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Commentary: Entrepreneurship and the academician FREE

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Commentary

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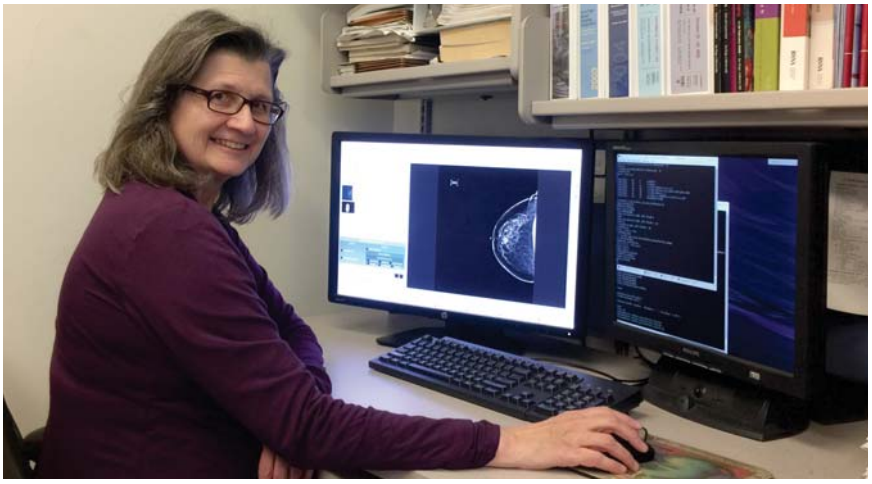

MARYELLEN GIGER, author of this commentary, is the A. N. Pritzker Professor of Radiology/Medical Physics at the University of Chicago. She is president of SPIE—the International Society for Photonics and Optics—and cofounder of Quantitative Insights, which has produced the first Food and Drug Administration–cleared machine-learning system to aid in cancer diagnosis.

As an undergraduate physics and mathematics student, I spent my summers working at Fermilab. While there, I was drawn to medical physics, because I felt that developments in that field might directly affect society during my lifetime. I completed my PhD degree in that broad discipline, which applies physical principles to biological and medical issues.

Many medical physicists have careers in either imaging science or radiation therapy. I chose imaging science, and that path has taken me on an exciting ride into the computer interpretation of medical images as a tool for radiologists and other physicians. For the past three decades, I have worked as an academician with the goal to create new knowledge and more recently as an entrepreneur to translate and commercialize that knowledge for the betterment of society.

The benefit of a medical imaging examination relies on both the physical quality of the images and the quality of their interpretation. For example, if a conventional chest radiograph is underexposed, the resulting image could include noise that would reduce the clarity of useful information. In another example, obtaining a three-dimensional CT (computed tomography) image instead of a single-projection radiograph may yield additional information. Development of CT, MRI, PET (positron emission tomography), and quality standards for radiography account for many milestone improvements in image acquisition.

The job of interpreting medical images is conducted by radiologists, whose interpretation could include missed detections, diagnostic misclassifications, and qualitative assessments of changes as perceived on an image. Having a computer yield reproducible quantitative analyses effectively and efficiently could improve the image interpretation process.

In the 1980s and 1990s, I was part of a University of Chicago team of imaging scientists and radiologists who established the field of CAD (computer-aided detection and computer-aided diagnosis). The company R2 Technology licensed our patents from the university and translated our research into a usable technology. A side benefit of the licensing process was that royalties and other payments came back to our academic labs and thus helped fund the team's continued research.

R2 further developed our work into the ImageChecker, which in 1998 became the first FDA-approved system for computer-aided detection in medical image interpretation, specifically as a second reader in breast cancer screening mammography. An interesting side note is that the ImageChecker included an early deep-learning neural network.

The public has seemed ready to embrace the use of computers in medical image interpretation.

During the past few years, a University of Chicago startup company, Quantitative Insights, worked to translate my lab's research on CAD into the artificial intelligence product QuantX. The process was initiated in 2009, when a team of one medical physics graduate student from my lab, one medical student, and two MBA students entered our research prototype in the University of Chicago's New Venture Challenge. As a finalist, our team benefited from mentoring from experts in the Chicago Innovation Mentors program and funding from the university's Innovation Fund. With continued access to the university's technology-transfer office—the Polsky Center for Entrepreneurship and Innovation—and with a focused team that included some of my former students, the prototype became a product. In July 2017, QuantX, through the *de novo* process, became the first FDA-cleared machine-learning system for use in cancer diagnosis.

The road from conception and identification of the clinical problem to comple-

tion of the FDA review is a long one, with many steps along the way. The journey involves investigation of potential mathematical techniques, development of methods, robustness assessment, validation, and translation and commercialization through company startup. All stages are crucial, and with each milestone, the sense of accomplishment is great.

Many research-lab developments have demonstrated performance on particular data sets or under particular conditions, resulting in grants, journal papers, and conference presentations. However, in going through the FDA, demonstrated performance is necessary on a range of cases, disease subtypes, physical acquisition systems, and ultimate users.

In medical imaging, the hype and hope of machine learning with deep learning is rapidly growing. Currently, computers are seen as augmenting and enhancing the radiologists' interpretation. Some tasks will ultimately be conducted by the computers, with radiologists handling interpretation of the computer output and patient management recommendations. Radiologists will need to integrate the analyzed data, relate it spatially within the patient, and continue to conduct interventional diagnostic and therapeutic procedures. Also, as there are many disease types, disease stages, imaging-system presentations, and patient populations, it will be a long time before all medical interpretations have associated artificial intelligence methods. Besides time needed for the development of the various AI methods, the testing within the FDA process will also take time.

As an academician, I've conducted basic research in applied mathematical methods for extracting information from medical images. As an entrepreneur, I've contributed to the conversion of that research into an FDA-cleared product for clinical use. Both parts of the process have solidified my views on innovativeness, teamwork, rigorous problem solving, and validation. I am grateful to the University of Chicago for the experience it has afforded me through the many programs in the Polsky Center. I encourage others with academic-lab discoveries and developments to seek out the tech-transfer offices at their institutions.

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