WEBINAR

TOP TAKEAWAYS

EXPLORING CONSUMER ENGAGEMENT WITH PRECISION MEDICINE

Precision medicine is changing the game in areas such as genetic testing and research engagement. In this webinar, our lawyers joined executives from Color Genomics and AllStripes—innovative health tech, diagnostic and research companies advancing the field of precision medicine—to explore the various stages of the engagement lifecycle in direct-to-consumer, B2B and B2B2C business models. The roundtable panel examined core business values around transparency and data privacy, considerations for engaging consumers in research, common legal and regulatory challenges, and the current legislative landscape with respect to the development or implementation of direct-to-consumer precision medicine services arrangements and platforms.

1. Direct-to-consumer and B2B models each carry their own challenges and considerations. The direct-to-consumer precision medicine space is relatively crowded, and as a result, engagement with testing arrangements can drop after the initial return of results. Some direct-to-consumer models can also experience a disparity gap if certain individuals choose not to access a product because of out-of-pocket costs or lack of interest. At the same time, direct-to-consumer models can be highly effective in reaching widely dispersed groups, such as individuals with rare diseases. Working with patient advocacy groups can help increase and maintain engagement.

2. In a B2B model, the majority of customers are not individuals, but entities such as employers, health systems, providers, or public health agencies and departments. The privacy legal framework in a B2B model, and the ability to define and control what permissions are sought from individuals for the use and sharing of their data, is fundamentally different than those applicable to a direct-to-consumer model. Each comes with its own advantages and disadvantages.

3. Many precision health tools are offered as laboratory-developed tests, which typically fall under US Food and Drug Administration (FDA) enforcement discretion. However, the FDA has a long-standing policy of not permitting tests to be offered directly to consumers without undergoing FDA review. A variety of state legal issues may also be implicated for direct-to-consumer testing. Having a licensed healthcare provider involved in ordering such tests can sidestep many of these legal issues. A provider's determination that a test is medically necessary is also typically required for reimbursement from third-party payors (if sought under this model).

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Even if a precision medicine tool or service is not FDA regulated, it still must comply with Federal Trade Commission (FTC) regulations. The FTC polices non-FDA-regulated products to protect consumers against unfair, deceptive and fraudulent practices. In addition to enforcing the FTC Act, the FTC enforces consumer protection laws enacted by Congress and FTC trade regulation rules. Advertising, labeling, consumer reviews and endorsements, social media and privacy issues all fall under the FTC's purview.

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Precision medicine stakeholders should keep in mind that social media reviews and endorsements are regulated just like any other form of advertising. Influencer statements and claims, for example, must be adequately substantiated. Similarly, social media promotions must be structured appropriately, so as not to inadvertently qualify as a sweepstakes or lottery.

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