AdvaMed
Advanced Medical Technology Association

March 16, 2023

By Electronic Submission to https://www.regulations.gov/

Ms. April Tabor
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW, Suite
CC-5610 (Annex C)
Washington, DC 20580

Re: Non-Compete Clause Rulemaking, Matter No. P201200

Dear Ms. Tabor:

The Advanced Medical Technology Association ("AdvaMed") appreciates this opportunity to submit the below comments in response to the Federal Trade Commission's ("FTC") Non-Compete Clause Rule Notice of Proposed Rulemaking ("NPRM"), published at 88 Fed. Reg. 3482 (January 19, 2023).

The FTC's proposed rule would significantly impede medical technology innovation and reduce competition, resulting in diminished quality and increased cost of healthcare available to patients. Any rule must take a more nuanced approach to regulating non-compete agreements to ensure patient health, innovation, and competition are not unintentionally sacrificed.[1]

I. AdvaMed and the Medical Technology Industry

A. Who We Are

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information

[1] AdvaMed notes there is a question as to whether the FTC has authority to issue this proposed rule. The FTC asserts authority for the proposed rule under Section 5 of the Federal Trade Commission Act, however, as a threshold matter, the following legal questions must be addressed: (1) whether the FTC has authority to engage in "unfair methods of competition" rulemaking, (2) whether the FTC has clear Congressional authority to conduct rulemaking on a "major question" that will impact the entire economy *(see West Virginia v. EPA*, 142 S. Ct. 2587 (2022)), and (3) to the extent Congress granted such authority, whether that grant was an impermissible delegation of legislative authority.

systems. Together, our members develop and manufacture much of the lifesaving and life-enhancing healthcare technology purchased annually in the United States and globally. These include technologies, devices, equipment, diagnostic tests, and health information systems that help patients stay healthier longer; recover more quickly after treatment; and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible, transforming healthcare.

Our members range from the largest to the smallest medical technology producers and include hundreds of small companies with fewer than 20 employees. They are committed to the development of new technologies and services that allow patients to lead longer, healthier, and more productive lives. As a result:

- Since 1980, five years have been added to the U.S. life expectancy attributed to advancements in medical technology;[2]
- Developments in medical technologies have dramatically reduced the number of patient-days spent in hospitals;[3] and
- Medical technology advancements have dramatically reduced disability rates, and dramatically increased disability-free life expectancy.[4]

At the same time, innovation and advancements in medical technology result in dramatically reduced healthcare costs.

B. Patient Health and Medical Technology Innovation

The role of medical technology innovation in improving patient health is well-known. As stated in a report requested by the Food and Drug Administration and prepared by the National Academy of Sciences, Institute of Medicine ("NAS Report"):

> Pain, suffering, and death from disease still plague patients worldwide. Even where solutions exist, many are suboptimal, and there is much room for improvement. Fortunately, the US economic system has created incentives and

[2] National Center for Health Statistics. "Health, United States, 2014: With Special Feature on Adults Aged 55-64." Hyattsville, MD. May 2015.

[3] Between 1980 and 2010, there was a 60% decrease in patient hospital days as a result of developments in medical technologies. National Center for Health Statistics. "Health, United States, 2014: With Special Feature on Adults Aged 55-64." Hyattsville, MD. May 2015.

[4] Disability rates declined by 25 percent from 1982 to 2000, and disability-free life expectancy has increased over time. National Center for Health Statistics. "Health, United States, 2014: With Special Feature on Adults Aged 55-64." Hyattsville, MD. May 2015.

> resources to promote and reward innovation. . . . That has created a medical device (also called medical technology) innovation ecosystem in which ideas can become realities that can affect health care.[5]
>
> The medical device innovation ecosystem has multiple components:
>
> - **'Fuelers'—**venture capitalists, investors, and public markets that support the process and invest in the innovators.
> - **Innovation catalysts—**small startups, large companies, incubators, and other entrepreneurs that invent the technology or take a concept through to commercialization.
> - **Regulators—**the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), third-party payers, and professional societies (which play a substantial role in patients' access to new technologies).
> - **Consumers—**patients, physicians, and hospitals.[6]

All these entities play an important role in the development and advancement of medical technologies. For example, practicing physicians often consult during the development of medical technology, where they share real-time feedback on how a device could be improved, communicating their essential knowledge from diagnosing and/or treating patients while company representatives share their essential knowledge of the technology with the physicians to ensure the best products are reaching patients.

As a result of the innovation ecosystem, the U.S. medical technology industry is responsible for a highly disproportionate share of medical advances globally.[7] Yet, this "medical technology innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial. . . .The system is already under immense economic pressure."[8] The fragility of the innovation ecosystem results from several factors, including (1) the short product device life cycle, in which products are replaced by new or improved products on average every two

[5] National Library of Medicine, National Center for Biotechnology Information, Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report at 17, available at https://nap.nationalacademies.org/download/12960.

[6] *Id*. at 18.

[7] The United States is ranked first in various measures of healthcare innovation. *See, e.g.,* 2020 FREOPP World Index of Healthcare Innovation, ranking the United States first in Science & Technology Healthcare Innovation with a score of 75.14, well above second-place ranked Netherlands (49.97). Available at https://freopp.org/wihi2020-505b1b60bce6.

[8] NAS Report at 21.

years;[9] and (2) the process from concept to product launch is extremely expensive.[10] Numerous additional obstacles can stifle ideas and cost-saving improvements in healthcare from successfully reaching the market to help patients, including funding challenges, particularly for small companies; insurers' resistance to cover new treatments; and the complexity of the regulatory process. Robust competition in medical technology innovation is critical to the continued, rapid, and often dramatic advancements in healthcare made by medical technology companies. Indeed, innovation, not price, is the primary driver of competition in the medical technology industry.[11]

Another factor contributing to the delicate nature of medical technology innovation is the vital role of small companies in that process. As the NAS Report observed:

> The survival of small companies is critical for delivering innovation to patients. . . . Most of the ideas that really change the practice of medicine come from small companies or individual inventors. Department of Commerce statistics show that in 2002, 3,725 of the 6,007 US medical device firms being regulated by FDA had fewer than 20 employees, and only 150 had more than 500 employees.[12]

For these and other reasons, the continued ability of medical device companies of any size to make rapid, significant, and sometimes transformational advances in healthcare technology depends upon their continued substantial investments in innovation, research, and development, *as well as* their ability to protect and recoup their investments in these activities and their employees through fair competition. Protecting the value of their intellectual property, trade secrets, and other confidential business information via non-compete agreements is critical to achieving these goals and essential to fair competition in this innovation-driven industry. That is, non-compete agreements safeguard innovation and competition within the medical technology industry.

[9] *Id.* at 20. Invention, development, and commercialization of new medical technologies is a lengthy, complex, labor-intensive process, however, the life cycle for similar replacement products is typically much shorter such that protecting an innovator's initial investment in creating new technologies is paramount.

[10] *Id.*

[11] Deloitte Center for Health Solutions, Medical Leaders Prioritize Technology and Consumers (2020), at 4 (available at https://www2.deloitte.com/us/en/insights/industry/life-sciences/medtech-industry-survey.html)

[12] NAS Report at 18.

II. The FTC's Proposed Rule Would Harm Innovation, Investment, and Competition to the Detriment of Patients

The FTC suggests that non-compete agreements harm competition, however, within the medical technology industry, innovation and investment drive competition and prohibiting non-compete agreements harms innovation and investment. Trade secrets, intellectual property, proprietary, and other confidential business information (collectively "confidential business information") reflecting and/or utilizing companies' innovation, research, development, and inventions are the lifeblood of the medical technology industry. The risks posed to the medical technology industry by an employee/consultant joining a competitor and taking with them high-value confidential business information are profound.

Former employees are a major, if not the primary, source of misappropriation of medical technology confidential business information.[13] Where a former employee is employed by a competitor in the same capacity as their former job, it is often impossible for that former employee in such circumstances to do the work expected of them in their new job *without* using the non-public, proprietary, and valuable knowledge they gained in their former job. Once they join the new company and begin work, the harm to the former employer is often inevitable and difficult to detect by the employee's former employer.

In order for the medical technology industry to continue delivering lifesaving/life-enhancing technologies to patients, companies must be able to freely share their confidential business information during the design, development, and commercialization processes without fear that the employees and consultants critical to these initiatives will walk out the door and take the information to a competitor. This free sharing of information and ideas is critical to fostering the collaboration needed to invent new technologies and timely deliver them to patients. Non-compete agreements allow innovator companies to protect their knowledge assets from knowledge spillovers, limiting the risk their confidential business information will be obtained and misappropriated by competitors.

The FTC proposes that Nondisclosure Agreements ("NDAs") and federal and state trade secret laws are sufficient to protect confidential business information, however, NDAs and/or trade secret laws alone cannot adequately protect the medical technology industry from the risk and harm of trade secret misappropriation. For example, given the short innovation cycle in the medical technology industry, an innovator would be unlikely to learn about the misappropriation of its trade secrets until after the competitor releases its new competing product, resulting in substantial marketplace loss to the innovator that cannot be recouped through any available

[13] After an eight-week trial, a Texas state court jury recently returned a verdict finding that more than a dozen former employees, including the company's former Executive Vice President, conspired to steal company trade secrets to benefit a rival company and owed their former employer millions in damages and legal fees. *DNOW LP vs. Toby Eoff et al.*, case number 22-DCV-294327, in the 434th District Court of Fort Bend County, Texas.

legal remedy. NDAs also do not protect against unintentional disclosure of negative knowledge[14] or confidential business information when an employee is conducting research and development for their new employer. Even if individuals do not directly disclose negative knowledge, it is impossible to prevent employees from using information already in their head, and it is similarly impossible for the employees themselves to ignore negative knowledge or other confidential business information that they have already acquired.

Numerous courts have recognized that money damages cannot adequately compensate a manufacturer for the actual and future damages resulting from misappropriation of confidential business information in the form of "loss of goodwill, loss of competitive advantage, and loss of research incentives."[15] Courts have also correctly recognized that the "loss of trade secrets cannot be measured in money damages" because a "trade secret once lost is, of course, lost forever," and the fact that a single trade secret may be disclosed to a new employer is enough to cause irreparable harm.[16]

The FTC's proposed rule would likely result in reducing competition in the medical technology industry because the majority of the industry could not afford millions of dollars in litigation costs or the loss of their entire investment in research and development, significantly curtailing advancements in lifesaving medical technologies available to patients. A 2019 report from the American Intellectual Property Law Association estimated the median cost to litigate a trade secret case was $4.1 million where the financial risk was between $10 million and $25 million. In fact, the same report estimated that where the financial risk was less than $1 million, litigating

[14] Negative knowledge is experientially acquired knowledge of what does not work or what paths to avoid. In the medical technology industry, negative knowledge can include information grounded in years of research and development but quickly acquired by employees/consultants entering the technology development process at any point.

[15] *See, e.g., Brake Parts, Inc. v. Lewis*, 443 F. App'x 27, 27 (6th Cir. 2011) (absent a preliminary injunction, plaintiff would suffer irreparable injury such as loss of goodwill, loss of competitive advantage, and loss of research incentives, arising from the misappropriation of its brake-pad formulations); *Bimbo Bakeries USA, Inc. v. Botticella*, 613 F.3d 102, 118 (3d Cir. 2010) (former employer would suffer irreparable harm absent injunctive relief because the disclosure of its trade secrets by a former employer to a new employer would put the former employer at a competitive disadvantage that a legal remedy could not redress); *Par Pharm., Inc. v. Quva Pharma, Inc*., 764 F. App'x 273, 278 (3d Cir. 2019) (former employer demonstrated a reasonable likelihood that its trade secrets had been misappropriated by its former employee, and absent injunctive relief it would suffer irreparable harm).

[16] *See, e.g., See, e.g., N. Atl. Instruments, Inc. v. Haber*, 188 F.3d 38, 49 (2d Cir. 1999) (a loss of trade secrets constitutes irreparable injury that cannot be measured in damages because once a trade secret is lost, it is lost forever); *FMC Corp. v. Varco Int'l*, Inc., 677 F.2d 500, 503 (5th Cir. 1982) (the fact that a single trade secret may be disclosed to a new employer is enough to cause irreparable harm); *Norbrook Labs. Ltd. v. G.C. Hanford Mfg. Co*., 126 F. App'x 507, 509 (2d Cir. 2005) (plaintiff will suffer irreparable harm where the ex-employee had shared misappropriated trade secret with his new employer, including the loss of the advantage of being a pioneer in the field); *Fres-co Sys. USA v. Hawkins*, 690 F. App'x 72, 73 (3d Cir. 2017) (affirming finding of likelihood of irreparable harm and entry of injunction where former employee in possession of trade secrets was hired by competitor for same job, in the same industry, and in the same geographic area).

trade secret misappropriation would cost even more than the financial risk itself.[17] This is a considerable burden for a company of any size to bear, but particularly threatening to the small- and medium-sized enterprises that make up the majority of medical technology innovators in the United States.

There are various examples of how reasonable non-compete agreements are appropriately used in the medical technology industry to protect critical confidential business information. For example, employees working on ongoing research and development prior to a company filing for patent rights hold confidential business information at a critical juncture of invention protection. If one of these employees moves to a competitor and uses technology developed/learned at the original employer, then questions can be created as to inventorship as well as scope of information in the "public domain" – both of which would impair the patent rights of the original employer. Likewise, a nefarious foreign company need only set up shop next to an innovator company and hire away a few key employees to gain access to the innovator company's confidential business information through intentional/unintentional disclosures by the former employees, undermining the survival of the innovator company and all its remaining workers. Without non-compete agreements, medical technology companies would likely be forced to limit the number of people involved in the research and development process because they would not be able to otherwise protect their intellectual property, stifling the collaboration and diversity of thought necessary for ideas to come to life and reach patients.

Similarly, medical technology companies devote tremendous resources training sales consultants who, in turn, train and develop close working relationships with physicians/surgeons, acquiring specialized knowledge of the companies' products and the medical procedures for which the products are used. This training and communication with physicians/surgeons are necessary because medical technologies often have unique settings and technical controls that must be used properly to ensure safe and effective care of patients. For instance, sales representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with medical technology that involves multiple devices and/or accessories. Non-compete agreements allow the medical technology industry to invest in this expensive, sophisticated training without fear that a competitor can simply hire that same sales consultant to sell similar products used in the same procedures with the same physician(s), thereby free riding on the previous employer's training investment. Without non-compete agreements, medical technology companies may be forced to limit the number of people with access to this training to protect their investments in new technologies, resulting in fewer sales consultants available to provide sophisticated operating room training.

[17] *See* American Intellectual Property Law Association, Report of the Economic Survey (2019), available at https://www.ipwatchdog.com/wp-content/uploads/2021/08/AIPLA-Report-of-the-Economic-Survey-Relevant-Excerpts.pdf

Likewise, as discussed earlier, physicians play an important role in the medical technology innovation ecosystem, often consulting during the development of medical technology.[18] During that process, it is important that inventors are able to communicate freely with the consulting physicians while protecting their confidential business information, and non-compete agreements are an essential tool for doing so. Consulting physicians are typically compensated for their time and experience and, in exchange, agree not to consult with competing innovators while having no restrictions on their practice of medicine.

Additionally, as part of the medical technology industry's mission to bring lifesaving/life-enhancing technologies to patients, mergers and acquisitions ("M&A") (as well as venture capital and private equity) play a key role. Medical technology startups are critical to innovation but often require the capability and financial backing of other organizations to advance their transformative technologies, which requires performing clinical studies, obtaining regulatory approvals, and commercializing their inventions to ultimately reach a broad patient population in need. Non-competes are necessary tools in M&A/investment agreements and are commonly bargained for – the skills and knowledge of a startup's founder(s) and workforce are essential to the value of its technology such that the founder(s) and workforce can demand a high price for their innovation *and* subsequent wages. The FTC's proposed rule disrupts this freedom to contract by introducing an unnecessary threat to the buyer/investor of losing the value of their investment. For example, if key leaders have the immediate freedom to establish competing companies or engineers swiftly depart to work on competing technologies, the substantial value of the target company is lost, disincentivizing innovation because innovators will not be able to trust that they can obtain the investments necessary through M&A to ultimately bring their technologies to market. A complete ban on non-compete agreements would have a widespread impact on M&A and the ability to obtain capital in the United States, likely resulting in the majority of medical technology companies (smaller companies) never bringing their products to market, reducing competition and depriving patients of lifesaving/life-enhancing technologies.

Ultimately, NDAs and trade secret laws are ineffective tools for preventing the misappropriation of confidential business information and protecting the medical technology industry's significant investments in innovation and talent.[19] Additionally, the FTC's proposed rule brings even more uncertainty to innovators' ability to protect their confidential business information and investments by seeking to ban NDAs and other "covenants" that the FTC deems "function as"

[18] *See supra* at 3.

[19] The FTC mentions fixed-term contracts as another available alternative to protect valuable investments (NPRM at 99-100), but these contracts do nothing to protect confidential business information once the contract ends and the employee/contractor is no longer working for the employer innovator. Fixed-term contracts are also arguably more restrictive to employees because they bind employees to a particular job for a specified period of time, prohibiting employees from freely (at will) seeking employment anywhere (not just competitors) during the entire duration of the contract.

non-compete agreements, calling these agreements *de facto* non-competes,[20] as well as threatening to preempt longstanding existing trade secret laws. Likewise, retroactively invalidating legal non-compete agreements also jeopardizes an extraordinary amount of lifesaving/life-enhancing technologies. For the medical technology industry, preventing the misappropriation of confidential business information and protecting the industry's investments in innovation and talent are essential for ensuring patient access to the best medical technology possible. The FTC's overly broad and nebulous ban on non-compete and "*de facto* non-compete" agreements prevents the industry's ability to do so. In fact, the FTC's suggestion that non-compete agreements harm competition does not apply to the medical technology industry where innovation/investment drive competition and prohibiting non-compete agreements harms innovation/investment.

III. The FTC's Proposed Alternatives / Carve-Outs Do Not Protect Innovation and Patient Health

In putting forward various alternative proposals allowing for non-compete agreements to be used in certain circumstances, it appears the FTC is acknowledging that non-compete agreements have value. The FTC's alternative proposals, however, do not protect innovation and patient health. Any rule should take a tailored approach and consider what confidential business information is appropriate to protect through a reasonably construed non-compete restriction. For example, in the medical technology industry, salaries alone do not dictate who has confidential business information that, if misappropriated, would derail innovation to the detriment of patient health. Salaries also often vary based on geography and size of a company.

Similarly, the FTC's carve-out permitting non-compete agreements for the sale of a business shows there is value in non-compete agreements, but limiting this exception to individuals owning a 25% share of the company being purchased is not founded in the realities of the market – i.e. no individual, even a founder, typically owns 25% of a target company by the time it is being acquired. Private equity firms, for example, often own large percentages of start-up companies in exchange for providing the capital needed to bring their transformative technologies to market. The FTC's rejection of non-compete protections in these contexts will limit innovation and stifle much needed investments in research and development of medical technologies in the United States.

[20] NPRM at 108-110.

IV. Conclusion

The FTC's proposed rule to ban reasonable, appropriately used non-compete agreements takes away the only reliable mechanism for medical technology innovators to protect their confidential business information and investments in innovation and talent such that they can continue bringing lifesaving/life-enhancing technologies to patients as quickly and effectively as possible. Any rule must take a more nuanced approach to regulating non-compete agreements and recognize that certain confidential business information needs to be protected – anything less jeopardizes patient health, innovation, and competition.

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Thank you in advance for your consideration of AdvaMed's comments to the FTC's proposed rule. Please do not hesitate to contact AdvaMed at (202) 783-8700 or Ida Nassar, Vice President, Assistant General Counsel, Compliance & Ethics (inassar@advamed.org) with any questions.

Sincerely,

/s/
Christopher L. White
Chief Operating Officer and General Counsel
Advanced Medical Technology Association (AdvaMed)