IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel* **BETTY JEAN SWARTZ**	
Plaintiff	Civil Action No.
v.	TO BE FILED "UNDER SEAL" PURSUANT TO 31 U.S.C. §3730
CELGENE CORPORATION 86 Morris Avenue Summit, New Jersey 07901	**JURY TRIAL DEMANDED**
Defendant	

COMPLAINT

Plaintiff, Betty Jean Swartz brings this *Qui Tam* action to recover treble damages and penalties pursuant to the Federal False Claims Act, as amended, 31 U.S.C. § 3729 *et seq.* ("FCA") and alleges as follows:

I. JURISDICTION AND VENUE

1. This is a civil action arising under the laws of the United States, specifically, the "False Claims Act" or "FCA." This Court has original jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337.

2. Venue is proper in this district pursuant to 31 U.S.C. § 3732 and 28 U.S.C. § 1391 because Defendant committed acts prohibited by 31 U.S.C. § 3729(a) in this district.

3. Further, Defendant maintains a business office in this district, conducts regular business in this district, and also actively advertises, sells and distributes the drug products at issue in this Complaint in this district.

II. THE PARTIES

4. Plaintiff, Betty Jean Swartz ("Swartz", "Relator" or "Plaintiff") is the former Vice President of U.S. Market Access at Celgene residing in Pennsylvania. Swartz is filing this FCA action as a "Relator" under 31 U.S.C. § 3279, *et seq*. based upon information she discovered while employed by Celgene. Her exact address is not being provided to protect her privacy interests.

5. Defendant, Celgene Corporation ("Celgene" or "Defendant") is a Delaware corporation operating a biopharmaceutical company that develops therapies/medications for certain cancers and inflammatory diseases. Celgene may be served at 86 Morris Avenue, Summit, NJ 07901.

III. INTRODUCTION

6. During the time that Swartz was employed at Celgene as Vice President of U.S. Market Access, Celgene was party to a Pharmaceutical Pricing Agreement under the 340B Drug Pricing Program. Manufacturers like Celgene who wish to have their drugs covered by Medicare Part B and Medicaid are required to enter into an agreement with the Secretary of Health and Human Services to charge a price that will not exceed a statutory amount (the "Ceiling Price") when selling covered outpatient drugs to 340B Covered Entities. This agreement must be signed by a manufacturer *as a condition* for participating in the program and receiving Medicare and Medicaid dollars for any of their products. Despite promising to comply with the 340B pricing requirements and collecting billions of dollars in federal funds, Celgene was selling three particularly expensive cancer drugs, Revlimid, Pomalyst, and Thalomid, for prices well above the Ceiling Price in violation of the express terms of the 340B statute. In a continuing effort to reap huge profits from sales of these three drugs above the Ceiling Price, Celgene violated the

pricing agreement by making a series of knowingly false statements to the government and 340B eligible healthcare providers, by closing their Limited Distribution Network to exclude 340B Covered Entities and falsely claiming that the Orphan Drug exception validated their refusal to sell the drugs at the Ceiling Price to 340B Covered Entities. In almost every instance these claims were knowingly false. At the same time, they were preventing Covered Entities from accessing the cancer drugs at the Ceiling Price, Celgene continued to increase the price of all three drugs in order to maximize their profits. As a result of their knowingly false statements, Celgene collected billions of dollars in federal funds under the false pretense of compliance with the 340B program and reaped huge profits from the sale of the three cancer drugs at inflated rates. Relator brings this action to recover federal funds collected by Celgene based on fraud.

IV. RELEVANT FACTS

The 340B Program

7. In order to be eligible to receive federal funds form the Medicaid and Medicare Part B programs drug manufacturers must participate in the Health Resources & Services Administration ("HRSA")'s 340B Drug Pricing Program ("340B program").

8. According to the HRSA website: "The 340B Program enables Covered Entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" by placing a cap or "Ceiling Price" on certain "covered outpatient drugs."

9. Drug manufacturers are required to enter into an agreement with the Secretary of the Department of Health and Human Services ("HHS") whereby the manufacturer must agree to accept a "Ceiling Price" that will not exceed a statutory amount when selling covered outpatient drugs to the 340B Covered Entities.

10. Specifically, 42 U.S.C. § 256b(a)(1) states that:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a Covered Entity … does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act … reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports … of the price for each covered outpatient drug subject to the agreement, that according to the manufacturer, represents the maximum price that Covered Entities may permissibly be required to pay for the drug (referred to in this section as the "Ceiling Price"), and shall require that the manufacturer offer each Covered Entity covered outpatient drugs for purchase at or below the applicable Ceiling Price if such drug is made available to any other purchaser at any price.

11. This agreement, known as the Pharmaceutical Pricing Agreement ("PPA"), and the subsequent PPA Addendum ("Addendum") were both signed by Celgene as a condition of their participation in Medicaid and Medicare Part B.[1]

12. The Ceiling Price is calculated by taking the Average Manufacturer Price ("AMP") and reducing that by the Unit Rebate Amount ("URA"), then applying an additional discount if the drug's AMP is rising faster than the rate of inflation as set forth below:

340B Ceiling Price =

All Drugs:

- AMP – URA

URA:

- For branded drugs, the greater of (AMP – 23.1% of AMP) or (AMP – BP)
  - If AMP is rising faster than the rate of inflation, an additional discount is owed: Current AMP – (Current CPI-U/Baseline CPI-U) x Baseline AMP
- For generic drugs, (AMP – 23.1% of AMP)
- For clotting factor and exclusively pediatric drugs, the greater of (AMP – 23.1% of AMP) or (AMP – BP)

[1] *See* 42 U.S.C. § 1396r-8; *see also* HRSA Website, at https://www.hrsa.gov/opa/index.html

- If AMP is rising faster than the rate of inflation, an additional discount is owed: Current AMP – (Current CPI-U/Baseline CPI-U) x Baseline AMP

13. Celgene agreed to this formula when their corporate officers signed the PPA:

> (a) for single source and innovator multiple source drugs, to charge Covered Entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;
>
> (b) for multiple source, non-innovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;
>
> (c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP, baseline AMP, and the Best Price of such covered outpatient drugs.[2]

14. The Addendum signed by Celgene included the following clause:

> 1. The Agreement "shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that Covered Entities may permissibly be required to pay for the drug"; and
>
> 2. The Agreement "shall require that the manufacturer offer each Covered Entity covered outpatient drugs for purchase at or below the applicable Ceiling Price if such drug is made available to any other purchaser at any price."[3]

15. Among the covered outpatient drugs that Celgene promised to distribute for sale at the Ceiling Price to 340B were three of the company's most expensive drugs.

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[2] *See* PPA attached as **Ex. "A"** hereto.
[3] *See* Addendum to PPA attached as **Ex. "B"** hereto.

16. These drugs, Revlimid, Pomalyst, and Thalomid, are sold primarily for the treatment of Multiple Myeloma ("the Myeloma drugs").

Celgene's Limited Distribution Network

17. The Relator was the Vice President ("VP") of U.S. Market Access for Celgene for approximately 18 months, from April 2016 until November 2017.

18. Prior to working for Celgene, Swartz had worked in the pharmaceutical industry for over 30 years and held executive positions at multiple Fortune 500 pharmaceutical companies.

19. As the V.P. for U.S. Market Access at Celgene, Swartz was responsible for ensuring that 340B eligible healthcare providers had access to Celgene products at the statutorily discounted prices.

20. This responsibility included ensuring that the Myeloma drugs as well as other Celgene products including Istodax, Vidaza, Abraxane, Idifa and Otezla were **all** accessible to 340B eligible providers at their respective Ceiling Prices.

21. During the first two weeks of her employment at Celgene, Swartz worked closely with the individual she was replacing as VP of U.S. Market Access, Gordon Wilcox ("Wilcox").

22. During their transition meetings Wilcox explained to Swartz that Celgene had established a "closed" network for distribution of the Myeloma drugs.

23. Swartz understood this as a reference to something called a Limited Distribution Network ("LDN").

24. The purpose of an LDN is to restrict access to potentially dangerous drugs in order to ensure they are distributed in accordance with specific patient safety requirements.

25. Wilcox explained that by creating an LDN for the Myeloma drugs and subsequently closing the LDN to new entities, Celgene was able to limit access to the Myeloma drugs by requiring consumers and Covered Entities to obtain the drugs from specialty pharmacies and through drop shipping.

26. LDNs are common in the industry and are frequently implemented in a manner which does not block access to 340B Covered Entities.

27. In most instances, when a manufacturer establishes an LDN for patient safety, they provide explicit instructions to 340B Covered Entities outside the LDN can still access the drugs at the Ceiling Price.

28. By way of example only, attached are various LDN distribution plans which provide instructions for obtaining drugs at 340B prices.[4]

29. In or about 2015, Celgene published a similar notice, however the notice did not provide instructions for obtaining 340B pricing, but simply an email address for entities seeking "information on how your patients may access [the Myeloma drugs]."[5]

30. Notably Celgene's notice does not even mention 340B pricing.

31. Despite the fact that the real purpose of closing the network was to deny access to the drugs at the Ceiling Price, Celgene falsely claimed that the closure of LDN was done in the interest of patient safety;

> "allowing more providers to enter the limited distribution networks could unnecessarily weaken the operation and effectiveness of [its] REMS ("Risk Evaluation and Mitigation Strategies") and could make the certification, training, auditing, and monitoring requirements of the REMS infeasible."[6]

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[4] *See* Other companies' Notices attached as **Ex. "C"** hereto.
[5] *See* Celgene Notice attached as **Ex. "D"** hereto. Celgene's notice is published on HRSA's website at: https://www.hrsa.gov/sites/default/files/opa/programrequirements/manufacturerletters/2015/celgeneletter.pdf
[6] *See* Ex. D.

32. REMS is a Food and Drug Administration ("FDA") program designed to ensure that certain drugs which pose a risk to a patient's health and safety are distributed in a manner that protects patient safety.

33. While training Swartz, Wilcox also provided her with a large binder that was filled with copies of letters addressed to 340B eligible entities who had complained that they were excluded from the LDN and could not access the Myeloma drugs at the Ceiling Price.

34. Upon information and belief, these letters were replies to correspondence received by Celgene in response to its published notice, from entities seeking to access the Myeloma drugs at the 340B Ceiling Price.

35. Each of the letters contained the same language advising the 340B healthcare providers that the reason they could not get the drugs at the Ceiling Price was because the LDN was "closed" based on the REMS.

36. Celgene's notice also falsely claimed that 340B status was not considered in the "selection criteria" for admission to the LDN and that 340B entities were "proportionately represented" in the LDN.[7]

37. In fact, entities were specifically excluded because of their 340B status and, upon information and belief, those entities were not proportionately represented in Celgene's closed network.

38. In the case of the Myeloma drugs, the REMS required basic precautions like ensuring distributors are aware of the risk associated with the drugs and preventing the Myeloma drugs from being prescribed to pregnant women.

[7] *See* Ex. D.

39. Celgene was improperly excluding 340B Covered Entities from its LDN not because it would "weaken" the REMS, but rather, for the specific purpose of avoiding providing its most profitable drugs at a capped Ceiling Price.

40. Whereas other manufacturers direct 340B entities to distribution sources where they could access the drugs at the Ceiling Price, Celgene funneled the Covered Entities to specialty pharmacies which did not offer the drugs to the Covered Entities at the Ceiling Price.

41. Swartz understood that the specialty pharmacies received dispensing fees for providing patients with the Myeloma drugs irrespective of whether they charged the AMP or the Ceiling Price.

42. Further, Swartz understood that it was the Celgene's responsibility to ensure that 340B Covered Entities had access to the Myeloma drugs at the Ceiling Price, regardless of whether they were purchased by an entity within the LDN or from a specialty pharmacy.

43. Such guidance is reflected in HHS' comments and guidance, which specifically states that "[t]he 340B Ceiling Price is set by statute and manufacturers are required to charge Covered Entities that Ceiling Price."[8]

44. Further, "[m]anufacturers are ultimately responsible for ensuring a Covered Entity receives a drug at or below the 340B Ceiling Price … regardless of the distribution system. If a manufacturer is using a specialty pharmacy to distributed covered outpatient drugs, it must ensure the Covered Entity is not overcharged if drugs are accessed through that pharmacy."[9]

45. By way of example only, Swartz learned from her review of the explanation letters that Yale University Health Center was one of the 340B Covered Entities that was improperly excluded from the LDN.

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[8] *See* https://www.federalregister.gov/documents/2017/01/05/2016-31935/340b-drug-pricing-program-ceiling-price-and-manufacturer-civil-monetary-penalties-regulation at printed page 1219.

[9] See Fn 4, at printed page 1224-5.

46. Yale University is one of the preeminent healthcare institutions in the world, but was denied access based on the false pretense that including them in the network would "weaken" the REMS.

47. While working for Celgene, Swartz visited Yale and had a meeting with the Chief of Staff of Yale's hospital, director of oncology as well as the heads of Yale's specialty pharmacy, who explained the hardship that Yale's exclusion from the LDN was causing and Yale's resulting inability to provide service continuity to its patients.

48. Yale's exclusion and the reasoning for such exclusion was particularly puzzling because Yale had a state of the art facility and specialty pharmacy and was entrusted by Celgene to conduct clinical trials for these exact same Myeloma drugs.

49. Swartz learned that other similar stellar healthcare providers were denied access to the Myeloma drugs at the Ceiling Price in violation of Celgene's obligations as a 340 participant.

50. Among the other 340B eligible healthcare providers that were denied access to the Myeloma drugs at the Ceiling Price were the following prestigious institutions;

- University of Pennsylvania Medical Center (DSH);
- Froeder Health System in Wisconsin (a 340B disproportionate share hospital ("DSH"))[10];
- Duke University Hospital ((DSH);
- Fairview Health System (DSH);
- Henry Ford Health System (DSH);
- The Ohio State University Wexner Medical Center (DSH);
- UNC Chapel Hill Medical Center (a 340B comprehensive hemophilia treatment center ("HM"));

[10] *See* 340B Hospital Eligibility Criteria at: https://docs.340bpvp.com/documents/public/resourcecenter/Hospital_Eligibility_Criteria.pdf

51. Notably, several of these excluded entities were also entities that Celgene utilized to conduct clinical trials for the Myeloma drugs.

52. Prior to retiring, Wilcox warned Swartz that she should avoid industry meetings where 340B Covered Entities would be in attendance because they would bombard her with inquiries about why they could not purchase these drugs at 340B Ceiling Prices.

The Orphan Drug Loophole

53. Swartz is unaware of any Covered Entity receiving any of the Myeloma drugs at the Ceiling Price at any time since the drugs were approved for the treatment of Myeloma.

54. According to Celgene's executives, a loophole enabled the company to avoid paying the 340B pricing – even to entities within the LDN – based on the "Orphan Drug" definition.

55. Upon information and belief, Celgene used the closed LDN in conjunction with the Orphan Drug exception to prevent entities from obtaining its Myeloma drugs at the Ceiling Price.

56. The FDA defines an Orphan Drug as "a drug intended to treat a condition affecting fewer than 200,000 persons in the United States, or which will not be profitable within 7 years following approval by the FDA."[11]

57. The Myeloma drugs are classified as Orphan Drugs.

58. However, the "Orphan Drug" exception the 340B program only applies to a limited number of entities defined as rural referral centers (RRC), sole community hospitals

[11] *See* FDA Website, at https://www.fda.gov/forindustry/developingproductsforrarediseasesconditions/default.htm

(SCH), critical access hospitals (CAH), and free-standing cancer hospitals (CAN) participating in the 340B Program.[12]

59. Because the term "covered outpatient drug" does not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition, manufacturers are not required to provide these types of Covered Entities Orphan Drugs under the 340B Program. However, a manufacturer may, at its sole discretion, offer discounts on Orphan Drugs to these hospitals.[13]

60. Notably, Yale and the other above referenced hospitals are not the type of entities to which the Orphan Drug exception applies and should have been able to obtain 340B pricing irrespective of the Myeloma drugs' Orphan Drug status.

61. Based on her experience and research, Swartz believed that Celgene was misleading HRSA by representing that they had closed the LDN because of the requirements of REMS, but in fact it was to prevent Covered Entities to which the Orphan Drug exception did not apply from obtaining the Myeloma drugs at the Ceiling Price.

62. Upon information and belief, Celgene either does not have entities that are exempt from the Orphan Drug exception in its LDN or it falsely excludes eligible Covered Entities from receiving the Ceiling Price based on the Orphan Drug exception.

Celgene's Misrepresentations During the HRSA Auditing Process

63. Upon information and belief, Celgene misled HRSA during the auditing process as set forth herein by representing that it was honoring its 340B pricing obligations when in fact it was making substantial efforts to avoid those obligations by making it difficult, if not impossible, for 340B Covered Entities to obtain the Myeloma drugs at the Ceiling Price.

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[12] *See* 340B Hospital Eligibility and Orphan Drug Exclusion Application Summary attached hereto as **Exhibit "E."** *See also* HRSA Website, at https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf

[13] *See* HRSA Website, at https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf

64. The following process is the standard Ceiling Price calculation and chargeback process and, upon information and belief, was used by Celgene for the drug products sold under the 340B program, with the exception of the Myeloma drugs:

a. Within 30 days of the end of a quarter, Celgene calculates and reports AMP and Best Price to CMS through a system called DDR.

b. Celgene uses AMP, Best Price, Baseline AMP, Baseline CPI-U, and Current CPI-U to manually calculate URA (Unit Rebate Amount).

c. A few weeks after the reporting in step (a) takes place, DDR displays the calculated URA that will be sent to the states for Medicaid purposes. Celgene checks their manually calculated URA against the DDR URA to establish accuracy.

d. Celgene will calculate a 340B price and notify wholesalers and specialty pharmacies of the 340B pricing 15 days before the start of the quarter where the price takes effect.

e. Wholesalers / specialty distributors purchase the product from Celgene at the Wholesaler Acquisition Cost ("WAC"), also known as the list price.

f. When a 340B Covered Entity orders the product from an authorized distributor (for drop shipping or otherwise), due to their eligibility, the wholesaler / specialty distributor sells the product to the entity at the discounted 340B price – the Ceiling Price.

g. The wholesaler / specialty distributor will submit a chargeback to Celgene so that they are reimbursed the difference between WAC and the 340B price.

h. Celgene would verify that the end customer was 340B eligible and then approve the chargeback.

65. This process permits the types of Covered Entities described above, to purchase Celgene's Myeloma drugs at the Ceiling Price instead of the non-Ceiling Price, and utilize the difference in price "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," as intended by the Government and the 340B program.

66. Instead, upon information and belief, Celgene utilized the following process to withhold Ceiling Prices from its wholesalers and specialty distributors and exclude Covered Entities from obtaining 340B pricing:

a. Within 30 days of the end of a quarter, Celgene calculates and reports AMP and Best Price to CMS through a system called DDR.

b. Celgene uses AMP, Best Price, Baseline AMP, Baseline CPI-U, and Current CPI-U to manually calculate URA (Unit Rebate Amount).

c. A few weeks after the reporting in step (a) takes place, DDR displays the calculated URA that will be sent to the states for Medicaid purposes.

d. Celgene fails to submit the 340B pricing to wholesalers / specialty distributors.

e. Wholesalers / specialty distributors purchase the product from Celgene at the WAC.

f. A 340B Covered Entity orders the product from a wholesaler or specialty distributor (for drop shipping or otherwise). However, because no 340B price is available, the Covered Entities are forced to pay higher, non-340B prices (most likely the WAC).

g. No chargeback is submitted because the wholesalers and specialty distributors sold the Myeloma drugs at the WAC.

67. The 340B Ceiling Price calculation process set forth above is evidenced by the attached "Ceiling Price Spreadsheet" which calculates the AMP, Best Price, Baseline AMP, Baseline CPI-U, Current CPI-U, and URA for the Myeloma drugs.[14]

68. The Ceiling Price Spreadsheet estimates that the Best Price is a 5% discount from the Best Price.

69. The Ceiling Price Spreadsheet estimates that only 5% of the Myeloma drug sales are to 340B Covered Entities.

[14] *See* Ceiling Price Calculation Spreadsheet attached as **Ex. "F"** hereto.

70. Based on the above estimates, by failing to publish and accept Ceiling Prices for its Myeloma drugs, Celgene has retained approximately $298,000,000 as profit from its Myeloma drugs—in 2018 alone—which was intended to be distributed and utilized by 340B Covered Entities.[15]

Damage Caused by Celgene's Conduct

71. Celgene's conduct caused 340B Covered Entities to spend hundreds of millions of dollars in federal funds to purchase the Myeloma drugs at inflated cost—because they were denied access to the drugs at the Ceiling Price.

72. There is a substantial difference between the Ceiling Price and the price charged by the Specialty Pharmacies where the Covered Entities had to go to for the Myeloma drugs.

73. By way of example, according to the enclosed estimates, the Ceiling Price for Revlimid is approximately $25,000 and the current cost of Revlimid without the 340B price limitations is $69,547.81, per month.[16]

74. As a result of Celgene's unlawful overcharging of Covered Entities, the federal government overspends approximately $45,000, per month, per patient, on Revlimid.

75. Those funds were intended to go to the provision of comprehensive care at hospitals that service low income patients. Instead they went to Celgene's profits.

[15] *See* Ex. F.
[16] *See* Ex. F.

76. The chart below details the revenues generated by Celgene from the Myeloma drugs—and the remaining drugs in Celgene's portfolio—since 2015 (in millions).[17]

	2017	2016	2015
REVLIMID®	$ 8,187	$ 6,974	$ 5,801
POMALYST®/IMNOVID®	1,614	1,311	984
OTEZLA®	1,279	1,017	472
ABRAXANE®	992	973	967
IDHIFA®	20	—	—
VIDAZA®	628	608	591
azacitidine for injection	36	66	84
THALOMID®	132	152	185
ISTODAX®	76	80	69
Other	9	4	8
Total net product sales	12,973	11,185	9,161
Other revenue	30	44	95
Total revenue	$ 13,003	$ 11,229	$ 9,256

77. As demonstrated above, the Myeloma drugs accounted for approximately 75% of Celgene's total revenue from 2015 through 2017 (Revlimid accounting for approximately $21 billion over three years, Pomalyst for approximately $4 billion over three years, and Thalomid for approximately $470 million over three years).

78. In total, since 2015, the Myeloma drugs have generated ***over $25 billion*** in revenue for Celgene.

79. Had Celgene adhered to their agreement with the Federal Government and provided access at the Ceiling Price to the 340B Covered Entities, their profits for the sale of the Myeloma drugs would have been dramatically reduced, by hundreds of millions of dollars per year, and those funds would be passed, as intended, to the 340B Covered Entities.

80. Moreover, while Celgene was fraudulently excluding covered 340B entities from its "closed" LDN for the Myeloma drugs, Celgene continued to reap the government benefits of

[17] *See* sales data Celgene Form 10-K filed December 31, 2017, **Ex. "G"** hereto.

its Pharmaceutical Pricing Agreement by selling the other drugs in its portfolio through the 340B program and accepting Medicaid and Medicare funds for those drugs.

81. Because offering **all** of a manufacturer's drugs at the 340B discounted price is a condition of participation of the 340B program, Celgene made material misrepresentations of fact to HHS and HRSA, by gaming the 340B program to exclude its most profitable drugs from the program's Ceiling Prices.

Celgene Acted Intentionally and Knowingly

82. Shortly after Wilcox's retirement, Swartz attended a meeting with Celgene CEO, Mark Alles, General Manager of Hematology/Oncology in the U.S., Tom Cavanaugh, the President of Hematology worldwide markets, Nadim Ahmed, Celgene Chief Counsel, Jerry Massoudi, and Executive Director of Pricing and Head of Celgene Contracting, Jim Kilgallon.

83. At this meeting, Swartz witnessed an animated discussion among the executives about their concerns that HRSA could audit Celgene's sales records for the Myeloma drugs and could force Celgene to open the LDN and reimburse Covered Entities that were improperly denied the Ceiling Price.

84. The executives all agreed that an audit of the Myeloma drug sales records would be a catastrophic financial event for Celgene.

85. Because Celgene had decided to close the LDN for 5 years, the executives were concerned that they would be exposed to potential civil penalties for that entire period.

86. Everyone at the meeting made it clear they were acutely aware of the catastrophic financial implications for Celgene if the company were forced to pay back the billions of dollars it earned by unlawfully selling the Myeloma drugs above the Ceiling Price.

87. At that same meeting, the senior executives collectively asked Swartz as the VP of U.S. Market Access if she had any questions about the LDN and Myeloma drug sales.

88. Swartz responded, "I hate to be a Debbie Downer, but how long have you been getting away with the excuse of not opening up the network based on an FDA mandated REMS and not have had to accept 340B pricing or offer qualified customers the same ability to be part of the network."

89. The executives at the meeting collectively responded that Celgene was told that they were protected by the FDA's mandated REMS and it was fully understood by HRSA that Celgene was fully compliant with the 340B program.

90. Based on her experience dealing with REMS and HRSA, as well as the qualifications of the institutions that were being denied access to the applicable 340B drug pricing, Swartz did not believe it was accurate or proper to claim that Celgene was compliant with the 340B program.

91. After the executive meeting, Swartz met individually with Jim Kilgallon, her direct report, who was—at the time of her employment and currently remains—the Executive Director of Pricing and Contracting, to garner a better understanding of the Celgene program and to see if he could explain why Celgene was not exposed to billions of dollars in penalties and repayment to the federal government based on the way they were pricing the Myeloma drugs.

92. Kilgallon reiterated that he believed that the "closed" network protected and permitted Celgene to exclude otherwise eligible providers from access to the 340B Ceiling Price.

93. In addition, Kilgallon explained that even among providers in the LDN, Celgene was not required to adhere to Ceiling Price for many of them because of a "loop-hole" based on the fact that the Myeloma drugs were categorized as rare Orphan Drugs.

94. Swartz understood that Celgene relied on the Orphan Drug definition for the Myeloma drugs to refuse to accept the Ceiling Price from 340B Covered Entities for the drugs.

95. Moreover, Kilgallon confided to Swartz regarding his concern about Celgene's approach and they discussed developing a contingency strategy, in the event that HRSA or one of its audits uncovered the details of Celgene's improper use of the LDN and Orphan Drug exception.

Swartz's Additional Investigation into Celgene's Improper Pricing Practices

96. Separately, Swartz was suspicious of the fact that the networks for Myeloma drugs were previously open, and Celgene closed them shortly prior to engaging in a campaign to raise prices on the drugs several times each year.[18]

97. Swartz became even more concerned after reviewing Celgene's 10-K public filing which stated that Celgene:

> received an inquiry from HRSA regarding our limited distribution networks for REVLIMID ®, POMALYST ®, and THALOMID ® and our compliance with the 340B program. We have cooperated fully in responding to this inquiry and believe that we have complied with applicable legal requirements. If, however, we are ultimately required to change our sales or pricing practices with regard to the distribution of these drugs, there would be an adverse effect on our revenues and profitability.[19]

98. In order to confirm her suspicions that the company was making false claims to the federal government, Swartz organized meetings with IDNs, wholesalers and other customers to get their perspective on Celgene's LDN.

99. She learned through this process that all of the excluded providers were obviously capable of meeting the requirements of REMS, without weakening the program.

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[18] *See* Change in Revlimid price over the course of the last ten years attached hereto as **Exhibit "H."**
[19] *See* excerpt from Celgene 10-K attached hereto as **Exhibit "I."**

100. Moreover, many of the excluded providers had previously received research funding from Celgene to conduct research and the qualifications to conduct research for Celgene exceeded the requirements of REMS.

101. None of the providers Swartz met with were subject to the Orphan Drug exception.

102. Prior to Swartz's departure from Celgene in November 2017, she requested a list of any customers from Hematology & Oncology practices, IHNs, Cancer Centers and Specialty pharmacies that had requested to be in the network to get 340B pricing and who received a letter from Celgene denying access based on the claim that the LDN had been closed.

103. Swartz's repeated requests for a list of 340B entities that were denied access to the network and the lower 340B pricing for Myeloma drugs were denied.

104. Swartz also requested a list of all of the 250 entities in the LDN and the date they had joined, so she could review the accuracy of the claim some of the providers in the LDN were not entitled to the Ceiling Price because of the Orphan Drug exception.

105. This information is well documented within Celgene's legal department as well as in the pricing and contracting department; however, it was not provided for Swartz to review despite multiple requests.

106. In 2017 Celgene increased the price of Revlimid by 19% over a 12-month period.

107. Swartz did not support the price increase and expressed her concerns to the CEO and to the Executive Management team at a pricing meeting.

108. Her objections were ignored, and the price increase was implemented.

109. In dismissing her objections, the Celgene CEO told Swartz, "Why would you be afraid to take an increase on our products? What could be the worst thing that happens….a tweet

here or there and bad press for a bit, but let's face it, Mylan took their huge price increase, Valeant has huge increases and Turing, however none of those companies have yet to reduce their prices despite the bad press."

110. At the time of her departure Celgene was still selling the Myeloma drugs at above the Ceiling Price and they had not taken any steps to increase access to the drug or sell it at the Ceiling Price as required by 340B.

Celgene's Violations of the False Claims Act

111. Pursuant to 31 U.S.C. §3729(a)(1), "any person who – (A) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; (B) knowingly makes uses or causes to be made or used a false record or statement material to a false or fraudulent claim" is liable under the False Claims Act ("FCA").

112. The Third Circuit recognizes "two categories of false claims under the FCA: a factually false claim and a legally false claim . . . a claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment."

113. The FCA at issue in the case are as a result of Celgene's factually and legally false claims presented to the Government.

114. "[U]nder [the false certification] theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 147 (E.D. Pa. 2012).

115. As set forth more fully herein, Celgene provided false and fraudulent information to HRSA (an agent of the United States) resulting in fraudulent claims for payments under the 340B program.

116. Specifically, Celgene made misrepresentations about its LDN network and intentionally exploited a non-applicable "loop-hole" involving an Orphan Drug exception to exclude entities from 340B pricing for its most profitable drugs.

117. In doing so, Celgene knowingly and purposely failed to provide Covered Entities with the Ceiling Prices proscribed by the 340B program.

118. Moreover, Celgene falsely represented that it was compliant with the 340B program in order to receive federal funds as reimbursement for its other drugs.

119. As a result, Celgene received federal funds for its other drugs, which it would not be entitled to receive if it was known that Celgene was not compliant with the terms of the 340B program.

120. Celgene's claims were false or fraudulent and its officers and authorized agents knew its claims were false or fraudulent and were made to allow Celgene to make profits above the Ceiling Price for its most profitable drug, Revlimid.

121. As a direct and proximate result of express and implied false certifications made to the Government in exchange for payment by Medicare and Medicaid under the 340B program, the Government paid Celgene billions of dollars.

122. As a direct and proximate result of the false fraudulent statements made by Defendant as set forth in this Complaint, the U.S. suffered billions of dollars in damages and is entitled to full compensation plus a civil penalty of up to $11,000 per FCA violation.

123. Celgene's claims for 340B payments were false even though some of the drugs were provided as claimed because Celgene was ineligible to participate in the program while it was intentionally violating the terms of the PPA, failing to comply with the 340B participant requirements, and misleading the HRSA by falsely certifying that it was complying with the PPA and the terms of the 340B program.

124. By way of example, Celgene provided the Government and private entities a misleading letter of explanation outlining why Celgene was not selling the 3 drugs at issue in this case at the Ceiling Price required by 340B.[20]

125. Paragraph 3 of the Celgene letter is false in that it claims:

> Celgene's selection criteria for accepting providers into the limited distribution networks is and has been based on factors unrelated to a pharmacy's 340B status. Those selection criteria have centered on the dispensing site's ability to protect patient safety and to serve a broad patient base. 340B Covered Entities are proportionately represented in the limited distribution networks for all three products. [21]

126. On the contrary, Celgene intentionally excluded qualified 340B entities and **did** consider their 340B status in determining whether to give these entities access to the Myeloma drugs at issue in this case at the applicable Ceiling Price.

127. Paragraph 4 of the Celgene letter is false in that it claims that:

> Celgene has analyzed the scope of the limited distribution networks and has determined that the less than 250 providers in the networks are sufficient to meet patient drug access needs. Allowing more providers to enter the limited distribution networks could unnecessarily weaken the operation and effectiveness of our REMS and could make the certification, training, auditing, and monitoring requirements of the REMS infeasible. Therefore, in 2013 Celgene closed the limited distribution networks to all new entities, 340B or otherwise, and we do not anticipate adding any new entities at this time.[22]

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[20] *See* Ex. D.
[21] *See* Ex. D.
[22] *See* Ex. D.

128. On the contrary, Celgene was aware that multiple 340B entities were fully capable of complying with REMS and participating in the network, but it denied them 340B pricing anyway.

129. In order to unlawfully circumvent the 340B Ceiling Price while also receiving billions of dollars in Federal funds for the sales of its other drug products to 340B entities, Celgene designed a scheme to mislead various medical institutions and the Government and its agents including HRSA.

130. Celgene's scheme resulted in federal funds, which were intended to be distributed to Covered Entities so that they could better serve low-income patients and communities, to unlawfully be funneled to Celgene's bottom line.

COUNT I

VIOLATION OF 31 U.S.C. § 3729 *et seq.*

131. Relator repeats and incorporates each allegation contained in paragraphs above as if fully set forth herein.

132. Relator's claims arise under the False Claims Act ("FCA") at 31 U.S.C. § 3729 *et seq*. Celgene violated the FCA when it falsely promised to abide by the terms of the 340B Program in order to gain access to government markets and funds for its drugs.

133. As described above the scheme, caused billions of dollars in claims to be submitted under the Medicare and Medicaid programs for the Myeloma drugs whose prices should have been capped for 340B Covered Entities but were not because of Celgene's fraud.

134. Celgene's knowingly false statements to HRSA and the Covered Entities were relied on by those 340B entities and the Federal Government when they submitted and paid claims for Medicare and Medicaid payments for the Myeloma drugs at their full market price.

135. Moreover, despite the fraud described above, Celgene continued to accept Medicare and Medicaid funds under the Pharmaceutical Pricing Agreement by selling the other drugs in its portfolio to 340B Covered Entities.

136. As a result, the Federal Government paid for Celgene's other drugs, which it would not have paid if it were aware of Celgene's fraudulent conduct as to the Myleoma drugs.

137. Celgene's accepting such Medicare and Medicaid payments was predicated on Celgene's false claims to the U.S. Government that it would offer ***all*** of its drugs to 340B entities at or below the Ceiling Prices when, in fact, Celgene knew that was not the case with its Myeloma drugs.

WHEREFORE, Relator Swartz respectfully requests that this Court award the following damages to the following parties and against Defendant:

To the UNITED STATES:

a) Three times the amount of actual damages which the United States Government sustained as a result of Defendants submission of false claims;
b) A civil penalty of up to $11,000 per violation for each false claim Defendant presented or caused to be presented to the United States for payment;

c) Prejudgment interest; and

d) All costs incurred in bringing this action.

To RELATOR SWARTZ:

a) The maximum amount allowed pursuant to 31 U.S.C.A. § 3730(d) and/or any other applicable provision of law;

b) Reimbursement for reasonable expenses which Plaintiff incurred in connection with this action;

c) An award of reasonable attorneys' fees and costs; and

d) Such further relief as this Court deems equitable and just.

Respectfully submitted,

Dated: August 22, 2018

By: _____

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EXHIBIT “A”

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, (link here) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:
The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

(1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the 340B Prime Vendor at 1-888-340-2787 or via email at ApexusAnswers@340BPVP.com.

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327;
Expiration Date: 08/31/2019

PHARMACEUTICAL PRICING AGREEMENT

(hereinafter referred to as the "Agreement")
Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary") and
THE MANUFACTURER
Identified in Section IX of this Agreement
(hereinafter referred to as the "Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) **"Average Manufacturer Price (hereinafter referred to as the "AMP")"** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) **"Best Price"** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) **"Bundled Sale"** refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

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(d) **"Covered Drug"** means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) **"Covered Entity"** means:

(1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and

(2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) **"Manufacturer"** has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug. The term includes:

(1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and

(2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) **"Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)"** means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) **"Medicaid Rebate Program and Medicaid Rebate Agreement"** mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) **"National Drug Code (NDC)"** means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) **"Over the Counter Drug"** means a drug that may be sold without a

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prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) **"Quarter"** means a calendar quarter unless otherwise specified.

(l) **"Rebate Percentage"** means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) **"the Secretary"** means the Secretary of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) **"Unit of the Drug"** means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) **"Wholesaler"** means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

II. MANUFACTURER'S RESPONSIBILITIES

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP,

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baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the HRSA Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c) to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

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IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access the elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process, that the entity is in violation of such prohibitions, the entity shall be liable to the Manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as described in section II(a) of the Agreement. Pursuant to section 340B(a) (4) and (5) a covered entity also could be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section 340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of

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the Act and the Agreement.

(e) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

V. CONFIDENTIALITY PROVISIONS

(a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.

(b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section IX of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

(c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request, the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the Secretary, except to the extent that there is a violation of the provisions of the Agreement.

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(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.

(1) Notice to the Secretary will be sent to:

Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane Mail
Stop 8W03A
Rockville, Maryland 20857

(2) Notice concerning data transfer and information systems issues is to be sent to the same address as listed above (section VII(a)(1) of this Agreement).

(3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.

(b) The Manufacturer will be permitted to audit the records of each covered entity

(1) that directly pertain to the entity's compliance with the prohibition on

(A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

(B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);

(2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and

(3) at the Manufacturer's expense.

(c)No provision in the Agreement shall prohibit the Manufacturer from charging a price

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for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between the Secretary and the Manufacturer.

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327;
Expiration Date: 08/31/2019

IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:_____ Date: _____

Title: Associate Administrator
Healthcare Systems Bureau
Health Resources and Services Administration

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: _____
(Signature)

Title: _____ Date: _____

Phone Number: _____ Ext.____ FAX Number: _____

e-Mail Address:_____

Manufacturer Labeler Code(s): _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

Contact Person: _____

Title: _____

Phone Number: _____ Ext._____FAX Number: _____

e-Mail Address:_____

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C- 03I, Rockville, Maryland, 20857.

EXHIBIT “B”

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

General Instructions for Completing the 340B Drug Pricing Program Pharmaceutical Pricing Agreement – Addendum

Section 340B(a)(1) of the Public Health Service Act (PHS Act) provides that the Secretary of Health and Human Services (the Secretary) will enter into a pharmaceutical pricing agreement (the Agreement) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage. Section 7102(b) of the Affordable Care Act amended section 340B(a)(1) of the PHS Act to add two new requirements for inclusion in the Agreement with the manufacturer:

1. The Agreement "shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug"; and
2. The Agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

Section 7102 of the Affordable Care Act also amended section 340B(d)(1)(B)(i)(II) of the PHS Act, which requires HRSA to develop a system to verify the accuracy of manufacturer-submitted quarterly pricing data with ceiling price data calculated by the Secretary.

Section 340B(d)(1)(B)(i) of the PHS Act, as amended by section 7102 of the Affordable Care Act, requires HRSA to develop a 340B ceiling price validation system to calculate and verify 340B ceiling prices for covered outpatient drugs as compared to the manufacturers' 340B prices offered to a covered entity. This system will enable HRSA to receive pricing information directly from manufacturers, which will allow HRSA to more efficiently identify discrepancies among the ceiling price variables and resolve them with minimal burden on the industry. As part of HRSA's oversight of the 340B Program, this Addendum to the Agreement will help to ensure that the requirements of the statute are met, including that manufacturers provide HRSA with their calculated prices for the pricing validation system, and the provision to offer covered entities drugs for purchase at or below the applicable ceiling price if such drugs are made available to any other purchaser at any price.

Please print the attached Addendum and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the signed document.

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-03I, Rockville, Maryland, 20857.

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

PHARMACEUTICAL PRICING AGREEMENT ADDENDUM

Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary")
and
THE MANUFACTURER
Identified in "Signatures" Section of this Addendum
(hereinafter referred to as the "Manufacturer")

This is an Addendum to the Pharmaceutical Pricing Agreement (the "Agreement") between the Secretary and the Manufacturer. The following terms are hereby incorporated as part of the Agreement:

1) Manufacturer shall furnish the Secretary with reports, on a quarterly basis, that include the price of each covered outpatient drug that is subject to the Agreement, that according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this addendum as the "ceiling price").

2) Manufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price.

Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ **Date:** _____

Title: Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration

ACCEPTED FOR THE MANUFACTURER

By: _____ **Date:** _____
(Signature)

Printed Name: _____ **Title:** _____

Phone Number: _____ **Email Address:** _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-03I, Rockville, Maryland, 20857.

EXHIBIT “C”

Agios TIBSOVO® Limited Distribution Plan

This notice provides information for eligible 340B covered entities about how to acquire TIBSOVO® (ivosidenib). Agios offers the 340B price to all eligible covered entities that satisfy the patient care requirements below.

TIBSOVO is an orphan oral oncologic therapy. Specifically, TIBSOVO is an isocitrate dehydrogenase-1 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Agios has developed a limited distribution plan designed to ensure that patients being treated with TIBSOVO receive the best possible care. All pharmacies – 340B and otherwise – are subject to this plan equally.

TIBSOVO is available for purchase by healthcare facilities that maintain in-house pharmacies that are equipped to meet the specific needs of patients with acute myeloid leukemia, including, for example, by maintaining an on-site prescribing oncologist and staff to monitor patients on cancer medications. If your facility meets these criteria, you may purchase TIBSOVO at the 340B price from the following specialty distributor partners: McKesson Plasma and Biologics, ASD Healthcare, Oncology Supply and Cardinal Health. Contact information for these specialty distributors can be found at www.myagios.com.

Agios also supplies TIBSOVO through two specialty pharmacies with deep oncology experience and with a focus on providing oncology-specific care and patient support: Diplomat Pharmacy, Inc. and Biologics, Inc. If your pharmacy does not meet the cancer care criteria, or you choose not to order through our specialty distributor partners, your patients can still access TIBSOVO through one of these specialty pharmacies. The specialty pharmacy will fill prescriptions from your institution and ship TIBSOVO directly to your patients' homes. Contact information for these specialty pharmacies can be found at www.myagios.com.

Agios is committed to both patient well-being and compliance with the rules of the 340B program. If you have any questions about this plan, or any difficulty obtaining TIBSOVO for your patients, please contact Agios at 1-617-649-8600.

Lexicon pharmaceuticals

340B Notice Regarding Limited Distribution plan for Xermelo (telotristat ethyl)
April 11, 2017

This notice provides information for 340B covered entities about how to acquire Xermelo (telotristat ethyl) (NDC: 70183-125-84), at the calculated 340B ceiling price. Lexicon is committed to both patient safety and compliance with the rules of the 340B program.

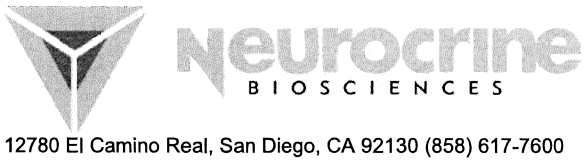
Xermelo is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy. Xermelo (telotristat ethyl) is an orphan oral drug therapy taken three times a day.

In order to ensure that patients who are prescribed Xermelo receive ongoing supportive care and are compliant to a three times a day therapy, Lexicon Pharmaceuticals has developed a limited distribution plan designed to achieve these goals. All pharmacies – 340B and otherwise – are subject to this plan equally.

If your pharmacy (a) is an oncology-specific facility, (b) employs on-site prescribing oncologists, and (c) dispenses to patients of record of your facility, we invite you to access Xermelo through our specialty pharmacy partner Biologics, Inc. Biologics, Inc. will fill Xermelo scripts from your institution and ship product to your pharmacy for dispensing. Biologics, Inc. will charge you no more than the then-prevailing 340B ceiling price.

Contact information for this specialty pharmacy can be found at www.xermelo.com/lexcares.

Lexicon takes its participation under the 340B program seriously and makes every effort to ensure that Xermelo is available to all 340B covered entities in a manner that is no more restrictive than for its non-340B entities. If you have any questions about this plan, or any difficulty obtaining Xermelo for your patients, please contact Lexicon directly at 1-844-937-6356.



12780 El Camino Real, San Diego, CA 92130 (858) 617-7600

340B Notice Regarding Limited Distribution Plan for INGREZZA™ (valbenazine) Capsules

May 22, 2017

This notice provides information to 340B covered entities regarding how to acquire INGREZZA® (valbenazine) capsules at the 340B ceiling price.

INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia (TD).

In order to ensure that patients being treated with INGREZZA receive the best possible care and to ensure optimal therapeutic adherence, Neurocrine has developed a limited distribution plan designed to achieve these goals. All pharmacies – 340B and otherwise – are subject to this plan equally.

If your facility is a 340B covered entity that maintains an on-site neurologist or psychiatrist, and dispenses from that location; you may be eligible to order from our specialty distributor partner ASD Specialty Healthcare at the 340B ceiling price and inventory INGREZZA on-site. For specific terms and conditions of our qualified dispensary program, please call 1-800-746-6273, Fax 1-800-547-9413 or email asd.customerservice@asdhealthcare.com

If your pharmacy is not eligible to inventory INGREZZA, you and your 340B-eligible patients can access INGREZZA through one of our specialty pharmacy partners:

PantheRx Specialty Pharmacy 1-855-726-8479 or FAX 1-855-246-3986

Orsini Healthcare 1-800-279-1676 or FAX 1-879-864-1681

These pharmacies will fill scripts from your institution at the 340B ceiling price, and ship INGREZZA directly to your patients at the location of their choosing.

Additional information can be found at www.INBRACE.com or by calling 84-INGREZZA (844-647-3992).

Neurocrine is committed to both patient safety and compliance with the rules of the 340B program. Our limited distribution plan attempts to address both concerns. If you have any questions about this plan, or any difficulty obtaining INGREZZA for your patients, please contact Neurocrine at 84-INGREZZA (844-647-3992).

Defined Distribution Network for Jakafi® (ruxolitinib)

June 2017

This notice provides information for 340B covered entities about how to acquire Jakafi ® at the 340B price.

Jakafi® is an orphan drug approved to treat patients with: (1) intermediate or high-risk myelofibrosis and (2) polycythemia vera in patients who have had an inadequate response to or are intolerant of hydroxyurea. To support high quality care for patients taking Jakafi®, Incyte distributes the product through a defined network of specialty distributors and pharmacies.

Incyte offers the 340B price to all covered entities, except those that are ineligible for 340B pricing for drugs, like Jakafi®, that are designated by FDA for an orphan use.[1] Eligible 340B covered entities may purchase Jakafi® at the 340B price for delivery to the covered entities' facilities through Incyte's network of specialty distributors: ASD Healthcare, Cardinal Health Specialty Distribution, and McKesson Plasma and Biologics. If a 340B covered entity does not have an in-house pharmacy capable of dispensing drugs to eligible patients, then Incyte will support a contract pharmacy arrangement for that covered entity, if the pharmacy:

- Closely manages its patients' care;
- Has expertise in the treatment of oncology and provides patient access to oncology nurses;
- Offers programs to support patients' access to prescribed medications;
- Has distribution capabilities that comply with applicable law; □ Can report adverse event and other data to Incyte; and
- Possesses URAC[2] accreditation.

These requirements match Incyte's criteria for evaluating specialty pharmacy requests to join the Jakafi® dispensing network and are designed to help ensure quality care for patients on Jakafi®.

Incyte takes seriously both its obligations to protect patient safety and to comply with the 340B statute, and has designed the defined distribution network accordingly. This defined distribution network may change from time to time. If a covered entity has any questions regarding how it may access Jakafi® at the 340B price, please contact Incyte at incyte_us_distribution@incyte.com.

###

[1] These covered entities are free-standing cancer hospitals, critical access hospital, rural referral centers, and sole community hospitals. *See* 42 U.S.C. § 256b(e).

[2] URAC is a nationally-recognized accreditor of specialty pharmacies.

EXHIBIT “D”

Celgene Corporation
86 Morris Avenue
Summit, New Jersey 07901
Tel 908-673-9000
Fax 908-673-9001

Notice Regarding Limited Distribution Network for Revlimid® (lenalidomide), Pomalyst® (pomalidomide), and Thalomid® (thalidomide)

This notice provides information for 340B covered entities regarding the distribution of Revlimid® (lenalidomide), Pomalyst® (pomalidomide), and Thalomid® (thalidomide) by Celgene Corporation ("Celgene").

At the direction of the FDA, Celgene has implemented Risk Evaluation and Mitigation Strategies ("REMS") for Revlimid®, Pomalyst®, and Thalomid®, which are Category X products that can cause severe birth defects and fetal death. The REMS for each of these products mandates that only a trained network of providers subject to contractual agreement with Celgene may dispense the product and, in turn, requires Celgene to engage in rigorous training, certification, auditing and monitoring activities. To satisfy its ongoing REMS obligations in a manner that optimizes both patient safety and access, Celgene has adopted a limited distribution network of specialty pharmacies, hospitals, and clinics that are authorized to purchase and dispense each of these three products.

Celgene's selection criteria for accepting providers into the limited distribution networks is and has been based on factors unrelated to a pharmacy's 340B status. Those selection criteria have centered on the dispensing site's ability to protect patient safety and to serve a broad patient base. 340B covered entities are proportionately represented in the limited distribution networks for all three products.

Celgene has analyzed the scope of the limited distribution networks and has determined that the less than 250 providers in the networks are sufficient to meet patient drug access needs. Allowing more providers to enter the limited distribution networks could unnecessarily weaken the operation and effectiveness of our REMS and could make the certification, training, auditing, and monitoring requirements of the REMS infeasible. Therefore, in 2013 Celgene closed the limited distribution networks to all new entities, 340B or otherwise, and we do not anticipate adding any new entities at this time.

Patients of providers that are not included in the limited distribution networks may access Revlimid®, Pomalyst®, and Thalomid® by purchasing these products from one of the specialty pharmacies within the networks. A listing of these specialty pharmacies is available at http://www.celgene.com/patients/rems-pharmacy-network/.

Celgene takes seriously both its obligations to protect patient safety and to comply with the 340B statute. We have reviewed the composition and selection criteria for the limited distribution networks with HRSA and are posting this notice at the Agency's request, in order to ensure that our distribution procedures are transparent to all 340B program stakeholders. If you have any questions regarding the limited distribution networks for Revlimid®, Pomalyst®, and Thalomid® or would like further information on how your patients may access these products, please contact Celgene at REMSnetwork@celgene.com.

EXHIBIT “E”

340B Hospital Eligibility Criteria

Eligibility for Participation in the 340B Drug Pricing Program

Purpose: The purpose of this tool is to provide specific eligibility criteria, as well as a description of hospitals eligible for participation in the 340B Drug Pricing Program.

Entity Type	Nonprofit/ Government Contract Requirement	DSH%	Subject to GPO Prohibition	Subject to Orphan Drug Exclusion
Disproportionate Share Hospital (DSH)	Yes	>11.75%	Yes	No
Children's Hospital (PED)	Yes	>11.75%	Yes	No
Free-Standing Cancer Hospital (CAN)	Yes	>11.75%	Yes	Yes
Critical Access Hospital (CAH)	Yes	N/A	No	Yes
Rural Referral Center (RRC)	Yes	≥8%	No	Yes
Sole Community Hospital (SCH)	Yes	≥8%	No	Yes

Disproportionate Share Hospitals:

Disproportionate share hospitals serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicare and Medicaid Services (CMS) to cover the costs of providing care to uninsured patients.

To be eligible to participate in the 340B Drug Pricing Program, disproportionate share hospitals must meet the requirements of 42 USC 256b(a)(4)(L).

Disproportionate share hospitals are defined in Section 1886(d)(1)(B) of the Social Security Act. For more information, see the Disproportionate Share Hospitals Fact Sheet.

Children's Hospitals

Children's hospitals must show that they are not part of a larger institution by demonstrating financial and administrative independence. Children's hospitals have a CMS designated 3300 series Medicare provider number. The defining legislation for children's hospitals is Section 1886(d)(1)(B)(iii) of the Social Security Act.

To be eligible to participate in the 340B Drug Pricing Program, children's hospitals must either

Have a disproportionate share adjustment percentage greater than 11.75 percent for the most recently filed cost report; or

Be eligible under a separate indigent care calculation that meets specific criteria, including location in an urban area, 100 or more beds, and net inpatient care revenues (excluding Medicare) for indigent care of more than 30 percent of net during the cost reporting period in which the discharges occur. This indigent care revenue must come from state and local government sources and Medicaid.

Children's hospitals are subject to the statutory 340B GPO Prohibition.

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Free-Standing Cancer Hospitals

Free-standing cancer hospitals are independent, nonprofit hospitals that treat patients with cancer. The defining legislation for free-standing cancer hospitals is Section 1820(c)(2) of the Social Security Act.

To be eligible to participate in the 340B Drug Pricing Program, free-standing cancer hospitals must either

Have a disproportionate share adjustment percentage greater than 11.75 percent for the most recently filed cost report; or

Be eligible under a separate indigent care calculation that meets specific criteria, including location in an urban area, 100 or more beds, and net inpatient care revenues (excluding Medicare) for indigent care of more than 30 percent of net during the cost reporting period in which the discharges occur. This indigent care revenue must come from state and local government sources and Medicaid.

Critical Access Hospitals

Critical access hospitals are designated by the CMS. The defining legislation is Section 1820(c)(2) of the Social Security Act. For more information, see the Critical Access Hospitals Fact Sheet.

To be eligible to participate in the 340B Drug Pricing Program, critical access hospitals must meet the requirements of 42 USC 256b(a)(4)(L)(i).

Rural Referral Centers

Rural referral centers are high-volume acute-care rural hospitals that treat a large number of complicated cases. Hospitals are designated as rural referral centers by the CMS. Rural referral centers are defined in Section 1886(d)(5)(C)(i) of the Social Security Act; requirements for rural referral centers can be found at 42 CFR 412.96. For more information about rural referral centers, see the Rural Referral Center Fact Sheet.

Hospitals classified as rural referral centers may be eligible to participate in the 340B Drug Pricing Program if they have a disproportionate share adjustment percentage equal to or greater than 8 percent for the most recently filed Medicare cost report and meet the requirements of 42 USC 256b(a)(4)(L)(i).

Sole Community Hospitals

Sole community hospitals are designated by the CMS. The defining legislation for sole community hospitals is Section 1886(d)(5)(D)(iii) of the Social Security Act. For more information on sole community hospitals, see the Sole Community Hospitals Fact Sheet.

To be eligible to participate in the 340B Drug Pricing Program, sole community hospitals must also have a disproportionate share adjustment percentage equal to or greater than 8 percent for the most recently filed Medicare cost report and meet the requirements of 42 USC 256b(a)(4)(L)(i).

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

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EXHIBIT “F”

Product	Revlimid	Revlimid	Revlimid	Revlimid	Revlimid	Revlimid	Thalomid	Thalomid	Thalomid	Thalomid	Pomalyst	Pomalyst	Pomalyst	Pomalyst
Strength	2.5MG	5MG	10MG	15MG	20MG	25MG	50MG	100MG	150MG	200MG	1MG	2MG	3MG	4MG
FDA Approval Type	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA	NDA
Orphan Drug	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Baseline Quarter	3Q2012	1Q2006	1Q2006	3Q2006	3Q2013	3Q2006	3Q2003	2Q2003	2Q2007	2Q2003	2Q2013	2Q2013	2Q2013	2Q2013
Baseline AMP	$36,672.09	$21,500.00	$21,500.00	$28,000.00	$41,294.32	$29,500.00	$481.30	$921.60	$4,155.48	$1,764.00	$49,740.00	$49,740.00	$49,740.00	$49,740.00
Baseline CPI-U	229.478	201.8	201.8	202.9	233.504	202.9	183.7	184.2	205.352	184.2	232.773	232.773	232.773	232.773
Current CPI-U (June 2018)	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989	251.989
Allowable Price Increase Factor	1.098	1.249	1.249	1.242	1.079	1.242	1.372	1.368	1.227	1.368	1.083	1.083	1.083	1.083
Max Allowable AMP	$40,269.50	$26,847.19	$26,847.19	$34,774.23	$44,563.32	$36,637.14	$660.22	$1,260.77	$5,099.22	$2,413.18	$53,846.16	$53,846.16	$53,846.16	$53,846.16
Current Estimated AMP	$69,547.81	$69,547.81	$69,547.81	$69,547.81	$69,547.81	$69,547.81	$4,785.25	$7,767.42	$8,305.28	$8,843.50	$79,165.53	$79,165.53	$79,165.53	$79,165.53
Estimated Inflation Penalty	$29,278.31	$42,700.62	$42,700.62	$34,773.58	$24,984.49	$32,910.67	$4,125.03	$6,506.65	$3,206.06	$6,430.32	$25,319.37	$25,319.37	$25,319.37	$25,319.37
Estimated Best Price Discount off WAC	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Estimated Best Price	$66,070.42	$66,070.42	$66,070.42	$66,070.42	$66,070.42	$66,070.42	$4,545.99	$7,379.05	$7,890.02	$8,401.33	$75,207.25	$75,207.25	$75,207.25	$75,207.25
URA Calculation:														
GREATER OF: AMP x 23.1%	$16,065.54	$16,065.54	$16,065.54	$16,065.54	$16,065.54	$16,065.54	$1,105.39	$1,794.27	$1,918.52	$2,042.85	$18,287.24	$18,287.24	$18,287.24	$18,287.24
OR: AMP - BP	$3,477.39	$3,477.39	$3,477.39	$3,477.39	$3,477.39	$3,477.39	$239.26	$388.37	$415.26	$442.18	$3,958.28	$3,958.28	$3,958.28	$3,958.28
Base Rebate	$16,065.54	$16,065.54	$16,065.54	$16,065.54	$16,065.54	$16,065.54	$1,105.39	$1,794.27	$1,918.52	$2,042.85	$18,287.24	$18,287.24	$18,287.24	$18,287.24
Total Medicaid Rebate	$45,343.86	$58,766.16	$58,766.16	$50,839.12	$41,050.03	$48,976.22	$4,785.25	$7,767.42	$5,124.58	$8,473.16	$43,606.60	$43,606.60	$43,606.60	$43,606.60
PHS Price (AMP - URA)	$24,203.95	$10,781.65	$10,781.65	$18,708.69	$28,497.78	$20,571.59	$1.00	$1.00	$3,180.70	$370.34	$35,558.93	$35,558.93	$35,558.93	$35,558.93
% off Current WAC	65%	84%	84%	73%	59%	70%	100%	100%	62%	96%	55%	55%	55%	55%
Difference between WAC and PHS	$45,343.86	$58,766.16	$58,766.16	$50,839.12	$41,050.03	$48,976.22	$4,784.25	$7,766.42	$5,124.58	$8,473.16	$43,606.60	$43,606.60	$43,606.60	$43,606.60
Estimated Sales Units	16,888	16,888	16,888	16,888	16,888	16,888	747	747	747	747	4,706	4,706	4,706	4,706
Estimated % of Sales that would be PHS	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Gross Sales w/ Access to PHS Pricing	$1,174,498,652.54	$1,174,498,652.54	$1,174,498,652.54	$1,174,498,652.54	$1,174,498,652.54	$1,174,498,652.54	$3,574,416.43	$5,801,994.40	$6,203,757.24	$6,605,788.98	$372,543,670.59	$372,543,670.59	$372,543,670.59	$372,543,670.59
Gross Sales w/o Access to PHS Pricing	$1,136,211,105.56	$1,124,877,552.09	$1,124,877,552.09	$1,131,571,004.26	$1,139,836,737.89	$1,133,144,008.39	$3,395,732.96	$5,511,932.03	$6,012,363.08	$6,289,330.95	$362,283,293.03	$362,283,293.03	$362,283,293.03	$362,283,293.03
Loss in Revenue	$38,287,546.97	$49,621,100.44	$49,621,100.44	$42,927,648.28	$34,661,914.64	$41,354,644.14	$178,683.47	$290,062.37	$191,394.16	$316,458.04	$10,260,377.55	$10,260,377.55	$10,260,377.55	$10,260,377.55

Total Incremental Cost to 340B in 2018 (EST): $298,492,063.18

EXHIBIT “G”

10-K 1 a2017123110k.htm 10-K

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2017

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-34912

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**22-2711928**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
86 Morris Avenue Summit, New Jersey	**07901**
(Address of principal executive offices)	(Zip Code)

(908) 673-9000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $.01 per share	NASDAQ Global Select Market
Contingent Value Rights	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2017, the last business day of the registrant's most recently completed second quarter, was $101,580,696,211 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 752,175,608 shares of Common Stock outstanding as of February 2, 2018.

CELGENE CORPORATION AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

19. Geographic and Product Information

Operations by Geographic Area: Revenues primarily consisted of sales of our primary commercial stage products including REVLIMID®, POMALYST®/IMNOVID®, OTEZLA®, ABRAXANE®, IDHIFA®, VIDAZA®, azacitidine for injection (generic version of VIDAZA®) and THALOMID® (sold as THALOMID® or Thalidomide Celgene® outside of the U.S.). In addition, we earn revenue from other product sales and licensing arrangements.

Revenues	2017	2016	2015
United States	$ 8,324	$ 7,010	$ 5,604
Europe	3,327	3,046	2,624
All other	1,352	1,173	1,028
Total revenues	$ 13,003	$ 11,229	$ 9,256

Long-Lived Assets[1]	2017	2016
United States	$ 768	$ 667
Europe	296	251
All other	6	12
Total long lived assets	$ 1,070	$ 930

[1] Long-lived assets consist of net property, plant and equipment.

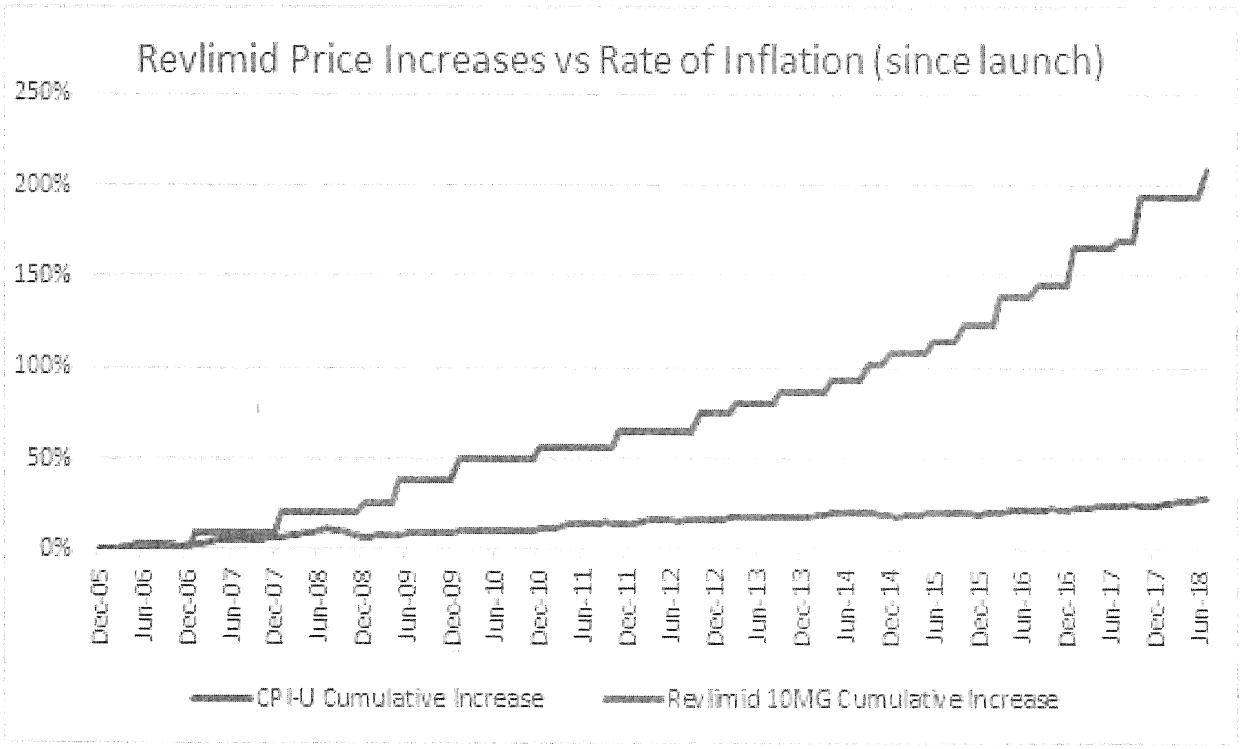
Revenues by Product: Total revenues from external customers by product for the years ended December 31, 2017, 2016 and 2015 were as follows:

	2017	2016	2015
REVLIMID®	$ 8,187	$ 6,974	$ 5,801
POMALYST®/IMNOVID®	1,614	1,311	984
OTEZLA®	1,279	1,017	472
ABRAXANE®	992	973	967
IDHIFA®	20	—	—
VIDAZA®	628	608	591
azacitidine for injection	36	66	84
THALOMID®	132	152	185
ISTODAX®	76	80	69
Other	9	4	8
Total net product sales	12,973	11,185	9,161
Other revenue	30	44	95
Total revenue	$ 13,003	$ 11,229	$ 9,256

Major Customers: We sell our products primarily through wholesale distributors and specialty pharmacies in the United States, which account for a large portion of our total revenues. International sales are primarily made directly to hospitals, clinics and retail chains, many of which are government owned. During the three-year period of 2017, 2016 and 2015, customers that accounted for more than 10% of our total revenue in at least one of those years are summarized below. The percentage of amounts due from these customers compared to total net accounts receivable is also summarized below as of December 31, 2017 and 2016.

	Percent of Total Revenue			Percent of Net Accounts Receivable	
Customer	2017	2016	2015	2017	2016
CVS Health Corp.	12.5%	12.0%	10.7%	9.7%	7.9%
McKesson Corp.	12.0%	10.3%	8.5%	9.6%	9.1%
AmerisourceBergen Corp.	10.0%	8.5%	8.1%	9.7%	8.7%

EXHIBIT “H”



Cost at launch for Revlimid was an estimate of **$22,000 per month** for (30) days of treatment equating to **@$124k annually**

Currently up through last price increase the cost of Revlimid is: **$69,547.81 per month** equating to **@ $847,573.72 annually**

EXHIBIT “I”

EDGAR pro
by EDGAR Online

CELGENE CORP /DE/

FORM 10-K
(Annual Report)

Filed 02/07/18 for the Period Ending 12/31/17

Address	86 MORRIS AVENUE
	SUMMIT, NJ, 07901
Telephone	(908)673-9000
CIK	0000816284
Symbol	CELG
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES

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There were 752,175,608 shares of Common Stock outstanding as of February 2, 2018 .

Documents Incorporated by Reference

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2017. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

Part II, Item 5.(d)	Equity Compensation Plan Information.
Part III, Item 10.	Directors, Executive Officers and Corporate Governance.
Part III, Item 11.	Executive Compensation.
Part III, Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

HRSA also issued proposed regulations to implement an administrative dispute resolution (ADR) process for certain disputes arising under the 340B program, including (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit, that a covered entity has violated the prohibition on diversion of covered outpatient drugs to ineligible patients or duplicate discounts. The exact timing and content of final action on these matters is uncertain at this time. Depending on their final form, these actions could affect our obligations under the 340B program in ways that may have an adverse impact on our business. Additionally, in early 2016, HRSA finalized a regulation regarding the 340B pricing methodology and providing guidelines for when civil monetary penalties may be issued for "knowing and intentional" manufacturer overcharges of 340B covered entities. HRSA has delayed the effective date of this regulation to July 1, 2018.

We have received an inquiry from HRSA regarding our limited distribution networks for REVLIMID ®, POMALYST ®, and THALOMID ® and our compliance with the 340B program. We have cooperated fully in responding to this inquiry and believe that we have complied with applicable legal requirements. If, however, we are ultimately required to change our sales or pricing practices with regard to the distribution of these drugs, there would be an adverse effect on our revenues and profitability.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations.

Many existing and potential customers for our products become members of group purchasing organizations (GPOs). GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of that contractual arrangement. Our failure to enter into or renew contracts with GPOs may cause us to lose market share and could adversely affect our sales.

Our long-term success depends, in part, on intellectual property protection .

Our success depends, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties and to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical companies, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that if claims of any of our owned or licensed patents are challenged by one or more third parties (through, for example, litigation or post grant review in the United States Patent and Trademark Office (USPTO) or European Patent Office (EPO)), a court or patent authority ruling on such challenge will ultimately determine, after all opportunities for appeal have been exhausted, that our patent claims are valid and enforceable. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using such products or processes, be subject to significant liabilities to such third party and/or be required to obtain license rights from such third party. Lawsuits involving patent claims are costly and could affect our results of operations, result in significant expense and divert the attention of managerial and scientific personnel. For more information on challenges to certain of our patents and settlement of certain of these challenges, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

In addition, we do not know whether any of our owned or licensed pending patent applications will result in the issuance of patents or, if patents are issued, whether they will be dominated by third-party patent rights, provide significant proprietary protection or commercial advantage or be circumvented, opposed, invalidated, rendered unenforceable or infringed by others.

Our intellectual property rights may be affected by certain provisions of the America Invents Act ("AIA") enacted in 2011. For example, under the AIA, members of the public may seek to challenge an issued patent by petitioning the USPTO to institute a post grant proceeding, such as a Post Grant Review (PGR) or Inter Partes Review (IPR). Once a post grant proceeding is instituted, the USPTO may find grounds to revoke the challenged patent or specific claims therein. For more information with respect to IPRs, see Note 18 of Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K. A similar procedure (known as a patent opposition) has existed in Europe for many years and we have defended our European patents in certain of those proceedings. We cannot predict whether any other Celgene patents will ever become the subject of a post grant proceeding or patent opposition. If a significant product patent is successfully challenged in a post grant proceeding or patent opposition, it may be revoked, which would have a serious negative impact on our ability to maintain exclusivity in the market-place for our commercial products affected by such revocation and could adversely affect our future revenues and profitability.

On October 2, 2014, the EMA adopted its clinical transparency policy, "Policy on Publication of Clinical Data for Medicinal Products for Human Use" (Clinical Data Policy), which became effective on January 1, 2015. In general, under the Clinical Data Policy, clinical data is not deemed to be commercially confidential data. Therefore, there is a risk that unpublished proprietary