NEW ADMINISTRATION CASTS DOUBT ON TRUMP'S IMPORTATION PLAN

Written By Andrew Silverio, Esq.

In July of 2019, then president Trump's HHS announced a "New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs"[1].

Much of this release was reiterating and repackaging previous policies and rulemaking authority, but a significant development was the announcement of that the HHS and FDA would review and approve pilot programs organized by the states to facilitate the importation of prescription drugs from Canada.

An awful lot has happened in the country and the world during the almost two years since this guidance, and we did not see any development at a federal level before the election and hand-off of the presidency.

Now, the Biden administration has touched on the issue for the first time.

In a court filing calling for the dismissal of a lawsuit against HHS by a pharmaceutical industry organization[2] the administration claimed that the plaintiff's claims are moot and their alleged damages far too speculative (the lawsuit against HHS claims that the importation rule impermissibly damages drug manufacturers and oversteps federal authority).

In the filing, HHS outlines that there is "no timeline" for the approval of any state programs, and that states still have numerous hurdles to get past before any such program could be approved begin operation (at this time, six states have passed laws providing for the formation of these programs, and two have actually submitted programs to the FDA for review).

Interestingly, HHS cites hostility to the proposed program(s) from Canada itself, noting that "Canada's interim order injects uncertainty into whether and to what extent the Rule could be implemented." This is actually closely in line with what we predicted when the rule was first released:

> It is worth noting that when the proposed rule came out, it was met with harsh criticism from our northern neighbors, many of whom discussed potential action by the Canadian government to counter any such importation efforts in order to protect their own drug supply. As such, action taken by the United States in regard to Canadian drug importation won't be the only factor in whether the practice ultimately becomes both legal and practical.

Of course, proponents of these programs shouldn't lose all hope just yet – this is an interesting situation where the posture of HHS is such that they must argue in order to defend the program against challenge that it may very well never actually get off the ground. That said, any optimism for imminent program approvals is essentially quashed with this filing. ■

Andrew Silverio, Esq. joined The Phia Group, LLC in the summer of 2014, dealing primarily with subrogation and third-party recovery, and other opportunities to recoup funds for benefit plans. He soon branched into the consulting branch of our company, assisting clients with compliance inquiries, plan document and contract drafting and revision, reviewing vendor programs, and addressing any and all other consulting questions.

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Andrew attended Berklee College of Music in Boston, earning his B.A. in professional music. He then attended Suffolk University Law School, graduating with an intellectual property concentration with distinction. There, he took the step into the healthcare realm of the legal world, serving first as an editor and content contributor, and then on the executive board of the Journal of Health and Biomedical Law. Andrew is licensed to practice in the Commonwealth of Massachusetts.

References

1 https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html)

2 https://www.politico.com/f/?id=00000179-b4ee-db57-abfd-b7fe4db60000