



Sustainability Report 2019

ESG



Table of Contents

Introduction

A message from the ESG Board Director	1
About Cumberland Pharmaceuticals Inc.....	2

Sustainability Disclosure Topics & Accounting Metrics

Environment, Social & Governance Highlights 2019.....	3
---	---

Environment

Manufacturing and Supply Chain Quality Management.....	4
--	---

Social

Employee Recruitment, Development, and Retention.....	4
Employee Health and Safety	5
Drug Safety and Side Effects.....	5
Safety of Clinical Trial Participants.....	6
Patient Affordability.....	7
Fair Pricing.....	7
Community Involvement.....	7

Governance

Counterfeit Drugs.....	8
Corruption and Bribery.....	8
Ethical Marketing.....	9
Data Protection	9
Patient Data Privacy.....	9
Cybersecurity Preparedness.....	9



To our shareholders, employees and partners

In 2004 *Cumberland Pharmaceuticals* celebrated the FDA approval and launch of the Company's first brand - Acetadote[®], a truly life-saving product designed to treat America's leading cause of poisoning.

Today we enjoy a diversified portfolio of seven FDA approved brands, along with a robust portfolio of new candidates in development that address unmet medical needs. All along, our mission has remained the same – *to advance patient care through the delivery of high quality medicines.*

In this inaugural report we provide you with an overview of Cumberland's *Environmental, Social, and Governance* (ESG) Standards. As the largest biopharmaceutical company founded and headquartered in the Mid-South, Cumberland looks to be a leader in transparency and commitment to sustainability.

Our ESG standards are based on the following pillars:

- We recognize and embrace our responsibility to provide ethically produced and delivered medicines, while minimizing risk to our patients.
- We are an active member of our community through our membership in relevant associations and ongoing contributions to the health, education and wellness of our neighbors.
- Our products are priced based on the value they deliver. We will continue to establish reasonable prices, with modest and appropriate annual increases.
- We are committed to a culture of compliance dedicated to meeting the vast rules and regulations that govern our business.
- Our organization prides itself in the extraordinary team of talented individuals including our board, advisors and all our employees. We are dedicated to providing a safe, rewarding and enjoyable working environment for all involved in our organization.

I am proud of the foundation Cumberland has built upon over the years and the momentum the Company now enjoys. This first ESG report represents a milestone for the organization and I look forward to sharing updates with you on our continued progress with this important initiative.

All the best,

Caroline R. Young

Caroline R. Young
ESG Board Director



About Cumberland Pharmaceuticals Inc.

We are a specialty pharmaceutical company that acquires, develops and commercializes branded prescription biopharmaceutical products. Cumberland (Company) is dedicated to providing innovative products that improve quality of care and address unmet or poorly met medical needs.

Our primary mission is to improve upon patient care with products that offer clear advantages over existing treatments. We also strive to deliver solutions that may help reduce costs for healthcare providers, systems and ultimately patients.

Cumberland's commercial portfolio includes seven FDA approved brands.

The key market segments we operate in include hospital acute care and gastroenterology. These medical specialties are characterized by relatively concentrated prescriber bases that we can serve through small, targeted sales forces.

We promote our approved products through our hospital and field sales divisions in the United States. We own the worldwide rights to our brands and have established a network of international partners to bring our medicines to patients in their countries.

The Company has both product development and commercial capabilities and we believe we can leverage our existing infrastructure to support our growth.

Our strategy involves maximizing the potential of our existing brands, while continuing to build a portfolio of differentiated products. We also look for opportunities to expand our products into additional patient populations through clinical trials, through new presentations, and through our support for select, investigator-initiated studies.

We also actively pursue opportunities to acquire additional marketed products, as well as late-stage development product candidates in our target medical specialties. Our clinical team is developing a pipeline of new product candidates largely to address unmet medical needs.

Furthermore, we are supplementing these activities with earlier stage drug development at *Cumberland Emerging Technologies* (CET), our majority-owned subsidiary. CET partners with academic research institutions to identify and progress promising, new product candidates, which Cumberland has the opportunity to further develop and commercialize.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. Our shares are traded on the Nasdaq stock exchange, NASDAQ: CPIX, and we submit regular financial and other reports to the *U.S. Securities and Exchange Commission*, (SEC) which can also be found on our website at www.cumberlandpharma.com.



2019 ESG Highlights

Environment	Supplies	We contract with third party companies for the manufacturing, packaging and warehousing of our products.	
	Waste	We ensure strict guidelines and processes for the safe, permanent disposal of all unused product.	
	Returns	During 2019 we received and disposed of 9,689 pounds of damaged and expired products.	
Social	Male/Female	52% / 48%	
	Minorities	19%	
	Employees	Ages	6% below 30, 34% from 30-50, 60% over 50
		Tenures	23% @ 5 or more years, 17% @ 10 or more years, 5% @ 15 or more years
	Turnover	15%	
	Additions	20%	
	Career Development Program	Available to all corporate employees	
	Cumberland Academy	Provides industry training for corporate employees	
	Training	Average \$3,521 per full time employee	
	Work related injuries	None	
Patients	Product provided	3.95 million patient doses	
	Drug Safety results	<ul style="list-style-type: none"> • <u>No</u> products listed in the FDA’s MedWatch Safety Alerts • <u>No</u> products identified in the FDA Adverse Event Reporting System • <u>No</u> products recalled 	
	Patient Affordability	We cover up to 98% of patient Rx costs through coupons for our GI brands	
	Clinical Trials Safety	<u>No</u> trials terminated due to failure to practice good clinical standards	
	Advocacy Groups supported	The Scleroderma Foundation, Muscular Dystrophy Association, Cure Duchenne and Parent Project Muscular Dystrophy	
Community Involvement	Cumberland Pharma Foundation	Contributed to Denver Health, Vanderbilt, Mississippi, Mississippi State and Belmont Universities	
	Associations	<ul style="list-style-type: none"> • Nashville Health Care Council • Life Science Tennessee • Nashville Chamber of Commerce 	
	Life Sciences Center	Helping to build the biomedical industry in middle Tennessee	
Governance	Independent	7 of 9	
	Board	Tenure	Average 8.4 years
		Age	Average 67 years
		Male / Female	8 / 1
		Turnover	None
		Board Meeting Attendance	100%
Government Relations	Cumberland Health & Wellness PAC	Supports candidates, elected officials and relevant legislation	
Compliance	Code of Conduct	Establishes guidelines for all Board members and employees	
	Ethical Marketing	No government judgements, decrees or fines	
	Health Care Professionals	All reports regarding relations filed on time	



Environment

Manufacturing and Supply Chain Quality Management

Manufacturing, packaging or warehousing services are provided to Cumberland through contracts with qualified third-party organizations.

The Company utilizes one or two primary suppliers to manufacture each of its products and product candidates.

All manufacturers of our products and product candidates must comply with current Good Manufacturing Practices (GMPs) enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Cumberland is responsible for manufacturing and signs off on the release of every product. We are only aware of a warning letter from the FDA to just one of our manufacturers. Additionally, Cumberland does not participate in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program.



Social

Employee Recruitment, Development, and Retention

Cumberland Pharmaceuticals has an extraordinary team of talented individuals who are dedicated to our mission. We aim to provide a work experience which our team finds challenging, enjoyable, and rewarding. We have implemented a variety of employee recognition programs and incentive structures for both corporate and field-based positions. These programs are intended to contribute to an engaging, stimulating, fulfilling, and supportive work environment resulting in a vital organization. Our continuing education programs and employee development initiatives give our work force opportunities to grow in their knowledge of Cumberland as well as in their professional goals.

Our one-year industry training program, *Cumberland Academy*, is available to all eligible home office employees. Our *Employee Career Development Initiative*, which is administered by Cumberland Human Resources, includes discussing responsibilities and goals while providing an opportunity to explore each employee's career development. In 2019 Cumberland spent an average of \$3,521 per full time employee for training and development expenditures including clinical, staff, human resources & management training, sales training, seminars, and professional continuing education programs.



We value our employees and focus on fostering a culture of recognition and celebration of the excellence of our workforce. Multiple times throughout the year Cumberland awards employees for outstanding dedication and effort through four different award categories.

Additionally, our employees' health is of the utmost importance to our organization. Through our *Cumberland Health and Wellness Program* we encourage self-care through various means such as incentivizing every member of our team to stay current on their annual physical.

An Independent firm audits and evaluates our diversity profile and personnel activity. Our most recent information reveals that women represent 48% of our workforce, and 19% of our employees are minorities. The company turnover breakdown for 2019 was three Mid-Level Managers and eleven others from various departments which represents 15% of our total workforce.





Employee Health and Safety

Cumberland is dedicated to providing a safe atmosphere of equality, respect, and dignity for our employees and addresses many safety policies in our employee handbook. We believe that everyone has the right to work in an environment free from any kind of discrimination and conduct which may be considered harassment. The company takes seriously the problem of drug and alcohol abuse and has adopted a formal policy related to substance abuse. As employees travel, we support their utilizing locations which ensure a safe travel experience from their choice of hotels to safely parking their vehicles. Additionally, our corporate offices are located in a weapons free facility. From 2018-2019 Cumberland had no work-related injuries and a Days Away, Restricted, or Transferred (DART) rate of zero.

Drug Safety and Side Effects

Drug safety is a priority at Cumberland. Working in concert with the FDA, we follow strict procedures to assure the safety of our drugs.

A key responsibility of the FDA is to regulate the safety and effectiveness of drugs sold in the United States. The FDA divides that responsibility into two phases: pre-approval (pre-market) and post approval (post market). The FDA reviews manufacturers' applications to market drugs in the United States; a drug may not be sold unless it has received FDA approval. The agency then continues its oversight of drug safety and effectiveness as long as the drug is on the market.

Cumberland must demonstrate the drug's safety and effectiveness according to criteria specified by law and FDA regulations.

Furthermore, the Company must ensure that its products are prepared according to Good Manufacturing Practices in facilities that are inspected and cleared by the FDA as meeting all the regulations needed for a quality supply. FDA approval includes the drug's labeling, packaging, prescriber information, promotional materials and patient brochures.

Once a drug is on the U.S. market, Cumberland continues to follow FDA regulations that address drug production, distribution, and use. FDA compliance activities are based on ensuring drug safety and effectiveness and address product integrity, labeling, reporting of research and adverse events, surveillance, drug studies, risk management, information dissemination, off label use, and direct to consumer advertising.

At Cumberland drug safety is critically important. We have appointed personnel and have established systems to ensure an ongoing quality supply. The FDA holds us responsible for the manufacture of our brands and we perform a quality review before the release of each batch.

In 2019, Cumberland Pharmaceuticals had no products listed in the FDA's MedWatch Safety Alerts for Human Medical Products, and no products were identified in the FDA Adverse Event Reporting System.

None of Cumberland Pharmaceutical's products were recalled during 2019.

Furthermore we ensure strict guidelines and processes for the safe, permanent disposal of unused product at the end of its lifecycle. In 2019, 9,689 pounds of damaged and expired products were received as returns for disposal.

Once product is accepted for disposal, it is sent to licensed facilities and processed in a variety of ways. Some of the waste goes through a process in which non-recyclables are converted into useable energy. The remaining waste is incinerated to destroy the hazardous components and leaves ash, gas, and heat. Before its release into the atmosphere, any gas by-product is treated and cleaned.



Safety of Clinical Trial Participants

The safety of those involved in clinical studies is our highest priority.

We ensure Cumberland's informed consent process provides any individual in one of our studies with adequate information which allows them to make an informed decision about participation in the clinical investigation.

We facilitate the individual's understanding of the information by having our investigator (or other study staff member who is conducting the informed consent interview) discuss the contents of the informed consent document. This process occurs under circumstances that minimize the possibility of coercion or undue influence.

We then provide an appropriate amount of time to ask questions and discuss with family and friends the research protocol and whether the applicant should participate. We offer reimbursement for travel, lodging, and other expenses that the participant incurs while taking part in the study.

Next, Cumberland obtains the potential subject's voluntary agreement to participate and continues to provide information as the clinical study progresses or as the situation requires.

The steps within the consent process are documented on an appropriate form and in a research note that is placed in the research file to ensure that an adequate consent process was performed from the onset. The document is then updated as needed.

Throughout our trials, Cumberland complies with all requirements in the *International Conference on Harmonization's Good Clinical Practice (GCP)* guidelines as well as the *U.S. Code of Federal Regulations (CFR)*. Each of our sponsored studies adheres to a study-specific Monitoring Plan which outlines the specific requirements appropriate for the individual study. The Plan includes the types of source records to be reviewed, percentages of data points to be verified, escalation and mitigation plans for potential issues, safety reporting for novel occurrences and other relevant information.

Monitoring and study management tasks for studies conducted in the United States are completed directly by Cumberland employees. For international research, contract monitors are utilized and overseen in a project management capacity by a Cumberland employee.

During each clinical study, Adverse Events are identified, verified and reported covering the following topics: Human Research Subject Protection, *Investigational New Drug (IND)* Safety Reporting, and Site Monitoring Visits.

Each of Cumberland's active IND applications has its own Safety Surveillance Plan which details the method and scope of collecting and reporting any safety issues that occur on the studies under that IND. A Safety Assessment Committee is chartered in the Safety Surveillance Plan. Members typically include Cumberland's Medical Monitor and Chief Development Officer as well as project managers; external experts in relevant disease areas or biostatistics may also be invited to join a Safety Assessment Committee.

During 2019, no trials at Cumberland were terminated due to failure to utilize good clinical practice standards. Also, there were no fines or settlements associated with Cumberland clinical trials, and Cumberland has had no FDA Inspections of Clinical Investigators used for clinical trials.



Patient Affordability

Cumberland is committed to providing prescription products designed to improve quality of care and address unmet medical needs. We strive to deliver solutions that help reduce costs for healthcare providers and patients.

Through the Cumberland coupon program, 98% of patient costs are covered for the company's gastrointestinal products. The patient pays 2%.

Fair Pricing

Cumberland's policy is to compete fairly and comply with all laws designed to regulate aspects of business, including competition and pricing. We have no settlements of *Abbreviated New Drug Application* (ANDA) litigation and have not attempted to delay bringing an authorized generic product to market.

In 2019, the *Consumer Price Index* increase was 2.3%. For the category Prescription Drugs, the Index from 12/18 to 12/19 rose 3%. In 2019, the Producer's Price Index (PPI), which represents the average movement in selling prices from domestic production, rose 1.3%. For the category pharmaceutical preparations, the PPI increase was 1.9% in 2019.

The average list price increase for Cumberland products was 5% during 2019. This represents the average Wholesale Acquisition Cost. For Cumberland's products, the increase in list prices ranged from 0% to 9% with 9% increase representing Cumberland's smallest product.

Community Involvement

Cumberland has developed from a start-up to a publicly listed Company. Our Board of Directors decided to form the *Cumberland Pharma Foundation* in order to give back to the community in which we live and work. With a focus on health and education, our Foundation provides sponsorship support for select events as well as financial and other contributions to a variety of worthwhile causes.

Acting as the philanthropic arm of Cumberland, the Foundation provides ongoing support to various organizations whose activities align with Cumberland's mission to improve the overall quality of patient care and address unmet medical needs. We are honored to have had the opportunity to donate over \$30,000 to various non-profit organizations in 2019.





Governance

Counterfeit Drugs

Cumberland is committed to producing the highest quality of pharmaceutical products to meet or exceed the expectations of our customers. All products are prepared according to *Good Manufacturing Practices* (GMPs) in facilities with appropriate accreditation. We understand counterfeit drugs exist in the pharmaceutical industry, and we have implemented stringent initiatives and procedures to prevent counterfeit drugs from entering the market under the Cumberland brand. We have had no raids, seizures, arrests, and/or filing of criminal charges related to counterfeit products.

Cumberland has implemented an initiative to serialize all commercial products sold in the United States allowing us to track every unit sold. Through the serialization system, the vendor sets up a communication platform with our manufacturing facilities. This communication platform enables the manufacturer to assign unique product identifiers to each product produced and packaged. Once the manufacturer ships the finished product to the warehouse, our warehouse then logs the unique identifier code into their system and verifies it as part of the quality control process. The unique identifier on the product received matches the list of the unique identifier on a list in the warehouse.

Upon shipment of product, the warehouse notifies the wholesaler of the unique identifier list. These identifiers are also printed on the units of sale which are then scanned by the wholesaler once received. Wholesalers record this information when they receive product purchased from Cumberland. This system enables wholesalers to know where each serialized unit has been sold as well as being able to identify what healthcare facility has returned specific unit(s) of product. Every serialization identifier is kept in a master database for Cumberland's reference at any time.

If there is a potential or known risk associated with a counterfeit product, Cumberland sends a letter of notification to all hospital corporate offices of hospital chains and integrated delivery networks. Additionally, the letter is sent to all hospital chain facilities nationwide, ambulatory surgery centers, affiliated health care facilities, wholesalers, distributors, pharmacies and corporate offices and is addressed to the attention of pharmacy directors and medical directors. The Cumberland Pharmaceutical sales team is notified and then contacts their individual accounts with the pertinent information. For retail product, Cumberland alerts all retail pharmacy and corporate offices of pharmacy chains.

Corruption and Bribery

All Cumberland Associates are expected to comply with the Company's Standards and follow the applicable laws and regulations wherever the Company conducts business. Cumberland prohibits bribery in the conduct of its business. All Associates adhere to Cumberland's Standards and all anti-bribery regulations and laws, and we have had no fines, settlements, nor corrective actions brought against the company. Cumberland has developed *Standards of Business Conduct and Ethics* which can be found on the company website.



Governance

Ethical Marketing

Cumberland is committed to the highest levels of integrity and ethical marketing, and our employees are dedicated to a culture of excellence in compliance. We strictly adhere to all laws, regulations, and guidelines established by government agencies and industry associates responsible for the oversight of pharmaceutical marketing and sales. As a result, in 2019, Cumberland had no fines, settlements, or corrective actions initiated against it.

In marketing our products, Cumberland employees abide by *Pharmaceutical Research and Manufacturers of America (PhRMA)*, *Office of Inspector General (OIG)*, and Cumberland policies regarding the illegal practice of off-label promotion for our pharmaceutical products. The only product message and promotional materials that are acceptable for use in communication with persons outside Cumberland are those that are strictly on-label, which are specifically developed and approved by our Regulatory Affairs department. Initiating any type of off-label discussion places an individual at risk for disciplinary action up to and including termination.

Data Protection

Cumberland's data and equipment use policies ensure data privacy and protection. These policies are communicated to all employees upon joining the Company and are regularly communicated to staff through various means. Violation of any data security or privacy policy is subject to disciplinary action.

A variety of relevant controls are built into Cumberland procedures. These controls include user authentication, secure storage of data, and audit trails. Audits and security reviews are performed regularly to ensure a rigorous Information Technologies governance framework.

Patient Data Privacy

We have established a series of procedures to protect the privacy of those enrolled in our clinical trials. Study participants provide a written consent to have Cumberland representatives see their Protected Health Information (PHI). Medical and study records are located only at the research center (e.g. hospital or clinic) and authorized Cumberland personnel can only access this PHI while physically at that site.

If images of the original medical records are removed or transmitted elsewhere, all identifying information including name, contact details, driver's license and social security numbers are redacted from the document. Additionally, all participants in clinical trials are identified with a subject number, and any patient information captured, viewed, or analyzed at Cumberland is only identified by that number.

Cybersecurity Preparedness

We are focused on managing Cyber Security risk to protect the Business against security threats. Systems are in place to detect and respond to security incidents. Internal staff receive periodic security training. Cumberland engages industry leading third party security solutions that follow industry best practices to manage Cyber Security risk.

