DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0028]

Timothy Baxter; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Dr. Timothy Baxter (Dr. Baxter) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Baxter for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Baxter was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Baxter's debarment, FDA has considered the applicable factors listed in the FD&C Act. Dr. Baxter has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable February 27, 2023.

ADDRESSES: Any application for termination of debarment by Dr. Baxter under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: Your application must include the Docket No. FDA–2021–N–0028. An application will be placed in the docket and, unless submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, *Rachael.Linowes@fda.hhs.gov,* 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act permits FDA to debar an individual if it finds that: (1) the individual has been convicted of a misdemeanor under Federal law ''for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products'' under the FD&C Act and (2) the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On August 31, 2020, in the U.S. District Court for the Western District of Virginia, Dr. Baxter pled guilty to a misdemeanor violation of the FD&C Act. Specifically, he pled guilty to causing the introduction or delivery for introduction of a misbranded drug into interstate commerce in violation of sections 301(a), 303(a)(1), and 502(a) of the FD&C Act (21 U.S.C. 331(a), 333(a)(1), and 352(a)). In the plea agreement pursuant to which Dr. Baxter pled guilty, he agreed that ''all the facts set forth in the Information [filed by the Federal government on the same day] are true and correct and provide the Court with a sufficient factual basis to support [his] plea.'' The Information provided that, at the time of the conduct underlying his conviction, Dr. Baxter was the Global Medical Director of Reckitt Benckiser Pharmaceuticals Inc. (RBP).'' [1] During that time, according to the Information, RBP's Medical Affairs Manager, who reported directly to Dr. Baxter, provided false or misleading analysis and charts to the Massachusetts Medicaid program (MassHealth), as a means of persuading MassHealth to

[1] As noted in the Information, ''on or about December 23, 2014, RBP was renamed Indivior, Inc, and became a subsidiary of Indivior PLC. After on or about December 23, 2014, Dr. Baxter was the Chief Medical Officer of Indivior PLC.''

reimburse patients for a drug named Suboxone Film, which RBP marketed.

As framed by the Information, the false and misleading data and analysis provided to MassHealth—relating to the unintended pediatric exposure rates for Suboxone Film relative to similar tablet products—constituted ''labeling'' for the drug under section 201(m) of the FD&C Act (21 U.S.C. 321(m)) and thus misbranded the drug under section 502(a) of the FD&C Act). As discussed further below, in pleading guilty pursuant to the Information, Dr. Baxter conceded that he was a responsible corporate officer (RCO) at RBP that ''failed to prevent and promptly correct the distribution of false and misleading unintended pediatric exposure data and marketing claims to MassHealth'' and ''caused the introduction and delivery for introduction into interstate commerce of . . . a drug [(Suboxone Film)] that was misbranded in that the drug's labeling was false and misleading'' (*see United States* v. *Park,* 421 U.S. 658, 673–74 (1975)).

By letter dated February 25, 2021, FDA's Office of Regulatory Affairs (ORA) notified Dr. Baxter of its proposal to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application and provided him with an opportunity to request a hearing on the proposal. ORA found that Dr. Baxter is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act on the basis of his misdemeanor conviction under Federal law for conduct both relating to the regulation of a drug product under the FD&C Act and undermining the Agency's process for regulating drugs. The proposal also outlined findings concerning the factors ORA considered to be applicable in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act. ORA found that a 5-year period of debarment is appropriate. Specifically, ORA found that the nature and seriousness of the offense and the nature and extent of voluntary steps to mitigate the effect on the public are unfavorable factors for Dr. Baxter. ORA stated that it viewed the absence of prior convictions involving matters within FDA's jurisdiction as a favorable factor. ORA concluded that ''the facts supporting the unfavorable factors outweigh those supporting the favorable factor and therefore warrant the imposition of a 5-year period of debarment.''

By letter dated March 26, 2021, through counsel, Dr. Baxter requested a hearing on ORA's proposal to debar him. On May 4, 2021, he submitted a ''Memorandum of Facts and Arguments in Support of Hearing Request'' (Memorandum). In this Memorandum, Dr. Baxter makes legal, factual, and policy-based arguments regarding the proffered basis for his debarment in ORA's proposal.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Dr. Baxter's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. As discussed in more detail below, hearings will not be granted on issues of policy or law, on mere allegations, on denials or general descriptions of positions and contentions, on data and information insufficient to justify the factual determination urged if accurate and presented at a hearing, or on factual issues that are not determinative with respect to the action requested (see § 12.24(b) (21 CFR 12.24(b))). The Chief Scientist has considered Dr. Baxter's arguments and concluded that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In his Memorandum, Dr. Baxter makes a series of legal and policy arguments challenging whether he is subject to debarment and, if so, whether debarment for 5 years is appropriate. Many of Dr. Baxter's arguments are intertwined with his efforts to raise a genuine and substantial issue of fact with respect to the findings in ORA's proposal to debar him. Dr. Baxter's legal and factual arguments largely turn on the extent to which the specific conduct underlying his conviction subjects him to debarment under section 306(b)(2)(B)(i) of the FD&C Act and the extent to which there are genuine and substantial issues of fact with respect to ORA's findings under section 306(b)(2)(B)(i) and the applicable considerations under section 306(c)(3). In challenging the facts underlying ORA's findings and the proposed period of debarment, Dr. Baxter contends that some of the findings in ORA's proposal go beyond the facts to which he admitted during the criminal proceedings and are demonstrably false. Specifically, he disputes ORA's proposed findings: (1) that he ''helped oversee [RBP's] efforts to secure formulary coverage for Suboxone Film from [MassHealth]'' and a strategy to that end; (2) that his misdemeanor offense involved the provision of false and misleading information to MassHealth that included ''overstated safety claims''; (3) that the conduct underlying his conviction ''put children at risk.''

In challenging those proposed findings, Dr. Baxter argues extensively that he is entitled to a hearing because not only are there genuine and substantial issues of fact with respect to them but they are conclusory and do not appear to rest on substantial evidence. He effectively contends, therefore, that he is entitled to a hearing on those findings for further development and an opportunity to challenge them. However, nothing in the relevant FDA regulations, section 306(i) of the FD&C Act, or the Administrative Procedure Act (APA) (5 U.S.C. 551–559) requires more than an opportunity to raise genuine and substantial issues of fact with respect to the findings in ORA's proposal. As Dr. Baxter notes, section 306(i) of the FD&C Act requires FDA to provide an ''opportunity for an agency hearing on disputed issues of material fact'' before debarring any person. As noted by ORA in its proposal, FDA implements adjudications required under section 5 U.S.C. 554(a), including debarment matters, as formal evidentiary hearings under part 12 (21 CFR part 12).

Under § 12.24(b), consistent with the APA and case law, there are criteria for granting a hearing. Pursuant to that regulation, the Agency will grant a request for hearing only if the material submitted in support of the hearing request shows, in relevant part: (1) ''[t]here is a genuine and substantial factual issue for resolution at a hearing,'' (2) ''[t]he factual issue can be resolved by available and specifically identified reliable evidence,'' (3) ''[t]he data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person,'' and (4) ''[r]esolution of the factual issue in the way sought by the person is adequate to justify the action requested.'' The regulation further clarifies that ''[a] hearing will not be granted on issues of policy or law'' and that ''a hearing will not be granted on factual issues that are not determinative with respect to the action requested.''

The factual challenges in Dr. Baxter's Memorandum, such as whether his conduct put children at risk, do not justify granting his hearing request. Dr. Baxter appears to acknowledge, as he must, that the facts to which he pled guilty—*i.e.,* the findings of the court that entered a criminal judgment against him—are not in dispute. Dr. Baxter's arguments highlighting those findings by ORA that go beyond the facts to which he admitted as part of his guilty plea do not create a genuine and

substantial issue of fact, nor are those findings determinative with respect to whether Dr. Baxter is subject to debarment and whether a debarment period of 5 years is appropriate. For reasons discussed in detail below, it is not necessary to go beyond the facts to which Dr. Baxter pled guilty and the other undisputed facts in ORA's proposal to conclude that Dr. Baxter is subject to debarment under section 306(b)(2)(B)(i) of the FD&C Act and that debarment for 5 years is appropriate under section 306(c)(3).

For the sake of simplicity and efficiency, what follows is an assessment of Dr. Baxter's legal, factual, and policy-based arguments by reference only to the facts to which he pled guilty or the other undisputed findings in ORA's proposal.

A. Dr. Baxter Is Subject to Debarment

Dr. Baxter first argues that he is not subject to debarment under section 306(b)(2)(B)(i) of the FD&C Act. Dr. Baxter maintains that a misdemeanor conviction for causing the introduction of a misbranded drug into interstate commerce under the Responsible Corporate Officer (RCO) doctrine is ''not sufficient to impose debarment'' and that his criminal conduct lacks a sufficient nexus to ''the regulation of drug products'' under the FD&C Act. Dr. Baxter contends that his conduct does not undermine the process for the regulation of drugs and that, because the drug product at issue had already received FDA approval, the misleading communication at issue did not relate to the approval or the approval process. In support of these arguments, he points to the legislative history of section 306 of the FD&C Act:

> As the House Report to H.R. 2454 explains, this section ''gives FDA the authority to debar a person . . . for conduct relating to the development or approval of generic drugs.'' In addition ''[c]onviction of certain other crimes, such as bribery, fraud, and obstruction of justice, could also be the basis for debarment'' because the seriousness of those crimes undermines the trustworthiness of the individual, such a conviction ''provide[s] evidentiary support for a finding that the individual should not be allowed to submit or assist in the submission of a generic drug application even though the crime did not directly involve the approval process'' [emphasis removed]. Thus, there is no indication that Congress intended to make any conviction under Title 21 grounds for permissive debarment, regardless of whether or not the conduct had anything to do with the drug approval process or fraud or similarly serious offenses.

Dr. Baxter contends that ''the legislative history makes clear that conduct that 'undermines the process for the regulation of drugs' is conduct that either undermines the approval process itself or constitutes such egregious fraud that it supports the conclusion that the individual can never be trusted to participate in the pharmaceutical industry'' (emphases removed). Finally, Dr. Baxter argues that ORA's finding that his conduct was of a type that undermines the process for the regulation of drugs is unsupported because, while it was ''technical misbranding,'' there was never any harm or risk to the public.

Section 306(b)(2)(B)(i) of the FD&C Act specifically provides for debarring individuals convicted of Federal misdemeanors related to the regulation of drug products. If the language of the statute is clear, there is no need to look outside the statute to its legislative history in order to ascertain the statute's meaning (*Chamber of Commerce of United States* v. *Whiting,* 563 U.S. 582, 599 (2011)). Furthermore, as the Supreme Court has repeatedly held, the language in the FD&C Act should be construed in a manner that is consistent with its overall public health purpose. When we are dealing with the public health, the language of the FD&C Act should not be read too restrictively, but rather as ''consistent with the Act's overriding purpose to protect the public health'' (*United States* v. *Article of Drug Bacto-Unidisk,* 394 U.S. 784, 798 (1969)).

Dr. Baxter's general argument that the conduct underlying his conviction lacks a sufficient nexus to the regulation of drugs to subject him to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act lacks merit. Simply put, he pled guilty to causing the introduction of a misbranded drug into interstate commerce in violation of the FD&C Act (specifically, sections 301(a), 303(a)(1), and 502(a) of the FD&C Act). In section 306(b)(2)(B)(i)(I), ''a misdemeanor under Federal law or a felony under State law for conduct . . . otherwise relating to the regulation of drug products'' subjects an individual to permissive debarment. There are no genuine and substantial issues of fact regarding whether Dr. Baxter pled guilty to—and therefore committed—a misdemeanor under Federal law. When that Federal misdemeanor is for conduct that directly violated the FD&C Act with respect to drug labeling, there is no question that such violation relates to the regulation of drugs under that statutory authority.

Dr. Baxter makes many similar arguments with respect to whether the conduct to which he pled guilty as part of his misdemeanor plea is ''the type of conduct [that] . . . undermines the process for the regulation of drugs'' under the FD&C Act in the sense contemplated by section 306(b)(2)(B)(i)(I) of the FD&C Act. In doing so, he attempts to distinguish between conduct relating to the development and approval process for drug products and conduct relating to other aspects of drug regulation under the FD&C Act. Although he supports that distinction by pointing to the legislative history of section 306 and offering policy arguments, neither section 306(b)(2)(B)(i)(I) nor the FD&C Act as a whole bear out that distinction. The plain language of section 306(b)(2)(B)(i)(I) does not draw the distinction urged by Dr. Baxter and indeed expands the scope of the statutory provision beyond conduct relating to the development and approval process by including the language ''otherwise relating to the regulation of drug products.'' With respect to the purpose of FD&C Act as a whole, the Supreme Court has found that its aims go well beyond the development and approval process for drug products: ''Its purpose [is] to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer'' (*United States* v. *Sullivan,* 332 U.S. 689, 696 (1948)).

The Chief Scientist also rejects Dr. Baxter's further arguments that he is not subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act because he pled guilty to a Federal misdemeanor offense without admitting any intent to violate the law or knowledge of wrongdoing and because the underlying offense did not involve ''fraud, bribery, [or] similar crimes.'' Given that section 306(b)(2)(B)(i) of the FD&C Act explicitly permits debarring individuals convicted of Federal misdemeanors related to the regulation of drug products and that a misdemeanor violation of the FD&C Act itself is a strict liability offense under section 303(a)(1) of the FD&C Act, it stands to reason that criminal intent is not required to subject an individual to debarment under section 306(b)(2)(B)(i)(I). As ORA correctly determined, however, his conduct went beyond a mere technical violation of the FD&C Act:

> [Dr. Baxter's] actions undermined the process for the regulation of drugs because [he] failed to prevent [RBC] from sending false and misleading data and information to MassHealth related to the rate of unintended pediatric exposure to Suboxone Film and did not promptly correct such information and data.

Indeed, the Information to which Dr. Baxter pled guilty provided that he, ''as a responsible [RBP] executive failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth'' and that, accordingly, he caused the introduction and delivery for introduction of a misbranded drug into interstate commerce. He cannot now hide behind his arguments that he lacked specific knowledge that the labeling for the Suboxone Film was false and misleading in an attempt to overcome the debarment resulting from the facts to which he admitted as part of his plea agreement. As the Supreme Court has reasoned, in keeping with the FD&C Act's purpose of protecting the public from adulterated and misbranded products, Congress chose to place the burden of protecting the public on those who play a role in manufacturing and distributing those products rather than on consumers, who cannot protect themselves (*United States* v. *Dotterweich,* 320 U.S. 277, 280–81 (1943)). The duty imposed on RCOs ''requires the highest standard of foresight and vigilance'':

> The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them (*Park,* 421 U.S. at 672–73).

The type of conduct to which Dr. Baxter pled guilty failed to meet the duty imposed on RCOs and undermined the process for the regulation of drugs in the sense contemplated by both section 306(b)(2)(B)(i)(I) and the FD&C Act as a whole.

In light of the foregoing, the Chief Scientist has found that Dr. Baxter has failed to raise a genuine and substantial issue of fact with respect to: (1) whether the conduct serving as the basis of his Federal misdemeanor conviction related to the regulation of drugs and is the type of conduct that undermines the process for the regulation of drugs and thus (2) whether he is subject to debarment under the terms of section 306(b)(2)(B)(i)(I) of the FD&C Act.

B. Appropriateness of a 5-Year Debarment Period

In support of his hearing request, Dr. Baxter further argues in his Memorandum that he is entitled to a hearing on ORA's findings with respect to the considerations in section 306(c)(3) of the FD&C Act. Dr. Baxter contends that ORA's assessment of the nature and seriousness of his offense and the nature and extent of voluntary steps to mitigate the impact on the public were based on errors of fact, logic, and law. Dr. Baxter also argues that ORA's proposal gave insufficient weight to the third factor, his lack of prior convictions involving matters within the jurisdiction of FDA. Additionally, Dr. Baxter challenges the appropriateness of the proposed 5-year debarment period.

Dr. Baxter first challenges ORA's assessment of the nature and seriousness of his offense under section 306(c)(3)(A) of the FD&C Act. Yet, as ORA found and has been discussed at length above, Dr. Baxter took responsibility for RBP's introducing, and delivering for introduction, a misbranded drug into interstate commerce. Dr. Baxter admitted as part of his guilty plea that he was in a position both to prevent the violations resulting from his subordinate's conduct—*i.e.,* the inclusion of false and misleading information in the labeling for Suboxone Film—or to correct them promptly. But he did not. Building on the reasoning above with respect to whether the type of conduct serving as the basis of Dr. Baxter's misdemeanor conviction undermined the process for the regulation of drugs, the Chief Scientist finds that Dr. Baxter's role and responsibility in the introduction of a drug whose labeling and false and misleading under section 502(a) of the FD&C Act—especially when the labeling at issue went directly to a State Medicaid agency and when viewed within the range of potential misdemeanor convictions that might subject an individual to permissive debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act—is sufficiently serious to warrant treatment as an unfavorable factor. In short, Dr. Baxter has failed to raise a genuine and substantial issue of fact with respect to ORA's findings regarding the nature and seriousness of his offense under section 306(c)(3)(A) of the FD&C Act.

Dr. Baxter next argues that, in evaluating ''the nature and extent of voluntary steps to mitigate the impact of any offense involved'' under section 306(c)(3)(C) of the FD&C Act, ORA did not fully consider that there was no negative impact on the public to mitigate and that he nonetheless did play a role in sending a correction letter to MassHealth. Specifically, Dr. Baxter maintains that he could not have taken any action prior to the Federal government's investigation into the matter because he was not aware of the wrongful conduct. Finally, Dr. Baxter also contends that ORA ''ignored that Dr. Baxter accepted responsibility for his violation and agreed to cooperate with the Government, as evidenced by the plea agreement.''

The facts to which Dr. Baxter pled guilty belie his arguments now that any role he played in correcting his violations should be construed as a voluntary step taken in mitigation in the sense contemplated by section 306(c)(3)(C) of the FD&C Act. As part of his guilty plea, he admitted that he was an RCO ''with authority to either prevent in the first instance or to promptly correct the provision of false and misleading information to MassHealth and that he took neither action.'' He cannot now claim that his corrective action was sufficiently prompt to be meaningful, and he does not dispute that he directed the correction ''only after an investigation was opened into this matter.'' Dr. Baxter states that ORA's proposal does not ''suggest there was any other action that Dr. Baxter could have or should have done to 'mitigate the impact to the public.' '' He does not, however, present any reason to believe that he took additional steps to mitigate the effect of his offense on the public. Additionally, Dr. Baxter's guilty plea does not qualify as a voluntary step to mitigate the impact of his offense on the public under section 306(c)(3)(C) of the FD&C Act. Accordingly, the Chief Scientist finds that Dr. Baxter has failed to raise a genuine and substantial issue of fact with respect to ORA's findings regarding the voluntary steps taken by him to mitigate the effect of his offense on the public under section 306(c)(3)(C) of the FD&C Act.

Based on the undisputed record before me, primarily encompassing the facts to which Dr. Baxter pled guilty, the Chief Scientist finds that a 5-year debarment is appropriate. Although Dr. Baxter has no previous criminal convictions related to matters within the jurisdiction of FDA, this sole favorable factor does not counterbalance the nature and seriousness of his offense and lack of voluntary steps promptly taken to mitigate the effect of that offense on the public. As has been discussed at length, Dr. Baxter admitted as part of his guilty plea that, as an RCO, he possessed the authority, opportunity, and responsibility to prevent or promptly correct conduct that caused false and misleading information to go to a State Medicaid agency and thereby caused the introduction of a misbranded drug into interstate commerce. His failure to prevent or promptly correct conduct breached the fundamental responsibility as an RCO when he

voluntarily assumed a ''position of authority in [a] business enterprise whose services and products affect the health and well-being of the public'' (*Park,* 421 U.S. at 573). In short, the Chief Scientist agrees with ORA's conclusion in its proposal that ''the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant the imposition of a 5-year period of debarment.''

C. Remaining Legal Arguments

Finally, Dr. Baxter argues that debarring him for 5 years would be arbitrary and capricious and an abuse of discretion. Dr. Baxter contends that debarment is a remedial measure and that his conduct is ''untethered'' to that remedial purpose because his conduct did not undermine confidence in the drug approval process and thus ''makes the deterrence value of any debarment practically nonexistent—and potentially harmful.'' Additionally, he argues that his one conviction does not warrant debarment. Dr. Baxter also argues that debarment would be arbitrary and capricious because FDA has not previously debarred an individual in a ''pure'' RCO case. Finally, Dr. Baxter contends that debarring him for the maximum period would be arbitrary and capricious because his conduct differs in meaningful ways from that of others who received 5-year debarments.

As is extensively discussed above, however, Dr. Baxter did not plead guilty based purely on strict liability. He admitted as part of his guilty plea that he was an RCO ''with authority to either prevent in the first instance or to promptly correct the provision of false and misleading information to MassHealth and that he took neither action.'' (*see Park,* 421 U.S. at 673–74). As discussed above, Dr. Baxter's role at RBP and his conviction as an RCO does not lessen the seriousness of the conviction or underlying conduct but instead elevates it to a higher level of concern given his role within the company.

As Dr. Baxter notes, FDA's debarment authority is a remedial measure, and not a punitive one, and a tool to protect the public health (*see generally DiCola* v. *Food and Drug Admin.,* 77 F.3d 504 (D.C. Cir. 1996); *Bhutani* v. *U.S. Food and Drug Admin.,* 161 F. App'x 589, 593 (7th Cir. 2006)). As explained extensively above, Dr. Baxter's conduct significantly undermined the process for the regulation of drugs. Therefore, his conduct is not ''untethered'' to the remedial purpose of debarment; rather, his conduct fits squarely into the category of conduct that warrants debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act. While Dr. Baxter contends that his conduct does not require any additional remedial measures, his arguments to that effect ignore that the conduct underlying his conviction calls into question whether, when in a position to prevent or promptly correct violations of the FD&C Act, he would do so and thus uphold the protections to public health afforded by that statute.

Based on Dr. Baxter's arguments and the case law he cites, he appears to be relying on the judicial standard for review of Agency decision-making in the APA at 5 U.S.C. 706(2), which directs courts to ''hold unlawful and set aside agency action[s]'' that are ''arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'' As the Supreme Court has held, the question under that standard is whether the Agency has provided a reasonable explanation for the substance its decision:

> The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. Judicial review under that standard is deferential, and a court may not substitute its own policy judgment for that of the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision (*FCC* v. *Prometheus Radio Project,* 141 S. Ct. 1150, 1158, 209 L. Ed. 2d 287 (2021)).

In this matter, as reflected in the lengthy discussion above, the Agency has reasonably considered the relevant issues and fully explained its decision to debar Dr. Baxter.

Although Dr. Baxter points to other individuals who pled guilty to misdemeanors based on liability as RCOs and who have not been debarred, he provides no details with respect to those individuals' convictions. Even assuming, however, that those individuals were similarly situated to him, his bare assertion that an agency cannot choose to begin pursuing debarment of individuals for certain discrete categories of Federal misdemeanor convictions because it has not done so in the past is unfounded.

Dr. Baxter further argues, however, that the Agency has debarred other individuals for less than 5 years when it was undisputed that those individuals did not act with knowledge or intent in violating the FD&C Act. For example, Dr. Baxter specifically points to a doctor who was a principal in a medical practice who unknowingly used an unapproved product on patients while representing that it was an FDA-approved product *(see generally Douglas M. Hargrave Denial of Hearing; Final Debarment Order,* 80 FR 11995 (March 5, 2015)). As Dr. Baxter notes, FDA debarred Dr. Hargrave for 2 years instead of 5 years. However, unlike Dr. Hargrave Dr. Baxter explicitly admitted during his criminal proceedings that he was in a position of authority that should have enabled him to prevent or promptly correct the violative conduct.

As discussed, in terms of section 306(b)(2)(B)(i)(I) and 306(c)(3) of the FD&C Act are clear, and the Agency has exercised its discretion here in a manner consistent with the permissive debarment of many other individuals convicted of Federal misdemeanors related to the regulation of drugs. Accordingly, Dr. Baxter's argument that debarring him is arbitrary, capricious, and contrary to law lacks merit.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to her by the Commissioner of Food and Drugs, finds that: (1) Dr. Baxter has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Dr. Baxter is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective February 27, 2023 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Dr. Baxter, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Baxter, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications

submitted by or with the assistance of Dr. Baxter during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 21, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023–03946 Filed 2–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0073]

Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment.'' This guidance is intended to provide recommendations to sponsors developing drugs intended to treat neovascular age-related macular degeneration focusing on eligibility criteria, trial design considerations, and efficacy endpoints to enhance clinical trial data quality and to foster greater efficiency in development programs.

DATES: Submit either electronic or written comments on the draft guidance by May 30, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0073 for ''Neovascular Age Related Macular Degeneration: Developing Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Wiley A. Chambers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm. 6108, Silver Spring, MD 20993, 301–796–0690; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment.'' This draft guidance document, once finalized, will foster greater efficiency in development programs for drugs intended to treat neovascular age-related macular degeneration.

This draft guidance is being issued consistent with FDA's good guidance