinu Pillai, Specialty's Corporate Counsel, copied to Chou, attaches a "spreadsheet which lists all of Oncology Supply's contracted manufacturer products" and refers to a DVD regarding the "OS syringe pre-fill program."[176]

In 2010, ABC engaged the law firm Ober Kaler to conduct a compliance and regulatory review of the Oncology Group—the review was announced to the Audit Committee as a routine review.[177] After the Audit Committee discussed Ober Kaler's finding and recommendations, the Audit Committee "instructed

[174] *Id.*
[175] *Id.*
[176] *Id.* ¶ 129.
[177] *Id.* ¶ 131.

management to undertake appropriate consideration and follow up of the recommendations."[178]

ABC made some changes after the Ober Kaler presentation, such as commencing viable air sampling in Pharmacy's cleanroom and anterooms and conducting glove fingertip testing on Pharmacy technicians.[179] However, many of the unsanitary and unsterile conditions at the Oncology facility continued after the Ober Kaler review and ABC failed to follow up on those issues.[180] This included no follow up testing when bacteria was found in the flow hoods, and when bacterial and fungal infections were identified in the cleanroom and anterooms, and lack of follow up when gloved fingertip testing came back positive for bacterial contamination.[181]

In February 2011, Chou reported to the Audit Committee that ABC "was proceeding to implement all of the recommendations that were presented" by Ober Kaler.[182] But the Audit Committee did not follow up on whether management actually carried out Ober Kaler's recommendations, and no policies or procedures were implemented, revised, or updated in response to Ober Kaler's compliance and regulatory review.[183] The review by Ober Kaler and its findings and recommendations were not presented to ABC's full Board, and neither the Board

[178] *Id.*
[179] *Id.* ¶ 133.
[180] *Id.* ¶ 134.
[181] *Id.*
[182] *Id.* ¶ 136.
[183] *Id.*

nor the Audit Committee received subsequent reports on the sanitary, hygiene and/or sterile conditions in the Pre-Filled Syringe Program.[184]

Meanwhile, on October 21, 2010, Mullen filed a *qui tam* complaint under seal in federal district court in New York.[185] Mullen alleged that the Pre-Filled Syringe Program was an "overfill laundering scheme" involving "illegal kickbacks and price concessions" to physician customers and undermined accurate pricing by government healthcare programs, and that Pharmacy employed additional discounts, price concessions, and/or "general pharmacy credit" issued to the accounts of medical providers in furtherance of the program.[186] Counsel for ABC's management learned of the *qui tam* complaint in November 2010 when it was inadvertently made public, and counsel engaged outside law firm Morgan Lewis & Bockius LLP ("Morgan Lewis") without notifying the Board.[187] Chou circulated an email on November 17, 2010 to CCO Swartz and an attorney from Morgan Lewis with the subject "New Qui Tam – Privileged and Confidential – Writeup for EY," which was not sent to any Board members.[188]

ABC publicly disclosed Mullen's *qui tam* complaint in its Form 10-K filed with the Securities and Exchange Commission ("SEC") on November 23, 2010:

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[184] *Id*.
[185] *Id*. ¶ 137.
[186] *Id*.
[187] *Id*. ¶ 138.
[188] *Id*.

> The Company has learned that there are both prior and subsequent filings in another federal district, including a complaint filed by a former employee of the Company, that are under seal and that involve allegations similar to those in the Federal District Court Action against the same and/or additional subsidiaries or businesses of the Company that are defendants in the Federal District Court Action, including the Company's group purchasing organization for oncologists and the Company's oncology distribution business.[189]

The "Federal District Court Action" was a "qui tam matter . . . pending in the United States District Court for the District of Massachusetts . . . naming Amgen Inc., as well as two business units of [Specialty] . . . as defendants."[190] This matter is referred to herein as the *Westmoreland* case.

ABC's Board—including then-CEO Yost and current Board members Gochnauer, Henney, Hyle, Long, and McGee—all signed the 10-K.[191] ABC's 2011 Form 10-K contained a similar disclosure regarding the Mullen *qui tam*, and was likewise signed by the Board.[192] No remedial action was taken against any employee for the misconduct identified in Mullen's *qui tam* complaint.[193]

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[189] *Id.* ¶ 139.
[190] Defs.' Opening Br. in Support of Their Mot. to Dismiss, D.I. 10 ("Defs.' Opening Br."), Ex. 17, at 14. I take judicial notice of ABC's 2010 10-K.
[191] Compl., ¶ 140.
[192] *Id.* ¶ 141. The 2011 10-K was signed by Board members Collis, Gochnauer, Henney, Hyle, Long, and McGee. *Id.*
[193] *Id.* ¶ 142.

4. Search Warrant; USAO Subpoena; Article on Pre-Filled Syringe Program

In 2012, FDA agents executed a search warrant on the Oncology facility in Dothan, Alabama where the Pre-Filled Syringe Program operated.[194] The incident was reported in the press, and an article on the search warrant quoted ABC's corporate spokesperson.[195] ABC's Form 10-K filed in November 2012 disclosed that Specialty had received a subpoena from the United States Attorney's Office.[196] The 2012 10-K was signed by current Board members Collis, Gochnauer, Henney, Hyle, Long, and McGee.[197] Neither the search warrant nor the subpoena were mentioned in the Audit Committee's or the Board's meeting minutes or materials.[198]

On November 15, 2012, ABC's Board held a meeting attended by current Board members Collis, Henney, Hyle, Long, and McGee—the Board minutes state: "Mr. Collis reported on a possible article being prepared by a reporter on pre-filled syringes and the Company's response to the article. There was discussion of a possible article on the subject of pre-filled syringes and developments in this area."[199] The Board appears to have discussed the article, but apparently did not then

[194] *Id.* ¶ 143.
[195] *Id.*
[196] *Id.* ¶ 144.
[197] *Id.*
[198] *Id.* ¶¶ 143–44.
[199] *Id.* ¶ 145.

discuss then underlying issues, *i.e.* compliance issues with the Pre-Filled Syringe Program.[200]

F. Closure of the Oncology Facility

In January 2014, ABC and Specialty ended the Pre-Filled Syringe Program by closing the Oncology facility in Dothan, Alabama.[201] The Audit Committee's first mention of ending the Pre-Filled Syringe Program was on April 23, 2014, where the Audit Committee was informed that "the [Specialty] operating income included the loss of income from a[] [Specialty] pharmacy closure in Dothan, Alabama."[202] The Audit Committee next discussed the Oncology facility closure at a meeting on July 23, 2014.[203] No discussion occurred regarding why the Oncology facility was closing.[204]

G. Procedural History

The Plaintiffs filed the Complaint on October 11, 2019. The Complaint pleads two counts of breach of fiduciary duty (Counts I and II).[205] Count I is asserted against Defendants Collis, Gochnauer, Greenberg, Henney, Hyle, Long, and McGee (the "Director Defendants").[206] Count I alleges that the Director Defendants

[200] *Id.* ¶ 146.
[201] *Id.* ¶ 147.
[202] *Id.*
[203] *Id.*
[204] *Id.*
[205] *Id.* ¶¶ 207–21.
[206] *Id.* ¶¶ 207–14.

consciously failed to implement and monitor compliance policies and systems and failed to exercise their oversight responsibilities.[207] The seven Director Defendants are all current directors of ABC.[208]

Count II is asserted against Defendants Collis, Chou, and Guttman (the "Officer Defendants").[209] Collis is ABC's Chairman, President, and CEO; Chou is the EVP of ABC and ABC's Chief Legal & Business Officer; Guttman was a senior executive at ABC from 2002 to 2018.[210] Count II alleges that the Officer Defendants consciously breached their fiduciary duties and violated corporate responsibilities by knowingly operating and maintaining an illegal business model, and failed to inform the Board about the Pre-Filled Syringe Program's regulatory compliance.[211]

Count III alleges unjust enrichment against Collis.[212]

The Defendants moved to dismiss this Action on December 20, 2019. I heard Oral Argument on May 27, 2020, and considered the matter submitted for decision on that date.

II. ANALYSIS

The Defendants have moved to dismiss the Complaint pursuant to Chancery Court Rule 23.1 for failure to make a demand on the Board and failure to plead

[207] *Id.* ¶¶ 210–11.
[208] *Id.* ¶¶ 34–35, 164.
[209] *Id.* ¶¶ 215–21.
[210] *Id.* ¶¶ 24, 32–33.
[211] *Id.* ¶ 220.
[212] *Id.* ¶¶ 222–23.

demand futility.[213] The Defendants have also moved to dismiss under Chancery Court Rule 12(b)(6) for failure to state a claim upon which relief may be granted.[214]

A. Rule 23.1

A "cardinal precept" of Delaware corporate law is that the board of directors, not stockholders, manage the business and affairs of the corporation.[215] Thus, ordinarily, in the aftermath of a corporate trauma it falls to the board of directors to determine the corporation's course of action, including whether to pursue litigation against the individuals involved.[216] But in a derivative suit, a stockholder seeks to sue on behalf of the corporation when the board fails to deploy a litigation asset.[217] Because a derivative action necessarily "impinges on the managerial freedom of directors," Rule 23.1 requires that, where a stockholder has not demanded the directors pursue the claim, the complaint must "allege with particularity the reasons for not making the effort to make a litigation demand."[218] In other words, "[t]o wrest control over the litigation asset away from the board of directors, the stockholder

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[213] Ch. Ct. R. 23.1.
[214] Ch. Ct. R. 12(b)(6).
[215] *Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984) (citing 8 *Del. C.* §141(a)). *Aronson*, along with six other cases, were overturned by *Brehm v. Eisner*, 746 A.2d 244 (Del. 2000) "to the extent they reviewed a Rule 23.1 decision by the Court of Chancery under an abuse of discretion standard or otherwise suggested deferential appellate review." *Hughes v. Hu*, 2020 WL 1987029, at *9 n.1 (Del. Ch. Apr. 27, 2020). *Aronson*, and the other overturned cases, otherwise remain good law, and this decision does not rely on *Aronson* for the standard of appellate review, and omits the subsequent case history. *See id*.
[216] *Hughes*, 2020 WL 1987029, at *9.
[217] *Aronson*, 473 A.2d at 811.
[218] *Hughes*, 2020 WL 1987029, at *10 (quoting Ch. Ct. R. 23.1).

must demonstrate that demand on the board to pursue the claim would be futile such that the demand requirement should be excused."[219]

The Plaintiffs have pled derivative claims and concede they have not made a litigation demand on the Board, but plead that demand would have been futile.[220] Because the Plaintiffs have not made a litigation demand, the Plaintiffs can only surmount Rule 23.1's demand requirement if "demand is excused because the directors are incapable of making an impartial decision regarding whether to institute [this] litigation."[221] In pleading demand futility, the Complaint "must comply with stringent requirements of factual particularity that differ substantially from the permissive notice pleadings governed solely by Chancery Rule 8(a)."[222] The Complaint must set forth "particularized factual statements that are essential to the claim."[223] However, on a Rule 23.1 motion all well-pleaded factual allegations are accepted as true, and "[o]nce a plaintiff has made particularized allegations, the plaintiff is entitled to all 'reasonable inferences [that] logically flow from particularized facts alleged.'"[224]

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[219] *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *11 (Del. Ch. Oct. 1, 2019) (citing *Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1044 (Del. 2004)).
[220] Compl., ¶ 163.
[221] *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 367 (Del. 2006).
[222] *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000).
[223] *Id*.
[224] *In re Ezcorp Inc. Consulting Agreement Derivative Litig.*, 2016 WL 301245, at *34 (Del. Ch. Jan. 25, 2016) (quoting *Beam*, 845 A.2d at 1048).

The Plaintiffs have pled that the Board that would consider a demand is composed of the seven Director Defendants and two non-parties: Ornella Barra and D. Mark Durcan (the Director Defendants, together with Barra and Durcan, the "Demand Board").[225]

Because the Plaintiffs challenge board *inaction*, and not a specific board decision, demand futility is analyzed under the test articulated in *Rales v. Blasband*.[226] To show that demand is futile in such an instance, a plaintiff must allege "particularized facts that 'create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand.'"[227] A director cannot exercise her independent and disinterested business judgment where a director is "either interested in the alleged wrongdoing or not independent of someone who is."[228]

A plaintiff can raise a reasonable doubt regarding a board's interestedness "by alleging particularized facts that reveal board inaction of a nature that would expose

[225] Compl., ¶¶ 34–35, 164.
[226] 634 A.2d 927 (Del. 1993); *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *11 (Del. Ch. Oct. 1, 2019); *In re Citigroup Inc. S'holder Derivative Litig.*, 964 A.2d 106, 120 (Del. Ch. 2009).
[227] *Citigroup*, 964 A.2d at 120 (quoting *Rales*, 634 A.2d at 933–34).
[228] *Hughes v. Hu*, 2020 WL 1987029, at *12 (Del. Ch. Apr. 27, 2020).

at least half of the directors to a substantial likelihood of personal liability."[229] To plead a substantial risk of liability, a plaintiff need not "demonstrate a reasonable probability of success on the claim," instead, a plaintiff "need only 'make a threshold showing, through the allegation of particularized facts, that their claims have some merit.'"[230]

Alternatively, the Plaintiffs could plead demand futility by raising a reasonable doubt that a majority of the Demand Board is independent.[231] "[A] lack of independence turns on 'whether the plaintiffs have pled facts from which the director's ability to act impartially on a matter important to the interested party can be doubted because that director may feel either subject to the interested party's dominion or beholden to that interested party."[232] All pled facts pertinent to a director's relationship to the interested party must "be considered in full context in making the, admittedly imprecise, pleading stage determination of independence."[233]

"If the board of directors lacks a majority comprising independent and disinterested directors, then demand is futile."[234]

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[229] *Oklahoma Firefighters Pension & Ret. Sys. v. Corbat*, 2017 WL 6452240, at *14 (Del. Ch. Dec. 18, 2017) (quoting *Horman v. Abney*, 2017 WL 242571, at *6 (Del. Ch. Jan. 19, 2017)) (internal quotation marks omitted).
[230] *Hughes*, 2020 WL 1987029, at *12 (quoting *Rales*, 634 A.2d at 934).
[231] *Rales*, 634 A.2d at 936.
[232] *Sandys v. Pincus*, 152 A.3d 124, 128 (Del. 2016) (quoting *Delaware Cty. Employees Ret. Fund v. Sanchez*, 124 A.3d 1017, 1023 n.25 (Del. 2015)).
[233] *Sandys*, 152 A.3d at 128 (quoting *Sanchez*, 124 A.3d at 1022).
[234] *In re Ezcorp Inc. Consulting Agreement Derivative Litig.*, 2016 WL 301245, at *34 (Del. Ch. Jan. 25, 2016).

Count I is styled as claiming breach of duty under the theory articulated by Chancellor Allen in *In re Caremark Int'l Inc. Derivative Litigation*.[235] The Plaintiffs also plead claims against three ABC officers (one of whom is also a director). The claims against the Officer Defendants are breach of fiduciary duty (Count II) and an unjust enrichment claim against Collis (Count III).[236]

Below, I analyze whether demand was excused as to Counts I, II, and III. I find that a majority of the Demand Board faces a substantial likelihood of liability as to Count I, and therefore the Demand Board cannot bring its independent and disinterested business judgment to bear in considering a demand. Consequently, demand is excused as to Count I. Because Count I is necessarily bound up with the claims against the Officer Defendants, demand is excused as to Counts II and III as well.

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[235] 698 A.2d 959 (Del. Ch. 1996); *see e.g.* Compl., ¶ 210 ("The Director Defendants consciously breached their fiduciary duties and violated their corporate responsibilities by failing to implement and monitor compliance policies and systems to ensure the safety of the Company's [Pre-Filled Syringe] Program.").

[236] Count II is *not* a *Caremark* claim but a conventional claim for breach of fiduciary duty. Compl., ¶¶ 216, 218–19 ("[T]he Officer Defendants owed and owe [ABC] and its stockholders the highest duties of good faith, due care, and loyalty . . . . The Officer Defendants consciously breached their fiduciary duties and violated their corporate responsibilities by knowingly operating and maintaining an illegal business model . . . . [T]he Officer Defendants also consciously breached their fiduciary duties and violated their corporate responsibilities by failing to inform the Board about the [Pre-Filled Syringe] Program's regulatory compliance.").

B. Demand is Excused as to Count I

Count I alleges that the Director Defendants "consciously breached their fiduciary duties by failing to exercise their oversight responsibilities."[237] Under *Caremark* and its progeny, "a director must make a good faith effort to oversee the company's operations."[238] "A *Caremark* claim contends that the directors set in motion or 'allowed a situation to develop and continue which exposed the corporation to enormous legal liability and that in doing so they violated a duty to be active monitors of corporate performance.'"[239] Such a claim "'is rooted in concepts of bad faith; indeed, a showing of bad faith is a necessary condition to director oversight liability.'"[240] Because a *Caremark* claim must plead bad faith, "a plaintiff must allege facts that allow a reasonable inference that the directors acted with scienter which, in turn, requires not only proof that a director acted inconsistently with his fiduciary duties, but also most importantly, that the director knew he was so acting."[241] A *Caremark* claim is "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."[242]

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[237] *Id.* ¶ 211.
[238] *Marchand v. Barnhill*, 212 A.3d 805, 820 (Del. 2019) (citing *Caremark*, 698 A.2d at 970).
[239] *South v. Baker*, 62 A.3d 1, 14 (Del. Ch. 2012) (quoting *Caremark*, 698 A.2d at 967).
[240] *City of Birmingham Ret. & Relief Sys. v. Good*, 177 A.3d 47, 55 (Del. 2017) (quoting *In re Citigroup Inc. S'holder Derivative Litig.*, 964 A.2d 106, 123 (Del. Ch. 2009)).
[241] *Oklahoma Firefighters Pension & Ret. Sys. v. Corbat*, 2017 WL 6452240, at *14 (Del. Ch. Dec. 18, 2017) (quoting *Horman v. Abney*, 2017 WL 242571, at *7 (Del. Ch. Jan. 19, 2017)); *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *12 (Del. Ch. Oct. 1, 2019)).
[242] *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 372 (Del. 2006).

Caremark claims can take two forms. A so-called "prong one" claim arises where "the directors utterly failed to implement any reporting or information system or controls."[243] Under "prong one," "a director may be held liable if she acts in bad faith in the sense that she made no good faith effort to ensure that the company had in place any system of controls."[244] A "prong two" claim, on the other hand, arises where "having implemented such a system or controls, [the directors] consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."[245] To state a "prong two" *Caremark* claim, the Plaintiffs must "plead [particularized facts] that the board knew of evidence of corporate misconduct—the proverbial 'red flag'—yet acted in bad faith by consciously disregarding its duty to address that misconduct."[246] "[A] plaintiff asserting a *Caremark* oversight claim must plead with particularity 'a sufficient connection between the corporate trauma and the board.'"[247]

The Plaintiffs allege that the Director Defendants face a substantial likelihood of liability under *both* prongs of *Caremark*.[248]

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[243] *Id*. at 370.
[244] *Hughes v. Hu*, 2020 WL 1987029, at *14 (Del. Ch. Apr. 27, 2020) (quoting *Marchand v. Barnhill*, 212 A.3d 805, 822 (Del. 2019)).
[245] *Stone*, 911 A.2d at 370 (Del. 2006).
[246] *Horman*, 2017 WL 242571, at *10 (quoting *Reiter on Behalf of Capital One Fin. Corp. v. Fairbank*, 2016 WL 6081823, at *8 (Del. Ch. Oct. 18, 2016)).
[247] *Reiter*, 2016 WL 6081823, at *8 (quoting *Louisiana Mun. Police Empls.' Ret. Sys. v. Pyott*, 46 A.3d 313, 340 (Del. Ch. 2012), *rev'd on other grounds*, 74 A.3d 612 (Del. 2013)).
[248] Compl., ¶¶ 179 ("By utterly failing to ensure that there was a system in place that would bring to the Board's attention flagrant violations of federal law . . . the Defendants scorned their fiduciary

Seven members of the Demand Board (the Director Defendants) are alleged to have served as ABC directors during the unlawful operation of the Pre-Filled Syringe Program. Five of the Director Defendants have served on the Board since at least May 2010.[249] Additionally, five of the Director Defendants served on the Audit Committee during the period most pertinent to this Action.[250] The Defendants *do not* argue that a majority of the Demand Board are insulated from a substantial likelihood of liability because they were not directors during the relevant time period. If the five Director Defendants who have served on the Board since May 2010 (at a minimum) face a substantial likelihood of liability, the Board cannot properly exercise its independent and disinterested business judgment in responding to a demand.

I find below that a majority of the Demand Board faces a substantial likelihood of liability for Count I because the Plaintiffs have adequately pled that a majority of the Demand Board consciously ignored red flags rising to the level of bad faith.

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duties. In doing so, the Director Defendants—including seven members of the Demand Board—face a substantial risk of liability."), 186 ("This repeated failure of the Board and its committees to supervise ABC's officers and employees to prevent illegal activity and to respond to red flags exposes the directors to a substantial risk of liability for their fiduciary breaches.").

[249] *Id.* ¶ 169. The tenures of the Director Defendants is as follows: Henney (since January 2002); McGee (since November 2004); Long (since May 2006); Gochnauer (since September 2008); Hyle (since May 2010); Collis (since 2011); and Greenberg (since May 2013). *Id.*

[250] *Id.* ¶ 148. These Audit Committee members and their tenures are as follows: Gochnauer (2011–12), Henney (2004–10), Hyle (2010–17; Chair 2011–16), Long (2011–17), and McGee (2009–15; 2018–present). *Id.*

1. Caremark's Second Prong and Drug Health and Safety as a Mission Critical Compliance Risk

Again, to state a "prong two" *Caremark* claim requires a pleading of particularized facts that the board knew of red flags but consciously disregarded them in bad faith. That is, to survive the Motion to Dismiss under Rule 23.1, the Complaint must plead particularized facts that the Defendant Directors knew of red flags, but acted in bad faith by consciously disregarding their duty to address the misconduct alerted to by such red flags.[251] "In this context, bad faith means 'the directors were conscious of the fact that they were not doing their jobs, and that they ignored red flags indicating misconduct in defiance of their duties.'"[252] "The court must remain mindful that 'red flags are only useful when they are either waived in one's face or displayed so that they are visible to the careful observer.'"[253] The "careful observer" in this regard is "one whose gaze is fixed on the company's mission critical regulatory issues."[254]

The concept of mission critical compliance risk emanates from our Supreme Court's decision in *Marchand v. Barnhill*.[255] In *Marchand,* the company, Blue Bell

[251] *Horman*, 2017 WL 242571, at *10.
[252] *Id*. (quoting *David B. Shaev Profit Sharing Account v. Armstrong*, 2006 WL 391931, at *5 (Del. Ch. Feb. 13, 2006), *aff'd*, 911 A.2d 802 (Del. 2006)).
[253] *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *13 (Del. Ch. Oct. 1, 2019) (quoting *Wood v. Baum*, 953 A.2d 136, 143 (Del. 2008)).
[254] *Id*. (citing *Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019)).
[255] 212 A.3d 805 (Del. 2019).

Creameries, distributed ice cream containing the deadly bacteria *listeria*.[256] The Supreme Court found that Blue Bell's board had failed to put in place a reasonable system of monitoring and reporting on food safety, which for a "monoline company that makes a single product . . . ice cream" was an "essential and mission critical" compliance risk.[257] In *In re Clovis Oncology, Inc. Derivative Litigation*,[258] this Court found that a complaint alleging with particularity that a biopharmaceutical firm (Clovis) whose board consciously ignored red flags that "revealed a mission critical failure to comply" with a market-standard protocol and associated FDA regulations stated a claim under *Caremark*'s second prong.[259] Like Blue Bell Creameries, Clovis was a "monoline company operat[ing] in a highly regulated industry."[260] Clovis's board's conscious disregard imperiled FDA approval of a promising drug that was "intrinsically critical to [Clovis's] business operation."[261]

Though ABC is a relatively more complex corporation than either Blue Bell Creameries or Clovis, that does not mean the concept of mission critical compliance risk is inapplicable here. ABC is a "manufacturer, distributor, and packager of pharmaceutical drugs."[262] ABC operates in a highly regulated industry.[263] The

[256] *Id*. at 807.
[257] *Id*. at 809, 824.
[258] 2019 WL 4850188 (Del. Ch. Oct. 1, 2019).
[259] *Id*. at *15.
[260] *Id*. at *1.
[261] *Id*.
[262] Compl., ¶ 40.
[263] *Id*. ¶ 86.

Plaintiffs have pled that "compliance with FDA regulations is [ABC's] primary regulatory concern and is absolutely critical to its business."[264] Laws and regulations governing the health and safety of drugs are thus the "most central . . . safety and legal compliance issue facing the company."[265] And "when a company operates in an environment where externally imposed regulations govern its 'mission critical' operations, the board's oversight function must be more rigorously exercised."[266] Thus, when regulations governing drug health and safety are at issue, ABC's Board must actively exercise its oversight duties in order to properly discharge its duties in good faith. The allegations here are a prime example: flouting laws meant to ensure the safety and purity of drugs destined for patients suffering from cancer is directly inimical to the central purpose of ABC's business. I now examine the purported red flags in light of this standard.

2. The Plaintiffs Have Pled Facts From Which I Can Reasonably Infer that the Board Consciously Ignored Red Flags[267]

The Plaintiffs allege that the Board and its committees failed to "supervise ABC's officers and employees to prevent illegal activity and to respond to red

[264] *Id.* ¶ 40.
[265] *Marchand v. Barnhill*, 212 A.3d 805, 824 (Del. 2019).
[266] *Clovis*, 2019 WL 4850188, at *13 (quoting *id.*).
[267] As noted, *supra*, the documents included in ABC's Section 220 production are deemed incorporated into the Complaint regardless of whether they are cited by the Plaintiffs. But "Section 220 documents, hand selected by the company, cannot be offered to rewrite an otherwise well-pled complaint." *Id.* at *14 n.216. "The only effect" of the condition that Section 220 documents are deemed incorporated into the Complaint "will be to ensure that the plaintiff cannot seize on a document, take it out of context, and insist on an unreasonable inference that the court could not

flags."[268] The Complaint pleads four separate instances of red flags (some multi-part) that the Plaintiffs allege were ignored by ABC's Board: (1) the 2006 capital expenditure request to expand the Oncology facility, (2) the 2008 Davis Polk Report, (3) Mullen's allegations and *qui tam* suit, and (4) the 2012 DOJ subpoena and FDA search warrant. Per the Plaintiffs, these red flags signaled to the Board that ABC was engaged in illegal conduct in operating the Pre-Filled Syringe Program.

a. 2006 Capital Expenditure Request

The Plaintiffs contend that the Board's consideration of the 2006 capital expenditure request demonstrated conscious disregard of a red flag because the capital expenditure request "did not address any compliance or safety issues or any expansion of compliance policies or procedures to correspond to the expansion of

draw if it considered related documents." *Id*. (quoting *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 798 (Del. Ch. 2016), *abrogated on other grounds*, 214 A.3d 933 (Del. Aug. 7, 2019)). In line with this standard, I determine, with reference to the Complaint, whether I can reasonably draw the inferences the Plaintiffs ask me to draw—the Section 220 documents are used only to test whether those inferences which are reasonable from the face of the Complaint are rendered unreasonable by reference to a document incorporated by reference. Where the Plaintiffs have adequately pled a fact, a Section 220 document *suggesting* the facts are otherwise is insufficient at the pleading stage to refuse to draw the reasonable inference in the Plaintiffs' favor. *Yahoo!*, 132 A.3d at 798 ("If there are factual conflicts in the documents or the circumstances support competing interpretations, and if the plaintiff makes a well-pleaded factual allegation, then the allegation will be credited. The plaintiff also will be entitled to 'all reasonable inferences.' This means that if a document or the circumstances support more than one possible inference, and if the inference that the plaintiff seeks is reasonable, then the plaintiff receives the inference." (internal citations omitted)); *accord id*. At the pleading stage, "Defendants cannot ask the court to accept their Section 220 documents as definitive fact and thereby turn pleading stage inferences on their head. That is not, and should not be, the state of our law." *Clovis*, 2019 WL 4850188, at *14 n.216.

[268] Compl., ¶ 186.

the facility," the Board "was neither asked to approve the expenditure of any funds for the expanded [Oncology] facility's compliance needs nor did it discuss the need for compliance at the facility," and "there was no indication there was any regulatory or other compliance system even in place (much less being followed) at the Dothan, Alabama facility."[269] But this is not a particularized pleading of facts demonstrating conscious disregard of a red flag, because nowhere does the Complaint plead *what the red flag was*. The Complaint instead appears to plead that it is obvious that a compliance discussion should have occurred in connection with the capital expenditure request, and the fact that such a discussion did not occur was itself sufficient to alert the Board that the Oncology facility was not operating in accordance with health and safety rules regarding drug manufacture and distribution. Although drug health and safety is a mission critical compliance risk for ABC, there is simply no particularized pleading of a red flag in connection with the expansion.[270] The allegation is that the Board did not ask enough questions. That, to my mind, tends to indicate that in bringing an expanded Oncology facility on line, the Board failed in its duty to implement a compliance system, a fact important to a "prong one" *Caremark* analysis. It does not, however, indicate that the Board ignored a

[269] *Id.* ¶ 92.

[270] *See In re Citigroup Inc. S'holders Litig.*, 2003 WL 21384599, at *2 (Del. Ch. June 5, 2003) ("'Red flags' are only useful when they are either waived in one's face or displayed so that they are visible to the careful observer.").

"red flag" pertinent to "prong two." Without a pleading of *something* that the Board ignored, even though the allegation concerns a mission critical compliance risk, it is not reasonably conceivable that the 2006 capital expenditure request constituted a red flag.

b. The Davis Polk Report

Next are the Plaintiffs' allegations regarding the Davis Polk Report. The Plaintiffs have pled that the Davis Polk Report indicated that Specialty and its subsidiaries—including Pharmacy and Oncology—were operating outside of ABC's compliance controls and that "there were no reporting structures in place to inform the Board of compliance-related violations or complaints pertaining to [Specialty's] businesses, including the [Pre-Filled Syringe] Program."[271] The Complaint also alleges that the Davis Polk Report indicated that ABC had no centralized compliance and reporting structure, that there was inadequate documentation and tracking of compliance and ethics processes, and that there was inadequate accountability for compliance violations at ABC.[272]

The Plaintiffs allege that the Audit Committee and the Board ignored Davis Polk's recommendations and "failed to take any steps to ensure that [ABC's] inadequate compliance and reporting program was remedied."[273] Indeed, per the

[271] Compl., ¶ 98.
[272] *Id*. ¶¶ 99–101.
[273] *Id*. ¶ 104.

Complaint, Pharmacy and Oncology were kept out of ABC's compliance programs for the entire period of the Pre-Filled Syringe Program's existence, and "ABC excluded the entire [Pre-Filled Syringe] Program from its standard regulatory audit and pedigree compliance programs."[274] Supporting this allegation, the Plaintiffs have pled that the Audit Committee never received *any* reports specifically concerning compliance at Pharmacy or in connection with the Pre-Filled Syringe Program.[275]

Again, the lack of a reporting system for the recently-acquired Specialty business suggests a "prong one" failure of *Caremark* oversight. But, pertinent to "prong two," it is reasonably conceivable that the Davis Polk Report, at a minimum, served as a red flag that Specialty's mission critical compliance mechanisms—which included both Pharmacy and Oncology—had substantial gaps. I need not decide whether the Davis Polk Report alone could serve as a red flag sufficient to make it reasonably conceivable that the Director Defendants face a substantial likelihood of liability. Instead, as the Plaintiffs urge, the Davis Polk Report serves as a backdrop against which the other pled red flags must be viewed. That is, the Audit Committee (at a minimum) was on notice in 2008 that it was likely that significant compliance

[274] *Id.* ¶ 105.
[275] *Id.* ¶ 110.

gaps existed at the Pre-Filled Syringe Program, creating a void in which illegal activity could occur undetected.

The Complaint's allegations concerning the Davis Polk Report cite to minutes from an Audit Committee meeting on February 27, 2008, where the Davis Polk Report was summarized to the Audit Committee.[276] The report itself is not among the Section 220 documents presented in briefing this Motion to Dismiss, and I presume it was not produced.

The Defendants refer to the same Audit Committee minutes in an attempt to refute the inferences the Plaintiffs ask me to draw regarding the Davis Polk Report. The Defendants cite that the minutes refer to efforts that had been implemented to increase oversight of Specialty compliance activities in response to the Davis Polk Report.[277] But the Plaintiffs have adequately pled that the Audit Committee *never* received *any* reports specifically concerning compliance at Pharmacy or in connection with the Pre-Filled Syringe Program. The citation by the Defendants that *some* efforts had been implemented is insufficient to render the inference unreasonable because it is unclear whether the efforts to increase oversight over Specialty's compliance activities targeted the mission critical compliance risk that undergirds the Complaint.

[276] *E.g. id.* ¶¶ 97 n.42, 99 n.45, 101 n.47, 108 n.50, 111 n.51.
[277] ABC-220 CONSOLIDATED R000001, at 0002 ("Ms. Swartz described efforts that have been implemented to increase oversight of [Specialty] compliance activities by [Corporate Security].").

Moreover, the Defendants argue that "Plaintiffs here simply seek to second-guess the . . . manner of the board's response to the red flags, which fails to state a *Caremark* claim."[278] The Defendants contend that the Audit Committee minutes "reflect that steps were taken to improve the systems and controls related to" drug health and safety regulations, and therefore, cannot represent a red flag consciously disregarded by ABC's Board.[279] But, as noted, the Defendants have not pointed to any part of the Section 220 production that refers to actions taken with regard to the shortcomings at Pharmacy concerning mission critical drug health and safety regulations. Moreover, the Davis Polk Report is the basis for the Plaintiffs' allegations that the Board was on notice of gaps in Specialty's compliance, making the later red flags all the more consequential. Consequently, I find that it is reasonably conceivable that the Davis Polk Report represents a red flag regarding Specialty's compliance failures and a potential void permitting illegal activity, and the Plaintiffs have adequately pled that the Board did not respond to the potential gaps regarding drug health and safety risks.

[278] *Oklahoma Firefighters Pension & Ret. Sys. v. Corbat*, 2017 WL 6452240, at *17 (Del. Ch. Dec. 18, 2017) (quoting *In re Qualcomm Inc. FCPA S'holder Derivative Litig.*, 2017 WL 2608723, at *4 (Del. Ch. June 16, 2017)).
[279] *Id*.

c. Mullen's Allegations and *Qui Tam* Action

The next alleged red flag is the allegations and *qui tam* suit by Specialty's former Chief Operating Officer Michael Mullen. The Complaint alleges that Mullen raised concerns regarding Specialty's oncology business model that created regulatory exposure, that after raising concerns for months Mullen was fired, and that Mullen's concerns were never documented nor were the concerns or Mullen's firing conveyed to the Board. The Plaintiffs also allege that Mullen continued his effort to convey his compliance concerns about Specialty and the Pre-Filled Syringe Program after his firing, including emailing Specialty's in-house counsel regarding "a long-standing, and very profitable [Specialty] oncology business group practice involving overfill and numerous oncology drugs."[280] While the Plaintiffs plead mutually exclusive occurrences, that is, the Board was not informed of Mullen's allegations (supporting a "prong one" *Caremark* claim) *and* that the Board consciously ignored Mullen's allegations (supporting a "prong two" *Caremark* claim),[281] the Board *did* sign ABC's 2010 and 2011 Form 10-Ks that disclosed Mullen's *qui tam* suit.[282] I may consequently draw the inference that the Defendant

[280] Compl., ¶ 125. Mullen's report has been withheld as privileged. Defs.' Opening Br., Ex. 14.
[281] *Compare* Compl., ¶ 183 ("[T]he Board had no reporting system and as such was not informed of [Mullen's] firing or the allegations he raised.") *with* Compl., ¶ 184 n.83 ("There is no doubt Defendants knew about the Mullen report.").
[282] *Id.* ¶¶ 139–41.

Directors then serving on the Board[283] were aware of Mullen's allegations.[284] For context, the Board disclosed Mullen's suit in November 2010, and the Pre-Filled Syringe Program continued operation until January 2014.

Mullen's inadvertently publicly disclosed *qui tam* complaint addressed mission critical drug health and safety risks, specifically citing the problematic use of overfill:

> [Pharmacy] purchased vials of injectable drugs from drug manufacturers, used sophisticated centrifuge and vacuum technology to extract all of the product from these vials (including the free overfill amounts) and filled syringes with this free product. By doing this, the Defendants were able to create free doses of the drug in the form of pre-filled syringes. These pre-filled syringes were then sold to medical providers through [Oncology] at a steeper discount than was offered on the vials.[285]

Mullen also pleaded the following regard his meeting with Yost:

> On March 23, 2010, Mr. Mullen had a face-to-face meeting with CEO Yost, during which Mr. Mullen provided an extensive "download" on the oncology business group and the status of ION.[286] During that meeting, Mr. Mullen was very direct and adamant with Mr. Yost as to the serious issues that needed to be addressed and the changes that needed to be made; he expressed grave concerns in a number of areas including business, competitiveness, and regulatory exposure and told

[283] This includes Henney, McGee, Long, Gochnauer, and Hyle—a majority of the Demand Board—who have served on the Board since at least May 2010.
[284] *See Rich ex rel. Fuqi Int'l, Inc. v. Yu Kwai Chong*, 66 A.3d 963, 984 (Del. Ch. 2013) ("Facially, these disclosures are enough to allow me to reasonably infer scienter on the part of the Defendants."). I note that *Fuqi* was a *Caremark* analysis under the "more lenient" 12(b)(6) standard.
[285] Defs.' Opening Br., Ex. 11, ¶ 8. I take judicial notice of this complaint, which was filed in the United States District Court for the Eastern District of New York on October 21, 2010.
[286] ION was a group purchasing organization and was part of the Oncology Group.

> Mr. Yost words to the effect that the situation was "worse" than Mr. Mullen had "thought."[287]

Based on the Board's disclosure of the Mullen *qui tam* complaint and the allegations of the complaint relating to the Pre-Filled Syringe Program, it is a reasonable inference at this pleading stage that ABC's entire Board knew of Mullen's allegations that Pharmacy was operating the Pre-Filled Syringe Program illegally.[288] The Complaint pleads that the Board never asked for any investigations, reports, or updates concerning Mullen's allegations.[289]

The Defendants retort that the Board responded to the substance of Mullen's allegations, and that they did not consciously disregard such allegations, because the Board was addressing similar claims in the *Westmoreland* case, which was, as noted, another *qui tam* action involving Specialty. Mullen's own *qui tam* complaint alleges that the *Westmoreland* case concerned Specialty's nephrology (not oncology)

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[287] Defs.' Opening Br., Ex. 11, ¶ 120.

[288] The Defendants argue that because Mullen's original complaint alleged that the Pre-Filled Syringe Program operated illegally based on Anti-Kickback Statute and False Claims Act theories, and not for failure to register Pharmacy with the FDA, Mullen's complaint *cannot* constitute a red flag for the failure to register and the attendant drug health and safety violations. However, separation of allegations at Pharmacy into baskets of illegality strikes me as artificial. Mullen's complaint was sufficient to alert the Board that Mullen's allegations concerned, at least in part, mission critical compliance failures. That is, the factual predicate underlying Mullen's *qui tam* complaint was that Pharmacy was harvesting and selling overfill. While it is illegal to bill for overfill (because it not intended for patient use), it is also illegal to sell overfill for patient use because the harvesting process imperils the safety and purity of the medicine. Because the drug health and safety regulations implicated by overfill harvesting are mission critical, the Board's "oversight function must be more rigorously exercised." *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *13 (Del. Ch. Oct. 1, 2019) (citing *Marchand v. Barnhill*, 212 A.3d 805, 822, 824 (Del. 2019)).

[289] Compl., ¶ 184.

business, that the allegations in *Westmoreland* were similarly applicable to the Oncology Group, and that the nature of the wrongdoing applied to a number of different oncology drugs.[290]

The Defendants contend that the Section 220 documents refute the contentions of Board inaction with respect to the allegations in Mullen's *qui tam* action. The Section 220 documents put forward by the Defendants, however, at most give rise to multiple inferences, and at this pleading stage that means the Plaintiffs receive the inference.[291] The otherwise nearly-entirely redacted[292] Audit Committee and Board minutes cited by the Defendants purportedly showing that the Board monitored and received updates pertinent to the Mullen allegations state as follows:

- "In Note 8, *Legal Matters and Contingencies*, the discussion of the Company's litigation matters and contingencies, including the updated disclosure concerning the status of the *qui tam* matter and related filings"[293]

- "In Note 8, *Legal Matters and Contingencies*, the discussion of the Company's litigation matters and contingencies, including the updated disclosure concerning the status of the Bergen Brunswig matter and the qui tam matter"[294]

[290] Defs.' Opening Br., Ex. 11, ¶ 118 ("Moreover, Mr. Mullen recognized that the allegations made in the Westmoreland Case with respect to ABC's *nephrology* GPO and wholesale practice . . . were also applicable to ABC's *oncology* GPO and wholesale practice . . . .").
[291] *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 798 (Del. Ch. 2016), *abrogated on other grounds*, 214 A.3d 933 (Del. Aug. 7, 2019).
[292] By this, I mean, other than the language quoted, they are redacted in their entirety other than the information necessary to know what body was meeting, who the attendees were, and when and where the meeting occurred.
[293] ABC-220 CONSOLIDATED R000005, at 0007.
[294] ABC-220 CONSOLIDATED R000020, at 0022.

- "Ms. Hyle stated that the Committee had received an update on compliance activities and calls to the Company's hotline since the last meeting of the Committee. She said that the Committee had also received an updated on the status of certain *qui tam* litigation relating to the Company, [REDACTED] and a *qui tam* matter relating to the Company's oncology supply business"[295]

- "Mr. Chou then presented the legal update, reporting on significant legal matters affect the Company, including the *qui tam* lawsuit"[296]

- "Mr. Chou presented the legal update, reporting on significant legal matters affecting the company. [REDACTED]. Mr. Chou discussed certain other matters, including the status of a pending *qui tam* action in New York involving a former employee of the Company"[297]

- "Mr. Chou presented the legal update, reporting on significant legal matters affecting the Company. [REDACTED]. Mr. Chou discussed certain other matters, including the status of a pending *qui tam* action in New York involving a former employee of the Company. There was a discussion of these matters"[298]

The Defendants also put forth a single slide (presumably part of a larger presentation) with the heading "Legal and CSRA FY 14 Accomplishments"—the only other unredacted text reads: "Defend [REDACTED] and Oncology Supply[299] *qui tam* investigations vigorously, with minimal disruption for business associates."[300]

[295] ABC-220 CONSOLIDATED R000306, at 0310.
[296] ABC-220 CONSOLIDATED R000231, at 0236.
[297] ABC-220 CONSOLIDATED R000334, at 0346.
[298] ABC-220 CONSOLIDATED R000372, at 0381.
[299] Oncology's full name is ASD Specialty Healthcare, LLC d/b/a Oncology Supply. Compl., ¶ 21.
[300] ABC-220 CONSOLIDATED R001043, at 1043.

The Section 220 materials cited by the Defendants *do not* demonstrate that in invoking the Mullen allegations and *qui tam* suit as a red flag, the Plaintiffs have "seize[d] on a document, take[n] it out of context, and insist[ed] on an unreasonable inference that the court could not draw if it considered related documents."[301] Many of the minutes referenced do not even obviously refer to the Mullen suit—as noted, *both* the *Westmoreland* case and Mullen's action were *qui tam* actions—and even those that inferably do refer to Mullen's *qui tam* action do not demonstrate *any* remedial action taken by the Board in response. The closest the Defendants get in this regard is the single slide, but that slide is titled FY14 [inferably fiscal year 2014] Accomplishments. Notably, Mullen's original complaint was filed in October 2010, and the Pre-Filled Syringe Program was ended in January 2014. Consequently, a reference to a fiscal year 2014 "accomplishment" of defending Mullen's *qui tam* does not refute the inference that the Board knew of Mullen's allegations and consciously ignored Mullen's allegations of wrongdoing in connection with the Pre-Filled Syringe Program.

The Defendants next argue that that Board specifically reviewed the legality the Pharmacy's business in the aftermath of Mullen's termination. Per the Complaint, in 2010 Ober Kaler was brought in to conduct a compliance and

[301] *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *14 n.216 (Del. Ch. Oct. 1, 2019) (quoting *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 798 (Del. Ch. 2016), *abrogated on other grounds*, 214 A.3d 933 (Del. Aug. 7, 2019)).

regulatory review in response to Mullen's allegations.[302] But the Plaintiffs allege that the Audit Committee never followed up to determine if Ober Kaler's recommendations were implemented, and that no policies or procedures were created or changed as a result of the review.[303] Moreover, even after the Ober Kaler review, "there were no reports to the Board or the Audit Committee regarding FDA compliance or the unsanitary and unhygienic conditions at the [Pre-Filled Syringe] facility."[304]

The Plaintiffs ask for the inference that Ober Kaler informed the Audit Committee of the "serious unsanitary and unhygienic conditions" in the Pre-Filled Syringe Program.[305] The extent of the information about the Ober Kaler review in the Section 220 production is that Ober Kaler was engaged to conduct a "compliance and regulatory review of [ABC's] ION and Oncology Supply businesses,"[306] and that ABC was "proceeding to implement all of the recommendations that were presented as part of the [review]."[307] It is unclear what Ober Kaler's recommendations were because the report was withheld as privileged.[308] But the Plaintiffs *do not need* the inference that Ober Kaler informed the Audit Committee

[302] Compl., ¶ 184 n. 84.
[303] *Id*.
[304] *Id*.
[305] *Id*. ¶ 135.
[306] ABC-220 CONSOLIDATED R000238, at 0238.
[307] ABC-220 CONSOLIDATED R000244, at 0248.
[308] *See* Defs.' Opening Br., at 51 n.25; Defs.' Opening Br., Ex. 14.

of concerns with the Pre-Filled Syringe Program because it is already reasonable to infer the Board's (as a whole) knowledge from their signed disclosure of Mullen's allegations.[309] Furthermore, based on the Complaint and incorporated Section 220 documents, that Ober Kaler conducted a review is insufficient to rebut the otherwise well-pled allegation that the Board consciously ignored Mullen's allegations because *it is unknown what Ober Kaler recommended*. Consequently, without knowing what these recommendations were, it is not possible at this time to draw an inference regarding the extent of the measures implemented, nor is it sufficient to render unreasonable the Plaintiffs' proffered inference: that the Board consciously ignored concerns about the Pre-Filled Syringe Program.[310]

The Plaintiffs have adequately pled that the Board knew of Mullen's allegations regarding the Pre-Filled Syringe Program and that the Board ignored such concerns in bad faith by failing take action regarding the operation of the Pre-Filled Syringe Program in response. These well-pled allegations are sufficient to

[309] As noted, the Complaint alleges that Ober Kaler presented *only* to the Audit Committee. The Complaint specifically pleads: "The review by Ober Kaler and its findings and recommendations were not presented to ABC's full Board, and the Audit Committee never followed up to confirm that the recommendations from this 'routine' review were actually implemented." Compl., ¶ 136.

[310] The Complaint concedes that ABC "made some changes after the Ober Kaler presentation, but failed to follow up and ensure that the unsterile and unhygienic conditions in the [Pre-Filled Syringe] Program were discontinued." *Id.* ¶ 132. Given that drug health and safety was a mission critical compliance risk, and given the other allegations in the Complaint, this concession is insufficient to render unreasonable the inference that the Board consciously ignored the substance of Mullen's allegations in bad faith, especially because it is unknown what Ober Kaler recommended.

reasonably infer that the Board consciously ignored red flags regarding the Pre-Filled Syringe Program and its attendant mission critical compliance risks.

d. The 2012 DOJ Subpoena and FDA Search Warrant

The final red flag alleged by the Plaintiffs is the FDA search warrant executed at Pharmacy's operations in 2012 and a subpoena received from federal prosecutors that ABC "believe[d] could be related to a qui tam action that remains under seal," inferably Mullen's *qui tam* action.[311]

The Plaintiffs allege that the search warrant was reported in the press, though there is no mention of it in any Board or Audit Committee minutes or materials, giving rise to a reasonable inference that it was never discussed by these bodies. As to the subpoena, it was disclosed in ABC's 2012 10-K, signed by ABC's Board, making it a reasonable inference that the Board had knowledge of the subpoena.

It is not reasonable to infer that the Board consciously ignored a red flag with regard to the search warrant, because there is no well-pled allegation that the Board had knowledge of the search warrant or the raid, and hence the scienter required to adequately plead bad faith is absent.[312] As to the subpoena, I can draw a reasonable inference of the Board's knowledge because the Board disclosed the subpoena in ABC's 10-K.

[311] *Id.* ¶ 185.

[312] The Complaint *does not* allege that the then-forthcoming article mentioned at the November 15, 2012 ABC Board meeting concerned the search warrant.

ABC's same 2012 10-K noted that ABC was "in the process of responding to the subpoena and is cooperating fully with the USAO."[313] But the Plaintiff is entitled to the inference that the Board never discussed the subpoena due to its absence from the Board's minutes.[314] The Defendants rely on the statement in the 10-K that ABC was "responding" to the subpoena to negate an inference that the Board failed to take action regarding the mission critical compliance shortcomings that the subpoena implicated. To my mind, that does not follow. It is reasonably conceivable that ABC could respond to the subpoena, in the way of handing over the information requested, without taking any action with regard to the *reason* why the United States Attorney's Office was asking for information, that is, the illegality of the Pre-Filled Syringe Program.

Given the Plaintiff-friendly standard at this pleading stage, I find that the absence of any discussion of the subpoena by the Board is sufficient to make reasonable the inference the Plaintiffs ask me to draw, that is, even after receiving the subpoena the Board did nothing to correct the underlying mission critical compliance shortcomings at Pharmacy. Whether this will bear out upon discovery is a matter that awaits a record.

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[313] Defs.' Opening Br., Ex. 15, at 57. I take judicial notice of ABC's 2012 10-K.

[314] *Hughes v. Hu,* 2020 WL 1987029, at *2 (Del. Ch. Apr. 27, 2020 ("Given [the stipulation that any remaining materials requested by Plaintiff either do not exist or had been withheld on privilege grounds], if the Company failed to produce a document that it would reasonably be expected to possess if a particular event had occurred, then the plaintiff is entitled to a reasonable inference that the event did not occur." (citing *Morrison v. Berry*, 191 A.3d 268, 275 n.20 (Del. 2018))).

3. Demand is Excused as to Count I Because the Complaint Contains Adequately Pled Allegations that the Board Consciously Ignored Red Flags

To repeat, demand on the Board is excused if the Plaintiffs can "alleg[e] particularized facts that reveal board inaction of a nature that would expose at least half of the directors to a substantial likelihood of personal liability."[315] Seven members of the Demand Board (the Director Defendants) are alleged to have served as ABC directors during the unlawful operation of the Pre-Filled Syringe Program, and five of the Director Defendants—a majority of ABC's Board—have served on the Board since at least May 2010. Therefore, a majority of ABC's current Board were on the Board when it disclosed the existence of Mullen's *qui tam* action—the principal red flag alleged—in November 2010.[316] Moreover, a majority of the Demand Board served on the Audit Committee around the time of the wrongdoing alleged.

The Plaintiffs have demonstrated that a majority of ABC's Board faces a substantial likelihood of liability by pleading particularized facts from which it is reasonably conceivable that a majority of the Board "knew of evidence of corporate

[315] *Oklahoma Firefighters Pension & Ret. Sys. v. Corbat*, 2017 WL 6452240, at *14 (Del. Ch. Dec. 18, 2017) (quoting *Horman v. Abney*, 2017 WL 242571, at *6 (Del. Ch. Jan. 19, 2017)) (internal quotation marks omitted).

[316] While it is true that a majority of the Demand Board was not on the Board at the time of the Davis Polk Report, even absent the Davis Polk Report the Complaint would survive a Motion to Dismiss based on the alleged knowing failure to respond to the Mullen *qui tam* action. Consequently, there is no need for a further inquiry regarding director independence.

misconduct—the proverbial 'red flag'—yet acted in bad faith by consciously disregarding its duty to address that misconduct."[317] That is, the Plaintiffs have adequately pled that the Board was aware of the Pre-Filled Syringe Program's contravention of mission critical drug health and safety regulations, and that the Board failed to act in response. The Board's knowledge of these failures can be reasonably inferred from, at minimum, the serious allegations of Mullen—Specialty's COO—regarding mission critical compliance failures regarding Specialty's oncology business. The Defendants have placed forth Section 220 evidence that shows that *some* Board-level (and Audit Committee-level) review was taken in regard to failures at Pharmacy, but have put forth nothing to show tangible action taken to remedy the underlying drug health and safety issues. Calling attention to the hiring of law firms to review alleged illegality, without more, is insufficient to refute well-pled allegations that the Board failed to address mission critical compliance risks. The Defendants have put forth nothing from the Section 220 production showing a tangible reaction to—as opposed to a review of—the mission critical compliance failures at Pharmacy.

Because a majority of the Demand Board faces a substantial likelihood of liability for Count I of the Complaint, demand is excused as to Count I and the

[317] *Horman*, 2017 WL 242571, at *10 (quoting *Reiter on Behalf of Capital One Fin. Corp. v. Fairbank*, 2016 WL 6081823, at *8 (Del. Ch. Oct. 18, 2016)).

Defendants' Motion to Dismiss under Rule 23.1 is denied. The Defendants have also moved to dismiss Count I under Rule 12(b)(6). "Because the standard under Rule 12(b)(6) is less stringent than that under Rule 23.1, a complaint that survives a motion to dismiss pursuant to Rule 23.1 will also survive a 12(b)(6) motion to dismiss, assuming that it otherwise contains sufficient facts to state a cognizable claim."[318] Consequently, because the Complaint otherwise contains sufficient factual allegations to state a cognizable claim, the Defendants' Motion to Dismiss under Rule 12(b)(6) is likewise denied.

4. *Caremark "Prong One" Allegations*

Because the Complaint survives under a "prong two" theory, I need not decide whether the Director Defendants face a substantial likelihood of liability under "prong one" of *Caremark*. I note, however, that the Davis Polk Report indicates that several years after acquiring Specialty, ABC had a woefully inadequate compliance system. While the implication of a "prong one" claim is unnecessary to survive the Defendant's Motion, it nonetheless speaks to a lax approach (at best) to compliance at ABC.

[318] *McPadden v. Sidhu*, 964 A.2d 1262, 1270 (Del. Ch. 2008) (footnotes omitted).

C. The Motion to Dismiss Counts II and III is Denied

As noted, *supra*, the Complaint also brings claims against officers of ABC: Defendants Collis (in his officer capacity), Chou, and Guttman (the Officer Defendants).

Count II alleges breach of fiduciary duty against the Officer Defendants. Specifically, the Complaint alleges that "[t]he Officer Defendants consciously breached their fiduciary duties and violated their corporate responsibilities by knowingly operating and maintaining an illegal business model" and that the Officer Defendants failed to inform the Board about the Pre-Filled Syringe Program's regulatory compliance.[319]

Count III alleges unjust enrichment against Collis. Collis was allegedly unjustly enriched because he "derived profits, benefits, and other compensation from ABC and were [sic] otherwise unjustly enriched during the time in which the wrongful practices occurred."[320]

Neither party disputes that the factual allegations underlying Counts II and III are congruous with those underlying Count I. An investigation of the alleged officer breaches of duty would necessarily implicate the same set of facts as Count I. Namely, the activities alleged as breaches of the Officer Defendants' fiduciary

[319] Compl., ¶¶ 218–19.
[320] *Id.* ¶ 223.

obligations is the same conduct that the Director Defendants allegedly failed to adequately oversee.

Because the Plaintiffs did not make a demand with regard to the Counts II and III, like with Count I they must show why demand would be futile. Of the Officer Defendants, only Collis is a member of the Demand Board. *Rales* applies because Counts II and III do not challenge an action of the Board, but instead actions of the Officer Defendants.[321]

"To evaluate a demand to assert the claim[s] posited in Count[s] II [and III], the Demand Board would have to investigate and then assert litigation based on the breaches of the duty of oversight that are the subject of Count I."[322] As noted, at a minimum a majority of the Demand Board—Henney, McGee, Long, Gochnauer, and Hyle, who have all been Board members since at least May 2010—face a substantial likelihood of liability with regard to Count I and hence cannot impartially consider a demand for the *Caremark* claim. In other words, the Director Defendants could not bring their business judgment to bear on a demand to prosecute Counts II and III, because such litigation would implicate their own wrongdoing adequately pled in Count I. Thus, because Counts II and III "would implicate the same conduct"

[321] *Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 833 A.2d 961, 977 (Del. Ch. 2003), *aff'd*, 845 A.2d 1040 (Del. 2004).
[322] *Hughes v. Hu*, 2020 WL 1987029, at *18 (Del. Ch. Apr. 27, 2020).

as Count I, demand is futile as to Counts II and III.[323] And for the same reasons noted, *supra*, because demand is futile with regard to Counts II and III, the Motion to Dismiss under Rule 12(b)(6) is likewise denied.

III. CONCLUSION

The Defendants Motion to Dismiss is DENIED. The parties should submit a form of order consistent with this Memorandum Opinion.

[323] *Id.*