

**House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record
Responses Submitted by Mr. Steven Collis
on Behalf of AmerisourceBergen Drug Corporation**

The Honorable Gregg Harper

- 1. Does AmerisourceBergen request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

Answer: ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers. When received, the dispensing data is reviewed to identify data patterns and trends that could be indicative of possible diversion, such as unusually high dispensing of formulations or strengths of controlled substances that are more likely to be abused.

- 2. Does H. D. Smith request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

Answer: H. D. Smith's customers are in the process of being integrated into the ABDC diversion control program and currently are treated in accordance with the response to Question 1 above.

Historically, H. D. Smith did periodically request dispensing data from current or prospective customers, which was analyzed to identify patterns or trends indicative of possible diversion.

- 3. In its contracts with pharmacy customers, is AmerisourceBergen able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

Answer: ABDC's contracts with its pharmacy customers do not typically include a provision that would require its customers to provide dispensing data, although such contracts do provide that ABDC can reject customers' orders or place restrictions on the ordering of controlled substances at the discretion of ABDC's Diversion Control Team. Such restrictions can include declining to ship controlled substances to a customer who refuses to provide dispensing data when asked. Nevertheless, ABDC is always evaluating additional measures it can take to enhance its Diversion Control Program and will consider potential contractual amendments as part of that ongoing evaluation.

- 4. In its contracts with pharmacy customers, is H. D. Smith able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

Answer: H. D. Smith will use ABDC contracts moving forward.

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H. D. Smith's historic contracts with its pharmacy customers do not include a provision that would require its customers to provide dispensing data. H. D. Smith did, however, periodically request such data of its customers and a customer's refusal to comply with that request may have resulted in the termination of the ability to purchase controlled substances and potentially the termination of the account, if the customer never complied.

- 5. As part of AmerisourceBergen's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: ABDC does not use the term "service region." ABDC's diversion control program believes factors besides the size of a service community are more relevant to analyzing the customer's purchasing patterns, including the pharmacy's purchases of both controlled and non-controlled substances, and the type of patients being served by the pharmacy. Moreover, ABDC recognizes that a pharmacy in a small town may serve a population much larger than the town itself. ABDC does not have access to the geographic dispersal of patients served by a pharmacy because of patient privacy protections.

Notwithstanding the above, as part of its diversion control program, ABDC does compare purchasing patterns of customers served by the same distribution center, and ABDC does currently consider various factors involving the customer's geographic location in making decisions about suspicious orders. These factors include population, opioid overdose death rates and Medicare part D prescribing rates for opioids.

- 6. As part of H. D. Smith's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: H. D. Smith's customers are in the process of being integrated into the AmerisourceBergen diversion control program and currently are treated in accordance with the response to Question 5 above.

Historically, H. D. Smith did occasionally consider the population of the town in which a pharmacy was located when evaluating that pharmacy, but did not have access to information regarding the patient population being served by a pharmacy because of patient privacy protections. The size of the town being served was not always considered and was only one of the factors H. D. Smith used in evaluating pharmacies because the population of the town in which the pharmacy is located may be smaller or larger than the patient population being served. Other factors considered by H. D. Smith included the proximity of hospitals, long term care facilities and hospice centers when evaluating customer orders.

- 7. Does AmerisourceBergen request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance**

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Answer: ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers. When received, the dispensing data is reviewed to identify data patterns and trends that could be indicative of possible diversion, such as unusually high dispensing of formulations or strengths of controlled substances that are more likely to be abused.

8. Does H. D. Smith request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

Answer: H. D. Smith's customers are in the process of being integrated into the AmerisourceBergen diversion control program and currently are treated in accordance with the response to Question 1 above.

Historically, H. D. Smith did periodically request dispensing data from current or prospective customers, which was analyzed to identify patterns or trends indicative of possible diversion.

9. In its contracts with pharmacy customers, is AmerisourceBergen able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Answer: ABDC's contracts with its pharmacy customers do not typically include a provision that would require its customers to provide dispensing data, although such contracts do provide that ABDC can reject customers' orders or place restrictions on the ordering of controlled substances at the discretion of ABDC's Diversion Control Team. ABDC can also decline to ship controlled substances to a customer who refuses to provide dispensing data when asked, so a separate contractual provision regarding dispensing data is not needed to achieve the goals of ABDC's Diversion Control Program.

10. In its contracts with pharmacy customers, is H. D. Smith able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Answer: H. D. Smith will use ABDC contracts moving forward.

H. D. Smith's historic contracts with its pharmacy customers do not include a provision that would require its customers to provide dispensing data. H. D. Smith did, however, periodically request such data of its customers and a customer's refusal to comply with that request may have resulted in the termination of the ability to purchase controlled substances and potentially the termination of the account, if the customer never complied.

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- 11. As part of AmerisourceBergen's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: ABDC does not use the term “service region.” ABDC’s diversion control program believes factors besides the size of a service community are more relevant to analyzing the customer’s purchasing patterns, including the pharmacy’s purchases of both controlled and non-controlled substances, and the type of patients being served by the pharmacy. Moreover, ABDC recognizes that a pharmacy in a small town may serve a population much larger than the town itself. ABDC does not have access to the geographic dispersal of patients served by a pharmacy because of patient privacy protections.

Notwithstanding the above, as part of its diversion control program, ABDC does compare purchasing patterns of customers served by the same distribution center, and ABDC does currently consider various factors involving the customer’s geographic location in making decisions about suspicious orders. These factors include population, opioid overdose death rates and Medicare part D prescribing rates for opioids.

ABDC does not maintain a list of pharmacies by potential geographic reach as doing so would have with little meaningful impact on ABDC’s ability to evaluate its customers’ orders. The retail pharmacy community is constantly shifting, with the opening of new pharmacies and the closure of existing pharmacies a regular occurrence. Even assuming the ability to track this activity, simply knowing the number of pharmacies servicing a particular geographic region would have limited value to the wholesale distributor without knowing the patient community that each pharmacy is servicing, how many and what controlled substances distributors are supplying to those pharmacies and what precisely those pharmacies are dispensing to their patient customers.

- 12. As part of H. D. Smith's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: H. D. Smith’s customers are in the process of being integrated into the AmerisourceBergen diversion control program and currently are treated in accordance with the response to Question 5 above.

H. D. Smith did not use the term “service region.” Historically, H. D. Smith did occasionally consider the population of the town in which a pharmacy was located when evaluating that pharmacy, but did not have access to information regarding the patient population being serviced by a pharmacy, which may be smaller or larger than the population of the town in which the pharmacy was located, because of patient privacy protections. The size of the town being serviced was not always considered and was only one of the factors H. D. Smith used in evaluating pharmacies. Other factors considered by H. D. Smith included the

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proximity of hospitals, long term care facilities and hospice centers when evaluating customer orders.

13. Why did AmerisourceBergen begin doing business with Beckley Pharmacy in 2016 after cutting the pharmacy off as a customer in 2015?

Answer: In 2016, Beckley Pharmacy sought reconsideration of the decision to terminate sales of controlled substances to the pharmacy. At that time, ABDC requested de-identified dispensing data from the pharmacy, which the pharmacy provided. A detailed review of that dispensing data revealed that several of the concerns that had resulted in the pharmacy's termination of ability to purchase controlled substances had been alleviated. As a result of that review, ABDC concluded that there was a reduced risk of diversion at the pharmacy which made allowing the pharmacy to purchase controlled substances appropriate. Beckley Pharmacy's purchases continue to be processed through ABDC's Diversion Control Program, which will allow ABDC to continue to monitor for signs of possible diversion from the pharmacy and take appropriate action again, if necessary.

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The Honorable Michael C. Burgess

- 1. While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?**

Answer: ABDC has accessed the information on purchasing by other distributors referenced in the DEA's February 14, 2018 press release and has found it useful, but with certain limitations. While knowing that a customer has purchased opioids from other suppliers can help to inform decisions, not knowing the quantities of such products purchased limits the utility of that information.

- 2. What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?**

Answer: ABDC has had in place since the 1980s a robust diversion control program. ABDC has continually enhanced and upgraded this comprehensive program over time and continues to do so to this day. We believe the lack of data sharing and transparency is certainly a challenge to our diversion control efforts. It is, however, only one of the challenges ABDC faces in its diversion control program. For example, ABDC's limited role in the supply chain also presents challenges when evaluating pharmacy orders; as a result of its limited role, ABDC has no access to patient-specific data, no access to prescriptions, no access to medical records, and no way to evaluate the legitimacy of patient need.

- 3. Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?**

Answer: As a preliminary matter, orders placed by ABDC's customers that exceed that customer's threshold are held and evaluated to determine whether that order is suspicious. If the determination was made that the order is suspicious, it is cancelled and reported to DEA. If, however, after evaluation of the order, ABDC determines that the order is not suspicious, it is released and shipped to the customer.

ABDC does not know whether DEA shares suspicious order reports with drug manufacturers, or even with DEA's own local field offices. ABDC does not provide its suspicious order reports to any drug manufacturers.

ABDC does not have visibility into DEA's internal processes and does not know how DEA processes, analyzes and uses the suspicious order data it provides. ABDC does know that pharmacies remain DEA-licensed even after suspicious orders are reported.

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4. **Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?**

Answer: ABDC would welcome the following measures:

- greater supply chain data transparency (including ARCOS data sharing and/or data sharing among distributors);
- additional resources for patient and prescriber education and medication safe storage and disposal;
- additional support for e-prescribing;
- mandating the use of electronic ordering for controlled substances;
- notice to distributors when one of its customers has ordered controlled substances from another distributor – including the amount of the order – before the order is processed;
- additional funding for DEA IT enhancement and future enforcement;
- creation of new DEA registration classifications, such as Pain Specialty Pharmacy, that would require more in-depth investigation by DEA and Boards of Pharmacy and allow greater scrutiny by distributors; and
- enhancing state prescription drug monitoring programs.

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The Honorable David B. McKinley

- 1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74**

Answer: ABDC acknowledges the provisions of 21 U.S.C. § 823 and 21 CFR 1301.74. ABDC administers a robust anti-diversion program in order to meet, and in fact exceed, the requirements imposed on it as a distributor. ABDC's Order Monitoring Program ("OMP") is the means by which the Company monitors for and reports suspicious orders of controlled substances and listed chemicals. The OMP is a multi-faceted approach to awareness, monitoring, investigation, and reporting overseen by ABDC Corporate Security and Regulatory Affairs ("CSRA").

- 2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?**

Answer: ABDC has operated a system to monitor, detect and report suspicious orders to the DEA for many decades. ABDC invests significantly in its effort to deter diversion, but there are unavoidable limits to ABDC's ability to monitor and prevent diversion given its limited role in the supply chain. ABDC has no access to patient-specific data, no access to prescriptions, no access to medical records, and no way to evaluate the legitimacy of patient need. ABDC has no control over, nor input into, the amount of controlled substances that are produced in a given year. Instead, production quotas are set by the DEA with input from manufacturers. Nor is ABDC involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances. That responsibility belongs to federal and state governmental agencies, including the DEA. Finally, ABDC does not promote the prescribing or use of opioids to physicians, healthcare providers or patients.

- 3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?**

Answer: ABDC does not ship the orders it reports as suspicious. In an effort to comply with all regulatory requirements, ensure a safe delivery system, and help address this crisis, ABDC has implemented rigorous anti-diversion policies and procedures and is actively engaged in various industry and policy group initiatives that support the fight against opioid abuse.

- 4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?**

Answer: ABDC identifies and reports suspicious orders. ABDC does not fill any suspicious orders.

Prescription opioid abuse is a multi-faceted problem with many causes. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to

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pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

5. Do you agree the United States is in the midst of a prescription opiate epidemic?

Answer: ABDC shares the Committee's concern about the tragic epidemic of opioid abuse.

ABDC desires to be part of much-needed, and unquestionably multi-faceted, solutions to address this public health crisis.

To that end, AmerisourceBergen funded a grant to the Health Care Improvement Fund to support prescriber education for post-surgical procedures. AmerisourceBergen has also partnered with Walgreens to support the safe disposal of unused controlled substances and has provided drug disposal bags to multiple communities to assist with the disposal of unused controlled substances.

AmerisourceBergen also supports mandatory e-prescribing, which would generate real-time information on opioid use and reduce the number of opioids obtained through fraudulent prescriptions or doctor shopping. We support policies to make state PDMPs interoperable, which would allow physicians and regulators to determine if patients are obtaining prescriptions from physicians in more than one state. We are also the only distributor member of the Collaborative for Effective Prescription Opioid Policies ("CEPOP"), which supports policies to reduce prescription opioid abuse and promote treatment options.

AmerisourceBergen is also eager to collaborate with policymakers and stakeholders throughout the pharmaceutical supply chain to improve distributors' ability to assess and act on possibly suspicious orders of prescription opioids. As part of the National Association of Drug Diversion Investigators, AmerisourceBergen has presented on effectively combatting drug diversion at the distribution level and collaborating with law enforcement. AmerisourceBergen also supports increased fees for DEA registration to help support such enhanced data capabilities.

6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?

Answer: ABDC identifies and reports suspicious orders. ABDC does not fill any suspicious orders.

The prescription opioid epidemic is a multi-faceted problem with many causes. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to pharmacies, physicians, or patients; (2) has no control over the amount of

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7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?

Answer: The prescription opioid epidemic is a complex problem that affects many aspects of our society. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

8. Do you believe the prescription opiate epidemic is a public nuisance?

Answer: The prescription opioid epidemic is a complex problem that affects many aspects of our society. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?

Answer: Since at least the 1980s, AmerisourceBergen Drug Corporation has had in place a system to monitor the orders it receives, the OMP. We worked with the DEA to enhance the system in 1998, and again in 2007, and have continually reviewed and improved it, including a comprehensive 2015 revision to build on current data, respond to trends in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools. ABDC's Order Monitoring Program has been consistent with DEA's guidance, including the September 2006, February 2007, and December 2007 letters sent by DEA to the distributors.

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10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?

Answer: ABDC reached out to the West Virginia Board of Pharmacy multiple times, including in 2012 after the litigation filed against ABDC on behalf of the Attorney General and certain West Virginia agencies was filed. During the course of those conversations, ABDC was instructed that it was not required to report suspicious orders to the West Virginia Board of Pharmacy as long as those orders were reported to DEA. Since that time, the head of the West Virginia Board of Pharmacy has repeatedly stated publicly, and testified in the litigation, that the West Virginia Board of Pharmacy received very few suspicious order reports prior to 2012 and, when it started to receive suspicious orders, took no action in response to those orders. ABDC began providing suspicious order reports to the West Virginia Board of Pharmacy in early 2017, once it received instruction to do so.

11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?

Answer: While ABDC does not have such a policy, the percentages of controlled substances purchased by its customers is one of the factors monitored by ABDC as part of its diversion control program.

Within West Virginia, controlled substances were only 3.9% of all ABDC prescription drug sales by dosage unit and 2.1% of all ABDC prescription drug sales by dollar value.

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The Honorable Frank Pallone, Jr.

1. **In AmerisourceBergen's response to the Committee, you provided the number of pills the company distributed to West Virginia. In 2016, AmerisourceBergen shipped about 6 million hydrocodone pills. But back in 2008 and 2009, AmerisourceBergen shipped 16.2 million and 17.5 million pills annually. What explains why in 2009 AmerisourceBergen shipped nearly 3 times the amount the company would later ship in 2016? Did additional due diligence or recognition of the unfolding opioid crisis lead AmerisourceBergen to ship far fewer pills in the later years than in 2008 and 2009? Were there other factors?**

Answer: The primary driver of ABDC's sales is and always has been the orders placed by its customers, licensed and regulated pharmacies, to fill prescriptions written by licensed and regulated practitioners. ABDC monitors orders placed by its customers and reports suspicious orders to the DEA, and did so in both 2008/2009 and in 2016. In addition to its suspicious order monitoring, ABDC conducted due diligence on prospective customers and monitored its current customers. As a result of that additional due diligence, ABDC refused to sell controlled substances to a number of pharmacies that were licensed to be able to purchase those products.

There are many factors that could have resulted in the reduction in orders placed by customers in West Virginia, including changes in physician prescribing practices that may have resulted in reduced ordering by pharmacies.

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The Honorable Jan Schakowsky

- 1. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?**

Answer: ABDC purchases prescription medications, including controlled substances, from the manufacturers. ABDC typically takes title to the product it sells but does, in limited circumstances, facilitate shipments directly from a manufacturer to a pharmacy.

- 2. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?**

Answer: ABDC sells some products at a mark-up (profit) and some products at a mark-down (loss). The price structure varies depending on product and contract. As a general matter, however, ABDC makes approximately 1% net profit on its entire suite of products.

- 3. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?**

Answer: ABDC sells some products at a mark-up (profit) and some products at a mark-down (loss). The price structure varies depending on product and contract. As a general matter, however, ABDC makes approximately 1% net profit on its entire suite of products.