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CLIENT ADVISORY

Federal Circuit Invalidates VA Dear Manufacturer Letter Concerning DoD's Retail Pharmacy Refund Initiative

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On September 11, 2006, the U.S. Court of Appeals for the Federal Circuit issued an important decision invalidating on procedural grounds a letter issued by the Department of Veterans Affairs ("VA") that would have authorized the Department of Defense's ("DoD") attempt to obtain refunds on prescription drugs sold to DoD healthcare beneficiaries in DoD's retail pharmacy network. The DoD Program, known as the "TRICARE Retail Pharmacy Benefit Program," or TRRx, involves an effort by DoD to extend the "Federal Ceiling Price" ("FCP") to drugs sold to DoD beneficiaries by retail pharmacies. The FCP is a price ceiling that, under the Veterans Health Care Act of 1992 ("VHCA"), applies to covered drugs procured by the DoD under Federal Supply Schedule contracts or through depot contracting systems.

The case before the Federal Circuit, styled Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs, specifically involved the Coalition's challenge to a "Dear Manufacturer" letter that the VA issued on October 14, 2004. The VA letter, which was not published for notice-and-comment rulemaking, announced the VA's determination that DoD was entitled to the FCP on drug sales to DoD beneficiaries through retail pharmacies because TRRx was a "depot contracting system" under the VHCA. Based on this conclusion, the VA determined that DoD was entitled to the FCP on sales made by retail pharmacies to DoD beneficiaries. Subsequently, DoD adopted procedures by which it would collect refunds from drug manufacturers that would allow DoD's expenditures for drugs dispensed in the retail pharmacy network to approximate the FCP.

The Coalition argued that the VA letter was both substantively and procedurally flawed. Substantively, the Coalition maintained that drug sales through retail pharmacies were not sales through a "depot contracting system," as required under the VHCA, because the drugs sold by retail pharmacies to DoD beneficiaries were not "procured by" DoD. Instead, the retail pharmacies acquired those drugs

Washington, DC
+1 202.942.5000

New York
+1 212.715.1000

London
+44 (0)20 7786 6100

Brussels
+32 (0)2 517 6600

Los Angeles
+1 213.243.4000

San Francisco
+1 415.356.3000

Northern Virginia
+1 703.720.7000

Denver
+1 303.863.1000

through commercial transactions with manufacturers or distributors. DoD is not a party to those commercial transactions. Unlike in the case of drugs that DoD dispenses to its beneficiaries through military hospitals and its mail order pharmacy, the drugs that retail pharmacies dispense to DoD beneficiaries are never owned or possessed by DoD or a DoD purchasing agent. Procedurally, the Coalition asserted that, by extending a statutory price ceiling to new types of drug sales, the "Dear Manufacturer" letter effected changes in the existing law and therefore was a "substantive rule" that the VA should have published for notice-and-comment rulemaking pursuant to the APA.

The Federal Circuit's decision invalidated the "Dear Manufacturer" letter on the procedural ground asserted by the Coalition. In reaching this result, the Court found that the letter: "changes existing law and affects individual obligations [under the VHCA]." Slip Op. at 18. Under TRRx, "manufacturers are required to pay refunds totaling $100 to $200 million annually to [DoD] for covered drugs purchased at network pharmacies." Id. In rejecting the government's argument that the "Dear Manufacturer" letter is an "interpretive rule" (which does not require notice-and-comment rulemaking), the Court also noted that "the Dear Manufacturer letter did more than just interpret the VHCA…The establishment of a refund system comprises a form of gap filling that is substantive in nature rather than a mere interpretation of a statutory term." Slip Op. at 19. On this basis, the Court vacated the "Dear Manufacturer" letter and remanded the matter to the VA for further consideration. The Court thus did not reach the issues associated with VA's substantive determination that the TRRx Program was a depot contracting system under the VHCA.

In addition to its implications for TRRx (which may include greater difficultly collecting refunds retroactive to October 2004), the Federal Circuit's decision may have important consequences for other matters. The VA administers the VHCA largely through informal guidance known as "Dear Manufacturer" letters. Those letters are not published for notice-and-comment rulemaking or incorporated into the VA's contracts with drug manufacturers (known as the Master Agreement). A court could find that certain VA "Dear Manufacturer" letters are "substantive" or "gap filling" in nature and suffer from the same procedural flaw that the Federal Circuit found in the October 14, 2004 letter. For this reason, drug manufacturers and other interested parties should exercise caution in relying on such letters, particularly if the letters are substantive in nature or if they are not consistent with statutory or contractual provisions. In such circumstances, the Federal Circuit's decision suggests that the language of the statute and contract would be entitled to greater weight than informal guidance not promulgated pursuant to APA procedural requirements.

If you have questions about this advisory, or other related issues, please feel free to contact your Arnold & Porter attorney or:

Jeff Handwerker
+1 202.942.6103
Jeffrey.Handwerker@aporter.com

Dara Corrigan
+1 202.942.5508
Dara.Corrigan@aporter.com

Ben Martin
+1 202.942.6441
Benjamin.Martin@aporter.com

Rosemary Maxwell
+1 202.942.6040
Rosemary.Maxwell@aporter.com

Ron Schechter
+1 202.942.5160
Ronald.Schechter@aporter.com

Jeff Smith
+1 202.942.5115
Jeffrey.Smith@aporter.com

Jim Turner
+1 202.942.5181
Jim.Turner@aporter.com