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Contract Corner

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Non-Lab Diagnostics: Consumer and User Agreements

The advent of the COVID-19 rapid antigen test launched at-home diagnostics to the forefront of conversation in the life sciences industry. Many believe this is only the beginning. As the share of telehealth services increases, drawing interest away from traditional health care services models, startups and established companies alike are positioning themselves to take advantage of the growing market for technologies and products that enable non-lab-based diagnostics capable of being purchased without a prescription and conducted entirely at home. But to minimize risk and maximize revenue, companies need to be careful in negotiating crucial provisions when contracting with third parties. The following is a list of the top nine issues to consider when drafting and negotiating agreements with consumers around the commercialization of at-home diagnostics in the United States.

Companies entering the at-home diagnostics space must take care to ensure that any user agreement governing the relationship between a company and its customers or end-users of a product is sufficient in scope and strength.

1. Include the Ability to Change Your Offering

Companies should take care to include the right to modify or discontinue any products or services at will or at least upon reasonable notice. Times are uncertain, and the past few years have demonstrated that companies may need to pivot their business to adapt to changing times. Failure to include the right to modify or discontinue an offering may obligate a company to continue servicing customers long after it has decided to move in a different direction.

2. Understand Your Counterparty and Other Stakeholders

A company may have multiple channels for its offerings. A company may provide its offering (a) directly to users, (b) to partners such as employers or other businesses, who then provide this offering to their employees or other individuals, or (c) to a combination of the two.

Companies should carefully consider how to structure their agreements so that all necessary parties are bound by terms to protect the company. This may include both a main agreement with a business counterparty and end-user terms binding individual users, such as through terms of service agreed to when opening a user account.

3. Include Favorable Intellectual Property Provisions

Companies should take care to include a comprehensive claim of ownership of any and all proprietary rights in their diagnostic products. Additionally, for tests that involve some interaction with users, companies should consider explicitly obtaining from users the right to use users' de-identified or anonymized information and test results for any and all internal research or commercial purposes, so as to allow for future avenues of research and development in addition to improving the specific product or service offered to the user. Companies should also consider including the right to generate anonymous and aggregate data sets using user information and test results and to use such information for any purpose, including publication and marketing.

Moreover, users may, in the course of their communications with a company, provide feedback or suggestions. Without specifying the company's rights to this feedback, the company may be left with unclear rights to use such feedback or may have an implied obligation to compensate the well-meaning user for such input. Companies should consider including a feedback provision that allows them to freely utilize and incorporate any such feedback into the creation of improvements to their products and services or in the development of new inventions. This is commonly accomplished through the inclusion of a present assignment provision or an unrestricted, royalty-free license

to use and otherwise exploit any feedback.

4. Carefully Limit Permitted Purposes Through Use Restrictions

Companies should consider including express limitations on the right of any user to use an at-home diagnostic (or the test results of such product) for any commercial purposes, any research or publication purposes, or any purpose other than for an individual user's personal use. This provision may need to be modified when the counterparty for such user agreement is a business, such as an employer on behalf of a group of employees, a healthcare provider, or a school.

5. Limit the Scope of Any Applicable Software Licenses

Many companies are pairing their at-home diagnostic devices with mobile software applications; as such, companies should ensure that their user agreement includes adequately narrow, non-exclusive license grants limited in scope. Companies should also include strong license restrictions that contain, in addition to other customary terms, prohibitions on the use of any software for commercial or research purposes, or any unauthorized reproductions, distributions, modifications, or reverse-engineering.

6. Include Relevant Disclaimers

The sale of diagnostic devices, like other goods, is governed by Article 2 of the Uniform Commercial Code (the UCC). The UCC includes implied warranties of merchantability, fitness for a particular purpose, and non-infringement. Unless disclaimed, courts may read these implied warranties into a company's user agreements. Companies should expressly disclaim these and any and all other warranties of any kind that are not explicitly set forth in the terms and conditions. Questions about liability regarding COVID-19 tests have largely been deferred while most companies have operated under the protection of the Public Readiness and Emergency Preparedness (PREP) Act's immunity from liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from administration or use of countermeasures to COVID-19.[1]

7. Include Strong Indemnification Provisions

Companies should clearly state that individual users are solely responsible for all acts and omissions arising from or in connection with any access or use of at-home diagnostics, and that such users must comply with all provided instructions and terms of use. It is important to allocate responsibility such that the users of the product, not the company, accept all consequences arising from or in connection with any access or use of such products.

Companies should consider including favorable indemnity provisions that require users to defend and indemnify the company for all costs and expenses incurred by the company from third-party actions arising out of the user's actual or alleged (a) access to or use of any products, or (b) violation of any terms, instructions, or applicable law.

8. Include Favorable Limitation of Liability Provisions

Companies should take care to include limitations on their liability pursuant to any user agreement, including express disclaimers of any indirect, incidental, consequential, special, exemplary, punitive, or multiple damages, including for lost profits. Such provisions should also be drafted to clearly indicate a company's aggregate liability amounts, which should be limited to the amount paid for the specific device.

9. Pay Attention to the Privacy Policy

The company's privacy policy should provide sufficient notice to individuals to comply with U.S. and foreign privacy laws regarding the collection, use, retention, disclosure, and other processing of personal information, including through the company's products and services. This will be of particular salience if a company is marketing at-home diagnostics that require a user to upload data to third-party processors, or if a company will send user information to health consultants, healthcare providers, or other third parties. Additionally, companies should take care to cover any other reporting requirements mandated by public health authorities or other applicable law or regulations. Companies that contract with a business counterparty should similarly take care to provide clarity to both the third-party partner and each individual user regarding the applicable privacy policy.

Furthermore, companies active in this space are often anticipating a future merger, sale, or other exit. As such, it is important that companies include the right to transfer their rights to any user information in connection with any actual or proposed asset transfer, merger, or change of control.

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1. According to the HHS PREP Act website, "[i]n general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a [PREP Act] Declaration."