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Recent milestone U.S. ophthalmic product approvals and clearances

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FOOTNOTES

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Disclosure: Gary D. Novack PhD consults with numerous pharmaceutical firms.

In recent months and years, there have been a number of milestone ophthalmic product licenses allowed for marketing from the U.S. Food and Drug Administration (FDA). These include drugs (approvals, Center for Drug Evaluation and Research, CDER), biologics (approvals, Center for Biologics Evaluation and Research, CBER) and devices (approvals and clearances, Center for Devices and Radiological Health, CDRH). The products are shown in Table 1. Given that only approximately 16% of drugs that enter clinical trials are eventually approved,[1] I think we should view this positively for our ophthalmic community.

Chronologically, the first of these products is the Intranasal Tear Neurostimulator (TrueTear®). This product was conceived and its initial development undertaken by Oculeve, a start-up company led by D. Michael Ackermann, Ph.D. Dr. Ackermann is an alumnus of the Stanford Entrepreneur program. Oculeve researchers were aware of work on electrical stimulation of the nasal lacrimal reflex.[2] They developed a patient-operated device that increased tear production to provided benefit to patients with ocular surface disease. This was cleared through the "de novo" process by FDA's CDRH to increase tear production.[3, 4]