A. Imposing Drug Price Caps Budget Proposal (S.2007 / A.3007 Part D)

The 2017-2018 Executive Budget proposed by Governor Cuomo contains language which would essentially empower the New York State Department of Health to establish "bench mark" prices for drugs identified as high cost drugs. The proposal is similar to but more expansive than that which Governor Cuomo advanced last year which the Legislature ultimately rejected.

The current proposal goes well beyond the Medicaid program and establishes, for those drugs identified as high price drugs, a 60 percent surcharge on the difference between the bench mark price set by the Department of Health and the price charged at the first point of sale in the state for all drug sales. The proposal grants the Department of Health extraordinary authority to review select drugs and compels manufacturers to produce to the Department voluminous and commercially sensitive information including the cost of developing, manufacturing, producing and distributing a drug; research and development costs including payments to predecessor entities; administrative, marketing and advertising costs. In addition to the 60 percent surcharge, the Department may require additional rebates when such drug is paid by the Medicaid program.

In 2014, the pharmaceutical industry employed over 19,000, paying an average annual wage of $73,375. The proposal represents a profound intervention into the private market place by a state. It would send a chilling message to the life science industry ultimately driving research, development and manufacturing activities outside of the State leading to a loss of New York State jobs. Further, the proposal mandates that pharmaceutical companies provide the State with highly sensitive, confidential and proprietary information, and is legally suspect.

Request:

MedTech respectfully **OPPOSES** the State's attempt to establish pharmaceuticals price controls for the following reasons:

- It will reduce pharmaceutical research and development investment decreasing innovation and leading to reductions in life expectancy and new therapies;
- the proposal will send a chilling message to the life science industry ultimately driving research, development and manufacturing activities outside of the State leading to a loss of New York State jobs;
- the proposal represents a unprecedented intrusion into the market place by a state and grants the Department of Health authority it is ill-equipped to exercise;
- the envisioned process places highly sensitive commercial information at risk, and
- the proposal is legally suspect.

B. New York Life Sciences Initiative

New York's life sciences industry is a significant part of the State's economy and has long standing roots throughout New York. A 2014 study commissioned by MedTech estimated that the bioscience industry has a total revenue impact on New York of $62.6 billion – including some $20.2 billion in Upstate New York alone. The bioscience industry employs over 205,000 people including 77,000 in Upstate New York. This includes direct, indirect and induced positions – so it is not just the bioscience industry that benefits from the life sciences. The region's more than 28,000 jobs make it large enough that if Upstate New York were a separate state, it would rank as the 18th largest bioscience industry in the U.S. Further, the average

annual bioscience wage in 2012 was $71,900, which averages about $30,000 annually MORE than the total private sector average for our region. These are highly skilled, highly prized jobs that contribute to the total economy of Upstate New York.

New York, however, faces stiff competition to retain and grow the life sciences industry here in New York from states which have advanced comprehensive life science initiatives including Massachusetts, North Carolina and California, as well as from other countries. Competing states have poached researchers from our leading academic institutions and companies, offered generous tax benefits and created workforce development programs targeted to the needs of life sciences companies. A survey commissioned by MedTech of 21 bioscience and medical technology executives, indicated that for growth in this important industry, New York needed a more formalized statewide system of academic partnerships, greater access to capital for startup companies and access to a skilled work force and key job skills such as research engineers and scientists, quality assurance/control/validation positions and product development.

The Governor's plan addresses these needs and more. It includes tax credits for research and development, supports key researchers in our academic centers, provides capital for startup companies and workforce development initiatives. It also makes available more than 3.2 million square feet of innovation space and 1,100 acres of developable land available tax free at 45 colleges and universities throughout New York which leverages the resources of the State's deep pool of leading academic institutions.

In short, the public-private initiative proposed by Governor Cuomo is comprehensive, and achievable. It raises the bar for New York as a leader in the life sciences industry and will accelerate the growth of the life sciences industry in New York.

Request:

MedTech fully **ENDORSES** Governor Cuomo's bold $650 million life sciences initiative. MedTech has long advocated for a comprehensive life sciences initiative and the Governor's initiative answers that call.

C. Device Warranty Bill (A.1964 Mayer / S.3942 Hannon)

Assemblywoman Mayer and Senator Hannon have proposed bills that would add an additional state requirement that electronic medical devices and implantable hip or knee devices be warrantied for five years.

Warranties are not appropriate for medical devices. Several factors involved with the performance of a medical device play a major role in the outcome of the device including surgical technique, hospital-related factors such as infection control procedures, the patient's overall health, anatomy, bone quality, weight, activity levels, and compliance with post-operative care. Consequently, even when a device functions correctly, negative outcomes may still occur.

There are also other means to ensure patient safety or educate practitioners about medical device outcomes. Currently, patients can track information relative to the outcomes of certain implantable devices through registries like the American Joint Replacement Registry (AJRR). The goal of the AJRR is to foster a national repository for data collection and research on total hip and knee replacement and serve as a vehicle for reduced morbidity and mortality, improved patient safety, improved quality of care and medical decision-making, reduced medical spending, and advances in orthopedic science and bioengineering.

Manufacturers, as well as, health care providers and patients, rely on the Food and Drug Administration's (FDA) extensive oversight over all aspects of medical devices to provide patients with safe and effective medical devices. This includes reviews prior to marketing a device and rigorous standards and inspections of manufacturing facilities and processes. The review process is well designed and balanced to assess the safety and effectiveness of medical devices while also fostering innovation with paralleled improvements in patient care. The FDA also administers all device recalls as a result of a device issue potentially causing minor, moderate or serious health risks.

Furthermore, the Federal Food, Drug and Cosmetic (FD&C) Act prohibits states from setting requirements on medical devices that go through the Premarket Approval (PMA) process that are "different from, or in addition to," the FDA requirements, or that relate to the safety or effectiveness of a medical device or any other requirement set up under the PMA rules. 21 U.S.C. § 360(k). The FDA does not require warranties for medical devices as set forth by the proposed legislation.

Request:

MedTech respectfully **OPPOSES** A.1964 / S.3942, which would require electronic medical devices and implantable hip or knee devices to be warrantied for five years. Warranties are not appropriate for medical devices given the multiple factors outside of the design and manufacture of a medical device influencing the outcome. The FDA provides strong oversight over medical devices and any potential issues, and further preclude state requirements in addition to or different from its own per the FD&C Act.

D. Right to Repair Bill (S.00618 Boyle)

Senator Boyle has introduced legislation to promote competition in the digital repair market and ultimately lower costs for consumers. The legislation would require manufacturers of digital electronic parts to make their non-trade secret diagnostic and repair information available for sale to third party repairers. It also requires manufacturers to produce clear contracts on what firmware is legally owned by the consumer and is retained by the manufacturer.

Unfortunately, while this bill is aimed at curbing monopolistic practices by electronics manufacturers (smartphones and computers), it also includes medical devices – a highly regulated environment where patient safety and efficacy are paramount.

Request:

MedTech requests **AMENDING** S.00618 (Boyle) with new language exempting medical devices and manufacturers from the legislation:

Add Section 1, (o):
Section 1, (o) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part, or accessory, as defined in the Federal Food, Drug and Cosmetic Act, 21 USC, Section 321 (h) as amended.

Add a new #7 on Page 4, as follows:
7. Nothing in this section shall apply to medical device manufacturers or any product or service of a medical device as defined in this section.