In Support of Patient Safety, Healthcare Access, and Medicare Payment for a Single-Use Bronchoscope Model

By **Lawrence F Muscarella PhD**

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TAGS: #AdverseEvents, #CMS, #COVID19, #Infections, #Medicare, #Bronchoscopes, #HealthcareAccess

This article discusses a rebuttal, by Lawrence F. Muscarella, Ph.D., to initial conclusions by The Centers for Medicare & Medicaid Services ("CMS") published in July that assess the risk of contaminated bronchoscopes infecting patients with potentially life-threatening diseases including multidrug-resistant organisms.

Two months after receiving his rebuttal in support of a company's application requesting a new device category for what's called transitional pass-through ("TPT") payment status for a single-use bronchoscope model, CMS reassessed its July decision and, in November, approved the application.

CMS's approval of TPT payment for a medical device can reduce financial obstacles that might otherwise limit Medicare beneficiary access to the device. For example, medical facilities using a company's approved medical device are eligible to receive additional Medicare reimbursement for up to 3 years. Payment status can therefore benefit both patients and applicants.

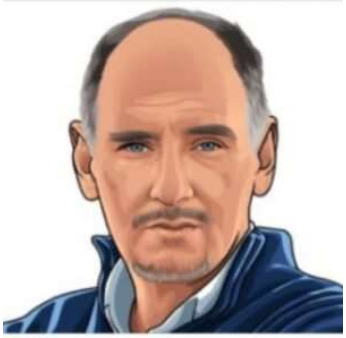
The complete Code of Federal Regulations describing Medicare's oversight of transitional pass-through payments for medical devices, known as 42 CFR §419.66, is available online.

Dr. Muscarella's rebuttal cites 84 references, in total, in support of his findings, assessments, and conclusions about the risk of bronchoscope-related infections. This article by Dr. Muscarella was written in the third person.

Excerpts from Dr. Muscarella's submitted rebuttal are appended below. His complete rebuttal, in its entirety, may be downloaded by visiting the Federal Register's public website and database, or by directly emailing Dr. Muscarella at: Larry@LFM-HCS.com.

January 8, 2024 – The *Centers for Medicare & Medicaid Services* ("CMS") published a response last summer to a company's application, submitted 5 months earlier in February, requesting a new device category for transitional pass-through ("TPT") payment status for a single-use bronchoscope model.

That response, published in the July 31, 2023, issue of the *Federal Register*, concluded that, in CMS's judgment, the evidence presented in the February application was not sufficient to approve the device for the payment, though the agency did invite public comment to help CMS better assess whether the nominated device might justify payment approval.



To be eligible to receive pass-through payment status, however, the nominated device must satisfy certain federal requirements identified in the Code of Federal Regulations (*e.g.,* the device has shown to be reasonable and necessary for the diagnosis or treatment of an illness or injury).

Certain other criteria detailed in the federal regulations must also be met for CMS to grant approval and establish a new category for a nominated medical device, including the application reaching a critical threshold — namely, the applicant having provided the agency with compelling evidence demonstrating that the device, in CMS's words, "represents a substantial clinical improvement over existing technologies."

According to CMS, the intent of TPT payment is "to help facilitate" access by Medicare beneficiaries to new, innovative technologies, which include medical devices.

The agency advances this goal by reducing, albeit temporarily, the cost to the medical facility of the approved device, providing Medicare beneficiaries with access to the device that might otherwise have been limited or even prevented due to financial obstacles.

Healthcare providers using a device approved for TPT payment status, for example, are eligible to receive additional Medicare reimbursement for up to 3 years, easing a potential hindrance to the device's use and sale. Approved payment can therefore benefit both patients and applicants.

Rebuttals, Expert Guidance, and Forensic Case Reviews: *LFM-Healthcare Solutions, LLC* provides medical expertise for healthcare facilities, device manufacturers and the public, specializing in healthcare-associated infections linked to contaminated reusable medical equipment.

CMS's July response

CMS's July response in the *Federal Register* details its initial reservations with the February application, including a concern that the submission does not directly demonstrate "any clinical improvement" resulting from the use of the nominated single-use bronchoscope model, compared to conventional (reusable) bronchoscopes.

Moving a defining step further, CMS noted in the response that: "We do not believe that we have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the nominated device."

A lynchpin critical for the nominated device to receive payment approval, therefore, would be to complement the applicant's initial submission by providing CMS with additional, convincing evidence demonstrating that the applicant's single-use bronchoscope model can provide improved patient outcomes.

A September rebuttal

Aiming to achieve just that goal, Lawrence F. Muscarella, PhD., wrote a rebuttal to CMS's published July assessment and findings retorting the agency's conclusion that the risk of bronchoscope-related infections

discussed in the initial February application was not sufficient for CMS to evaluate the nominated device's claims of substantial clinical improvement.

In September, the applicant of the nominated single-use bronchoscope model submitted Dr. Muscarella's rebuttal to CMS for review and consideration. (Dr. Muscarella was not involved in the application submitted in February.)

Dr. Muscarella is the president and founder of *LFM-Healthcare Solutions,* LLC, an independent company committed to patient safety and the improved quality and design of medical devices. His September rebuttal was sponsored, in part, by this single-use bronchoscope model's applicant.

In his rebuttal to CMS, Dr. Muscarella reemphasized the applicant's original claims that the nominated device provides substantial clinical improvement over existing technologies by his focusing, in replete detail, on several published reports describing contaminated bronchoscopes exposing patients to potentially life-threatening bacteria, including multidrug-resistant organisms.

Excerpts from Dr. Muscarella's submitted rebuttal are appended below. His complete rebuttal may be downloaded by visiting the *Federal Register's* public website and database, or by directly emailing Dr. Muscarella at: Larry@LFM-HCS.com.

In short, Dr. Muscarella's September rebuttal concluded that the additional supporting information and evidence he presented therein "provide justification, at least *vis-à-vis* the prevalence of bronchoscope-related cross-infections due to ineffective reprocessing and other risk factors," for approval of the applicant's request to receive a new device category for TPT payment status for the nominated single-use bronchoscope model.

Dr. Muscarella's rebuttal to CMS cites 84 references, in total, in support of his findings, assessments, and conclusions. Click here to view the bibliography

CMS approves the application for TPT payment status

This past November, CMS approved the applicant's single-use bronchoscope model for transitional pass-through payment status beginning one week ago (on January 1, 2024), having now concluded that the company's application satisfied all the requirements of the applicable federal regulations.

Publicized in the November 22, 2023, issue of the *Federal Register*, CMS wrote that this approval superseding its earlier July assessment was based on the documentation and additional studies it received since July in support of the

application — for example, alerting the agency to the study in 2020 by Mehta and Muscarella.

According to CMS, this new information now addresses "our concerns and provide evidence of substantial clinical improvement that is required." (Dr. Muscarella's rebuttal may not have been the only new documentation the applicant provided to CMS between July and November that influenced CMS's reassessment and final approval.)

Timeline of events

- *February 2023:* A company submitted an application to CMS requesting TPT payment status for a single-use bronchoscope.
- *July 2023:* CMS concluded that the application does not directly demonstrate "any clinical improvement" resulting from the use of the nominated single-use bronchoscope model. The Agency did not approve the application, requesting more information to assess whether the nominated device meets all of the federal requirements to receive TPT payment status.
- *September 2023:* The applicant submitted Dr. Muscarella's rebuttal to CMS in support of the company's application to receive TPT payment status for a single-use bronchoscope model.
- *November 2023:* CMS reassessed its earlier decision and approved the application.

Excerpts from Dr. Muscarella's Rebuttal to CMS

The following sections or excerpts, written in first person, are from Dr. Muscarella complete rebuttal that was submitted to CMS in September in response to the agency's findings presented in the July 31, 2023, issue of the *Federal Register*.[1]

1. Mehta and Muscarella (2020)

A recently published peer-reviewed article by Atul Mehta, MD, and myself in *Chest*, in 2020,[2] focuses specifically and comprehensively on many of the infection-related topics relevant to this transitional pass-through ("TPT") application. Indeed, that article provides evidence both for the significance of this application and the prevalence of infection due to, among other risk factors, the inadequate reprocessing of (reusable) bronchoscopes. Consequently, Mehta and Muscarella (2020), which details multiple clinical

cases of bronchoscope-related infections, is referenced throughout this response.

Copies of Dr. Muscarella's complete rebuttal may be downloaded by visiting the *Federal Register's* public website and database, or by emailing him directly at: Larry@LFM-HCS.com.

2. Cross-infection risk

Based on the evidence provided herein, CMS may now conclude that: (*a*) it has "sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the nominated device"; (*b*) the risk of infection due to the inadequate reprocessing of bronchoscopes (among other risk factors) is significant today; and (*c*) single-use bronchoscopes (when used according to their FDA-cleared labeling) do not merely reduce, but rather eliminate, the risk associated with standard bronchoscopes (*e.g.*, comparator devices) of:

(i) cross-infecting patients not only with "low-concern" organisms but also with patient-borne "high-concern" organisms, including multidrug-resistant organisms such as carbapenem-resistant *Enterobacteriaceae* (CRE) and colistin-resistant gram-negative bacilli;[3],[4],[5] and

(*ii*) contamination of the bronchoscope and subsequent infection of the patient with infectious waterborne organisms (*e.g., Pseudomonas aeruginosa* and *Legionella spp.*) during bronchoscope reprocessing's terminal water-rinsing step (after disinfection and prior to patient use).[6],[7]

Relevant to the topic of cross-infection, Mehta and Muscarella (2020) "identified cases that suggest the cleaning and HLD (high-level disinfection) of bronchoscopes performed in accordance with published guidelines/standards and manufacturer instructions may not always be sufficiently effective to eliminate the risk of transmission of CRE and related MDROs (multidrug-resistant organisms), such as in an outbreak setting and/or if the bronchoscope is persistently contaminated with an inaccessible biofilm of carbapenem-resistant bacteria."[8]

Further germane to this topic and TPT application, *The Centers for Disease Control and Prevention* (CDC) reported in 2008 that "more healthcare–associated outbreaks have been linked to contaminated endoscopes than to any other medical device."[9]

3. Multidrug-resistant organisms (MDROs)

Performing a review of the medical literature and FDA's adverse events ("MAUDE") database, Mehta and Muscarella (2020) identified several cases linking (reusable) bronchoscopes to infections of CRE and other multidrug-resistant organisms (*i.e.*, "superbugs").[14] Multidrug-resistant bacteria can be associated with a mortality rate of as high as 50%.[15]

By way of one example, Galdys et al. (2018)[16] linked exposure to a contaminated bronchoscope to an outbreak and pseudo-outbreak of multidrug-resistant *P. aeruginosa* and carbapenem-resistant *K. pneumoniae (i.e., CRE),* in 2014. These investigators reported that the implicated bronchoscope's lumen was "physically defective," and that "proteinaceous debris" had accumulated in the bronchoscope "despite compliance with manufacturer's recommended reprocessing procedures." Culture of the implicated bronchoscope was positive for the bacteria.

By eliminating the risks of bronchoscope-related cross-infections and outbreaks of multidrug-resistant organisms including CRE[17] (as well as preventing the potential for the accumulation, over time, of infectious materials inside the reusable device[18]), a stakeholder may reasonably conclude that use of a single-use bronchoscope provides a substantial clinical improvement *vis-à-vis* reusable comparators in the context of the risks of multidrug-resistant cross-infections.

4. FDA adverse events

Another recent analysis I performed[21] found that the number of submitted FDA adverse event reports involving a standard (reusable) bronchoscope that describe inadequate reprocessing, confirmed or potential device contamination, and/or infection increased from 2014 to 2021 by almost 400% (*i.e.,* from 52 to 259 reports). (These data and trends can be independently validated for accuracy and completeness.)

That same analysis also found that, comparing 2020 to 2021, the number of these specific types of adverse events reports involving bronchoscopes increased by approximately 34% (from 193 to 259).[22] A recent review (unpublished) of the MAUDE database that I performed revealed that, between January and June of this year (2023), several FDA reports involving a reusable bronchoscope describe similar cases reporting inadequate reprocessing, confirmed and potential device contamination, and/or bronchoscope-related infection.[23]

The published literature, along with these FDA reports, suggest, first, that this risk of contamination and bronchoscope-related infections, including from CRE and related multidrug-resistant organisms, continues to emerge as a

public health concern within U.S. healthcare facilities; and second, that the use of single-use bronchoscopes, by preventing patient-to-patient transmissions of multidrug-resistant organisms, offers substantial clinical improvement.

Note 1: As stated, an analysis found that, comparing 2020 to 2021, the number of confirmed and potential cases of contamination involving a bronchoscope increased by approximately 34%.[24] In contrast, that same analysis found that the number of similar types of FDA reports describing actual or potential contamination of a urological endoscope in 2021, compared to 2020, increased from 209 to 244, or by approximately 17%,[25] which is a significantly *smaller* increase than for bronchoscopes during the same timeframe. (These data and trends, too, can be independently verified for accuracy and completeness.) Despite their being associated with a smaller increase in these types of FDA reports during this timeframe compared to bronchoscopes, however, single-use urological endoscopes were provided a pass-through device code (*i.e.*, C1747).

Note 2: It is acknowledged herein that linking or associating an bronchoscope or other type of flexible endoscope with an infection or outbreak does not confirm the endoscope transmitted or otherwise caused the infection, as one or more other factors could be, in part or solely, responsible. More data would be required to conclude more definitively that the endoscope caused an infection. It is also acknowledged that the FDA's MAUDE database has limitations and that its housed adverse event reports may be incomplete, inaccurate, untimely, unverified, or biased.

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5. A "positive correlation"

In response to CMS's statement in the *Federal Register* suggesting it may not necessarily be valid to conclude, or assume, that "inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection,"[26] published studies directly link inadequate reprocessing of bronchoscopes to an increased infection risk.[27] Indeed, as Mehta and

Muscarella (2020) documented, use of a bronchoscope persistently contaminated with a biofilm is a documented risk factor for (*i.e.,* poses an increased risk of) transmission of multidrug-resistant organisms, including CRE.[28]

Moreover, FDA updated an April 2022 safety communication to include content that exemplifies a direct positive correlation between a reduction in the endoscope's contamination rate, due to more effective reprocessing, and a reduction in the infection risk.[29] While that FDA safety communication focused specifically on duodenoscopes, published evidence,[30] including conclusions by the FDA, suggests the same positive correlation also applies to bronchoscopes.

For example, FDA published a guidance document in March 2015 stating: "FDA has identified a subset of medical devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed. This identification is based on knowledge gleaned through MDRs; recalls; periodic outbreaks of microbial transmission or patient infection reported in the literature or media; reports provided by the Centers for Disease Control (CDC), the Veterans Administration (VA), and other health care settings; and manufacturer-initiated surveillance studies. These device types are listed in Appendix E";[31] this list includes bronchoscopes.

Moreover, FDA stated in a 2021 safety communication: "If the reprocessing process is not followed meticulously by trained staff, the bronchoscope can remain contaminated, potentially resulting in infection transmission from one patient to the next."[32]

These FDA statements appear to indicate that, indeed, inadequate reprocessing of bronchoscopes is positively correlated with an increased infection risk (*i.e.,* the less effective the reprocessing steps, the more likely the endoscope will remain contaminated and expose the patient to the potentially transmissible infectious materials).

Underscoring concerns about bronchoscope-related infections and the effectiveness of today's bronchoscope reprocessing practices, Travis et al. (2023) reported earlier this year that cross-contamination associated with reusable flexible bronchoscopes has been, and remains, "a relevant and persistent healthcare issue. The current reprocessing methods and surveillance strategies are flawed, and new approaches must be considered." [33] These authors advised further that: "To eliminate the risk of cross-contamination, innovative single-use technologies should replace RFB (reusable flexible bronchoscopes) where feasible."

Consistent with Travis et al.'s (2023) conclusions, FDA's 2021 safety communication focusing on updated recommendations for reprocessing bronchoscopes advised healthcare facilities to consider using a single-use bronchoscope (albeit in certain described situations, such as where there is increased risk of spreading infections of multidrug-resistant microorganism).[34]

6. Is the bronchoscope-related infection risk under-reported?

CMS refers in the *Federal Register* to a 2015 FDA safety notice wherein FDA stated that "compared to the number of bronchoscopy procedures performed in the U.S. each year," the number of medical device reports (MDRs) reported to FDA between January 2010 and June 2015 (n=109) describing bronchoscope-related infections or device contamination is considered "a small number of MDRs."[35] In response to assessments that state or imply that the risk of bronchoscope-related infections is apparently small and within allowed tolerances, however, emphasis by the FDA in its guidance document published in March 2015[36] that a subset of medical devices, which include bronchoscopes, poses a greater likelihood of microbial transmission and represent a high risk of infection if inadequately reprocessed would appear to suggest the risk of bronchoscope-related infections is significant.

Humphries et al. (2017)[37] (in the context of infections associated with duodenoscopes) reported that "most hospitals do not perform postprocedure surveillance for infections and would not be able to identify an outbreak from baseline postprocedural infection rates." This observation is also generally applicable to the use of bronchoscopes, and without performing post-bronchoscopy surveillance of patients for infection, the possibility cannot be ruled out that the risk and incidence of both clinical and subclinical infections (and colonizations) involving a bronchoscope (including the more complex EBUS models) are significantly higher in the U.S. than currently estimated (*i.e.,* that bronchoscope-related infections are an under-reported threat).[38],[39],[40] Guidelines have not generally recommended routine monitoring of patients for infection following bronchoscopy.[41],[42]

Suggesting that the risk of bronchoscope-related infections is likely under-reported, CDC published in 1999 that the incidence of bronchoscope-related infectious complications "is probably underestimated, with many episodes unrecognized or unreported."[43] In further support of the conclusion that the incidence of bronchoscope-related infections is higher than reported, Culver et al. (2003)[44] concluded: "True infections and pseudoinfections are notoriously difficult to detect and therefore likely under-recognized." These authors added that: "Under-recognition and under-reporting of (cases of bronchoscopic pathogen transmission) have contributed to a sense of complacency regarding infection control in the bronchoscopy suite."

Mughal et al. (2004) similarly reported that transmission of infections "through the flexible bronchoscope is underrecognized and underreported," adding that "microbial transmission may occur via any part of instruments or anything in contact with the instruments including cleaning solutions, automated washers, and rinsing water."[45] These authors further acknowledged that: "Numerous surveys have suggested poor adherence to published preventive guidelines." Indeed, reports document inadequate reprocessing of bronchoscopes (with and without infection) due to an inadvertent failure to comply with published guidelines and/or manufacturer's bronchoscope reprocessing instructions.[46],[47],[48],[49]

More recently, Mehta and Muscarella (2020) clarified that, based on a review of the literature, "calculations of the risk of endoscope-related infections, including those associated with bronchoscopes, are based almost exclusively on infections disclosed in the peer-reviewed literature and do not include undisclosed (or, of course, undetected) infections, or infections recorded only in the (FDA's adverse events) database. These latter infections reported only to the FDA can become 'lost' and inadvertently overlooked, introducing a potential publication bias toward underreporting that can cause published estimates of the risk of bronchoscopes transmitting (multidrug-resistant organisms) to underestimate, potentially significantly, the true incidence."[50]

7. Visual endoscope examination

Use of single-use bronchoscopes also eliminates periodic visual examination of the internal surfaces of the bronchoscope's working channel (*e.g.*, using a borescope) to ensure the bronchoscope is not damaged and/or contaminated with potentially infectious materials prior to use on a patient.[63],[64] Investigating bronchoscope-associated clusters of multidrug-resistant bacteria, Galdys et al. (2018)[65] recommended that the visualization of the bronchoscope's lumen "to confirm integrity should be a critical component of device reprocessing." In response to CMS's comments in the *Federal Register*, single-use bronchoscopes eliminate this reprocessing (if also quality assurance) step (*i.e.,* single-use bronchoscopes provide clinical improvement *vis-à-vis* reusable comparators in the context of cross-infection risks and certain quality assurance procedures).

Notably, visual assessments (by healthcare personnel) of a bronchoscope's working channel and biopsy port for contamination and/or damage are not foolproof and can be inconclusive.

Moreover, if the techniques are not properly validated, visual assessments can be subjective and yield false-negative findings resulting in the advertent use of a contaminated and/or damaged bronchoscope on a patient. Kovaleva et al.

(2013) noted that: “Any small damage can be the source of bacterial contamination within the scope, which is difficult or impossible to detect by routine inspection and testing.”[66]

8. Endoscope damage

Use of single-use bronchoscopes also eliminates the requirement to perform

periodic maintenance (per manufacturer instructions) and repair of the endoscope (as warranted). Indeed, use of a damaged, improperly maintained and serviced, and/or inadequately repaired bronchoscope – like persistent contamination of the device — are risk factors for ineffective reprocessing and transmission of multidrug-resistant organisms including CRE.[67],[68] In agreement, FDA acknowledged and stressed in a 2021 safety alert that factors that can increase the infection risk include “failure to follow manufacturer instructions, or continued use of devices despite integrity, maintenance, and mechanical issues.”[69]

Further underscoring these concerns, Klefisch et al. (2015)[70] – describing possibly the first reported case linking a reusable bronchoscope to a CRE outbreak – reported that an implicated bronchoscope remained contaminated despite reprocessing (which is a risk necessarily eliminated by single-use technologies). This bronchoscope, along with a second bronchoscope, was returned for repair to the manufacturer, who identified worn parts and surface defects in the working channel of both bronchoscopes. Following these repairs, no additional infections of the outbreak’s bacteria were identified.

Klefisch et al. (2015) concluded that, among other potential factors, biofilms forming at damaged sites within the bronchoscope may have contributed to this outbreak. Others have similarly reported the increased risk of infection associated with the unwitting use of a damaged (or inadequately repaired) reusable bronchoscope (with or without a formed biofilm).[71],[72]

In response to CMS’s comments in the *Federal Register*, use of a single-use bronchoscope also eliminates the risk of outbreaks of multidrug-resistant organisms associated with a facility’s inadvertent use of an improperly maintained, serviced, and/or repaired bronchoscope (*i.e.,* single-use bronchoscopes can provide a substantial clinical improvement *vis-à-vis* reusable comparators in this context).

9. A 2015 FDA Safety Alert

On the heels of safety alerts highlighting the risk of duodenoscopes cross-infecting patients, FDA published a safety communication on September 17, 2015, advising health care facilities of the potential for (reusable) bronchoscopes, too, to transmit disease.[73] In the context of this application, CMS refers to this specific FDA communication in the *Federal Register,* stating that: "We question the relevance of the 2015 FDA safety notice to the nominated device because as stated above, the guidance applies to reprocessed flexible bronchoscopes broadly, but not to disposable, single-use devices comparable to the nominated device."[74]

In response, respectfully, this 2015 FDA notice is relevant to this application for a number of reasons. First, while it is true that this notice does not directly apply to or recommend use of single-use bronchoscopes (it is my understanding that FDA did not clear the first completely disposable duodenoscope until four years later, in 2019[75]), the FDA's 2015 notice provides important historical significance and context, and most important, provides stakeholders with a better understanding and appreciation for some of the clinical benefits that single-use technologies can offer (*e.g.*, clinical enhancements in the context of multidrug-resistant cross-infection risks).

Second, FDA stated in this 2015 notice about bronchoscopes its awareness of reports (albeit a small number of reports at that time in 2015) indicating "persistent device contamination despite following the manufacturer's reprocessing instructions."[76] This assessment is germane to this application. As noted herein, single-use (sterile) bronchoscopes are not prone to ineffective reprocessing and/or their remaining persistently contaminated and cross-infecting patients, including with multidrug-resistant organisms, despite trained healthcare personnel following the manufacturer's reprocessing instructions.

Third, also demonstrating its relevance to this application and concerns about bronchoscope's infecting patients, FDA's 2015 notice references an FDA guidance document, published the same year (2015), that states that users of bronchoscopes (and other semi-critical devices) "should be instructed to thoroughly clean these devices and then reprocess them by sterilization. If the device design does not permit sterilization (e.g., device materials cannot withstand sterilization), then high level disinfection should be used."[77] In the context of reprocessing, this FDA guidance document concludes that bronchoscopes (among the other listed devices) pose "greater risks to the public health."

Fourth, further acknowledging their cross-infection risks, FDA wrote in this 2015 guidance document that bronchoscopes are "part of a subset of devices that pose a greater likelihood of microbial transmission and represent a high

risk of infection if they are not adequately reprocessed."[78] In fact, discussing disposable technologies, FDA wrote in this same document: "From the earliest stages of device design and engineering, manufacturers should consider alternative designs to facilitate effective reprocessing (e.g., replace features that are challenging to reprocess with single-use parts; include flush ports; specify and/or provide dedicated cleaning accessories)."[79]

Fifth, FDA issued a 2021 alert (six years later) that states it is "a supplement to the 2015 safety communication on reprocessed bronchoscopes."[80] FDA acknowledges in this more recent notice a reported association between a bronchoscope and multidrug-resistant clusters. Germane to this application, FDA recommends in the 2021 alert that healthcare facilities consider using a single-use bronchoscope (in certain situations, which are described in more detail below).

Reading the 2015 FDA safety alert, along with the FDA's 2015 guidance document (which this alert references) and FDA's 2021 safety alert, yields the reasonable conclusion that, indeed, germane to this application, bronchoscopes (like duodenoscopes) can pose a risk of remaining persistently contaminated and cross-infecting patients with multidrug-resistant organisms, and that the use of single-use bronchoscopes, which eliminates this concern, additionally satisfies the FDA's apparent preference that this (semi-critical) endoscope be sterile (when feasible), justifying a stakeholder concluding that single-use bronchoscopes provide substantial clinical improvement at least *vis-à-vis* reusable comparators in the context of the contamination and cross-infection risks, sterility, and a single standard of care.

10. One standard of care

Single-use (sterile) endoscopes offer a single standard of patient care, obviating clinical assessments about their need based on a patient's infection or immuno-status (*e.g.*, patients with prion disease[82]). Disposable

bronchoscopes provide the facility and every patient with a sterile instrument (*i.e.,* an associated sterility assurance level, or SAL, of 10^{-6}).

Acknowledged in the CDC's guidelines focusing on disinfection and sterilization, some healthcare facilities have modified their reprocessing procedures "when endoscopes are used with a patient known or suspected to be infected with HBV, HIV, or *M. tuberculosis*. This is inconsistent with the concept of Standard Precautions that presumes all patients are potentially infected with bloodborne pathogens. Several studies have highlighted the inability to distinguish HBV- or HIV-infected patients from noninfected patients on clinical grounds. In addition, mycobacterial infection is unlikely to be clinically apparent in many patients. … Endoscopes and other semicritical devices should be managed the same way regardless of whether the patient is known to be infected with HBV, HCV, HIV or *M. tuberculosis*."[83]

Use of single-use endoscopes is consistent with this CDC recommendation and promoted standard, offering facilities the option to provide a sterile bronchoscope to every patient (*i.e.,* a single standard) irrespective of whether the patient is known, suspected, or might be infected with *M. tuberculosis*, a blood-borne pathogen, or with CRE or another multidrug-resistant organism. Reports have linked transmission of multidrug-resistant *M. tuberculosis* to the inadequate reprocessing of (reusable) bronchoscopes.[84]

11. COVID-19

Dr. Muscarella's complete rebuttal discusses COVID-19 in the context of reprocessing bronchoscopes and using single-use technologies. Email him directly at: Larry@LFM-HCS.com to receive a copy of his complete rebuttal.

[End of rebuttal's excerpts]

Dr. Muscarella's expertise, experience:

Dr. Muscarella is an expert in the causes and preventions of hospital infections linked to endoscopic and other types of medical procedures. He also specializes in forensic case reviews, medical errors, medical device designs, risk assessments and gap analyses. His "bio" is available here.

Dr. Muscarella is an independent safety expert with almost 30 years of professional experience in the relevant fields of medical device design,

infection prevention, aseptic technique, risk management, disinfection and sterilization, and endoscope reprocessing.

He has authored more than 200 articles on these topics, including on the causes and prevention of endoscope-related bacterial outbreaks. Several of his peer-reviewed articles have been published in *Chest, The American Journal of Infection Control*, *Gastrointestinal Endoscopy*, *Infection Control and Hospital Epidemiology*, and *The Journal of Hospital Infection.*

Dr. Muscarella's research, findings and perspectives on these topics have been discussed by more than two dozen news media outlets, including *CNN, NBC's The Today Show, NBC Nightly News, ABC World News Tonight, Al Jazeera America,* and *the CBS Evening News*.

Additionally, his guidance and advice have been discussed on the front pages of *The Wall Street Journal, The Los Angeles Times, The Seattle Times, The San Juan Weekly, The Seattle Times,* and *The Denver Post*, among other printed newspapers.

More about Dr. Muscarella "bio" may be read here. Copies of his *curriculum vitae* (c.v.) are available upon request.

Details about the quality and expert services Dr. Muscarella provides healthcare facilities, patients, device manufacturers and legal representatives are available here.

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