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Mitigating Risks Of Developing Drugs And Devices With AI

By **Mark Sentenac, Micha Nandaraj Gallo and Simran Modi** (July 6, 2023, 5:09 PM EDT)


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The predictions about our AI-driven future — from finally realizing fully autonomous driving, human-level intelligence and even superior fortune cookies — are seemingly bound only by our meager, machineless imaginations.

Industry 4.0, the AI-driven fourth industrial revolution, is also fundamentally changing the way we think about drugs and medical devices.

The integration of AI is changing how researchers are identifying new target therapies, conducting clinical trials, and manufacturing and selling drugs and devices. AI is already part of hundreds of medical technologies in use today — the U.S. Food and Drug Administration approved 91 devices incorporating AI last year alone.

With recent advancements in AI and machine learning, the use of these technologies to design, test, manufacture and sell drugs and devices is only anticipated to accelerate. Indeed, some have even observed that the industry is on the cusp of a new AI-driven golden age of scientific discovery.

Use of AI to manufacture and sell drugs and medical devices, however, poses a number of novel issues, and the rapid advancement of AI and machine learning is far outpacing our current legal and regulatory systems' ability to provide clear direction.

Companies deploying AI should be aware of these new areas of potential risk and start thinking about how traditional legal and regulatory frameworks may evolve to address them.

Companies would do well to take steps now to mitigate these potential risks, because, while it is often true that science outpaces our legal and regulatory frameworks, both always catch up.

AI-Driven Health Care

AI has already fundamentally changed how drugs and medical devices are being designed, tested, manufactured and sold, and its impact will only increase with time.

One of the most profound impacts AI is already having is on how researchers discover and design new

therapies, diagnostics and devices. AI's ability to analyze massive amounts of data, combined with new computing power, is expediting the preclinical discovery stage.

AI can eliminate the time-intensive testing of thousands of iterations of a potential product, allowing companies to rapidly model different designs and evaluate outcomes in a fraction of the time.

Once a target is determined, AI can also help developers identify optimal drug properties, including dose, taste, texture and color. In fact, AI promises the ability to personalize therapies and medical devices in a way never before possible.

The ability to analyze massive amounts of outcome data, identify new patterns and trends, and predict the likelihood of successful outcomes with increased precision will fundamentally change not only how and what your doctor prescribes for you, but how your drug products and medical devices are made and delivered — more precisely tailored to you and your unique biology and needs.

AI is also improving how researchers design and analyze clinical trials.

For example, AI can help researchers identify and recruit ideal trial candidates by automating analysis of voluminous and traditionally disaggregated datasets like medical records and social media.

It can also be used to identify new safety signals and efficacy patterns by comparing and analyzing more data about individuals in clinical trials than ever before possible. The results of these increased efficiencies are establishing more appropriate clinical endpoints and identifying the optimal patient for successful therapy.

AI is not only revolutionizing the development and testing phases of drug and device life cycle, it is improving how drugs and devices are manufactured, distributed and tracked. Like in product development, AI is helping manufacturers improve their manufacturing and distribution processes, to help predict and avoid deviations before they occur and plan better to avoid under- and over-supply.

Finally, AI is also changing how companies market and sell drugs and devices. AI is being used to target individuals and health care providers more precisely for marketing and promotion of products.

Conversational AI is also revolutionizing the way companies interact with health care providers and consumers about their health and product experience, helping break down information barriers, while also collecting a trove of real-time data about their products and customers.

Risks From Evolving Regulatory and Legal Frameworks and How to Mitigate Them

In 2019, the FDA announced that it was taking "steps to consider a new regulatory framework specifically tailored to promote the development of safe and effective medical devices that use advanced artificial intelligence algorithms."

That same year, the FDA proposed a regulatory framework for medical devices incorporating artificial intelligence.

Under the FDA's proposal, manufacturers would be required to include a change control plan in their premarketing submissions that would identify the anticipated AI-driven changes and the processes in place to ensure changes are implemented in a controlled manner. The FDA would also require

manufacturers to periodically update the FDA on changes.

Then, in May this year, the FDA released two discussion papers relating to AI in drug development and AI in drug manufacturing. In each of these discussion papers, FDA shared certain concerns on AI and thoughts on how the rapidly advancing technology's use in the design, manufacture and sale of drugs and devices should be regulated.

One of the FDA's primary concerns is that "AI/ML algorithms have the potential to amplify errors and preexisting biases present in underlying data sources."

The FDA raised concerns about use of black box algorithms that are opaque to both manufacturers and the FDA and also expressed concerns about how much data companies are generating through implementation of AI in the product development life cycle, and how companies should store, process and act upon that data.

Although these are frequent critiques of AI, they are indeed real concerns for companies that must demonstrate to regulators that their products are safe and effective for human use, and, as the frequent target of lawsuits, explain to judges and juries why the decisions made were informed and reasonable. Companies discussing use of AI should be taking steps to identify and mitigate these areas of potential risk.

1. Data Biases

First, and foremost, companies must take reasonable steps to eliminate biases in their data.

While AI greatly expands the amount and efficiency of data processing, the results are only as good as the input data and algorithm. Human choices on the algorithm used, the input data and results' validation processes will still be judged for their reasonableness. This issue will arise in numerous places in the development and testing of drugs and devices.

For example, in the context of clinical trial design and analysis, where companies are already on notice from the FDA that accounting for diversity in testing is a focus and priority for the agency, particular attention should be paid to data biases and diversity within data inputs.

It is critical that industry participants are helping establish the standards for human health data inputs and implementing safeguards to ensure that algorithms and datasets are appropriate, implementing checks to ensure that machines are learning and evolving as intended, and documenting the bases and reasonableness of decisions in real time.

2. Balancing Confidentiality With Transparency

Second, maintaining the confidentiality of proprietary and competitively sensitive AI algorithms and the transparency that is at the core of the regulatory approval process will be a source of tension in the AI space.

Companies must, however, have enough information on how algorithms work and the safeguards in place to ensure that products will operate as intended before incorporating AI-enabled technologies into their product development, manufacturing and sales workspaces.

3. Responsibility Toward Collaborators

Third, companies must carefully vet those they work with in this new forum. AI is set to disrupt the traditional life sciences space.

Drug and device development and manufacture will now exist at the confluence of technology and biology, resulting in the introduction of a number of new, nontraditional health care companies in the drug and device development space that will blur the line on who is within the chain of distribution for establishing responsibility for a drug or device.

Companies must ensure that vendors and joint-venture partners understand regulators' unique expectations for the design, development and manufacture of drug products and medical devices, and ensure that they have robust compliance and training programs in place to meet those expectations. Companies should also ensure that they have strong indemnification agreements in place.

4. Data Management

Fourth, companies must have a data management plan. The scope of a manufacturer's duty is often defined in terms of foreseeability. AI will be both a new source of large amounts of data, and increase companies' ability to process that data for potential signals.

With those new tools may come increased expectations and changing industry norms. Companies may ultimately be charged with knowledge of information that could have been revealed through analysis of those new datasets. Conversely, failure to take advantage of new tools to better evaluate data collected on the experience of users of drugs and devices could ultimately be viewed as unreasonable.

How companies collect, process, store and analyze new datasets and how learnings from these analyses will be operationalized and communicated to the FDA and customers, are all critical parts of operating in a new AI-driven environment.

5. Promotion

Fifth, new conversational AI is changing how drug and device companies interact and target for promotion health care providers and patients. Companies need to continue to be mindful of how these evolutions may affect both regulatory requirements and legal doctrines, like the learned intermediary doctrine, that are premised, at least in part, on traditional notions of how health care is provided.

Conclusion

AI is set to drive massive change in the life science space that will bring about exciting improvements in human health.

While the use of AI in drug and medical device development is advancing at a rapid pace, it is important that companies implement safeguards to ensure that it is being utilized reasonably and that the bases for decisions on how to implement AI are being documented now to justify those decisions later, when they are inevitably second-guessed.

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