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ANALYSIS

Transforming The Medical Device Industry: Road Map To A Circular Economy

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ABSTRACT A circular economy involves maintaining manufactured products in circulation, distributing resource and environmental costs over time and with repeated use. In a linear supply chain, manufactured products are used once and discarded. In high-income nations, health care systems increasingly rely on linear supply chains composed of single-use disposable medical devices. This has resulted in increased health care expenditures and health care–generated waste and pollution, with associated public health damage. It has also caused the supply chain to be vulnerable to disruption and demand fluctuations. Transformation of the medical device industry to a more circular economy would advance the goal of providing increasingly complex care in a low-emissions future. Barriers to circularity include perceptions regarding infection prevention, behaviors of device consumers and manufacturers, and regulatory structures that encourage the proliferation of disposable medical devices. Complementary policy- and market-driven solutions are needed to encourage systemic transformation.

The health sector is responsible for 4.6 percent of global greenhouse gas emissions, more than a quarter of which stem from the US health care system, and approximately the same proportion of pollutant air emissions.[1] Micro and macro plastic pollution is ubiquitous.[2] Environmental pollutants create a considerable public health burden. In the US alone, pollution from the health care industry results in up to 614,000 disability-adjusted life-years (DALYs) lost annually.[3] The vast majority of health care global greenhouse gas emissions originate in the supply chain, making this the area of highest impact for health care decarbonization.[1]

During the past thirty years the health care industry has become increasingly reliant on single-use disposable medical devices, particularly in high-income nations. Medical devices include all equipment used in the provision of medical care that does not primarily function through biological or chemical means. The health care supply chain can be grossly dichotomized into medical devices and pharmaceuticals. This article focuses exclusively on the former.

Single-use disposables are emblematic of a linear (or "take-make-waste") economy in which products are manufactured, used once, and disposed. This inherently unsustainable model of production and consumption contributes to global ecological destruction by depleting natural resources and generating excessive solid waste, global greenhouse gases, and other harmful environmental emissions. The effects imperil human health via air pollution, soil and water contamination, ozone depletion, ocean acidification, biodiversity loss, and catastrophic climate change.

A more sustainable framework that has gained traction with industry and policy makers is a circular economy, in which products are maintained in use at the highest-value application for as long as possible without terminating in disposal. By maximizing resource productivity and minimizing waste, a circular economy offers a means of operating within planetary boundaries, with the added benefits of building resilient supply chains and creating social value.

In this article we describe the current linear structure of the health care supply chain and its associated vulnerabilities. We examine barriers to achieving a circular economy, including assumptions regarding infection prevention, the behavior of health care institutions and providers (the "consumers" of devices), profit motivations, and regulatory structures that encourage the proliferation of single-use disposables and associated waste. We propose policy- and market-driven solutions to transform the health care supply chain into a circular economy. Because of the disproportionate contributions of the US health care industry to global health care emissions, this article focuses on the US market and regulatory landscape.

The Linear Health Care Economy

The shift toward single-use medical devices has resulted in environmental and public health damage, supply-chain vulnerability, and increased health care expenditures. The environmental and economic effects can be captured using life cycle assessment, a standardized modeling approach that accounts for resource inputs and emissions throughout a product's life cycle, including extraction of raw materials, manufacturing, transport, use and reuse, and disposal.[4] Published life cycle assessments of medical devices provide a foundation for quantitative comparison of linear versus circular consumption.[5] Several studies comparing single-use versus reusable equipment reveal that single-use disposables typically result in severalfold higher petrochemical use and global greenhouse gas emissions on a life-cycle basis.[6–9] Total facility cost-effectiveness studies further reveal that although single device acquisition costs are often lower for single-use disposables (leading to the perception of decreased cost), reuse distributes the cost over many uses and typically renders the lifetime cost of reusables substantially lower than that of single-use disposables.[7,9]

As the linear supply chain has become entrenched, many health care systems have transitioned to "just-in-time" ordering to minimize storage requirements and product expiration and thus have reduced their internal infrastructure for managing reusables. Such institutions are ill prepared to manage reuse, with limited ability to scale up supply in response to demand surges. Just-in-time consumable supply-chain systems are also vulnerable to disruptions from manufacturing shortages, interrupted transportation systems, international trade dynamics, and price shocks. These vulnerabilities have been especially visible during the coronavirus disease 2019 (COVID-19) pandemic, demonstrating that although single-use disposables are convenient under business-as-usual conditions, reliance on them increases the risk for catastrophic failure.

A Circular Health Care Economy

In contrast to a linear economy, in which the value of embedded materials and energy is lost with disposal, a circular economy is restorative or regenerative by design. Manufactured products flow in loops throughout the system, cascading through technological cycles of reuse, reprocessing, repair, repurposing, and recycling, maximizing material value and minimizing waste disposal (see online appendix exhibit 1).[10]

A circular economy minimizes resource input, waste, and emission and energy leakage by slowing and closing material and energy loops.[11,12] Slowing loops encompasses extending product longevity by designing for durability and developing reuse systems to maximize product life cycle. Closing loops refers to the creation of value from waste by finding new applications for spent materials. This includes industrial symbiosis in which outputs from one industry become feedstock for another. The concept of circular economy is a convergence of ideas spanning industrial ecology, biomimicry, natural capitalism, the performance economy, and other disciplines.[12]

Implementation of a circular economy is typically considered at one of two levels. Macro-level strategies involve economywide (for example, national, subnational, transnational) implementation, such as China's Circular Economy Promotion Law and the European Union's Circular Economy Action Plan. Micro-level implementation focuses on a group of sectors, products, or materials.[13] A number of studies have investigated the application of circular principles to medical device design[14] and business models.[15,16] Regulation and incentives are core implementation tools that encourage innovative business models for micro-level implementation.

Notably, some medical devices are best designed as single use. These are typically low-complexity devices that are difficult to clean,

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such as intravenous catheters, tubing, syringes, and needles. For these products, recycling to recover the base materials may be the best option.[14] At the other end of the spectrum are high-complexity devices such as medical imaging equipment, designed for long lifespans and maintained with cycles of maintenance, repair, and refurbishment. In between are devices for which circular design coupled with reprocessing protocols offers the possibility of maintaining product integrity—that is, keeping the device in use as close to its original state for as long as possible. The more complex the device, the higher the economic and environmental savings of maintaining product integrity.[14] On a system level, high-volume use of low-complexity devices accounts for considerable health care expenditures[17] and pollution and thus should not be discounted as an area for product recovery.

Transition to a circular economy requires the cooperation of diverse stakeholder groups moving toward a shared goal of systemic transformation. This article is structured around the respective roles of hospitals and health care providers (the consumers of medical devices); original equipment manufacturers; and regulators, accreditors, and professional standards organizations (exhibit 1).

Barriers To The Adoption Of A Circular Economy

There are a number of forces driving the single-use disposable–dominant health care supply

EXHIBIT 1

Stakeholders in the medical device industry

Stakeholders	Responsibilities
CONSUMERS OF DEVICES	
Hospitals, health care facilities, health systems	Develop supply-chain contracts and associated infrastructure; make purchasing decisions that determine the array of medical devices available for use by health care workers
Health care providers	End users of medical devices; make clinical decisions that determine necessity/volume of resource use; may have agency to influence procurement decisions and to select between medical devices where options exist
MANUFACTURERS	
Original equipment manufacturers	Research and development of new medical devices; marketing; ensuring compliance with regulation
Medical device reprocessors	Safe reprocessing and potential resale of used medical devices; ensuring compliance with regulation
REGULATORS, ACCREDITORS, AND PROFESSIONAL STANDARDS ORGANIZATIONS	
Governments US Congress	Shape regulatory landscape by legislation; set environmental targets; set government-funded health care budgets and strategic priorities; fund public health infrastructure
Regulators Food and Drug Administration Centers for Disease Control and Prevention Centers for Medicare and Medicaid Services Department of Health and Human Services Occupational Safety and Health Administration State and local departments of public health	Ensure safety and efficacy of medical devices, including the introduction of new devices to market and safe device reprocessing
Independent oversight bodies Joint Commission DNV GL Healthcare Center for Improvement in Healthcare Quality	Enforce regulations for hospital and health care organizations; accredit and recognize facilities for meeting or exceeding established standards
Professional organizations Society for Healthcare Epidemiology of America American Society for Microbiology Association for Professionals in Infection Control and Epidemiology Association of Operating Room Nurses American College of Surgeons American Society of Anesthesiologists	Translate knowledge and standards into policy and practice; standardize care within professions; inform regulators

SOURCE Authors' analysis of actors and their responsibilities in health care systems. **NOTE** Examples are not comprehensive and are limited to the United States.

Transition to a circular economy begins with a commitment to high-value care.

chain. The primary driver is a perception that single-use disposables are safer than reusable devices. Despite broad adoption of single-use disposables, however, there is no compelling evidence that they reduce health care–acquired infections. The risk of such infections is multifactorial, and the event rate is low enough that studies of specific consumables would require prodigious sample sizes under controlled circumstances that are not feasible. For example, to demonstrate a 10 percent (0.2 percent absolute) reduction in surgical site infections from a single intervention would require enrollment of almost 500,000 patients.[18] Most of the decrease in surgical site infection rates from 4–6 percent in 1987–90 to 2 percent in 2009 can be attributed to the use of evidence-based protocols to standardize care and enhance host defense mechanisms (for example, glycemic control and normothermia).[19–21] Furthermore, the goal of zero health care–acquired infections, although laudable, is unrealistic. A recognized proportion of events are unpreventable, and efforts to achieve zero adverse events may create other harms.[22]

Medical device consumers, manufacturers, regulators, accreditors, and professional standards organizations share responsibility for the throwaway culture of modern health care systems. To understand the barriers to a circular economy in health care and to formulate appropriate policy-driven reform, it is worth examining each stakeholder group's contribution to the status quo.

DEVICE CONSUMERS A linear supply chain minimizes liability and complexity for hospitals. Adoption of single-use disposables is a relatively easy way to minimize the possibility of human error in reprocessing reusable devices. Single-use blood pressure cuffs, for example, have been introduced to obviate the need for cleaning, despite little evidence that reusable cuffs are significant vectors of pathogens when properly reprocessed.[23] For more complex medical devices, such as endoscopes, bronchoscopes, and ureteroscopes, the possibility of a single-use alternative has not historically been entertained. Occasional outbreaks due to improperly cleaned scopes were addressed by enhanced cleaning protocols and validation processes. More recently, the possibility of single-use alternatives has been applied even to these expensive, complex devices.[24]

Many single-use disposables, ranging from low to high complexity, can be safely reprocessed. Hospitals, however, have largely eschewed this option, primarily because of concerns about liability and the costs and complexity of developing and maintaining the necessary in-house reprocessing infrastructure. Third-party commercial vendors have emerged to allow hospitals to outsource both liability and infrastructure. The resulting single-use disposable reprocessing industry extends the lifetimes of many products, allowing from one to many reuses, depending on the device, which translates into cost savings for device consumers. Reprocessing also reduces pollution from repetitive natural resource extraction, manufacturing, and disposal. In 2018 reprocessing companies in the United States, Canada, and Europe reduced hospital solid waste generation by almost 7,100 tons and generated cost savings of more than $470 million for device consumers.[25] Despite increased uptake of third-party reprocessing, however, only a small proportion of single-use disposable devices approved by the Food and Drug Administration (FDA) for reprocessing are actually reused.[26]

ORIGINAL EQUIPMENT MANUFACTURERS Original equipment manufacturers have driven the shift to a linear economy by manufacturing obsolescence into medical devices and engaging in anticompetitive behavior. Current business models incentivize single-use disposables over reusable alternatives because single-use disposables maximize profits through high-volume consumption. As a result, original equipment manufacturers promote their uptake by manufacturing obsolescence—for example, by arbitrarily labeling devices as single-use even if they might be safely reused, shortening "best before" dates to reduce shelf life, and designing products for short lifespans such as through flimsy construction. Strategies to prohibit reprocessing include covering critical pieces of the device in glue to prevent disassembly, designing unnecessary holes or creases to impede cleaning, and incorporating electronic chips and updating proprietary software to make capital equipment incompatible with reprocessed devices.[27]

Original equipment manufacturers have also acquired a number of third-party reprocessors and have subsequently reduced FDA submissions for approvals to reprocess additional types of single-use disposables.[28]

REGULATORY, ACCREDITORY, AND PROFESSIONAL STANDARDS ORGANIZATIONS Regulation and oversight of the medical device industry oc-

curs via a complex network of organizations, within which roles and responsibilities are sometimes ill defined. The lack of clear mandates and boundaries has contributed to proliferation of single-use disposables through the abrogation of responsibility for regulation to parties with conflicting interests. Lack of clear and consistent guidelines has resulted in confusion around standards for reusable device reprocessing. In this environment, many device consumers have resorted to single-use disposables to avoid the potential for error, citation, and liability.

▶ **CONFLICTING INTERESTS:** The FDA is responsible for authorizing medical device reprocessing. Regulatory protocols are commensurate with the degree of risk posed to the patient by the device (exhibit 2). The Centers for Disease Control and Prevention (CDC) dictates requirements for disinfection and sterilization in health care facilities. In general, these are based on the Spaulding classification,[29] a system that stipulates the level of decontamination based on medical device invasiveness. Unfortunately, the FDA and CDC have functionally divested themselves of these responsibilities and allotted them to manufacturers. For example, to market a device as reusable, the FDA requires the manufacturer to demonstrate that the product can be safely reprocessed, but there are no requirements for marketing devices as single use.[30] This creates a regulatory incentive for manufacturers to label devices as single use to avoid the time and financial resources required to validate a reprocessing protocol.

▶ **RECLASSIFICATION OF INFECTION RISK:** Manufacturer instructions for use are intended to describe decontamination procedures based on CDC-designated device class, not to designate device class itself.[31] On some occasions, however, the CDC has deferred to original equipment manufacturers' instructions for use instead of stipulating an infection risk class designation,

EXHIBIT 2

Systems for classifying medical device infection risk, reprocessing, and regulatory requirements

	Centers for Disease Control and Prevention (CDC) classification system				Food and Drug Administration (FDA) classification system		
Risk level	Category (infection risk)[a]	Contact tissue	Reprocessing requirements[b]	Examples	Category (safety)	Regulatory requirements	Examples
Low	Noncritical	Intact skin	Low-level disinfection (for example, alcohol, bleach, quaternary ammonium)	Stethoscopes, blood pressure cuffs, pulse oximetry probes, laryngoscope handles	Class I	General controls[c]	Bandages, tourniquet cuffs, single-use disposable scissors
Intermediate	Semicritical	Mucous membranes	Intermediate- or high-level disinfection with chemical disinfectants	Endoscopes, laryngoscope tongue blades, vaginal specula	Class II	General controls, performance standards, postmarket surveillance, patient registries, and premarket notification	Ultrasound probes, blood pressure cuffs, bronchoscope biopsy forceps, pulse oximeter sensors, compression sleeves, most laparoscopic equipment
High	Critical	Blood and normally sterile tissues	Sterilization with steam, ethylene oxide, or other chemical sterilants	Surgical instruments, implants, scalpels, needles	Class III	General controls, class III premarket notification, premarket approval	Implanted pumps, intra-aortic balloon pumps, transluminal coronary angioplasty catheters, percutaneous tissue ablation electrodes

SOURCE Authors' analysis based on the following sources. For reprocessing requirements: Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008 [Internet]. Atlanta (GA): Centers for Disease Control and Prevention; 2008 [last updated 2019 May; cited 2020 Oct 15]. Available from: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. For regulatory requirements: Food and Drug Administration. Regulatory controls (see note 31 in text). **NOTES** Reprocessing regulations are provided in different ways by the CDC and the FDA. CDC classes relate to defining infection risk, which dictates reprocessing requirements, whereas FDA classes relate to requirements for demonstrating safety, including pre- and postmarket surveillance, for market approval. The risk categories for each are overlapping but not equivalent. [a]Based on the Spaulding classification (see note 29 in text). [b]All devices must be cleaned before they are disinfected. That is, foreign material (for example, soil and organic material) must be removed. This is normally accomplished using water with detergents or enzymatic products. [c]FDA general controls pertain to the following: adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification and repair, replacement, and refund; records and reports; restricted devices; and Good Manufacturing Practices.

which has resulted in the manufacturers up-classifying device risk and thus overstating the difficulty of decontamination and reuse. This practice increases costs, emissions, and management complexity without demonstrated safety improvement. As health care organizations are required to follow instructions for use, many choose the convenience of single-use disposables to ensure that they remain in regulatory compliance.

Professional societies issue their own decontamination guidelines and designations of device infection risk, which may or may not be congruent with those of regulators and accreditors. For example, rigid laryngoscopes consist of two components; historically, the tongue blade was considered semicritical according to the CDC's infection risk classification, as it is placed in the mouth, and the handle was noncritical (exhibit 2). Discrepancies exist between professional societies, with some guidelines now calling the handle semicritical, requiring high-level disinfection, or calling the tongue blade critical, requiring sterilization.[32] The CDC has not made a clear infection risk determination and instead defers to the original equipment manufacturer instructions for use. The manufacturers recently began up-classifying laryngoscope instructions for use risk designations, despite the inherent conflict of interest and lack of authority to do so.[32] Many health care facilities have adopted an entirely single-use disposable laryngoscope to avoid navigating these guideline inconsistencies.

▶ **ACCREDITATION PRESSURE:** Hospital accreditation and certification bodies, such as the Joint Commission, are responsible for regulatory oversight, with deeming authority granted by the Centers for Medicare and Medicaid Services (CMS). Driven by the assumption of increased safety, accrediting bodies tend to favor single-use disposables. Because unfavorable accreditor reports may have serious consequences, including loss of eligibility for CMS reimbursement, and because decontamination processes are frequently the target of negative findings, many hospitals preemptively adopt single-use disposables.

▶ **ASYMMETRIC REGULATION:** The FDA is responsible for approving and monitoring the safety and efficacy of medical devices and has special controls for original equipment manufacturer class II and class III medical devices for which manufacturers are seeking marketing authorization. These include premarket data requirements that help provide a reasonable assurance of the safety and effectiveness of the devices.[33] In response to lobbying by the original equipment manufacturers, the FDA instituted more stringent regulation for single-use disposable reprocessors than for original equipment manufacturers for the same processes.[30] For example, the FDA terminated premarket approval exemptions for single-use disposable reprocessors to return to market the devices they reprocess while maintaining the exemptions for original equipment manufacturers' new device applications. Furthermore, to gain approval for single-use disposable reprocessing, reprocessors must include in their premarket submissions a whole category of validation data for cleaning, sterilization, and functional performance of devices to show that the reprocessed single-use disposable versions "will remain substantially equivalent."[30] This is not required by original equipment manufacturers of single-use disposables and only recently has been required for reusable devices.

Road Map To A Circular Health Care Economy

Achieving a circular economy in health care will require systemic transformation with buy-in from device consumers, original equipment manufacturers, regulators, accreditors, and professional standards organizations alike. This will require the introduction of complementary market- and policy-based solutions toward the shared objectives of eliminating waste and maximizing material and societal value.

DEVICE CONSUMERS Hospitals and health care providers can take a number of important steps to create conditions that promote a circular economy.

▶ **COMMITTING TO HIGH-VALUE CARE:** High-value care encompasses eradication of waste and inefficiency while maximizing patient outcomes and the experience of care in accordance with the triple bottom line framework.[34] Full-cost accounting incorporates traditionally externalized environmental and social costs of care along with financial costs, and weighs these costs against patient and population outcomes to determine value.[5]

Transition to a circular economy begins with a commitment to high-value care. This broader framework can drive efficiency of facilities operations with respect to energy and waste management and can nudge clinicians to be mindful of resource consumption and to select environmentally preferable drugs and devices where choices exist. Adoption of such high-value principles in procurement will foster circular and ethical supply chains.

▶ **REORGANIZING FOR REUSE:** Opportunities for slowing and closing material and energy loops should be sought and facilitated across

traditionally siloed clinical areas within institutions, and ultimately across sectors. For example, reusable surgical gowns are typically FDA approved for seventy-five reuse cycles before they are no longer suitable for high-level barrier protection. Multiple life cycle assessments have shown that reusable gowns can generate up to sevenfold less solid waste and half the amount of global greenhouse gas emissions compared with single-use gowns.[35] The environmental benefits would be amplified by repurposing spent surgical gowns as personal protective equipment for nonsterile clinical applications. This also bolsters supply-chain resilience by reducing dependence on single-use disposables. At the end of their clinical life cycle, reusable gowns can be used as fiber fill in other industrial applications—for example, upholstery or insulation.

Hospitals should have infrastructure for collecting recyclable materials for which reuse or reprocessing is not possible, such as packaging. Although recycling is the lowest-yield circular solution to reduce waste and emissions, clinical plastics are typically high grade, with the potential for recovery of embedded material and emissions. The challenges of securing recycling vendors for clinical materials have been successfully overcome in many systems.[36]

▶ **UPDATING PROCUREMENT POLICIES:** When health care facilities adopt procurement policies that favor reusable devices over single-use disposables, they send a strong market signal that innovation toward reuse will confer a competitive advantage.[37] Procurement policies can stipulate that disclosure of product environmental emissions through life cycle assessment is a necessary condition for entering into a service contract. This allows health care facilities to conduct true cost accounting in the framework of the triple bottom line.[5]

Large health systems and group purchasing organizations can leverage their considerable purchasing power for value co-creation by procuring ethically and sustainably sourced products and helping ensure a living wage, safe working conditions, and job security along the global supply chain.[5]

ORIGINAL EQUIPMENT MANUFACTURERS A circular economy requires that original equipment manufacturers adopt innovative business models and processes that reduce the profitability of excess consumption.

▶ **PERFORMANCE-BASED BUSINESS MODELS:** A recent systematic review identified nine circular business models in the medical device industry.[15] These ranged from established practices such as in-house reprocessing (for example, steam sterilization of steel surgical instruments) and third-party reprocessing (for example, laundry service providers) to more novel innovations such as sharing platforms to match supply and demand across health care institutions and full product-service system approaches. The latter is an example of a performance-based business model, also known as servicization, in which the manufacturer sells the service or function that a product provides, along with ongoing support and maintenance. Servicization is characterized by bundles of customer-focused combinations of goods, services, support, self-service, and knowledge.[38] Health care is particularly well suited to servicization because of the need for continuous, uninterrupted service and safe functioning.[16]

Regulation of medical and professional standards should prioritize circular product design and safe reuse.

Servicization has gained momentum in various industries because of the inherent material savings and value creation for both user and manufacturer. Rolls-Royce sells performance hours to airlines—not the jet engine itself. Philips offers lighting as a service instead of selling physical bulbs and fixtures. In the health sector, GE sells product-service packages that include the purchase or use of medical imaging equipment along with product maintenance. In so doing, companies expand their markets by avoiding high up-front capital equipment costs and are incentivized to ensure optimal durability for reuse and repurposing of spent components and materials. A case study of a product-service package approach to hemodialysis demonstrated a 50 percent reduction in overall costs and environmental impacts compared with business as usual.[16] Users should be vigilant to avoid entering into contracts with capital equipment service vendors that require purchasing high volumes of consumable components, often proprietary, that increase waste and hide costs.

There are many short- and long-term benefits to a servicization model, most notably the alignment of user-retailer incentives. Hospitals would receive higher-quality, durable, easy-to-clean medical devices, which are more desirable than

A circular health care economy offers an alternative to the unsustainable consequences of current practices.

single-use disposables manufactured for obsolescence. Use would be facilitated by technical support and product servicing. Original equipment manufacturers would design products and protocols to optimize reprocessing, instead of engaging in anticompetitive maneuvers with reprocessing vendors. Finally, by gaining visibility into the real-world use of their products, original equipment manufacturers could observe malfunctions and inefficiencies in action and innovate in harmony with clinical needs.

▶ **CIRCULAR PRODUCT DESIGN:** A servitization model encourages the design of durable products that are easy to disassemble and amenable to reprocessing and repair. Modularity, adaptability, and versatility are hallmarks of circular design. Because the original equipment manufacturer is responsible for product performance and safety, it is in its best interest to devise reprocessing protocols that are safe, effective, and easy to perform. When a product is worn out, the original equipment manufacturer is motivated to repurpose materials efficiently for new applications. The incentive to extend product life and maintain product value at the highest level drives innovation, encouraging optimal materials selection and circular product design.

REGULATORY, ACCREDITORY, AND PROFESSIONAL STANDARDS ORGANIZATIONS Policy-based solutions to drive a circular health care economy include both legislative and regulatory mechanisms. Governments have a role in establishing emissions targets and environmental regulations, and regulatory, accreditory, and professional standards organizations can drive circularity by considering population health in addition to individual patient risk.

▶ **REGULATIONS AND EMISSIONS TARGETS:** Governments shape the regulatory landscape in which private- and public-sector innovation occurs. Environmental targets for emissions and waste reduction can influence health care facilities' operations and help drive supply-chain reform. The recent commitment by the National Health Service of England to achieve net zero emissions in advance of the 2050 national mandate is an example.[39]

▶ **RIGHT TO REPAIR:** In recent years consumer advocacy groups and environmental organizations have objected to original equipment manufacturers' efforts to restrict repair and reuse of products. The right-to-repair movement has gained global traction, lobbying for legislation that mandates that manufacturers facilitate repair, including providing spare parts, manuals, and service equipment. Beginning in 2021 European Union legislation will require manufacturers to supply replacement parts for up to ten years.[40] In addition, Massachusetts passed the Motor Vehicle Owners' Right to Repair Act in 2013,[41] and twenty states have considered similar legislation for electronics, including medical devices unless specifically exempted. If right-to-repair were applied to original equipment manufacturers, it could be considered illegal to design devices that preclude reprocessing.

▶ **REGULATORY ENVIRONMENT TO DRIVE CIRCULARITY:** Regulators, accreditors, and professional societies focus almost exclusively on individual patient risk. Thus, they have tended toward the default position that patient safety is optimized by eliminating reuse of medical devices. An expanded notion of patient safety that considers population health would take into account the social and environmental damages of the current single-use disposable–dominant health care supply chain and encourage regulation and oversight that simultaneously promote population health.[5]

Regulators must reclaim responsibility for the safe sale and reuse of medical devices, including infection risk classification and value-based analyses that incorporate public health and environmental impacts. Regulation of medical devices and professional standards should prioritize circular product design and safe reuse. For example, regulators could restrict single-use disposable labeling to products for which safe reuse cannot be reasonably demonstrated, instead of allowing single-use disposable labeling by default.

▶ **ENVIRONMENTAL PRODUCT DECLARATIONS:** One challenge in developing guidelines that incorporate environmental impact is that most products are proprietary, and original equipment manufacturers have resisted disclosing information on product design and environmental emissions. Federal regulation mandating environmental product declarations for all medical devices, analogous to Health Product Declarations in the building industry, would require original equipment manufacturers to provide

environmental emissions transparency that would facilitate independent life cycle assessment verification and cost-effectiveness analyses.

▶ **EXTENDED PRODUCER RESPONSIBILITY:** Extended producer responsibility is a policy approach in which manufacturers and importers are given significant responsibility for the lifecycle environmental impacts of the products and packaging they bring to market. This creates incentives toward circular design, product longevity, and responsible postconsumer management. Extended producer responsibility was instituted provincially in British Columbia, Canada, in 2014 and has given rise to robust local markets for postconsumer materials. Producers pay for the collection, processing, and recycling of materials they create. The result is extremely high recycling rates (for example, 80 percent of beverage containers) and retention of resource value within the province.[42] A similar mandate from regulators of the medical device industry could drive circular design of products and packaging, improving resource life extension.

Conclusion

The pervasive and ongoing proliferation of single-use disposables in the health care supply chain has arisen from a multifactorial synergy of health care stakeholders. The costs of linearity, including environmental and public health damage, must be internalized as part of a commitment to high-value care so that the true cost of modern health care delivery can be captured and critically evaluated. A circular health care economy, built on principles of resource conservation, efficiency, and cycles of reuse and material recovery, offers an alternative to the unsustainable consequences of current practices. This requires comprehensive industry transformation driven by user demand and novel business models and encouraged by a favorable regulatory and professional environment that values public health and sustainability as highly as individual patient safety. ■

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10 To access the appendix, click on the Details tab of the article online.

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