SEALED

EXHIBIT 12

Dr. Tim Baxter
[redacted]
Richmond, VA [redacted]

Dear Judge Jones,

I would like to take this opportunity to tell you about myself and take responsibility for the conduct for which I am being sentenced. I am 58 years old and a British born US citizen. I have been living in the Richmond area since 2006. Before that I lived mainly in England except for a brief period before I went to medical school when I lived in Australia.

My Early Life

I am the middle child with four siblings. I have two older brothers and two younger sisters, so the house was always very busy growing up. My father was an architect and my mother, who is now approaching 90, was an elementary school teacher. [redacted]

At 11 years of age I was sent to the Royal Masonic School for boys. This was a boarding school for the children of Free Masons who had lost a parent either through death or divorce. I remained in boarding schools until I was 18 years old. At this time, I went to work in a sugar factory until I made enough money to buy a ticket to Australia where I spent six months traveling and working for the Australian Quadriplegic Association. I had always been interested in a career in medicine from a very early age. I remember vividly our family doctor, [redacted] and being interested in what he was doing and how he made me feel better. I think that that was the point at which I started to say that when I grew up, I wanted to be a doctor. However, it was my experience with the AQA – working directly with patients and caregivers and seeing what a difference concerned, dedicated people could make in patients' lives – that confirmed that a career in medicine was my calling. I came back from Australia that September and immediately enrolled in medical school in London where I spent the next 5 years studying.

When I graduated, I went to work on a surgical ward and met my wife. We married a year after meeting. At the time I was training in anesthesia which I found extremely rewarding, but very demanding as it required one hundred and twenty-hour weeks and shifts sometimes lasting up to fifty six hours. It was because of these long working weeks that when our first son was born, I went to work at a clinical trials clinic. This was intended to be a temporary break from my intended career in anesthesia, but I found the work so fulfilling that I stayed in the pharmaceutical industry. Since then, I worked in various roles for a number of different companies until I joined Reckitt Benckiser in 2000 in England. In 2006 I moved to the US, with my family, in 2006 to assist with their substance use drug, Suboxone.

My Family Life & Health Issues

This was a big move for us. Upon arriving in the US, my two older children [redacted]

When the children were younger, I was extremely active in supporting youth activities. I set up and grew a local soccer club for children U6 to U16. I was also the chairman of the local Boy Scout group.

After moving to the US, my job and other pressures made it more difficult for us to be hands on with community activities. My wife and I [redacted] are involved in various advocacy activities for the LGBTQ community as well as other charities such as animal charities like ASPCA and the Richmond SPCA. We are active supporters of the Christian Children Fund and have sponsored two children in third-world countries, enabling them to get an education, and be properly clothed and fed. I am also an active supporter of the Wounded Warrior Program, assisting returned veterans overcome various physical or emotional issues associated with their service.

Unfortunately, [redacted]

My own health [redacted]

My Professional Life

As a pharmaceutical physician I was always extremely focused on putting patients' safety and ethical behavior ahead of concerns such as profit. As a doctor we are taught to first do no harm. It is a central tenet of my faculty, the Faculty for Pharmaceutical Medicine of the Royal Colleges of Physicians in the United Kingdom, that pharmaceutical physicians should assume that every patient taking a drug for which they have responsibility is his/her own patient and their safety should be put before all other concerns. This is a message that has always remained at the forefront of my mind.

Indeed, my commitment to this principle is evidenced via my initiating (with other non-commercial colleagues) educational initiatives to encourage Suboxone be used instead of Subutex because it had been shown to have a lower abuse potential; to encourage doctors to prescribe the lowest appropriate dose possible; and to encourage doctors against issuing prescriptions that would allow large numbers of tablets to be dispensed at any one time. We called this appropriate dosing and put in place a training program that used treatment thought leaders, doctors called Treatment Advocates, to cascade these key concepts down to other prescribers.

I understand that there may be some confusion over my motivations with respect to the development of Suboxone film and my support of the company's decision to remove Suboxone tablets from the market. To be certain, my interest in patient safety has always trumped monetary interests. When a replacement product for Suboxone tablets with the potential to have an improved safety profile over the tablet in terms of paediatric exposure was presented to the company, I was very excited by the possibility of improving the safety of our product. I know that the commercial part of the company was interested in the patents and related exclusivity as a route to retaining the Suboxone business, but my interest was always in the potential improvement in safety. Whilst I knew that this would only be proved once a film product was developed and marketed, I said from the very first presentation in which we saw the film that if there was evidence showing that the film had a better safety profile than the tablet, it would be unethical to continue to market the less safe tablet product, and that it should be withdrawn.

I repeated this message many times during the development of the product, up to the point at which we received data from RADARS which confirmed my safety hypothesis. At that time I felt strongly not only that we should withdraw the Suboxone tablet as it was less safe than the film, but that FDA should encourage, or preferably require, other manufacturers of buprenorphine products to present their products in unit dose packaging. However, as the link between paediatric safety and the packaging of the film at that time was a logical argument only, which could not be directly proved because of absence of the correct sort of data, FDA declined to take this step. Since then, however, I believe that both CDC and FDA have adopted the same, or a similar, position on packaging.

Since leaving Indivior I have set up a consulting business and worked on various projects including women's health, breast cancer and infertility; however, my primary focus has remained substance use. I am currently working on a number of projects including the development of a treatment for cocaine overdose, which is one of the major causes of death (after opioid overdose)

amongst substance abusers. I am also involved as the U.S. safety physician for a Department of Defense project developing an anti-malarial drug. In addition, I am working on two different projects in conjunction with DOD to combat weaponized fentanyl for active military personnel or accidental fentanyl exposure for first responders. Whilst I know that no-one is indispensable, I believe that these important programs would be set back if I were unavailable to contribute to them.

This Case

I am a medical professional in the pharmaceutical industry. I have always had a focus on safety through appropriate information and labeling and compliance. I have intervened on various occasions when I have not agreed with statements made by my commercial colleagues and have always put good medical practice ahead of profits. I am very disappointed that one of my medical managers misrepresented data in Massachusetts by making an inappropriate and incorrect calculation based on existing data on the paediatric exposure rates for Suboxone film versus a combined rate for Suboxone and Subutex tablets, and that she represented the calculation to have come from the study authors. I very deeply regret that this misrepresentation of data happened, and knowing what I know now, I would not have trusted that she did in fact receive the data from the study authors and I would have followed up to ensure that this had in fact happened. And, of course, if I had done so and learned that she did not get the information in the manner she represented, she would have been removed and the subsequent misbranding would have been prevented (or at worst, promptly corrected). I acknowledge that I failed as a responsible corporate officer and that misbranding occurred; however, this was a supervisory lapse and with no deliberate or commercial motivation.

I would ask Your Honor for leniency in sentencing me as, although I admit and regret that misbranding occurred, there was no intent on my part in my role as a responsible corporate officer. Any custodial sentence has the potential to have a serious negative effect on my health and put me at risk for COVID-19 infection for which I am at increased risk for potentially serious complications. In addition, I would ask that Your Honor bears in mind the risk that any prolonged absence would bring to the health [redacted]. Finally, I would ask that Your Honor consider the potential impact on the important cocaine overdose project and DOD projects involving weaponized fentanyl and antimalarials in which I am involved.

Yours sincerely,

/s/ Tim Baxter

Dr Timothy Baxter

November 16, 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

RE: Tim Baxter, Case 1:20-cr-32

Dear Judge Jones,

My name is Rodrigo Alberto Avendano, MD; I had known Tim Baxter, MD on a professional and personal capacity. He was my direct supervisor at Indivior when I worked as his Senior Medical Director since June 2013 until September 2016. I can attest that during and after my tenure at Indivior, Dr. Baxter professional behavior and direction were undoubtedly honest and following the compliance regulations that the company have established. He was a leader that sincerely put the patient first and that because of his work and his direction to Medical Affairs on my case, we were able to help many patients with substance use disorders (Opioid Use Disorder). His genuine interest and compassion for our patients' population, gained my respect and admiration both professionally and personally.

Your honor, I can also share with you that Dr. Baxter was an extremely hard worker and he led us by example by always exceeding our expectations at the workplace. He also demonstrated his civic life by being a responsible citizen and demonstrating his real concern for our mission helping patients that many people and doctors in our society don't even want to see or help because the misunderstanding about addiction as a disease of the brain and not a flaw or character. I remember him shaking hands and sharing a message of optimism to patients that attend a conference where I was attending with him.

I know for a fact that Dr. Baxter although not by his direct action, regretted and was saddened for the situation that brought him to the present predicament. I personally think that he needs to stay active in our society and that taking his freedom away will not benefit our community. I am proud of my work with him and to call myself his friend. Should you have further questions or need more information, please do not hesitate to contact me at the address and contact information that will be under my signature. Thank you in advance for your attention to this letter.

Cordially,

Rodrigo Alberto Avendano, MD
[redacted]
Durham, NC, [redacted]
M: [redacted]
Email: aallatin@gmail.com

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

[redacted] Baxter
[redacted]
Richmond, VA [redacted]

10/21/20

RE: Tim Baxter, Case 1:20-cr-32

Your Honorable Judge Jones,

I'm writing to you today to talk about my dad, Tim Baxter.

[redacted]

[redacted].

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Respectfully yours,

[redacted] Baxter

[redacted] **Baxter**
[redacted]
North Chesterfield, VA, [redacted]
[redacted]

12th October 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Your Honor,

I am writing to you today in regards to my father, Dr. Tim Baxter and his case before you on December 17th 2020, case number 1:20-cr-000032.

[redacted]

[redacted]

Sincerely, [redacted] Baxter

[redacted]

[redacted]

Long Melford

Suffolk

[redacted]

16th October 2020

The Honorable James P. Jones

United States District Judge

180 West Main Street

Abingdon, VA 24210

Dear Judge Jones

Re. Dr. Tim Baxter; Case 1:20-cr-32

Tim is my brother of 58 years. Growing up, Tim was always a caring person and from an early age had set his sights on a career in medicine. As a family, we were very proud of his achievement when he graduated as a junior doctor and took up his first post. Professionally, I hold Tim in the highest esteem and personally he is a friend and confident.

Tim is very much a family man, supporting his [redacted] through their education both here in the UK and later in the US following his career move to Virginia. He was always centrally involved in community activities, first qualifying and then volunteering to coach junior soccer and also chairing the local scout group. More recently, Tim has shown his absolute love, compassion and support for [redacted]

Since taking the career step from practising medicine and healthcare into the pharmaceutical industry, Tim has spent almost 20 years working in substance use treatments, making a major contribution to patient safety, the education of doctors and patients, and the clinical development of new products. In conversation, he has always maintained the importance of social responsibility and scientific accuracy in his work, particularly when leading teams and engaging with specialists.

Tim's career has been one of total commitment and integrity, travelling thousands of miles around the globe each year to fulfil his professional obligations. In addition to his roles with pharmaceutical companies, he has been engaged by contract research organisations working in conjunction with government departments to develop specific and critical treatments.

Tim's current professional activities are much more inclined towards the benefit and safety of public health, rather than pharmaceutical company profit. He is consulting on safety for a product in opioid overdose, involved in development of a product in conjunction with the Department of Defence for use by military and first responders to protect them from

weaponised fentanyl, and a development programme for a product to reverse potentially fatal cocaine overdose.

Tim has explained in detail the circumstances surrounding his plea of guilty to a non-intent crime and the possible severity of the consequences to both his professional and family life. I have, accordingly, offered him my fullest support through the period prior to sentencing and am in regular contact with him.

I am aware that Tim deeply regrets that erroneous information was shared, and that he failed in his professional duties as Chief Medical Officer at Invidior to promptly detect and correct the situation. By pleading guilty, he has, in my opinion, accepted full responsibility for his misdemeanour and understands the severity of it. This said, I still maintain the strongest opinion of his honesty and integrity as a person, and know that he wishes to move forward with his life.

Should Tim be sentenced to a prison term as an outcome of this process, I believe this would have a serious consequence on his ability to continue practising the excellent work in which he is involved and for which he is most proud. Equally this would have a devastating impact on his family group, which he so closely supports financially and emotionally.

Respectfully yours

[redacted] Baxter

[redacted]Baxter

Date 10/30/2020

[redacted] Baxter
[redacted]
Richmond, VA[redacted]

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

RE: Tim Baxter, Case 1:20-cr-32

Dear Judge Jones,

I am writing this letter of support for Dr. Tim Baxter in relation to Case: 1:20-cr-32.

As Tim's oldest son, I[redacted]

[redacted]

Respectfully yours,
[redacted] Baxter

[redacted]

[redacted]
Richmond
VA [redacted]

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

October 23rd, 2020

Re.: Tim Baxter (1:20-cr-000032)

Dear Judge Jones,

I write this letter with regards to Tim's character and to help you understand what a good, upstanding gentleman that he is. I have known Tim for 34 years and have been married to him for the last 33 years so I can honestly say that I know him better than he knows himself. He is a devoted husband and a wonderful hands on father to our [redacted] children.

When I first met Tim he was a junior doctor and I was a staff nurse on the surgical ward where Tim was doing his surgical rotation. From the start I knew that this man was kind, compassionate and caring. [redacted] Tim has always been by my side socially, physically and emotionally. He is my rock and my soulmate.

[redacted] loved playing soccer Tim went above and beyond to start a soccer club and qualified as a coach so that he knew his children were being coached correctly. He started the club with the help of other dads with roughly 10 children under the age of 7 when we had to relocate for Tim's career there were over 150 players enrolled. To this day that soccer club is still thriving. Tim has always been an active dad and as well as soccer he has been involved in the scouting movement, rugby, tennis, jiu jitsu and archery to name but a few of the activities that he has become involved in due to [redacted] expressing an interest.

[redacted]

Although Tim is no longer active in community commitments he contributes monthly to many charities including animal charities and charities for military veterans. He also sponsors a child from Peru through Christian Child Fund.

Tim's career has always been important to him and the reason we are now citizens of the US is because of his passion to overcome the opioid addiction that affects every country in the world. He truly believes that he was given a chance to change things when he was offered the job with Indivior. We have spoken extensively about his case and I understand the consequences but I am 100% supportive of Tim.

Judge Jones, I know Tim regrets the situation that he is in and if he could change things I know he would. This has been part of our life for 7 yrs. And we want to move forward. I don't think it will help anyone, especially me and our children if he were to be given a prison sentence. [redacted] know this man well and he is a good, honest, courageous man.

Respectfully yours,

[redacted] Baxter

[redacted] Baxter

[redacted]
Richmond
VA [redacted]

The Honorable James P. Jones

United States District Judge

180 West Main Street

Abingdon, VA 24210

10/29/20

Re: Tim Baxter, Case, 1:20-cr-32

Dear Judge Jones,

This letter is in regards to my father Dr. Tim Baxter and his upcoming court date on Dec 17. [redacted]

[redacted]

Respectfully yours,

[redacted] Baxter

1st December, 2020
Via email: bmoss@wiley.law

From
Dr. Iylen Benedict
[redacted]
[redacted] Kuala Lumpur
Malaysia
Email: iylenbenedict@yahoo.com

To
The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Dear Judge Jones

Re: Tim Baxter, Case 1:20-cr-000032

I, Iylen Benedict, am a medical doctor with postgraduate qualifications in Occupational Health. I served in the Ministry of Health Malaysia and my last position held was Assistant Director, Environmental Health Unit, Ministry of Health Malaysia. In 2012, I joined Reckitt Benckiser Pharmaceuticals (RBP), as the Regional Medical, Clinical and Scientific Affairs Director, Developing Markets. (In the performance objective documents of RBP, this position was entitled Regional Medical and Scientific Affairs Director). The company later became Indivior. After three years with RBP/Indivior, in 2015, I was offered the opportunity, to move to Sydney, Australia to head the regional medical department there. At that point in time, I was unable to take on this role (as I was the main care-giver for my 83.5 year old bedridden mother, who passed on in 2018, after being bedridden for 6.5 years). Since I was unable to accept the Sydney, Australia offer, I left Indivior in 2015. At present, I volunteer as a medical doctor in Kuala Lumpur, with the Aborigines of Malaysia (Orang Asli), a Myanmar refugee camp, a religious Catholic convent (looking after the medical health of the elderly religious sisters), support care-givers' wellbeing and end-of-life care in my community. I work on a part-time basis, as a lecturer in Occupational Health, attached to the Federation of Manufacturers Malaysia.

I worked with Tim at RBP/Indivior from 2012 to 2015 and am writing this letter in my own personal capacity.

I have known Tim since 2012, i.e. three years within RBP, and eight years in total. I first came to know Tim in February of 2012 when I was interviewed by Tim, as an applicant for the position of Regional Medical, Clinical and Scientific Affairs Director, Developing Markets, RBP, based in Singapore. In April 2012, I gained employment in RBP and reported to two global heads for medical, one of them being Tim Baxter. During my initial interviews and then meeting Tim in person (i.e. 2012), my first impression of Tim, a genuine person who is kind, sincere, honest,

responsible, very respectful, a good listener, a person with empathy and compassion. We spoke at length about medical objectives and Tim repeatedly emphasied the importance of medical governance, patient safety and well-being for this region of the Developing Markets.

During the three years of reporting to and working closely with Tim in all medical areas for the Developing Markets, there were many instances, Tim came across as a thinker who approached problems systematically. He was assertive and hard working. My reports from this region contained technical details. Tim, the Global Medical Director reviewed these reports with me. With each presentation, there was this in-grained principle to always be ethical and honest, we were both dealing with patient data and patient safety which are of utmost importance. I worked with Tim, in the development of new treatment modalities and guidelines for this region, so that we, as medical doctors, could provide better access to treatment for our patients, ensuring better patient wellbeing and outcome. Herewith are some examples:-
In the area of the Revision of Clinical Guidelines for Opioid Dependence for Malaysia and Indonesia (2013-2014), Tim was persistent in ensuring strict adherence to local medical/clinical guidelines. These guidelines were successfully launched in Malaysia by the Director General of Health, Ministry of Health and was also launched in Indonesia, endorsed by Madam Minister Indonesia.
In the area of revision of Prescriber Training Modules 2013 and Opioid Dependence Guidebook 2014, Tim went the extra mile to ensure that in the clinical practice for this region, the patient was the first priority. This region being the Developing Markets.
In the area of clinical trials, Tim was careful and compliant when allowing approvals for the use of medication on a 'compassionate-use basis/named patient basis'.
In the area of medical information, a strict timely response with correct information was disseminated for South East Asia, Thailand, Australia, and New Zealand, a directive from Tim as the Global Medical director.
In the area of patient advocacy groups, I had reached out to Tim for guidance in ensuring patients' data protection, patient safety, medical governance and compliance.
Additionally, he put in place a strict directive for all, including his direct reports to undergo mandatory pharmacovigilance training to ensure medical compliance and governance was adhered to, at all times. I did the same for this region, for all who were coming on board into RBP. We worked in-sync and were one big medical platform.
In 2012, I remember clearly being reminded by Tim, to be absolutely certain that my performance objectives were strictly medical and did not/should not carry any commercial activity or any commercial implication.

On a personal note, when I was juggling between working at RBP/Indivior and caring for my bed-ridden mother at home, I remember clearly Tim showing empathy and compassion on countless times and recollect words of constant encouragement, including "patient care starts from home". This is the true nature of Tim.

With a good heart for people and patients, above all, Tim is a good man. A decent person dedicated to medical ethics and patient safety, with the welfare of patients at heart. Tim has proven to be of prime value to patients, to the medical fraternity, to colleagues and to friends. It is saddening to learn recently about Tim and a regulatory misdemeanor. Despite challenges, I

have absolutely no doubt that Tim is committed to doing the very best for patients. As Tim goes through this journey, it is my sincere hope that Tim continues to be courageous and trusting in God's protection. The society in this region and especially the medical fraternity would be at an unquantifiable loss to see Tim being impeded for all the good work he has done.

Respectfully yours,

(Dr. Iylen Benedict)

The Honorable Judge James P Jones

United States District Judge

180 West Main Street

Abingdon, VA 24210

[redacted]

[redacted]

[redacted]

[redacted]

Lincolnshire [redacted]

England

13th November 2020

Your Honour,

Character Reference - Tim Baxter Case 1:20-cr-000032.

I joined Reckitt & Colman (now Reckitt Benckiser) in 1977 as a Medicinal Chemist based in Hull, England and was promoted to Head of Research & Development in the late 1980's with responsibility for their ethical prescription and self purchase pharmaceutical products. This included the opioid analgesic projects with a special interest in buprenorphine, the active ingredient in Buprenex (Temgesic in rest of the world). The NIH's National Institute on Drug Abuse (NIDA) had expressed interest in buprenorphine during the 1980's as a potential treatment of Opioid Dependence - ultimately this resulted in a formal approach by NIDA requesting the Company to enter into a joint research programme with the aim of developing buprenorphine products for the treatment of opioid dependence. The Cooperative Research and Development Agreement was officially signed and published in May 1994 in the Federal Register and I was appointed the Principal Investigator on behalf of Reckitt & Colman. At this stage I became Director of the Buprenorphine Business. The products developed, 'Subutex' and 'Suboxone', were finally approved by the US FDA on October 8th 2002 and were launched in the US in 2003. The opioid problem, which was largely associated with heroin addiction, escalated significantly in the mid 1990's and this led to a number of European countries approving 'Subutex' by the late 1990's. In France however the authorities fast tracked the approval process resulting in 'Subutex' being launched in 1996.

I have known Dr Tim Baxter for about 20 years as he joined Reckitt & Colman in 2000 and as the Company's Pharmaceutical Medical Director I worked very closely with him especially during the ongoing clinical programme supporting the development of Subutex and Suboxone. Although Tim relocated in 2006 to our offices in Richmond, Virginia, I maintained a very close working relationship with him because in the enlarged global business, following the launch of Suboxone in the US and Australasia, I became the Scientific and Clinical Affairs Director for Reckitt Benckiser (and later for Indivior). In this capacity I was a member of Tims' Medical Affairs team and together with Tim I was a member of the CEOs' senior management team until my retirement in 2016. I now work as an independent Consultant to the Pharmaceutical Industry and have kept in touch with Tim since my retirement. In writing this letter I do so in my personal capacity.

From the very first meeting with Tim when he joined the Company my views of him have never changed – he came across as a caring, sympathetic and highly knowledgeable family doctor rather than a traditional commercial medical practitioner. Throughout his time in the business he has always demonstrated a caring attitude to his fellow workers as well as, importantly, patients who would benefit from the medical treatments either in development or those already commercially available. It was refreshing to me to witness him focussing on the needs of patients and their safety in his non-commercial role as the Global Medical Director. On relocating to the US as Medical Director for the buprenorphine business Tims' focus changed because his focus was now to support this expanding business based on the treatment of opioid dependence. This is a very different business to the pharmaceutical business that Tim first joined and I was impressed by his enthusiasm for the challenges he now faced in an atypical therapeutic area which included political and societal issues coupled with a marginalised/stigmatised patient population in addition to their medical considerations. Tim quickly gained an understanding of, and empathy for, the needs of patients who were often viewed as 'bad people doing bad things' and were therefore considered undeserving of any treatment in many parts of the world. In this regard he always had as the most important criteria the well-being and the safety of the patients first and foremost - this was evident in his pursuit of gaining a better understanding of the patients' views and past experiences in treatments so as to be better positioned in knowing which treatment is the most appropriate for that particular patient.

Tim was responsible for ensuring that all employees within the business received adequate and appropriate training with regard to full compliance with our legal and regulatory requirements (pharmacovigilance) which included aspects of the safety of our products as well as how to manage any complaints that might be raised in the presence of an employee. He personally ensured that all new employees received such training as soon as possible after joining the Company and then throughout their career in the Company mandatory refresher training courses which were run on a regular basis. I remember well the refresher courses that Tim ran which included interesting examples of complaints and issues that had been raised about our products and we had to determine the most appropriate course of action – people appreciated these real life examples as a means to understand better the importance of such training.

In all the time I have known Tim I have viewed him as a confidant, a person with honesty and integrity and therefore someone who I could confide in as if he were my family doctor. Others have also expressed to me that they have felt the same as I do about their relationship with Tim – always prepared to listen to you, provide you with an honest and informative response with helpful and constructive advice. I was always confident in discussing anything and everything with Tim because he is a trustworthy and highly responsible person who cares for you as if you were his patient. He is always willing and able to provide advice and if appropriate you can rely on Tim to follow up with you if only to check on your progress.

Externally to Indivior Tim has always been held in high regard by those who have interacted with him, from patients to other physicians as well as researchers who are involved in the

area of addiction treatment. He always has time to speak to anyone who approaches him as often happens at conferences and exhibitions he attends. People do reach out to Tim for his advice and views and he is always forth coming with sound clinical, medical and caring advice which is much appreciated – this can be likened to Tims' commitment to understanding and helping his 'patients'.

I submit this statement to you so that you can appreciate the essential work that Tim has performed at the global level, but especially in the US, with the aim of improving access to, and the quality of, treatments of opioid dependence, hence making a positive contribution to the US's efforts in tackling the ongoing opioid crisis. I know that Tim sincerely regrets what has happened and, as a responsible citizen, is keen to move forward in a positive manner to continue his work in helping patients to improve their health and well being. As a dedicated, compassionate and sincere physician with patients as his focus he has so much to offer that in my view a custodial sentence would be detrimental to all concerned. I trust that the above is of assistance to you in your judgement of Tim.

Christopher B Chapleo

[redacted]
Cirencester
[redacted]
United Kingdom

T: 01285 770668
M: [redacted]
E: Thomas.corran@btinternet.com

November 17th, 2020

The Honorable Judge James P. Jones
United States District Judge
180 West Main Street

Abingdon, VA 24210

Your Honor,

Case 1:20-cr-000032. Dr. Tim Baxter

I was Senior Vice President at Reckitt Benckiser PLC (RB) from 1998 to 2008 responsible, inter alia, for corporate communications, investor relations, corporate social responsibility, and secretary to the Executive Board of the Company. Since retiring in 2008 I have held a number of consultancy roles with major companies such as Reckitt Benckiser PLC (2011-12), Trust Partnership PLC (2012-13) as part of its IPO, Imperial Brands PLC (2013-2014) and Indivior PLC (2014 to date). I have also served on several not-for-profit Boards during this time, including Blue Cross, the leading UK animal charity.

I first met Dr. Tim Baxter in my role at RB in the early 2000s when he was Medical Director at RB Health Care in Hull. I got to know Tim much better when I started to work as a consultant on the demerger of RB Healthcare – subsequently Indivior PLC – in 2014. Tim helped to educate me on the patient experience of opioid addiction, the role of Buprenorphine as a stabiliser of patients in medication assisted treatment conjoined with other therapies designed to address addictive behaviour. Throughout this education, Tim was always at pains to stress the importance of Indivior's patient focus and the need for strict adherence to compliance in medical affairs, particularly in relation to the delicate relationship between a pharmaceutical company, evidence of better treatment options, and the role of healthcare professionals. He would repeatedly emphasise that healthcare professionals were and are responsible for treatment, that all a pharmaceutical company can do is provide evidence of better treatment options, supported by research findings.

I subsequently saw Tim at work in Indivior where he was responsible for the Patient Advocacy meeting of the Executive Committee, held every couple of months, to focus the most senior executives minds on what was needed to make a difference to patients' experience of treatment. He was always an eloquent proponent of good pharmaceutical practice in respect of compliance, and of the needs of the patient and the healthcare professional in addressing the opioid addiction epidemic. Indeed, I remember that Tim could appear uncommercial to his colleagues in his focus on doing what was right, both in terms of patient needs and patient safety. Tim never forgot that he was, and is a medical doctor first, a businessman second. The Hippocratic oath remains at the core of everything he advocated for and did.

I do not know Tim that well socially, but I do believe him to be a good family man, proud of his children's achievements. I have always had not just respect, but considerable liking for him and count him one of the world's good people. I am sure that he regrets getting caught up in the events connected to his plea and wishes to put them behind him and move on with the rest of his life. He has lost his job at Indivior PLC, he has been effectively in limbo now for several years professionally, and he will already suffer from this for the rest of his life. I believe he has suffered enough and is repentant.

Tom Corran
Business Consultant

Berkeley Greenwood
[redacted]
London
[redacted]

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

13th November 2020

Your Honor,

Ref: The case of Dr Tim Baxter - 1:20-cr-000032

I have known Tim both professionally and personally since 2000. During that time I have found him to be a straightforward, decent and highly reliable person, who I am pleased to be able to call a friend.

I met Tim when I acted for Reckitt Benckiser with respect to the company's Gaviscon (alginate) brand in the UK. He was UK Medical Director at that time. This was during a period when PPI manufacturers were aggressively promoting the merits of their brands when, for many patients, a cheaper and less chemically-intrusive alginate would have been just as effective.

In our dealings together with the UK Government at the time on this issue, Tim's approach was markedly restrained. He presented the literature to those audiences and pointed out that many patients were placed and left on PPIs even as they became asymptomatic. He noted that there were potential savings to the system and benefit to some patient by using alginates instead. This was done in a calm and scientific way. At no point did I ever see him exaggerate the benefits of the product to key NHS audiences and he was conspicuously keen to avoid making unreasonable claims.

This was entirely consistent with what I knew and know of him as a man.

I have spent 30 years in and around the pharma industry and, in that time, I have met quite a few characters who have sometimes been dismissive of the rules that govern the industry.

Tim is not one of those people. He always struck me as someone who fully understood the weight and responsibilities that his role carried. As his career progressed, I think he was glad to be working at edge of pharmaceutical development and understood that this brought with it important duties, which he took very seriously.

It is entirely in keeping with him that he would take full responsibility for what has happened in the instance of Indivior and not try to push any blame elsewhere. I understand that this has been his reaction to what has been discovered in this instance.

On a personal level, Tim has been a great friend to me, providing positivity and sound advice when my marriage was ending and at a time when some others found it easier to look the other way. He is not someone to turn away from difficult situations or circumstances and has broad shoulders.

In situations such as the current one, people always talk about what a great family person, so-and-so is/was. With Tim this description is actually true. He is, and always has been, quietly proud of his family, watching them develop and guiding them along the way. I have always had a sense that their well-being came first and I have seen him wrestling decisions, more than once, on the basis of the impact that his choices might have for them.

Settling in the US was something he obviously greatly enjoyed doing and he was grateful for the positive effect that US society and US values had on his children. He has embraced life in Richmond and in particular the countryside and sporting opportunities it offers.

I cannot think that a period of incarceration for Tim would achieve, in this instance, what it has the potential to in others. This is because I should be extremely surprised if Tim does not already blame himself totally for what has happened and, knowing him, will have punished himself many times over, not least because of the impact of it all on his family. He will not have not have taken this matter in any way lightly.

I have no hesitation in commending Tim Baxter to the court. He is a modest, upright and morally well-guided man and I hope my words will be given due weight by the Court in deciding upon the next steps for him.

Yours sincerely,

Berkeley Greenwood

{ [redacted], Ph.D. }

[redacted] Richmond, VA [redacted]

November 16, 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

RE: *U.S. v. Dr. Tim Baxter,* 1:20-cr-000032

Dear Judge Jones,

I am a clinical psychologist licensed in Virginia [redacted]

[redacted]

[redacted]

[redacted]

Sincerely,

[redacted], Ph.D.
Licensed Clinical Psychologist

TELEA R
[redacted] La Ville France [redacted]
te ea.her in mai .c m

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

R T R B M .

My name is Telea Herpin and I have known Mr. Tim Baxter for the past 19 years. I started my career as an anesthetic nurse and ended up moving my career into the pharmaceutical industry. I worked for various companies but I really didn't find my passion or place until I started working at Reckitt Benckiser, this is where I first met Tim Baxter. I spent 13 years working passionately in the area of addiction and have since continued my pharmaceutical career as I believe it is an important industry contributing greatly to patient outcomes.

Tim and I connected as healthcare professionals, Tim was an anesthetist and I was an anesthetic nurse. Tim was a quiet, humble decent man and was still to this day the best Medical director I had ever worked with. Tim cared deeply about the vulnerable patients we were treating and was committed to always doing the right thing. I was proud to work with Tim. We saw many treatment atrocities to the vulnerable patient group around the world and Tim was a positive agent of change for that.

Tim's deep understanding and knowledge about the opioid addicted patient was evident in the way he made the decisions about what we did. Over the 13 years we worked together I saw Tim always being committed to progressing addiction treatment around the world. This included some countries where human rights in this population didn't exist. Tim always made decisions in order to progress treatment in the best interest of the patient. As a result of the work that Tim contributed to there are many patients that have benefited and live better lives because of the medical direction Tim gave in our expansion globally.

Tim was also a man who cared for the people he worked with. During the time that I worked with Tim I travelled extensively whilst pregnant and Tim was always caring and ensuring I was looked after. Tim to me was someone I trusted and had the utmost respect for. We had good values as a company before they were ever written down, you see this company was formed in the early days of a bunch of clinical and medical people that cared about the patient, I am proud of the work we did and the medical leadership that Tim provided at that time provided.

I am deeply saddened by the current circumstances that Tim is in and I hope that you can make your decision regarding his sentencing with the same chance he gave to many opioid addicted patients around the world. Tim was a man who led with an enormous amount of empathy and compassion. Tim is a decent human being and I am still proud to have worked with him. I understand that Tim regrets the situation that he has found himself in and I don't believe a custodial sentence will benefit society in any way. I believe it would be detrimental to all concerned especially the family that Tim loves and adores.

Telea Hope Herpin (nee Slavin)

November 13, 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abington, VA 24210

Re: Tim Baxter, M.D.,
Case # 1:20-cr000032

Dear Judge Jones:

The purpose of this letter is to apprise the Court of my experience working with Dr. Tim Baxter and the insight into his character that experience provided. I have known and worked with Dr. Baxter for approximately 15 years in his role as Indivior's (f/k/a/Reckett-Benckiser) Global Medical Director. I write in support of leniency for Dr. Tim Baxter in connection with his upcoming sentencing.

I would like to introduce myself and my credentials to the Court. My name is Mark L. Kraus, M.D., DFASAM, DABAM. I practice medicine in two capacities in Waterbury, Connecticut: Internal Medicine and Addiction Medicine with Trinity Healthcare of New England and Chief Medical Officer (CMO) at Connecticut Counseling Centers (CCC) which provide methadone treatment programs for Opiate Use Disorder (OUD). I have been very involved in Addiction Medicine, both nationally and internationally. Nationally, I am a former Vice President of the American Society of Addiction Medicine (ASAM), former Board Member of ASAM and Chairman of ASAM's Legislative and Public Health Committees. Internationally, I have presented at numerous medical conferences on addiction issues in several European countries. Many articles of mine have been published in National and International Journals, some of which are based on original research in the addiction space. I hold a faculty appointment at the Yale University School of Medicine as Assistant Clinical Professor of Medicine and have taught a clinical elective in Internal Medicine/Addiction Medicine.

I was engaged by Reckett-Benckiser along with a colleague to teach fellow physicians about the use and the benefits of Buprenorphine/Naloxone (Suboxone) for their patients. We developed a program for that purpose that addressed the safety, efficacy and pharmacokinetics of Buprenorphine/Naloxone, the way to identify, treat and manage patients with OUD., and then traveled around the country to meet with groups of physicians lecturing on our educational program. Dr. Baxter actively participated in our discussions. Based on my long experience with Dr. Baxter, I firmly believe that he is a dedicated and compassionate scientist, determined to train our physician colleagues in a safe and effective method to treat patients with OUD. His dedication to that effort has helped thousands of patients with OUD around the globe. In light of his long-term good work, I very strongly urge the Court to show leniency and not sentence him to prison, which I believe would be excessively punitive, particularly with the high risk of COVID-19 transmission in prisons.

The opioid epidemic started in the mid-2000s and has increased exponentially since then, without any sign of slowing down. I first become aware of Buprenorphine/Naloxone from colleagues. Buprenorphine/Naloxone practice requires a physician or APRN to become waivered by the Substance Abuse Mental Health Services Authority (SAMHSA). In practicing Addiction Medicine, I was included in one of the first groups of physicians who received a waiver to prescribe Buprenorphine/Naloxone. As CMO of CCC, I led the adoption of its use to treat the opioid-addicted patients who presented to our clinics. For background, it is noteworthy that Buprenorphine/Naloxone expanded the treatment options for patients whose treatment options, up to that point, had been limited to Methadone. Buprenorphine/Naloxone does all that Methadone does, but, unlike Methadone, has a ceiling effect which is a safety feature that lowers the risk of misuse, dependency and side effects such that any dose beyond 32 mg has no harmful side effects. By way of contrast, Methadone has no ceiling effect and can produce significant side effects, including coma and death. Buprenorphine/Naloxone can be prescribed by a waivered physician in any treatment milieu whereas Methadone can only be prescribed in a Methadone Treatment Program. Both treatment approaches require psychosocial evaluation, referral to self-help groups and enrollment/participation in addiction treatment programs.

Dr. Baxter's efforts to address the opioid epidemic generate positive results to this day.

Respectfully yours,

Mark L. Kraus M.D., DFASAM, DABAM
Assistant Clinical Professor of Medicine,
Yale University School of Medicine
Diplomate, Distinguished Fellow and Past Vice President of the American Society of Addiction Medicine
Trinity Health of New England Medical Group
Chief Medical Officer, Connecticut Counseling Center
Home address: [redacted], Cheshire, CT
Cell: [redacted]

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Dublin, November 29th, 2020

Reference: Case 1:20-cr-000032 Tim Baxter

Your Honor,

I am Philippe Larrouturou. I worked with Tim Baxter at Indivior and would appreciate if you had few minutes to read some of the memories I have from my exchanges with him.

Firstly, how do I know Tim Baxter?

I joined Reckitt-Benckiser Pharmaceuticals [RBP now Indivior] in April 2011 as consultant to support the team preparing an inspection by ANSM [the regulatory agency in France similar to FDA in USA]. I later became European Regulatory affairs manager at the RBP European head office in Slough [UK], and since September 2013, I have served as Qualified Person for Pharmacovigilance [QPPV] in front all the regulatory authorities in the 31 states of the European economic area [EEA](based in Slough [UK] and Dublin [Ireland]). In all these roles I had opportunities to engage through virtual or actual meetings or by emails with Tim Baxter. I reported to Tim Baxter when he appointed me as QPPV in September 2013 and indirectly after March 2015.

The memories I wish to share with you are related to three aspects of Tim Baxter: how patients and what he has done for them are important for him; how he cares for his colleagues, and how accuracy is important for him.

Patient care has always been Tim Baxter's focus. Once Tim Baxter and I were talking about best practices for encouraging communication of adverse events and I asked him about “occupational exposure” in the company. Tim Baxter explained to me, that when working for RBP UK he was called on as a physician to go to the manufacturing site to assess an individual presenting symptoms of occupational exposures and how important it was to take time to explain the importance of the good dressing practices to reduce the risk of occupational exposure. He explained me how it was important to take time to listen to the Patients and talk and explain to them. Tim Baxter needed this time with the Patients even while working for a pharmaceutical company. When he joined Reckitt-Benckiser UK, Tim Baxter negotiated his contract to allow him to practice every Saturday morning in a surgery in Hull [UK] not far from the manufacturing sites. While he regretted that he could not continue this practice in the USA, as he did not have time to go back to the university to be qualified physician in USA, to keep the possibility of the connection with the Patients Tim Baxter maintained his UK license by taking time to attend to regular courses in person in UK. The attendance to these courses at the university in London [UK] was also important to Tim Baxter. He wanted to keep his

medical skills up to date as it was the only way for him to be able to take the right decision for the Patients as Chief medical officer of RBP/Indivior.

Tim Baxter is also a caring colleague. A few weeks after I joined RBP France, the ANSM [the regulatory agency in France, similar to FDA in USA] came for a planned "opening inspection" covering all the good pharmaceutical practices including Medical information and Pharmacovigilance. Through the weeks before the notification of this inspection, we had few meetings with the heads of these two departments and Tim Baxter to agree on how RBP France, once validated by ANSM, would communicate and work with the global teams. On July 5th, 2011 the two colleagues responsible for Medical information and Pharmacovigilance were in the Richmond [VA] office available to be interviewed by the ANSM inspector by video-conference. It was 02:30am [EST], Tim Baxter was aside his direct reports. Once the interviews related to Medical Affairs and Pharmacovigilance were completed, Tim Baxter asked the ANSM inspector if his US colleagues could leave to go to sleep before the start of their working day, in exchange for his staying as long as they needed him to take any further questions related to these activities. Tim Baxter knew the system set-up satisfied the regulations, he knew every question would be answered successfully by the US or French colleagues, and that all he needed to do was introduce his team and not so much more. But Tim Baxter wanted to support the US colleagues working at 02:30am just after the Independence Day as well as the French team and let us know the French entity was important for him and the company.

On January 31st, 2013, about 10:30pm, while waiting a document from the USA colleagues to submit it to the UK authorities before midnight, I was walking in the UK office thinking to be alone. Suddenly I realised that Tim Baxter was in an office. He had arrived that morning directly from the airport after flying from Washington Dulles overnight. I asked if I could help him so he could go and rest. He answered he was sending an email to the Richmond office to ensure I got the document on time, and that we could look at it together before I submitted it. Once the document arrived, we looked at it and agreed to submit it. Tim Baxter waited until I had finished the submission, checked I had a car, before leaving. After he resigned from Indivior, once he had recovered from his health conditions, Tim Baxter came few times to UK – at least once for attending courses at the university of medicine in London. Each time he let some of us know he was around and could be available if we wanted to have time with him. We truly appreciated his taking time to get news of our family, to listen us and coach us.

On May 8th, 2013, in Pisa [Italy], Tim Baxter, at the exit of the Europad [European conference on opioid dependence] congress, invited me to walk back to the hotel. We talked of a report he was expected to sign shortly. I read it the night before and gave examples of little inconsistencies between the executive summary and the core of the report [it was something like 40.2% in the executive summary and 40.1% in the core of the report]. Tim Baxter, few minutes after being back to his room, sent back the documents to the authors for assessing the data and the consistency of the different parts of the document. Tim Baxter and I talked of how to ensure the quality of the massive documents he was expected to sign as Chief medical officer [CMO]– I have in mind this discussion each time I review one of these reports.

As CMO of RBP/Indivior, Tim Baxter was one of the most senior members of the Global labeling board, a committee responsible for maintaining the "Reference safety information" of the products. These documents are then used by the Regulatory affairs team to submit to the Regulatory authorities [FDA in USA] proposed updates to the Product Information which, once approved, is made available to the Healthcare Pprofessionals and Patients. Tim Baxter arrived at each of the meetings having obviously read the documentation by the way he was commenting on the updates or proposing new wording to improve the accuracy of the information related to the data from a clinical trial or the frequency of an adverse event.

Above, I wrote about the evening of the January 31st, 2013, when we waited late into the night for the document. We were waiting late for the document because that afternoon Tim Baxter had sent it back to the US colleagues after he discovered that the numbers in the reports were not correct. The differences were not signification, and the conclusion was correct, but the numbers should be those we know.

I could talk more of Tim Baxter, who regularly took time to ensure I was receiving all the information I needed to carry out my responsibilities as QPPV and who worked to "educate" the US colleagues on the requirements of my role because compliance for him is not matter of discussion.

When, in 1996, two English senior Qualified Persons [QP person authorised by the regulatory authorities to release the batches of medicinal products in Europe] trained me to become QP, one of them explained me the "critical handling" of the Deviation and its CAPA [corrective and preventive actions]. As we are human, we can miss or misread one information or not understand its importance... When this error/deviation is identified, it is critical to investigate properly what has happened, to identify how to correct the situation, the data.... [corrective actions] and how to prevent it from occurring again [preventive action]. If this happened a second time, this shows the investigation was not done thoroughly enough or the CAPA was not designed or implemented appropriately, so it should be conducted again. If this happened a third time, something is definitively wrong and cannot be forgiven. "A deviation should be never forgotten. It can be forgiven if it does not reoccur" this senior QP said me as conclusion of this training session.

Looking at what happened within Tim Baxter's team, the matter of the DoJ investigation, he corrected the information in front the misled state regulator in Massachusetts. Through his behaviour and what he taught us collectively and individually Tim Baxter put preventive measures to ensure this does not reoccur and we don't have evidence this has failed again. So, we are at the first step of the good quality management of a Deviation which should not be forgotten, I am sure Tim Baxter did not and will not forget. The decision to forgive is yours.

Respectfully yours,

Philippe Larrouturou

Philippe Larrouturou
[redacted]
Co Dublin, Ireland

[redacted]
[redacted]
[redacted] Salzkotten
Germany

26 October 2020

To the Honorable Judge James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

RE. Dr. Tim Baxter; Case 1:20-cr-32

Your Honor,

I am glad to have the opportunity to write this letter on behalf of my brother of 56 years, Timothy Baxter. Tim is a dedicated, diligent and much-respected medical professional of many years standing. The offence to which he has pleaded guilty therefore came as completely unexpected for me. For this reason, I would like to provide information that bears witness to my brother's good character.

Tim is a family man through and through. We grew up together in a large family, he married into an even larger family, and has four children from his long-standing and happy marriage. Since moving to the United States, he has always made time to visit our mother in the UK, even on the most flying visits, and I know how much these visits mean to her as she grows older.

Despite living in different countries, I have been able to observe over the years what an active, caring father he is. He is the kind of parent who is at the hub of family activity, creating a safe space in which his children have been able to grow and follow their chosen paths. I have been particularly impressed by [redacted]

Compassion is central to medical practice, the career path that Tim chose to follow at an early age. I was personally inspired by the dedication with which he pursued his vocation, and strongly believe that these same character traits – compassion and dedication – have always been at the heart of his professional activity, both as a practicing doctor and, subsequently, in his work in the pharmaceutical industry. In conversations about his work, I have been struck by his commitment not only to the job, but also to public health, to the social responsibility of the pharmaceutical industry, and notably to procedural and scientific diligence. Indeed, since moving to the USA, Tim has served the scientific community by passing on his knowledge, experience and professional values in his capacity as Associate Professor of Clinical Medicine at Virginia Commonwealth University.

Bearing all this in mind, Tim's oversight in his supervisory role as CMO at Indivior, which has led to the current charge, is completely out of character. He has explained to me the circumstances surrounding the case and it is clear that he most deeply regrets not having identified and immediately corrected the erroneous information that was shared. His remorse is plainly intense. He completely understands the seriousness of his non-intent misdemeanor and has taken full responsibility for it in pleading guilty. That said, I remain wholly convinced of Tim's absolute professional integrity, as supported by his excellent previous record. I most sincerely hope that he will be able to continue his service to the community, to science and to healthcare. Above all, from a familial perspective, my greatest hope is that he will be able to remain within the family unit, for whose well-being he plays such an essential role.

Sincerely,

[redacted]

[redacted]

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Walter Ling, M.D.
Professor Emeritus
David Geffen School of Medicine at UCLA
Department of Family Medicine
Center for Behavioral & Addiction Medicine
lwalter ucla.edu 310 476 6940

Dear Judge Jones

I am writing in regard to Dr. Tim Baxter, a friend and professional colleague, in the hope that Your Honor will take my input into consideration regarding his character, his reputation, and his overall service to the community as a dedicated, caring physician who helped revolutionize effective, safe treatment for opioid addiction. Dr. Baxter is to appear before you for sentencing (Case 1 20-cr-32) on December 17, 2020.

I am an emeritus professor at the University of California at Los Angeles, David Geffen School of Medicine. I am Board Certified in neurology and psychiatry by the American Board of Medical Specialties and I am considered an expert in opioid addiction with a worldwide reputation. For over 20 years prior to my recent retirement, I headed as its founding director UCLA's Integrated Substance Abuse Programs, one of the world's leading organizations conducting addiction research, developing treatments for addictions, and training the next cadre of addiction researchers and clinicians.

I was involved in the research and development of buprenorphine as a treatment for opioid addiction from the initial clinical trials and I led many of the critical research studies leading to its FDA approval in 2000. My research included studies on buprenorphine's safety and efficacy compared to methadone and naltrexone, showing its superior clinical safety and its advantage of relatively low abuse liability. Even so, the pharmaceutical developers blended naloxone (an opioid antagonist that renders opioids ineffective) into buprenorphine to further diminish its potential for abuse. The incredibly high safety profile of the buprenorphine naloxone combination products like Suboxone distinguishes them from conventional buprenorphine. I also led studies that explored this important distinction.

In more than two decades of clinical efforts in which I was involved to develop and test buprenorphine as a treatment for opioid addiction, I have come to know Dr. Tim Baxter as an honest and compassionate physician dedicated to doing his best for opioid-addicted patients. Addiction research is a small, close-knit field where everyone involved gets to know one another very well, not only through work but also through personal contacts and interactions.

The development of buprenorphine as a treatment for opioid addiction was in fact conducted under an agreement between Indivior and the National Institute on Drug Abuse, one of the NIH institutes. Much of the research and development was indeed funded from U.S. tax dollars. Although I was considered a major figure in buprenorphine's development and in its implementation as a unique pharmacotherapy for opioid addiction, my research efforts were supported by competitive, peer-reviewed grants from the National Institute on Drug Abuse. And while I had been well acquainted with the people at Indivior through our research efforts, I have never been an employee of the company, I have never held any positions on the Indivior company Board, nor have I ever owned a single share of the company's stock.

I did get to know Dr. Tim Baxter personally and professionally. I was impressed with his honesty, his personal warmth, and his professional integrity. As a fellow physician, I was keenly aware of his concern for doing what's best for patients, including when doing so would likely result in some financial detriment to the company. An example in which I was personally involved concerns the issue of weaning patients off buprenorphine after they have become clinically stable and they have gotten a life, perhaps seeking, with clinical concurrence, to cease their medication. Tapering patients off the company's primary product cannot benefit the company financially. Even so, Dr. Tim Baxter was most vigorous and helpful in encouraging and supporting work to determine when and how to transition successful patients off of Suboxone and other buprenorphine products so patients could cease all opioids, including medications.

The U.S. government has made major commitments to develop medications for the treatment of opioid addiction. After the acceptance of methadone as a treatment for addiction, two medications have successfully achieved FDA approval LAAM and buprenorphine. LAAM is not available because the manufacturer stopped producing it simply because there is no money to be made from its marketing. Buprenorphine is the only commercially available medication specifically developed, approved, and promoted by our government to treat opioid addiction. I had participated in those government-supported efforts from the very beginning.

Now in my 80s, I can attest without reservation that Dr. Tim Baxter has contributed significantly to developing buprenorphine as a treatment for opioid-addicted patients. There is no credible evidence to support the claim that buprenorphine has contributed to opioid overdose deaths. On the contrary, it has directly saved the lives of tens of thousands of opioid addicts and indirectly improved the lives of countless individuals associated with those addicts. Tim Baxter has played a significant part in addressing one of the most difficult medical conditions, which afflicts almost 2 million people in the nation.

Your Honor, times have been difficult for all of us in the past months. Our social and personal isolation highlights our need for family contact and support. It is something we need more now than ever before. I pray that you will take into consideration that Dr. Baxter, while he has erred, has also contributed much in our effort to combat opioid addiction. He is, like all of us, imperfect, and we all fall short, which is why we need salvation. Dr. Baxter is no exception. He has consistently tried his best to do right by our patients, and his efforts in regard to the

development and implementation of buprenorphine pharmacotherapy have been vastly contributory to the betterment of a society struggling with millions of opioid addicts.

I thank you, Judge Jones, for your consideration of my humble testimony.

Respectfully yours,

Walter Ling, M.D.

Professor Emeritus
David Geffen School of Medicine at UCLA
Department of Family Medicine
Center for Behavioral & Addiction Medicine

[redacted]
Los Angeles, [redacted]
lwalter ucla.edu [redacted]

THE CESTRIA PARTNERSHIP LIMITED
CHARTERED ARCHITECTS.

[redacted],
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The Honourable James P. Jones,
United States District Judge,
180 West Main Street,
Abingdon, VA 24210
U.S.A.

16th October 2020.

Dear Judge Jones

RE: CASE NUMBER 1:20-cr-000032 [Doctor Tim Baxter]

I was introduced to Tim Baxter during the early part of 2008, by his father, [redacted] who, at that time, was a work colleague in my Architects Practice. Tim, then, of course, resident in the United States, owned a picturesque farmhouse and redundant barn buildings in the village of Drax near the port of Hull in Yorkshire. It had been his family home for many years before their move abroad.

It was Tim's intention to develop Castle Hill Farm as a high quality residential complex [redacted]

The work proceeded smoothly through the design stages until, [redacted]

At this point I became aware of Tim's extraordinary generosity of spirit when he voluntarily paid the various Consultants' fees directly. He had now paid twice with no possibility of recovering the debt [redacted] He also recognised my own lack of complicity and continued the professional relationship with complete cordiality and trust.

I had by this time still not met Tim in person. However, we did meet shortly afterwards at Castle Hill Farm during a survey visit. I found him to be as civil, charming and humorous as I had expected him to be. He was happy to continue the professional relationship with me and my practice for the ongoing progress of his project, albeit he had every justification for not

doing so. He recognised, I think that I had been as much a victim of deceit as himself. He is a trusting and generous hearted man.

At the conclusion of a prolonged series of unsuccessful Planning Applications, I felt that I had failed him and admitted as much to him. He refused to accept that, implying that local village politics was at the heart of the problem. He may well have been right but it only served to increase my regard for him.

While I no longer have a working relationship with Tim, we have remained in friendly personal contact over several years. Indeed, he has continued to offer support in times of personal stress during my wife's ongoing cancer therapy.

While I am not familiar with the legislation involved in the charges against him, it has been carefully explained to me. I truly believe that a custodial sentence for a man guilty of excessive trust, however misplaced, must surely reflect adversely on the Judicial system. I can only ask, Your Honour, that when you come to pass judgement in this case, you acknowledge the generous and trusting nature of this admirable man.

Yours sincerely

ANTONY RATCLIFF, Dip.Arch. RIBA
Cestria Partnership Ltd.

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

17 November 2020

Ref: The case of Dr Tim Baxter - 1:20-cr-000032

Your Honor,

This is a character reference for Tim Baxter, with whom I worked at Reckitt Benckiser Pharma (RBP) March 2008 through July 2012 and again as unpaid development consultants for a project at Columbia University and at present on a mostly unpaid Pharma program as consultants to continue development of that same project. I ask your patience as I further describe my professional experience with Tim Baxter.

I have a degree in microbiology/infectious disease. I have attained, over 40 years, an expertise in Good Clinical Practice (GCP) Compliance and clinical operations of pharma drug development products, and project management. I continue to train and speak on these areas through webinars. I have trained US Government, international and US pharma and academic pharma development professionals. Good Clinical Practice is the regulations (law) based on research patient rights as defined in the Declaration Of Helsinki and best clinical research practices. My professional goals are all SERVICE related.

For context, I admit to being burdened with an exaggerated sense of right and wrong. I will not be a participant in what I perceive as wrong corporate behavior. My history of leaving employment positions or reporting noncompliance and fraud in 1979, 1989, 2000, and 2003 has not been without significant financial consequences, but has been true to my character.

In January 2008, I was invited by RBP to consider a position in that small company to rescue a failing clinical program on their opiate treatment product, to begin a program on a novel cocaine OD treatment product, to build internal clinical product development resources so that they did not have to outsource this function, and to provide a GCP compliance program including SOP, and sponsor oversight of clinical trials program. I remember three things of relevance here from that first interview. I do not recall if Tim Baxter was one of the people who interviewed me.

1) The company was very small. Their personal commitment to providing treatment to opiate addicted patients for a disease that was then not widely recognized as a disease was truly inspiring. I felt privileged to serve, to share, that mission.
2) I told each of the CEO and two directors with whom I met that I was focused on compliance to the GCP FDA regulations and that I would serve only as long as they shared that perspective.
3) I would serve only as long as I was empowered by management to direct the company activities relevant to my responsibility. Notably, four years later, that is exactly why I left the company.

Through many iterations, as I built the RBP development function, I became Sr Manager, Global Clinical Operations, GCP. I had oversight of all global clinical operations, specifically the conduct and compliance of all clinical trials. I built an internal staff of 10 persons to provide this function. I reported to the group

of directors. Tim Baxter was one of those Directors. I did not report to him nor did he have oversight of my function. He did, however, have the sign off responsibility for the SOP and on clinical protocols which I also approved.

Each of these Directors had their own function, be it sales and marketing, science, medical, financial, etc. They were each focused on their functional objectives. They were not always aligned with my focus on GCP compliance, sponsor oversight, documentation and due diligence. Tim Baxter was the Medical Director. His clinical development and GCP experience most closely matched my function. Conflicts between me and this group of Directors was inevitable. All of my activities were documented and reported and were potentially subject to the review of the Directors. I required their authority to implement many of my decisions.

To be fair, it was only the rare case where my advice was not taken and when my decisions were questioned. I can remember several instances where, except for Tim Baxter and his support, I would have left the company because I felt that corporate leadership was not aligned with what I thought was ethically correct. In each case, Tim Baxter was my ally. He either supported my position or took a more aggressive position as a Director. Not once in four years did Tim fail to authorize what I thought to be the correct decision. In many ways, he was, along with Ed Johnson, a mentor for me in an increasingly difficult corporate environment.

The following examples reflect the character of Tim Baxter. His focus was on FDA GCP compliance (ethical and regulatory requirements) even if that was not the most direct path forward. Specifically:

1) There was a corporate effort to conduct clinical studies in China, on subjects currently imprisoned for opiate use. My advice to Directors was that this was illegal and not GCP compliant. My advice was not well received. Tim Baxter took charge of the discussion. The decision was made to accept my advice and abandon the plan to study the drug in prisoners (not voluntary informed consent). I would not, could not, have conducted those studies in prisoners.
2) The company planned a phase 2 clinical study with an investigational product for which the drug and a cocaine challenge would be given to volunteer subjects. I objected because the study design relied on giving cocaine to non cocaine users. I felt that not knowing how these subjects would react to the cocaine challenge and the possibility that they might become addicted to cocaine was a significant ethical/ safety issue. Some of the Directors and others in the company rejected my objection. I asked Tim for support, and received it. The study design was changed to accommodate my position. Again, without his empowerment, I would not have implemented that study design.
3) There was a large international study funded and conducted by a major university on a RBP product. I was asked to conduct GCP compliance audits of the European and US investigator sites and the University a data management provider to determine if compliance was sufficient to allow RBP to use/submit the study data. My findings were that GCP compliance was critically compromised. I advised that the study data should not be used to support the RBP program. There was resistance to my position from the Directors. Support from Tim Baxter enabled me to prevail.
4) The FDA position on sponsor IND obligations is that the pharma sponsor must demonstrate DUE DILIGENCE in the selection of investigators, conduct and oversight of the clinical trial, including termination of the program if necessary where GCP noncompliance could not be assured. Tim Baxter understood the need for documentation of Due Diligence. This case was an international study inherited, already well underway, from the parent RBP company. The program was being

conducted by a CRO (clinical research organization) over which we had had no control or supervision visibility, and where the investigators were key opinion leaders in their country who had little incentive to be FDA GCP compliant. This was essentially a post approval market study in that country. I was asked to audit the CRO and 18 investigator sites and bring the program into the GCP compliance standards that were in place at RBP. The investigators had not reported serious AE as required, nor had they obtained voluntary informed consent prior to the first study related procedure or in some cases prior to the first dose. The CRO and the investigators refused to report these noncompliance events as required to the ethics committees. I insisted to the Directors that the study program be terminated and restarted under RBP control and oversight, and that reports of noncompliance would have to be filed with the various ethics committees under whose direction the key opinion leaders conducted their studies. This advice was not well received by the RBP Directors. I tried, without success, to convince them that this was an investigational product in the US and subject to US IND FDA sponsor obligations. RBP must exercise and document DUE DILIGENCE, they being now aware of the issues. Tim Baxter once again rose to the occasion. He supported my position. "Due Diligence", in so far as it applied then, as now, can exist only as limited by visibility of those conducting the clinical trial. Perhaps this applies beyond the conduct of clinical trials.

5) FDA requires that Pharma sponsors have clinical SOP in place and to assure that the clinical trail conduct is in compliance with those SOP. It was my function to make this happen, especially as FDA had requested to see the RBP clinical SOP. The CQA (clinical quality assurance) function at RBP rejected my SOP. I did not have the authority to over ride their objection. I asked Tim Baxter for support on this matter. My SOP were accepted by both RBP and FDA.

<u>Volunteer product development beyond RBP/ Indivior:</u>

I initiated a development program at RBP in 2008 for an antidote to cocaine overdose where potentially fatal cardiac symptoms suddenly escalate and for which a therapeutic treatment is not currently available. I was the Project Director for this program at RBP until I left in July 2012. I was the unpaid Project Director at Columbia University (who invented the original product) from 2016 to 2019. RBP, then Indivior, had returned the license for the product back to CU in 2016. Tim and I have always shared the commitment to see this product in patients. It is my mission. I am even now working as a consultant to the Pharma company that bought the license from CU in 2019. Tim has been my partner since 2018 , unpaid and recently as a paid consultant on this journey. Together, we are the only two people in Pharma with the depth of legacy knowledge on this one of a kind biologic therapeutic product so urgently needed by cocaine overdose patients. Tim's medical guidance continues to provide direction as we are preparing for the third clinical trial on this program. Tim is still positioned as a volunteer to CU as we work together to develop an analog of this product to treat cocaine addiction; the addiction arena with the highest remission and treatment failure rate. That Tim volunteers his services is greatly appreciate by Dr Donald Landry (Chief of Medicine at CU) and I. Our product has great promise to address this need. I am retired except for this project. This project is my, our, legacy.

Your Honor,

Tim Baxter consistently chose the development path that was compliant with FDA and ethical principles that protected study subject rights and safety, even on issues for which I was not a participant. Many of the decisions that he made have impacted my function at RBP. It was his authority as a Director upon which I relied to implement my decisions. My function had great responsibility but little authority.

Further, Tim enabled me to serve in the development of a treatment for cocaine overdose. I am proud of my time at RBP. Together, and separately, Tim and I made a difference there and to patients.

Eventually, cocaine overdose patients will survive their cardiac crisis because of what Tim and I have done and are doing.

One last point.
The various functions at most Pharma companies, especially RBP, operate in "silos". This is very inefficient as there is little communication, and no operational visibility between the functional compartments. Based on what I observed at RBP, I feel that Tim Baxter would have had no way of knowing if sales or medical information was misrepresented.

AS an example:
I worked closely for four years with Tim and his very competent pharmacovigilance staff. This is a very difficult function. It involves the gathering clinical data from multiple outside sources that are well beyond RBP control and visibility. The reporting requirements per FDA regs are exquisitely rigid and complicated. He was very "hands on" in the design and training and management of his internal pharmacovigilance team. I note here that training and training materials do not assure compliance absent the opportunity for direct supervision. "DUE DILIGENCE" is then the only reasonable compliance criteria, as applied by FDA. I had extensive, almost daily, interaction with Tim and his internal PV team on this function. Tim Baxter was fully engaged with their activities and management. His oversight of pharmacovigilance was enabled by the internal nature of this function. I feel absolutely confident that Tim would have immediately addressed any sales, marketing, or medical related noncompliance had he been aware of it.

Thank you for taking the time to read this very long letter. I am not a lawyer. My experience with FDA enforcement is that intent is required for the charge of fraud or misconduct, which is the basis for FDA to refer enforcement to DOJ. I know Tim. He has, like me, made the career choices in Pharma to keep to the straight and narrow path. That is often difficult. I know that there was no intent. He has told me that he did not know about the medical misinformation/ statements. The training, and training materials that he authorized constitute the "DUE DILIGENCE" that I would have expected from him and which he demonstrated with the PV internal team. It is not clear to me that he had the opportunity to know about the issue before the court. I know that having to plead guilty to a crime must be very painful for him.

Please understand that this letter, and specifically this last paragraph, is my opinion and is not endorsed by Tim Baxter or his attorneys. I feel that Tim Baxter may be very much the victim here. It is disturbing to me that Tim and I operated under the same paradigm. I see that I was responsible for the conduct of global clinical trials by persons who reported to me but who provided the service externally at a distance. I, like Tim, had no visibility of what they might or might not have done. Some did not perform to my expectations of compliance. My "DUE DILIGENCE" is all I had. I hope that the examples of what Tim Baxter's activities, related to my position at RBP and our shared volunteer work with Columbia University demonstrate to you WHO he is.

I would certainly be pleased to respond to any questions should you or the Court wish to contact me.

Stephen Schwartz
[redacted]
Doswell, Virginia [redacted]
[redacted]

Consultant Services, Solaris Research LLC

Sunil Sehgal
[redacted]
Oakton, BVA [redacted]

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

November 23, 2020

Re: Tim Baxter, Case 1:20-cr-000032

Dear Judge Jones,

I am writing to you in my personal capacity as a former colleague and Manager of Tim Baxter. I have known Tim Baxter since 2010 when I joined Reckitt Benckiser Pharmaceuticals as Area Director for the Developing Markets Area and was based in Singapore. Subsequently, based on my respect for Tim Baxter's capabilities and focus on Patient's well-being, as President and CEO of Ascend Therapeutics, LLC, Herndon, VA, I recruited Tim Baxter as Medical Director. As a conscientious, individual with global experience, at Ascend Therapeutics, Tim Baxter brought much needed professional maturity to a multinational senior leadership team, many of whom lacked experience as a senior leader. I hold Tim in high regard, have the utmost respect for his professionalism and am proud to have him as a friend.

Over the years, I have reached out to Tim for his professional advice and recommendations to make operational decisions. Most recently, at Ascend Therapeutics, the first manufactured batch of a new prenatal vitamin was destroyed and the launch delayed upon Tim's medical advice that levels of Vitamin D exceeded specification and could pose a risk to the health of a patient group.

During the preparation for launch of Suboxone Film in Australia, Tim Baxter was very helpful in enabling the Australian Authorities to understand and appreciate that an abrupt mandated transfer from Suboxone Tablet to Suboxone Film had a high risk of patients falling off of treatment and returning to using heroin with the increased associated risk of needle sharing and incidence of HIV.

Similarly, at a meeting in East Malaysia, with Tim in attendance, on the podium shared by a 32 year old former multi drug user, his mother and the patient's physician, we heard the young man talk about hiding the parang (machete) during his drug using days due to fear that his mother would use it to kill him. He shared with us his mother's frequently telling him to go to the main road and step in front of a moving bus or truck. The mother talked about the constant harassment by the police and how her son was a burden than a help in managing the shop they owned. At the end, the physician talked about treatment options for drug abuse and applauded

the patient centered approach adopted by Reckitt Benckiser Pharmaceuticals Malaysian team. I have no hesitation in acknowledging Tim Baxter's contribution in helping train the Reckitt Benckiser Pharmaceuticals Malaysia team and the broader Developing Markets Area team.

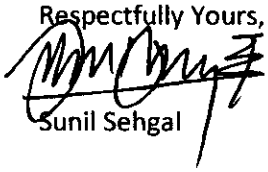
During my tenure with Reckitt Benckiser Pharmaceuticals with Tim Baxter's patient centered training, advice and recommendations, Developing Markets Area achieved significant success in treating opioid dependent patients and advancing treatment of patients. Amongst the successes, in Israel, homeless drug addicts were reintegrated into society and gainfully employed, treatment of opioid addiction was introduced in The Middle East. Measures were put into place to manage misuse, abuse and diversion of buprenorphine in Eastern European countries. Comprehensive training of physicians on treatment of addiction was launched in South Africa. Tim has always championed and continues to champion patient care, patient's safety and patient's outcomes well above commercial results

Tim went beyond and was willing to help and support others. Our local partner appreciated Tim's support when they were developing their local policies and SOPs. While living in Singapore, I faced a 12-13-hour time difference between EST and Singapore. Tim Baxter was one of the few, if not the only, US based member of the Global Leadership Team who answered my calls and/or returned my calls. I appreciated Tim's responsiveness due to the frequency of issues which arose and needed to be addressed in the Developing Markets Area. Please note that the Developing Markets Area comprised of Eastern European countries, Middle East, Africa, Asia, Asia Pacific and Latin America.

Tim Baxter pleading guilty to a misdemeanor does not come as a surprise as he is an individual who does not shirk responsibility. As a decent individual and a professional leader should, he passes on credit to his team and holds himself accountable for the outcomes of his team members. My opinion about Tim Baxter has not changed and I continue to hold him in high regard.

Keeping in view that Tim pleaded guilty to a misdemeanor, holding himself accountable for misrepresentation by a member of his team, speaks well of him as a good law-abiding citizen and human being. Incarcerating Tim would not serve society. He truly regrets the current situation and the hardship it is placing on his family and mental health. I also believe that it would erode and be a blemish on the numerous contributions he has made for the well-being of drug dependents patients around the world. Patients who have successfully reintegrated with society, are gainfully employed and leading productive lives. May I request leniency for Tim Baxter

Respectfully Yours,



Sunil Sehgal

November 14, 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Dear Judge Jones,

I am writing regarding Dr. Tim Baxter (Case 1:20-cr-000032), as I understand he will be coming before you for a judgement of his case next month. I am a physician who has worked in the area of addictive disorders for most of my career. I'm on the faculty at Johns Hopkins University School of Medicine, where I am a Professor, but I am writing this in a personal capacity.

I have known Tim for years – I can't really recall when he and I first met, but it was probably well over ten years ago and may date back to 15 or more years ago. I have conducted research with buprenorphine, primarily in the 1990s and early 2000s, and our paths inevitably crossed as this medication was being developed and eventually was approved for opioid dependence treatment. My research sought to tease apart the pharmacological profile of the drug and look at characteristics such as the relative abuse potential of buprenorphine versus buprenorphine combined with naloxone (we showed the latter had lower abuse potential). In addition to these clinical pharmacology studies, I also conducted larger, randomized controlled outpatient trials comparing the efficacy of buprenorphine to other medications, such as methadone. Finally, I became involved in the development of the curriculum used for training providers in the use of buprenorphine based upon my research and my work as a clinician.

I'd note that the period of the late 1990s and up to 2002, when buprenorphine was approved for the treatment of opioid dependence, and even in the early years after its approval, were a time of considerable excitement for many of us in the substance abuse treatment field – especially for opioid dependence treatment. To put things into context, the only real medication at the time to use for opioid dependence treatment (what is now called opioid use disorder) was methadone. (Naltrexone was used much less frequently.) Methadone treatment was only available through special clinics that were often poorly run and often not really a part of the medical system – they were marginalized and run in some cases by local business people who sought to maximize their profit. I can recall in the early 1990s being told by a counselor at a methadone clinic that I was a nice guy and seemed like a good physician, but that the only person who could really understand an opioid user was an opioid user. He was both a counselor and a patient at the clinic, and he believed methadone patients were best suited to be methadone counselors.

Many of us saw that buprenorphine was going to disrupt that status quo, and that disruption was going to be a good thing. The hope was that the treatment of opioid dependence would become a part of routine medical practice – that it would not exist in this marginalized area where it was not viewed as a part of what physicians (and other providers) addressed with their patients. That *did* happen. It didn't happen overnight, and there were other steps along the way, such as the training of physicians, but I think it is safe to say that hundreds of thousands of lives have been positively impacted by the availability of buprenorphine. It is hard to imagine how the methadone treatment system, which tended to be sclerotic in its operations and limited in its availability at the time, could have accommodated and addressed the opioid crisis.

In part, I raise this as it highlights that Reckitt Benckiser (the forerunner of Indivior) was critically important in making this happen. I confess I haven't fully followed the machinations of the government's case against people at Indivior, and the company, although it does trouble me that there is purported to have been problems and misbehavior by the company and its employees. I know I felt like the company and professional societies and researchers were trying to do something good to help people who suffer from opioid dependence – at least in those years that I was more involved with the medication's development.

I interacted with Tim periodically over those years. We didn't work closely, although we would see each other at scientific conferences, as I recall, and I think we were together at a meeting somewhere on the west coast and spent some time in airports together on the way back. I believe he may have visited our research program as the company was preparing the FDA submission in the early 2000s. My overall memory of my interactions with him were that they were good, collegial, and professional – I've had a fair number of interactions with professionals at drug companies over the years, and I've certainly met some who seemed mercenary and frankly slick. I never got that sense from Tim. He was interested in furthering the science related to the medication's development, and brought a fair and balanced perspective in those interactions.

In closing, I'm advocating for leniency as you consider this sentencing. I'm not sure how it helps to send him to jail, and he and I have been in touch about this and I've heard his regret and acceptance of responsibility. I think it would be good to let him move on with his life, with the recognition that these events have had a powerful impact upon him.

Thank you for considering these reflections.

Eric C. Strain, M.D.

Anthony Tommasello, Pharmacist, Ph.D.
Medical Affairs Manager
Indivior

November 17, 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Dear Honorable Judge Jones

I am writing on behalf of Dr. Tim Baxter under whom I worked while a field medical advisor at Reckitt Benckiser which became Indivior. I started my employment in 2008.

Dr. Baxter was dedicated to patient safety and to ensure physicians were properly educated about buprenorphine pharmacology as it applied to the treatment of opioid dependence (now opioid use disorder). This was a new approved use of buprenorphine and it was clear that most physicians were poorly informed about opioid dependence treatment having had very little education about this condition during their medical school training. In addition, of all the drugs approved for the treatment of opioid use disorder the pharmacology of buprenorphine (a partial agonist) differs from that of both methadone (a full agonist) and naltrexone (an antagonist).

Dr. Baxter formed the Field Medical Advisor team (FMAs) to evaluate the practices of physicians who were authorized to prescribe buprenorphine under the Drug Addiction Treatment Act passed by Congress in 2000 (referred to as DATA-2000) after completing an 8-hour course offered under the auspices of the National Institute on Drug Abuse. For most physicians starting in the practice area the 8-hour training was the total education received before seeing patients. Our job was to visit physicians whose prescribing seemed questionable. For instance, some prescribers exceeded the recommended dose and/or were treating more patients than the law allowed. We engaged in scientific exchanges with them, reviewed the prescribing information approved by the FDA and the DATA-2000 law, and in egregious cases listed them for reporting to federal authorities.

Dr. Baxter had a large plate of responsibilities and wanted to ensure the proper management of the FMAs. He transferred the operation of the team to Dr. Ed Johnson. Shortly thereafter I was selected as the team manager reporting directly to Dr. Johnson. My duties involved coordinating visits to physicians of concern nationwide, evaluating the hiring of new

FMAs, articulating the team's mission, and working with the medical department to evaluate the effectiveness of the FMA effort.

Dr. Baxter continued meeting with the team and consistently displayed honesty, integrity, and concern for both patient safety and treatment efficacy. During our meetings he and Dr. Johnson would provide updates on the challenges faced by the treatment community and visions of the internal policies of the company. We also used the meetings to engage in literature reviews germane to the evolving science related to opioid dependence treatment.

Since my job was field based, I worked from a home office in Maryland and spent very little time in the Richmond headquarters, generally only to attend FMA meetings. Thus, I did not engage in deep personal interactions with Dr. Baxter. However, we often enjoyed a team dinner following a day of meeting. During dinners Dr. Baxter was jovial in all our conversations and did not seem overwhelmed. He was friendly, a good listener, patient, never terse. Overall, I believe Dr. Baxter to be of high character and a man who was dedicated to ensuring that DATA-2000 and the FDA approved prescribing information were followed by prescribers so that patient safety and treatment efficacy would be established and maintained.

Sincerely

Anthony Tommasello, Pharmacist, Ph.D.
Medical Affairs Manager
Medical Affairs, North America
Indivior Treatment Services, Inc.
10710 Midlothian Turnpike, Suite 430
Richmond, VA 2323 , USA

Patricia M. Weston, PhD
[redacted]
Sarasota, FL [redacted]

November 30, 2020

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Dear Judge Jones,

This letter is to convey my experiences to you regarding Dr. Tim Baxter and my interactions with him at Reckitt Benckiser Pharmaceuticals/Indivior. These examples are representative of his usual behaviors from my perspective. I can also speak to his character as we grew to respect each other and speak on a first name basis.

My first interactions with Tim were in 2008 when I was hired for the role of Marketing Assistant to help senior members with the oversight of the Here to Help pilot study. At that time, the nurses from the Medical Information Unit were trained with scripts and FA s for calls to patients who gave their permission to participate in the study.

Tim Baxter was a very important part of the Review Committee who approved the scripts and FA s. I watched senior marketing and the agency who created the documents trying hard to highlight the product attributes to patients, as they said that it was marketing s job. I watched Tim pushing back, when it was too far. Tim was intent on not overselling ourselves.
Being that this was my first review committee experience, I was very impressed with the detail, the discussion, and the scrutiny that Tim gave to the scripts, the FA s and the process for the study.

My further interactions with Tim Baxter were related to patient education and promotional material reviews. The material was created by our advertising agency. I recall several instances when the agency and the senior marketing team again fought for language that could be questionable. The committee stopped the meeting to check the FDA guidance regarding the specific topic and language. Tim, being the medical representative, was actively involved in this process with a keen eye for patient safety and the integrity of his approval. If the company went overboard, it was not because of Tim. He was the voice of reason in this process.

During these meetings, Tim and I engaged in numerous professional conversations about patient treatment and opioid use disorder. I have a license as a clinical psychotherapist with a specialty in substance abuse treatment. It was through these discussions that Tim encouraged me to go back to school for my PhD. It took a bit of coaxing on his part, but I embarked on that

endeavor. It took me almost years, and I completed it last year. I will be forever grateful for his encouragement and his confidence in me.

In conclusion, Tim is one of the most compassionate and honest people I have known at RBP/Indivior. I trust Tim to always be respectful and to listen to what people say. Tim could always be counted on to be levelheaded and to defend lower-level employees against unfair criticism when others at RBP/Indivior would not.

These are qualities I respect and admire. Additionally, I would work with Tim Baxter any time in the future if the opportunity would occur.

indest regards,

Patricia Weston, PhD

Family Practice Associates

[redacted]
FAAFP
Board Certified
American Board of Family Practice

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[redacted] FNP

[redacted] CFNP

[redacted], CFNP

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210
RE: *U.S. v. Dr. Tim Baxter*, 1:20-cr-000032

11/5/2020

Dear Judge Jones,

Your honor, Dr. Tim Baxter is my patient and has been under my care since 2015.

He has dealt with many medical conditions:

[redacted]

If he were to be incarcerated, I would have concerns about the ability to safely manage his current medical conditions. [redacted]

His medical conditions place him at an increased risk of serious complications or death if he were to acquire COVID-19 or other community spread infectious disease like influenza. The nature of living in a facility where many others reside makes it difficult to conform to CDC guidelines for social distancing. If the infection starts to spread in a group facility, it can be very difficult to stop the spread to other residents.

13911 St. Francis Blvd
Midlothian, VA 23114

Family Practice Associates

Because of these reasons, I am requesting as Dr. Baxter's physician that your honor consider a sentence like probation, home confinement, community service or a combination so he may continue to receive his current care and so he may limit the chance of becoming infected with COVID-19.

I am concerned that if he is imprisoned during the COVID-19 pandemic, given his medical condition, it would pose a dangerously high risk to his health and life.

Thank you for your consideration.

Sincerely,

[redacted] M.D.

CC: S. Taylor-Sargent, USPO

13911 St. Francis Blvd
Midlothian, VA 23114

The Honorable James P. Jones
United States District Judge
180 West Main Street
Abingdon, VA 24210

Date: November 12, 2020.

Re: Timothy Baxter Case 1:20-cr-000032

Your Honor,

As a health economist and clinical outcomes researcher that for the past 20 years works globally with both Pharma (over 40 global companies) and the Ministry of Health (in more than seven countries) on healthcare cost, clinical effectiveness, value of new and existing medications and medical devices in the healthcare industry, I come forward as a fellow scientist and a colleague. I had the pleasure to first meet Dr. Tim Baxter in May 2010 in my capacity of an external consultant for Health Economics and Outcomes Research (HEOR) work reporting to the Indivior Medical Department. My consultant relationship with Indivior was during the time period of March 2008 through November 2017. I have had many interactions with Tim per different medical study designs /outcomes during this time and still today.

Buprenorphine and Buprenorphine-Naloxone, Generally

Before going into my work with Tim, it is important to set the stage with some background information on Buprenorphine (Subutex) and Buprenorphine-Naloxone (Suboxone or BUP/NAL). BUP/NAL is part of Medication-Assisted Treatment (MAT), which is a combination of counseling and behavioral therapies with a medication. Buprenorphine is a long-acting, partial agonist at a mu-opioid receptor developed in the 1970s as a safer opioid than morphine or heroin for treating pain. Suboxone combines buprenorphine with Naloxone. Naloxone has no effect on the sublingual use of buprenorphine. However, naloxone does block intravenous or intranasal abuse of buprenorphine. Buprenorphine alone as a medication can easily be crushed to be smoked or snorted, or dissolved (heated) into a solution to be injected. On the other hand, when BUP/NAL is inhaled, snorted or injected, it will produce instant and intense withdrawal, as all of the opioid content in the user system becomes completely blocked.[1] For this specific reason, Suboxone is generally used over buprenorphine monotherapy in patient maintenance treatment.

My Work with Tim Studying Suboxone

Since 2010, I have come to know Dr. Tim Baxter very well both professionally and personally. Tim is very approachable, hard-working, highly professional, and a brilliant

[1] Suboxone can be abused if the naloxone molecule is separated from the buprenorphine molecule. With the BUP / NAL tablet, it is possible to achieve this effect by heating it in a spoon. However, with the Film formulation, naloxone does not easily separate from buprenorphine while heating.

person. As a healthcare professional, Tim is highly committed to patients and patient safety, scientific accuracy, and ethical behavior. He is an outspoken patient advocate with great integrity, honesty, and courage to stand his ground.

For example, in 2012 when my team performed retrospective dataset analysis on private insurance medical claims (60 million+ patients) for the period January 2006 through November 2011, observing healthcare costs and resource use among opioid dependence patients prescribed and initiated on buprenorphine-naloxone (BUP/NAL) tablet and BUP/NAL film (Suboxone) formulation,[2] Tim raised the question to investigate opioid dependence patient persistence (patients who do not discontinue treatment during initial 12 months of treatment), as there was no solid evidence in the scientific community that explored this question. We did, and the results were both significant and ground breaking.[3] Since then, the scientific community has repeatedly demonstrated that the biggest issue with opioid use disorder is a "revolving door" effect of patients discontinuing the treatment and then again re-initiating it.[4] Keeping patients in treatment until they taper down to low BUP/NAL dose while remaining stable is associated with a further decrease in their utilization of healthcare services during treatment, as well as after treatment.

Tim has consistently challenged any research areas for further improvement and accuracy, where applicable, thus minimizing potential bias. When reviewing study results, Tim would always raise questions in the search for absolute clarity per study results and any variable that would impact the results being accounted for. It was through our paired diligence that the minimal length of treatment study was selected as a Podium presentation at the 2016 annual meeting of the American Society for Addiction Medicine (ASAM) – an esteemed addiction professional body.[5]

Tim also initiated retrospective medical claims studies investigating the impact of BUP/NAL dosing in a real world setting that generated results demonstrating the importance of prescribing patients doses within the recommended range (16-24mg). In a retrospective

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[2] For further clarity on the value of providing patient treatment, Indivior initiated a retrospective medical insurance claims study compared to patients diagnosed and received BUP/NAL treatment versus those who did not receive treatment. Both groups of 5,578 patients had similar demographics, comorbidity characteristics, and healthcare costs six months prior to diagnosis (same size apples). Patients who were BUP/NAL treated had significantly lower healthcare costs vs. patients without treatment ($13,782 vs. $19,730; p=0.0012). Patients that did not have treatment had 2.5 times higher inpatient care.

[3] Retrospective medical claims study results reported a significant difference in terms of treatment persistence in the group of Suboxone initiated patients after September 2010 (Suboxone launch date) vs. BUP/NAL tablet matched patients in the same time period (53.0% vs. 43.4%, log-rank test: p=0.0004); as well as by observing Suboxone film vs. BUP/NAL tablet patients who initiated treatment prior to September 2009 (53.3% vs. 40.4%, log-rank test: p<0.0001)1. The studies above were performed among patients matched using propensity score matching (comorbidities, demographics) to diminish bias (comparing same size apples to apples).

[4] OUD was called opioid dependence prior to DSM-V (Diagnostic and Statistical Manual of Mental Disorders, 5th edition 2015),

[5] The minimal length of treatment study demonstrated that, on average, patients who remain in opioid addiction treatment minimum of 9-17 months will experience significantly less healthcare resource utilization and costs associated with an emergency room, hospital services, or outpatient visits in the immediate twelve months after treatment completion. The study above was performed among patients matched using propensity score matching (comorbidities, demographics) to diminish bias (comparing same size apples to apples).

medical insurance claims study of 25,437 BUP/NAL prescribed patients, two patient groups were compared: 1) Patients with average recommended daily dose and patients who had 200%+ higher than the recommended dose prescribed during treatment duration (potential abuse and diversion). It was found that the average daily recommended group of patients remained in treatment significantly longer than the potential abuse and diversion patients (407 days vs. 100 days). While its not immediately helpful to any company's bottom line to tout studies showing the value of prescribing LESS of their drug to patients, this study provided the company with an important educational tool for doctors.

The above-presented research is a snapshot of just some of the scientific studies that I am very proud of, as well as the collaboration with Tim.

I firmly believe that Tim regrets the situation encountered and is very remorseful. It would be a significant loss for the scientific community for Tim to be sent to jail. A prison sentence would be detrimental to all concerned. Tim is very actively engaged in critical work developing new treatments designed to improve patient health and quality of life. Indeed, just a few months ago he helped with a study design relating to patients experiencing anaphylaxis. His input was critical for a successful study execution that will help anaphylaxis patients down the road.

I continue to maintain a high opinion of Tim and believe that by allowing him to continue to practice in healthcare, will only make him more driven to continue his mission of helping patients and improving healthcare. Tim is one of the most knowledgeable medical persons in opioid addiction research globally, whose expertise in this area is indispensable. I hope for him to continue to advance patient-centered medicine.

_____

Prof. Vladimir Zah, PhD.
November 12, 2020.

From: Baxter, Tim
Sent: Tuesday, March 30, 2010 3:42 PM
To: [redacted] Thaxter, Shaun; [redacted]
Subject: RE: Viewdocument (2).pdf - Adobe Acrobat Standard

Not sure of the relevance of this to the REMS. It looks like they are trying to deny us the ability to make a claim on additional paediatric safety of the film. I believe that we will need to collect data on this as a post marketing exercise before we can make any specific claim, although we will be able to describe the nature and intent of the packaging in marketing materials.

Tim Baxter
Global Medical Director
[redacted]

Reckitt Benckiser Pharmaceuticals Inc, 10710 Midlothian Turnpike
Richmond, VA 23113, USA
[redacted]
www.reckittbenckiser.com

From: [redacted]
Sent: Tuesday, March 30, 2010 3:32 PM
To: [redacted] Thaxter, Shaun; [redacted] Baxter, Tim
Subject: RE: Viewdocument (2).pdf - Adobe Acrobat Standard

I see FDA's response to our Question 4 can be a bigger issue as it may imply the overall risk/benefit is not favorable for our film (vs tablet). See if we can develop any sound strategies to mitigate the risk here.

[redacted]

From: [redacted]
Sent: Tuesday, March 30, 2010 3:14 PM
To: [redacted] Thaxter, Shaun; [redacted] Baxter, Tim
Subject: RE: Viewdocument (2).pdf - Adobe Acrobat Standard
Importance: High

Please formulate questions for the FDA, and tell me your availability for early next week.

Please see the bottom of pg 2 and top of pg 3 of the FDA REMS letter, and the words "Suboxone and Subutex will only be dispensed to", "each patient" and "documentation" for each patient. I want to better understand the FDA expectation, and practicalities of implementation with respect to protecting patient privacy, avoiding interference with patient-physician relationships, and ultimately preserving patient access to treatment.

Page 5 indicates that only a sampling of patients is by KAB survey is needed to confirm that the REMS is ultimately working, but to "ensure" that the specific FDA conditions #1 and #2 are being met for all patients, as outlined on pages 2 and 3 of the FDA letter, seems like a tall order.

I will forward the letter to the rest of the team to start work.

[redacted]
Senior Manager, Regulatory Affairs
[redacted]

Reckitt Benckiser Pharmaceuticals Inc.
10710 Midlothian Turnpike, Suite 430
Richmond, VA 23235
[redacted]
www.suboxone.com

From: [redacted]
Sent: Tuesday, March 30, 2010 2:40 PM
To: Thaxter, Shaun; [redacted] Baxter, Tim
Subject: Viewdocument (2).pdf - Adobe Acrobat Standard
Importance: High

We finally got comments on the REMS, and I am working to set up a meeting with FDA.
This is my first wave e-mail. I will give you a few minutes before sending it to the rest of the team.

[redacted]

From: Baxter, Tim
Sent: Wednesday, July 25, 2012 12:37 PM
To: [redacted]
Cc:
Subject: Root cause analysis of the [redacted] paediatric exposure data

[redacted]

I want to bring to your attention the potential need for a decision on the future of the current Suboxone tablets based on the probable outcome of our root cause analysis of the [redacted] paediatric exposure data.

As you know, since approval of the tablet, accidental paediatric exposure had been increasing until about 2009 when the occurrence seemed to plateau. Then in 2010 the incidence of paediatric exposure started to decrease. We have run one analysis that tells us that there is less exposure on film than tablet. We are now looking into why that is the case. This is the so called root cause analysis. This should be able to tell us what it is that has stimulated the decrease in exposures. We are specifically examining three factors: our education campaign which kicked off at around the same time that the incidence plateaued, the REMS and the film packaging. My suspicion is that the education programme will be causative of the plateau in incidence and that the unit dose packaging will be causative of the drop in cases.

Without prejudging the outcome of this analysis, if my suspicion is correct, we are faced with an ethical dilemma over the existing tablet presentation of Suboxone. It may be that there is a significant public health risk with the tub packing of tablets as compared to the unit dose packaging approach used with the film. With this in mind I feel that it would be appropriate for you to consider what actions we should take in terms of addressing this potential public health concern (EG, repacking the tablet into child resistant unit dose blisters, withdrawing the tablet etc). The report on the route cause analysis is scheduled to be available at the end of August. Should it confirm my assumptions then I feel that we are bound to take action to protect the public health.

Clearly neither course can be conducted instantaneously. Much thought planning and communication with our prescribers and patients will need to take place in either case. Accordingly, I believe that you should be giving consideration at this stage to what we as a company would need to do to appropriately respond in the event that the analysis establishes a public health risk relative to tub packaging of tablets.

Thank you for your consideration of this important concern

Regards

Tim

Tim Baxter
Global Medical Director
[redacted]

Reckitt Benckiser Pharmaceuticals Inc, 10710 Midlothian Turnpike
Richmond, VA 23113, USA
T +1 804 379 1090 F +1 804 379 1215
www.reckittbenckiser.com

From: [redacted]
Sent: Monday, November 19, 2012 9:27 PM
To: [redacted]
Subject: RE: Exposures Data

Hi [redacted]

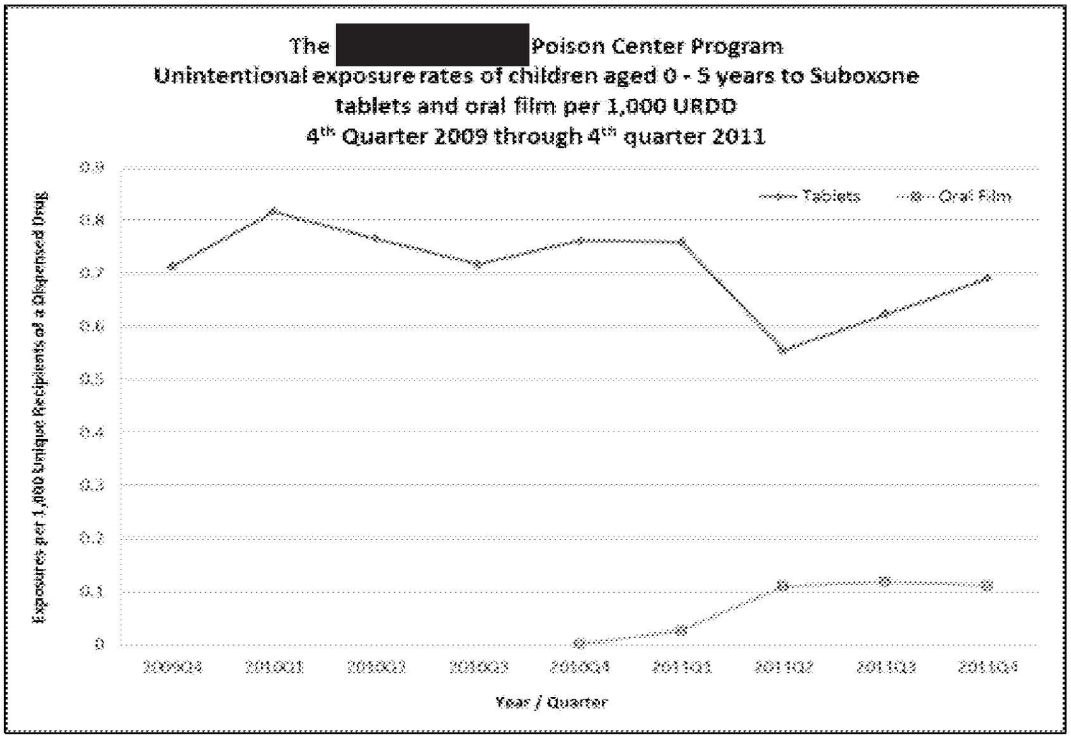
Here are the conferences where they have been presented:

- [redacted] 36th Annual Conference Nov. 3, 2012, 10:15 am. Bethesda
- [redacted] 15th Annual European Congress: Poster, Nov. 7, 2012, 12:45 pm. Berlin

And here is the next one planned:

- [redacted] 23rd Annual Meeting and Symposium: Poster, Dec 7, 11:30 AM – 1:00 PM, 2012. Aventura, FL

Attached please find a copy of 2012 [redacted] Book of Abstracts from their website. If you search for my last name both abstracts will come up for the pediatric exposure presentation as well as for the abstract for the HEOR poster we briefly discussed. In the abstract for the pediatric exposure study the following graph was presented to the public and appears in the poster.



As always, please advise if I can assist further.

All the best,
[redacted]

[redacted]
Medical Affairs Manager
Reckitt Benckiser Pharmaceuticals, Inc./NA
[redacted]

From: [redacted]
Sent: Monday, November 19, 2012 3:54 PM
To: [redacted]
Subject: Exposures Data

[redacted],
I misplaced my notes – what is the name of the conference the tablet/film data was presented. Thanks.
[redacted]

[redacted]
Deputy Director, Office of Clinical Affairs
Director of Pharmacy, MassHealth
[redacted]
www.mass.gov/masshealth/pharmacy

From: [redacted]
Sent: Tuesday, October 16, 2012 3:38 PM
To: [redacted]
Subject: RE: Thank you

Hi [redacted]:
It was my pleasure and I will be happy to provide you with the information as soon as it is published.

As an aside, and since [redacted] has the ability to collect and analyze this type of data to the three digit zip code, I asked [redacted] if he could provide me with the rates of unintentional pediatric exposures between Suboxone tablets and film in Massachusetts and he sent me the following:

In the Poison Center program, over the time period 2010Q4 – 2012Q2, the average rate of mentions by unintentional exposures patients aged 0 – 5 years in Massachusetts was:

- Buprenorphine tablets: 5.1 exposures / 10,000 URDD
  - 95% CI: 3.2 – 10.7 exposures / 10,000 URDD
- Buprenorphine film: 2.7 exposures / 10,000 URDD
  - 95% CI: 1.3 - 5.8 exposures / 10,000 URDD

I hope this helps in the meantime.

Best regards,
[redacted]

[redacted]
Medical Affairs Manager
Reckitt Benckiser Pharmaceuticals, Inc./NA
[redacted]

From: [redacted]
Sent: Tuesday, October 16, 2012 2:58 PM
To: [redacted]
Subject: RE: Thank you

[redacted],

Thanks for your help. If you can provide me with a copy of [redacted] abstract and any supporting materials (e.g., slides) once they are in the public domain after the Nov 3 meeting, I would be grateful.
[redacted]

[redacted]
Deputy Director, Office of Clinical Affairs
Director of Pharmacy, MassHealth
[redacted]
www.mass.gov/masshealth/pharmacy

From: [redacted]
Sent: Wednesday, October 10, 2012 5:38 PM
To: [redacted]
Subject: Thank you

Dear [redacted]:
Just a note to thank you for your time yesterday. I enjoyed meeting you and appreciated your perspective on the pediatric data. I have asked [redacted] to calculate out each state's rates of unintended pediatric exposures to Suboxone tablets for comparison to utilization as [redacted] is capable of drilling down to the three digit zip code. I will advise you as to how Massachusetts ranks in the nation when I receive the information.

In the meantime, if I can assist you with any additional scientific information, please do not hesitate to reach out to me directly.

Best regards,
[redacted]

[redacted]
Medical Affairs Manager
Reckitt Benckiser Pharmaceuticals, Inc./NA
[redacted]

NOTICE

 Please Consider the Environment before printing this Email

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
100 Hancock Street, 6th Floor
Quincy, MA 02171

[redacted]
Governor

[redacted]
Lieutenant Governor

[redacted]
Secretary

[redacted]
Medicaid Director

RE: Suboxone Film and Unintentional Pediatric Exposures December 2012

Dear Prescriber:

Recent press releases by Reckitt Benckiser (the manufacturer of Suboxone sublingual tablets and film) and data published by t[redacted] program have documented a greater unintentional exposure risk of buprenorphine/naloxone tablets than with that of the film in children 0 to five years of age.[1] Data from October 1, 2009, to December 31, 2011, shows the unintentional exposure rates to be 0.68 cases/1,000 unique recipients for the tablets vs. 0.08 cases/1,000 unique recipients for film. Accordingly, we will be adjusting our approval criteria to provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age. A prior authorization request must be submitted stipulating this circumstance.

MassHealth is aware of Reckitt Benckiser's planned withdrawal of Suboxone tablets. Please be assured that MassHealth will continue to pay for available formulations of buprenorphine/naloxone for members who require treatment. MassHealth will issue additional advisories on this matter as necessary.

Further information on buprenorphine and buprenorphine/naloxone treatment, including applicable prior authorization requirements, is set forth in the MassHealth Drug List (see Table 36 and the related Evaluation Criteria). The MassHealth Drug List and other information can be found on the MassHealth Pharmacy website at www.mass.gov/masshealth/pharmacy.

We appreciate your continued support and dedication to providing care to MassHealth members.

Sincerely,

[redacted]
Pharmacy Director
MassHealth

References:

[redacted]

IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF VIRGINIA

ABINGDON DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Criminal Case No.
	)	1:20-cr-00032-JPJ-PMS-1
vs.	)	
	)	
TIMOTHY BAXTER,	)	Thursday, December 17, 2020
	)	
Defendant.	)	**AMENDED**

TRANSCRIPT OF SENTENCING HEARING
HONORABLE JAMES P. JONES PRESIDING
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S

On Behalf of the Plaintiff:

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Ben Franklin Station
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Washington, DC 20044

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Abingdon, VA 24210

Proceedings taken by Certified Court Reporter and transcribed using Computer-Aided Transcription

A P P E A R A N C E S (Continued)

On behalf of the Plaintiff:

Matthew Joseph Lash
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450 Fifth Street, Suite 6400
Washington, DC 20001

For the Defendant:

Brandon Jacob Moss
Wiley Rein LLP
1776 K Street, NW
Washington, DC 20006

Kevin Brian Muhlendorf
Wiley Rein LLP
1776 K Street N.W.
Washington, DC 20006-2304

Ralph Joseph Caccia
Wiley Rein LLP
1776 K Street N.W.
Washington, DC 20006-2304

(Proceedings commenced at 10:36 a.m.)

THE COURT: I understand, ladies and gentlemen, that we're ready to go now.

We're here today for the sentencing of the defendant in the case of United States of America versus Timothy Baxter. It's Case No. 1:20cr32.

And is the government ready?

Mr. Mayer, are you primarily speaking for the government today?

MR. MAYER: Yes, Your Honor, and we're ready.

THE COURT: And is the defendant ready today?

MR. CACCIA: Here, Your Honor. Ralph Caccia for the defendant, Dr. Timothy Baxter. I'm here with two of my colleagues, Kevin Muhlendorf and Brandon Moss.

We're ready to go, Your Honor.

THE CLERK: Your Honor, I'm sorry to interrupt. I don't see Mr. Baxter on the screen now.

There he is. Okay. He's on there now. Okay.

THE COURT: I can see him.

THE CLERK: Okay. Thank you.

THE COURT: All right. Thank you, Counsel.

Let me ask Mr. Baxter, Mr. Baxter -- excuse me, Dr. Baxter. Dr. Baxter, it's my understanding that you are agreeable to proceeding today by this video teleconference rather than appearing in court in person as you have a right

to do; is that correct?

THE DEFENDANT: That's correct, Your Honor.

THE COURT: All right. Thank you.

I need to make some findings in order for us to proceed in this fashion.

I hereby make the following findings as required by the CARES Act. I find that the Judicial Conference of the United States has found that emergency conditions due to the national emergency declared by the President with respect to the coronavirus disease will materially affect the functioning of the federal courts generally.

And the Chief Judge of this district court specifically found in Standing Order 2020-07, entered March 30, 2020, as extended by First Amended Standing Order 2020-15, entered September 28, 2020, that felony sentencings under Rule 32 of the Federal Rules of Criminal Procedure cannot be conducted in person without seriously jeopardizing public health and safety.

In the particular case before me, I further find that the sentencing cannot be further delayed without serious harm to the interest of justice. I make this finding for the following specific reasons: Further delay may cause the loss of relevant evidence helpful to either the prosecution or the defendant, it will prolong uncertainty and anxiety by the defendant and family members concerning the outcome of the

case, and it may damage the public reputation of the criminal justice system absent the speedy resolution of the case.

Now, I understand that this, in fact, is a misdemeanor case. But for certainty, I want to make those findings.

Does either the government or the defendant object to these findings or their sufficiency?

Does the government object, Mr. Mayer?

MR. MAYER: No objection, Your Honor.

THE COURT: And does the defendant object, counsel?

MR. CACCIA: No, Your Honor.

THE COURT: Because we're conducting this matter by video teleconference, I remind those persons who may have access that photographing, recording, or rebroadcasting of this proceeding is prohibited. Any violation of these prohibitions may result in sanctions by the court.

I have reviewed the presentence investigation report, of course, as well as the materials, sentencing memoranda filed on behalf of counsel. The defendant has filed certain objections to the presentence investigation report. Most of those objections have been accepted by the probation officer.

Does defense counsel wish to make any further argument in regard to any of the objections that were not accepted by the probation officer?

MR. CACCIA: No, Your Honor. We're thankful to Ms. Taylor for the time and attention that she gave to this matter.

Not an objection, more an observation. We do believe that the guideline note under 2N2.1, this was our objection 14, would indicate that a downward departure might be appropriate here. Ms. Taylor declined to accept our invitation. I think, ultimately, it's academic. This is a guideline level four offense. So we're pretty well in guideline A to begin with, but we did observe a downward departure might be appropriate. But I don't believe when all is said and done, Your Honor, that it makes any material difference.

THE COURT: Well, I'm going to overrule the objections for the reasons stated by the probation officer.

Now, I understand that the parties have entered into a stipulated sentence under Federal Rule of Criminal Procedure 11(c)(1)(C). But I do want to -- before I determine that issue, I do want to procedurally adopt the advisory sentencing guideline range.

I find that the defendant has a total offense level of 4 and a criminal history category of I, which translates into a custody range of 0 to 6 months, supervised release of 1 year, probation of 0 to 3 years, a fine range of $500 to $9500, and a special assessment of $25.

After careful consideration, I hereby accept the parties' agreement under Federal Rule of Criminal Procedure 11(c)(1)(C) as set forth in their written plea agreement, which is at Docket No. 3, filed August 31st, 2020. The relevant portion of it, which states, "The United States and I agree that I shall be sentenced to a period of incarceration, if any, within the range of 0 months to 12 months, a fine of $100,000, a mandatory assessment of $25, no restitution, and a period of supervised release or probation for a term of 1 year."

Now, the parties, again, have filed lengthy sentencing memoranda with exhibits. There has been an issue raised as to the government's desire to present certain exhibits with respect to argument presented at sentencings related to this case in earlier sentencing, and the defendant has objected to that. And I'll be glad to hear brief argument on that if counsel wishes to make any further argument.

First --

MR. CACCIA: Your Honor, can I ask Your Honor's indulgence for one moment. To avoid technical issues, we're working off one laptop. So I'm just going to pass this to my colleague, Kevin Muhlendorf.

MR. MUHLENDORF: Good morning, Your Honor. Kevin Muhlendorf for Dr. Baxter.

Our main concern, Your Honor, is while 3661 allows

information on the background and character and conduct of a convicted person, as we read that transcript of Mr. Thaxter's sentencing and, as I'm sure you'll recall, there was a point-by-point recitation that was argument by counsel for the government and for Mr. Thaxter that had nothing to do with Dr. Baxter about, you know, his net wealth, about things he had said and things he had done, we don't contest that you can consider a whole host of things, you know, very broad. But argument about another defendant in another case is not evidence, it's argument. That's why we have that instruction in every trial in the land. I recognize this isn't a trial, but argument still isn't evidence. And we understand the desire to put in Dr. Jeffrey and not recall him. And we actually -- we agree you're allowed to consider Dr. Jeffrey's testimony, there's no question about that, just like you're allowed to consider letters from family and friends and from colleagues and hearsay is accepted.

Our main argument is with the consideration of argument when we weren't there and didn't have the ability to object to it and when it's not evidence of anything.

It's not about the reliability, as the government claims. We're not saying the transcript isn't reliable. What we're saying is that argument isn't evidence. So considering argument from another defendant's sentencing is inappropriate, we think. I have no doubt that the government has its

exhibits, and it will have its argument today, and you'll consider it and make your ruling. But considering argument which isn't evidence in a hearing from another defendant is just not appropriate in this situation.

THE COURT: All right. Thank you.

Mr. Mayer.

MR. MAYER: Thank you, Your Honor.

As we explained in our brief yesterday afternoon, a transcript of a federal district court hearing is a reliable source of information. That doesn't mean the Court needs to accept or apply all arguments or facts in the transcript, but there's no question that a transcript of a federal district court hearing is a reliable source of information that may be considered at sentencing.

THE COURT: Well, what is it in the transcript that the government believes is relevant or significant for me to consider in this case?

MR. MAYER: Your Honor, first and foremost, the questioning of Dr. Jeffrey. But also parts of the argument that touched on Indivior's conduct. I accept defense counsel's point that not all of it was about Indivior's conduct because some was directed specifically to Mr. Thaxter or Indivior Solutions, but much of it was about Indivior's conduct, the company where Dr. Baxter worked. And it would just be more efficient for everyone, and it's perfectly

reliable for the Court to accept that in this proceeding rather than have us repeat it all.

THE COURT: All right. Well, I'm going to overrule the objection and allow the government to introduce it. It is -- while some of it, I agree, would be irrelevant, I can easily parse that out even though it's part of the matters presented to me and it will not influence me in my determination of the appropriate sentence in Dr. Baxter's case.

So, we're in the position now that I will hear any additional evidence that the parties wish to present in regard to the appropriate sentence, then I'll hear any oral argument. Of course, I've read carefully the sentencing memoranda that have been filed. And I'll, of course, give Dr. Baxter an opportunity for allocution. I've read his letter to me and the other letters that have been written on his behalf, which have been, I must say, impressive. But, in any event, I'll give him an opportunity before I announce my sentence in the case. But that's how we'll proceed.

So, I'll first hear from the government in regard to any evidence that they wish to present, then from the defendant, other than what has been presented to me already as exhibits in the memoranda. I've read all of that. It's lengthy, and I've taken the time to read it all, and I think I'm fully prepared in that regard.

So, Mr. Mayer, you may proceed.

MR. MAYER: Thank you, Your Honor.

The government has no witnesses to call today. We do have an argument. And in the course of that argument, we'd like to walk through a few of the exhibits that were attached to the sentencing memorandum, as well as two additional exhibits: One of which was previously discussed in the Shaun Thaxter hearing. And one of which is Dr. Baxter's severance agreement from the company. So we don't wish to call any witnesses or present further evidence, but I'd like to cover those exhibits in my approximately 20-minute argument.

THE COURT: All right. You may proceed.

MR. MAYER: Thank you, Your Honor.

My argument today will cover three main points. The first point is the longest; the others are short. First, the sentence for Dr. Baxter should promote general deterrence. It should send a clear message to medical directors of other companies and to the medical community generally that making misrepresentations about the safety of an opioid drug, or allowing subordinates to do so, will be severely punished. This clear message will dissuade other people from making misrepresentations about the safety of an opioid drug or allowing subordinates to do so.

In this case, Dr. Baxter made misrepresentations about the safety of an opioid drug and allowed subordinates to

do so in four ways: Number 1, Dr. Baxter allowed his direct subordinate to send inaccurate data on the safety of Suboxone Film to the Massachusetts Medicaid Program. Dr. Baxter actually received one of these false communications in realtime and had good reason to verify it, but he took no action. As a result, the Massachusetts Medicaid Program was tricked into thinking the Suboxone Film was safer than it really was and expanding coverage of it.

To briefly review Dr. Baxter's role in this incident, let's look at Exhibits 15 and 16 to our sentencing memorandum.

Your Honor, I move for the admission of these exhibits.

THE COURT: They will be admitted.

(Plaintiff's Exhibits 15 and 16 received.)

MR. MAYER: I've highlighted parts of the exhibits I plan to discuss for efficiency. In Exhibit 15, we see Dr. Baxter's subordinate received three rates of telephone calls to poison control centers regarding buprenorphine drugs in Massachusetts. There's a high rate for Suboxone Tablet of 3.3, a medium rate for Suboxone Film of 2.7, and a low rate for Subutex and generic buprenorphine-only tablets of 1.8. We see the subordinate asks whether she can just add the two tablet rates to make it seem like Suboxone Film had the lowest rate, which is mathematically invalid and scientifically

unsound.

Then we see that Dr. Baxter commented that the rates the researchers had actually sent appeared to make Subutex and generic buprenorphine-only tablets look best, not Suboxone Film. This shows that Dr. Baxter was aware of what was happening and was actively participating in the discussion.

Turning to Exhibit 16, we see that Dr. Baxter's subordinate, in fact, added the two tablet rates and sent new, inaccurate rates to the Massachusetts Medicaid Program. Then the subordinate wrote to Dr. Baxter, "I hope this helps us get some movement in Mass."

Regarding this incident, Dr. Baxter has responded, in essence, that his subordinate acted alone.

THE COURT: Let me interrupt you, Mr. Mayer.

He says, "Am I mid-reading?" Does he mean mind reading?

MR. MAYER: Your Honor, we think he means misreading.

THE COURT: Misreading, okay. Thank you.

MR. MAYER: Yes, Your Honor.

So Dr. Baxter has responded, in essence, that his subordinate acted alone here. But the evidence showed that Dr. Baxter was right there on the e-mail chain in realtime. Moreover, Dr. Baxter knew that the Massachusetts Medicaid Program was not just another customer, but one of the largest

Suboxone purchasers who Indivior had been trying to persuade to adopt Suboxone Film for years.

Number 2. When Indivior's marketing department asks Dr. Baxter for approval to show doctors an incomplete graph on the safety of Suboxone Film that made Suboxone Film seem safer than it really was, he responded, "Nock yourself out."

When Dr. Baxter did that, he actually had a more complete version of the graph. Dr. Baxter knew that showing doctors the incomplete version would make Suboxone Film seem safer because the marketing department had told him it would, quote, "make such a huge difference."

Dr. Baxter's direct subordinate separately sent the incomplete version of the graph to the Massachusetts Medicaid Program and this, too, helped trick the program into expanding coverage of Suboxone Film.

To briefly review Dr. Baxter's role, let's look at Exhibits 11 and 19 to our sentencing memorandum.

Your Honor, I move for admission of these exhibits.

THE COURT: They will be admitted.

(Plaintiff's Exhibits 11 and 19 received.)

MR. MAYER: In Exhibit 11 we see a study that Dr. Baxter received from researchers on September 14, 2012, and then edited in collaboration with others. It contains a graph with three lines. The high line is for Suboxone Tablet. The middle line, which is fairly low, is for Subutex and

generic buprenorphine-only tablets. And the low line is for Suboxone Film. That middle line for Subutex and generic buprenorphine-only tablets tends to weaken Indivior's argument that Suboxone Film is safer than tablets because it's fairly low. It's not as low as the one for Suboxone Film, but it's also somewhat low. Dr. Baxter submitted this data to the FDA. And that happened in September 2012.

Turning to Exhibit 19, two months later, on November 9, 2012, an Indivior marketing person asked Dr. Baxter whether the salespeople could show doctors a version of the graph that did not have the unfavorable line. And Dr. Baxter approved that, saying, "nock yourself out," meaning that they could show doctors the less complete version of the graph that didn't have that line.

Regarding this incident, Dr. Baxter has countered that multiple versions of the graph were published. That is true. But it is beside the point. The point is that Dr. Baxter had a more complete version of the graph, and he knew that missing that middle line would make such a huge difference to the marketing people and to the doctors they were trying to sell Suboxone Film to, and he allowed them to use that less complete version even though he had the more complete version and, in fact, had used the data underlying the more complete version sending it to the FDA.

Number 3. While Dr. Baxter was Indivior's top

medical officer and Indivior was marketing only one drug, Suboxone Film, Dr. Baxter allowed the company's salespeople to overstate the safety of Suboxone Film to doctors and pharmacists. Dr. Baxter knew the limits of what Indivior could rightly say about Suboxone Film's safety because he helped develop Indivior's safety claims and supervised relevant studies. Yet, Indivior salespeople said things that Dr. Baxter knew were overstated; such as that Suboxone Film is the safest medication for opioid dependence when, in fact, there are non-opioid drugs for opioid dependence such as Vivitrol, that it lowers diversion, weeds out drug seekers, helps doctors stay off the witness stand, protects the community, and protects office-based opioid dependence treatment from being banned. Certainly there are things Indivior's salespeople could rightly have said about Suboxone Film, its packaging, and pediatric exposure, but the salespeople went far beyond what they could rightly say.

To briefly review Dr. Baxter's role, let's look at Exhibit 3 to our sentencing memorandum; new Exhibit 23, which is a redacted version of Exhibit 3 to Dr. Baxter's sentencing memorandum; and new Exhibit 24, which is a salesperson's report.

Your Honor, I move for the admission of these exhibits.

THE COURT: They will be admitted.

(Plaintiff's Exhibits 3, 23, and 24 received.)

MR. MAYER: In Exhibit 3 to our sentencing memorandum, we see Dr. Baxter's notes from February 9, 2007, an early meeting -- where Indivior discussed raising a negative safety issue with tablets and the superior safety/efficacy of film, recognizing they would need clinical data to support that. This shows that Dr. Baxter was there in the room when the safety messaging was conceived.

Turning to Exhibit 23, we see that in 2012, five years later, Dr. Baxter remained actively involved in this issue as he and a colleague provided Indivior salespeople with guidance on what they could and could not say to doctors, stressing that the salespeople could not say Suboxone Film was safer or better than tablets. Dr. Baxter continued to understand that clinical data was needed to support sales claims, and he continued to advise the sales force about what they could and could not say.

Turning to Exhibit 24, we see an example of an Indivior salesperson reporting that she went far beyond what she could rightly say. We chose this example because it's from Northern Virginia, right where Dr. Baxter worked. The salesperson told doctors that Suboxone Film was, quote, "the safest medication available" even though there were non-opioid medications available for opioid dependence and pleaded with them, "Is it worth the risk of pediatric exposure? Is it

worth the risk of abuse and diversion? Is it worth the risk of ending office-based treatment?" implying that Suboxone Film was necessary to avoid these consequences. This interaction is a prototype of fraudulent drug marketing.

Regarding this issue, Dr. Baxter has countered that he was not involved in telling salespeople what they could and could not say. But the evidence shows he was involved in that. He helped conceive of Indivior's safety plan and part of his role was letting the salespeople know the limits of what they could and could not rightly say.

Number 4. Dr. Baxter signed a sworn petition to the FDA about the safety of Suboxone Film that had the wrong attachment. Let me explain that. On September 14, 2012, Indivior received a study on the safety of Suboxone Film from researchers. Then, Indivior, its attorneys, and some of the researchers edited that study removing caveats such as that the results should be interpreted with considerable caution.

Finally, Indivior submitted Dr. Baxter's sworn petition to the FDA together with the new version of the study but representing that it was the original version of the study. As a result, the FDA could not see that the study had been edited and could not see the caveats in the original version of the study. To briefly review Dr. Baxter's role, let's look at Exhibits 10 and 11 of our sentencing memorandum.

Your Honor, I move for the admission of these

exhibits.

THE COURT: They will be admitted.

(Plaintiff's Exhibit 10 received.)

(Plaintiff's Exhibit 11 previously received.)

MR. MAYER: In Exhibit 11, which we reviewed earlier, we see the study that Indivior received from researchers on September 14, 2012. And we see that it was edited, including the deletion of caveats. I'll scroll down to where that happened.

Here at the bottom we see a caveat. "Therefore, any results related to the original packaging should be interpreted with considerable caution."

We also see the addition of a conclusion section at the bottom with these new handwritten conclusions. So, this document was edited substantively after it was received on September 14, 2012.

Turning to Exhibit 10. We see a petition submitted to the FDA 11 days later on September 25, 2012.

Sorry, Your Honor, I brought up the wrong exhibit. Just one moment.

Scrolling to the bottom of this document, or near the bottom of it, we see that it was signed by Dr. Baxter under penalty of perjury. So this is a petition to the FDA under penalty of perjury signed by Dr. Baxter.

And if we go up to where it discusses the study,

here's the issue. It says:

> "RBP Discontinues Marketing of Suboxone Sublingual Tablets Due to Safety Concerns.
> "Review of the pediatric exposure analysis revealed significant safety risks posed by buprenorphine products for opioid dependence in multi-dose packaging."

And then it says:

> "Based on the ready availability of safer alternatives for opioid dependence treatment through Suboxone Film, on September 18, 2012, RBP notified FDA of its intent to discontinue marketing Suboxone Tablet."

So this is a key point, because this says why Indivior discontinued Suboxone tablets. It's saying, "Review of the pediatric exposure analysis."

So what's that analysis? If we scroll up a couple pages, we see what it was. So here's what the pediatric exposure analysis was. It says, "A recent study by independent experts further explored the risk of pediatric exposure (hereinafter, pediatric exposure analysis)."

We scroll down. It's footnoted, discussing the study, and then here's the footnote. It says, "See Exhibit 1," and then it says the name of the study, with the date September 14, 2012. So what it's indicating is that's going to be the study that Indivior received on September 14, 2012, that it based its decision to discontinue Suboxone tablets on. But when we see what they actually attached, it is not that study, it is not the original version of the study

that Indivior received on September 14, 2012. What's actually attached is the edited version of the study that has been changed. It still says it was prepared September 14, 2012, but it wasn't prepared then. It's based on an original prepared then, but it was edited.

As we scroll down, we see that the caveat that I walked through in the original version of the study is gone. And this section on the potential role of product packaging, it no longer has the caveat that those results should be interpreted with considerable caution. If you go to the conclusions, those new conclusions that were handwritten on the original version have now been added.

So, regarding this incident, Dr. Baxter counters that the edits were approved by lawyers and researchers. Again, that is true but beside the point. The point is that Dr. Baxter concealed from the FDA that the original version of the study on which Indivior purportedly relied on discontinuing Suboxone Tablet was not actually attached. This attachment was a different document, a newer version which had been edited. The FDA was entitled to know that and ask for the original study if it wanted. The FDA devoted considerable resources to analyzing this submission and gave a lengthy response, all the while not knowing that there were actually different caveats and no conclusions like this in the original version on which the company had based its decision. It may

have been fine to edit the study, but that should have been disclosed to the FDA so they could have full information.

To conclude my first point today, the four incidents I've just described are examples of making misrepresentations about the safety of an opioid drug and allowing subordinates to do so. That conduct must be generally deterred. Doctors, pharmacists, patients, Medicaid programs, the FDA, and others, should receive accurate and complete information to help them make difficult decisions about opioid drugs.

Turning to my second of three main points, the sentence for Dr. Baxter should reflect the seriousness of the offense. It should send a message to the public that making misrepresentations about the safety of an opioid drug is a serious crime. This is especially important because in this case and the related cases involving Indivior and Shaun Thaxter, defendants have argued that their statements about Suboxone Film didn't really matter. The defendants have tried to change the subject away from the statements at issue in this case to different statements that government personnel made about Suboxone film's packaging. This tactic of changing the subject and minimizing the statements actually made should be rejected. We should acknowledge that the statements at issue in this case matter.

Factually, we know that the statements at issue in this case matter because the pharmacy director of the

Massachusetts Medicaid Program, Dr. Jeffrey, has testified that the false data and incomplete graph Dr. Baxter's subordinate sent to him mattered to him. His testimony exemplifies how the statements at issue in this case mattered to health care providers. Further, we know that the statements mattered because Indivior's own survey conducted in 2011 found that many doctors heard and accepted Indivior's salespeople's statements. Moreover, on a practical level, the statements at issue in this case are what health care providers actually heard before making difficult decisions about an opioid drug. That mattered.

This case is not about parsing people's words for technicalities. We have never used an example where someone just misspoke while presenting accurate and complete information. In this case we are talking about false data, an incomplete graph that is missing an important line, categorical statements such as that Suboxone Film, an opioid, is the safest drug for opioid dependence when there are non-opioids for opioid dependence, and a sworn petition to FDA with the wrong attachment.

To conclude my second point today, Dr. Baxter's offense is serious because making misrepresentations about the safety of an opioid drug is serious. It is too serious to be side-stepped or minimized as defendants in these cases have tried to do by downplaying the statements they actually made

in changing the subject to different statements by the government on Suboxone film's packaging that do not validate the defendant's statements. The sentence for Dr. Baxter should reflect that the statements at issue in this case are a serious offense.

Turning to my third of three main points, I'd like to address Dr. Baxter's history and characteristics and respond to the main theme of his sentencing memorandum. That theme is that Dr. Baxter should receive a lenient sentence because he has good character. Dr. Baxter argues that he has good character because he is altruistic and committed to scientific accuracy.

We have read the letters attached to Dr. Baxter's sentencing memorandum arguing that he is altruistic and committed to scientific accuracy. Certainly, the letters seem genuine. The problem is that in this case Dr. Baxter has displayed the opposite characteristics. In order to keep his money, he has compromised scientific accuracy.

Let me explain that. One of the most important issues in this case, and the cases against Indivior and Shaun Thaxter, is that Indivior salespeople overstated the safety of the Suboxone Film to doctors. That issue is so important because it's what doctors actually heard before making difficult decisions about prescribing opioid drugs.

Earlier in my argument I reviewed an example where

an Indivior salesperson reported that she told doctors in Virginia that Suboxone Film was the safest medication available even though there were non-opioids available, and we have examples like that from other states too. That kind of overstatement is why this case happened. That kind of overstatement had to be corrected. Yet, in all 45 pages of his sentencing memorandum, and through all seven years since Dr. Baxter learned of the government's investigation, he has never corrected or even addressed the salespeople's statements. Instead, he has avoided them. He keeps changing the subject to a CDC official's statement in 2016 endorsing Suboxone film's packaging. We acknowledge the CDC's official's statement, but what about the specific statements that Indivior's salespeople made to doctors? Why won't Dr. Baxter address them? As Indivior's top medical employee, his voice could be very powerful not only in his case but in all of the cases. The likely reason why Dr. Baxter has avoided the statements at issue in this case is that Indivior gave Dr. Baxter a $3 million severance payment and Indivior has absolute discretion to take it back.

Let's look at Dr. Baxter's separation agreement which is marked as Exhibit 25.

Your Honor, I move for the admission of this exhibit.

THE COURT: It will be admitted.

(Plaintiff's Exhibit 25 received.)

MR. MAYER: Here is Dr. Baxter's separation agreement. And on the first page we can see that he received a severance package from the company. The severance package was an amount equal to about $2.9 million.

Scrolling to a later part of the document, we see that it comes with a significant condition. It says that:

> "If at any time prior to February 2021 the Remuneration Committee of Indivior determines in its absolute discretion that:
> "There has been, at any time during Dr. Baxter's employment with the company, serious misconduct by Dr. Baxter, then Indivior may, to the extent that it considers appropriate, determine in its absolute discretion that:
> "Dr. Baxter must repay to company in cash as clawback such amount of the Severance Payments as Indivior's Remuneration Committee may determine."

So it gives Indivior the ability to take a $3 million severance -- or $2.9 million severance back from Dr. Baxter in its discretion.

And more broadly, during the pendency of this investigation, Dr. Baxter has received more than $5 million from Indivior. For the first two years of the investigation, he was sitting on some key e-mails that we've discussed here today, they were in his e-mail account, while Indivior sought to thwart the government's investigation by moving to quash government subpoenas.

So it seems likely that Dr. Baxter has avoided addressing the specific statements that this case is about,

particularly the salespeople's statements, and continues to do so even now because he does not want to risk Indivior taking back any of his money.

And his decision, which is his decision to make, is a reason why this case has taken seven years. This should not be held against Dr. Baxter. The point is simply that he has placed his character at issue seeking a lenient sentence for altruism and scientific accuracy when in this very case he's kept his money by refusing to even address scientific inaccuracy. He should not receive leniency for personal characteristics that are the opposite of what he has displayed in this case. He made this decision, and he has to live with it. He can't have it both ways.

Before I conclude, two brief notes: First, the government is requesting a term of incarceration of six months because that is the same term that Indivior's former Chief Executive Officer, Shaun Thaxter, received. While Mr. Thaxter occupied a higher office at Indivior, Dr. Baxter was more directly involved in the events at issue having received his subordinate's false statements to Massachusetts Medicaid in realtime, approved the use of the incomplete chart, and signed a petition to the FDA that had the wrong attachment. He and Thaxter should receive the same term of incarceration.

Second, if the Court determines that Dr. Baxter's health conditions make it too dangerous for him to be

incarcerated during the coronavirus pandemic, then the Court could delay Dr. Baxter's report date until he has had an opportunity to receive a vaccine.

In closing, to promote general deterrence and reflect the seriousness of the offense, and because Dr. Baxter has not displayed altruism and a commitment to scientific accuracy in this case, the government asks that a term of imprisonment of six months be imposed.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Mayer.

And I'll be glad to hear from counsel for the defendant.

MR. CACCIA: Your Honor, may I indulge you for a moment? You've heard the government's argument. You've read our brief. Is there anything in particular that the Court wants to hear?

Because I just listened to a recitation of the facts, which is -- I want to be very careful not to use certain language -- but are so misleading, and so grossly inappropriate, and so at odds with what we know and what we believe to be the evidence in this case, that we could spend the better part of the day going through each of these things. To the point, quite frankly, Your Honor, that when we were getting ready for this hearing and talking to the government in advance, I said, listen, if we're going to be having a

situation where you're going to be making factual representations, then let's get witnesses and let's get evidence on that.

So we just heard this litany of, quite frankly, misrepresentation with respect to my client's conduct. The same misrepresentations, Your Honor, that were putting us in a position that since the inception of this case our client said he would never plead guilty to anything that in any way, shape, or form suggested that he had ever made a factual or an intentional misrepresentation.

Your Honor, this is a man who for 20 years has devoted his life to treating opioid addiction. This is a man who held firm while at this company to ensure that when representations were made, they were accurate. Mr. Mayer knows, Mr. Ramseyer knows, the number of instances, one of which we cited in our brief, where our client specifically told the salespeople that they couldn't make the representations about which Mr. Mayer is so uncomfortable with right now. Similarly, our client specifically told the head of sales, you need to do something about this. And then in an e-mail, which is in our brief and which is cited, the head of sales basically tells his people, you know, just FYI, and doesn't act upon it.

This is a case involving a Responsible Corporate Officer Doctrine, Your Honor. It involves the things for

which my client has responsibility. It does not involve a situation where he is involved in everything about which the government has a problem.

I'm happy to go through each one of these documents that Mr. Mayer just put in front of the Court, but I'm going to hit just a couple, Your Honor. But I want to be respectful of both the Court's time and also to know what it is the Court would like me to focus on. Because I can take each one of these things -- and, Your Honor, I've lost track of time, but we're going to be here until 2:00.

The factual representations that were just made are wholly and entirely inappropriate. The fact is that the government, Your Honor, knows better with respect to certain of these things. They know, which they didn't share with you, really that there is an e-mail which is in Exhibit 5 in our pleading where our client specifically asks whether or not the person who made the misrepresentation with Massachusetts has checked with the relevant entity as to whether or not it is appropriate for purposes of adding these two numbers together. Specifically asks. Did it come to happen that he didn't go back and double-check? Yes. That's the reason we're here. That's the reason we're here. That is the only reason we are here. Which is that one of his subordinates made a representation to the Massachusetts authority which was not accurate. And it's unfortunate, but on that one my client

didn't catch it. Why didn't he catch it? It was because, quite frankly, the subordinate didn't honestly represent to him what she had and had not done. So Mr. Mayer knows that. Mr. Mayer knows those e-mails are there and nonetheless suggests that my -- and infers that my client is involved in making a knowing misrepresentation to Massachusetts. That is untrue.

Similarly, Your Honor, they're citing documents -- and I sat with Mr. Ramseyer, with Mr. Mayer on the phone, with now the acting U.S. Attorney, and pointed out to them that these documents that they cite to, 2007, which suggest that my client has done something wrong not only do not illustrate that they did nothing wrong, but that they affirmatively show that he's trying to do the right thing. So he's in a meeting in 2007 where he's taking notes about what other people are saying. And for reasons that -- I'm sorry, Your Honor, I'm having trouble finding it. For reasons that I can't really understand, Mr. Mayer and the government don't want to focus on the handwritten note that specifically says, "We need to develop clinical data to support the representation."

What do you want a medical director to do? Someone said something. He says, "We can't say that unless we have clinical data to support it. Let's develop the clinical data." He says it in the document that the government holds out to you as being some evidence of misconduct. It is

borderline absurd. And the number of instances where that happens in this case, Your Honor, are manifest. There's any number of those instances.

Every one of these documents -- Mr. Mayer holds out the document with respect to the "nock yourself out." Mr. Mayer knows, he knows, because it's in our pleading, that that had to do with a different chart. It's a chart that had been published. Someone asked, "Is it okay to use this chart?" It had been published several days earlier, and he says, "Yes, nock yourself out." And somehow they seek to transmogrify that into some sort of affirmative misrepresentation. It is not true. It is not true. It is an affirmative misstatement. And, Your Honor, the fact that the government continues to do this is the reason that I wanted to try this case. These are not accurate representations. And if you want to have a contested evidentiary hearing, Your Honor, I suggest we defer the sentencing, and I'm more than happy to contest each one of these things. Because, quite frankly, Your Honor, this is argument of counsel. This is the government's interpretation of documents which is not consistent with reality.

Similarly, Your Honor, they point out this citizen's petition. They continue to point out this citizen's petition. The citizen's petition that my client -- yes, my client signed it. My client signed it. My client believed it to be true.

The edits to this, made by the study author. So the suggestion that there's something hinky going on -- before it goes to final, the study authors review it. And they're the ones that they ask to sign off on whether or not these changes are faulty. And I don't know why it only seems to matter to me that competent, skilled, outside FDA counsel ultimately reviewed and signed off on this.

Your Honor, if we had a trial in this case, those lawyers would be up on the witness stand, and I've got an advice-of-counsel defense with respect to the integrity of the whole process. And I don't know why, I don't know why in this slavish attempt to mischaracterize this man's good name the government continues to ignore what I think are clearly objective facts. And, again, Your Honor, it's not right.

This is a responsible corporate officer plea, Your Honor. My guy is on the medical side of this case. My guy is not on the commercial side.

Even -- you know, even as you get -- you had the back and forth with Mr. Muhlendorf, Your Honor, where the government says, you know, we want you to take notice of these things because they relate to the conduct of Indivior. I don't represent Indivior; I represent Tim Baxter. I worry about what Tim Baxter's conduct is, what Timothy Baxter's representations were, the conduct that Tim Baxter engaged in. And that conduct, Your Honor, I'll stand here all day and talk

through it.

We've addressed these things, Your Honor, one by one in our brief. I'm happy to go at it. But, you know, we talk about, you know, he was responsible for telling the doctors not to do certain things. Yes. And guess what? When he was aware of things, he did. What do you expect or what do you want the medical director to do different than what it was he did here? He didn't affirmatively make any misrepresentations. Not a one. Not a one. There is not, from where we sit, a single piece of evidence where my client made an affirmative -- an intentional affirmative misrepresentation about a single fact. What he did was he stood against the tide. And when he heard that there were representations being made, he did something about it. This man's whole life, Your Honor, his whole professional life, has been driven by the desire to treat and care for opioid addiction. And for anyone to suggest he was motivated primarily by profit, Your Honor, respectfully, is a damnable lie. The man's whole life is about treating addiction. That's what he did. That's what he focused upon.

And a driver for him, Your Honor, a driver for him throughout this entire process is to ensure that nothing happens, that misrepresentations aren't made which could put at risk the program to allow one to operate and treat addiction in this medical setting, this medication setting.

So to suggest anything to the contrary -- the government, for whatever reason, they cite these bar reports. The government knows my client never saw those. The government knows it. They know it. And notwithstanding that, they put an exhibit in, and they know my client didn't see it. I don't know why, Your Honor, the government doesn't tell you that Dr. Baxter was responsible for establishing the program that was designed to try to identify over-prescribing doctors and to set up a program where people would go out and talk to them, and counsel them, and ensure, Your Honor, and ensure that they did everything they could as a manufacturer, that they were educating and counseling these people. He did everything you would want him to do, Your Honor. Everything you would want him to do. And yet, and yet he's here. Yet, he's here.

Your Honor, I'm at this 25 years from the defense side. I've never felt more personally invested in the integrity of a client. I have never in 25 years of doing this, Your Honor, ever for a moment felt that I was standing next to someone whose best intentions were always the driving force for him. Never, Your Honor. Never. And any suggestions to the contrary as to what his motivation was -- and to suggest that because he got a severance after 20 years of work that that's somehow inappropriate. He was there for 20 years, Your Honor. They talk about what the company did

during the course of the investigation. He hasn't been with the company for five years. What does Mr. Mayer want him to do when, A, he doesn't believe he did anything wrong? and B, he's no longer with the company?

And then they extract a financial penalty here. There's a financial penalty, Your Honor, where my client had to pay $100,000, which one may they think, well, jeez, you know, he made 2.8 million. Your Honor, that represented approximately 10 percent of his net worth -- 8 and a half percent of his net worth at the time the government took the 100k from him.

And this notion that he is living high on the hog as a result of any of this, I mean, honestly, Your Honor, the government should know better. They should know better. It's not right. It's not right that these representations are going unchallenged. And, Your Honor, we were ready to try this case for exactly the reasons that I'm articulating right now; that these representations that Mr. Mayer is making are not true. They are factually inaccurate. They are misleading. I'll go through every one, Your Honor, in detail with you if you want to have an evidentiary hearing. But do not, Your Honor, for a minute, please, do not for a minute accept those representations as evidence. Because I'm telling you, Your Honor, they're contested facts.

As to the notion of general deterrence,

Your Honor --

By the way, Your Honor, I asked you a question, is there anything you wanted to hear? And then I proceeded to talk for 15 minutes. Is there anything in particular, Your Honor, that you'd like me to focus upon?

THE COURT: You're doing fine.

MR. CACCIA: All right.

Your Honor, just a couple of -- just a couple of other points. The Responsible Corporate Officer Doctrine to which my client pled guilty, -- and Your Honor knows this, I'm not educating, Your Honor, but Your Honor knows -- this is a strict liability offense. It is a status offense. It is simply that by virtue of you are in a position that someone under you did something and by virtue of the report chain you are responsible for it.

The notion that the government is arguing general deterrence is absurd. It is absurd because you can't deter someone from not doing something about which they didn't know. Even the FDA, which has guidance on this and it's in our brief, speaks specifically to the fact that it's meant to be general deterrence as to organizations but not as to individuals, because it doesn't make sense that we're going to deter them. And, quite frankly, Your Honor, you don't want to deter a Tim Baxter. You want to encourage a Tim Baxter. You want every company to have a Tim Baxter as their medical

director. You want every company having someone who when he sees something calls it out and raises it with the head of sales, and raises it with the marketing people, and looks at documents and is careful and says, you can't say that, you can't say that, you can't say that. And the government knows he did.

You know, Your Honor, the government's plead -- this is from the government's pleading. This is the government's pleading. They say Baxter oversaw Indivior's medical function on page 2. "Baxter spoke with attorneys regarding the need for clinical data to prove superior safety of the new version of Suboxone."

Government's pleading, page 5. "Baxter took notes, including that they would need clinical data before making the claim." That's out of the government's brief.

"Baxter with others told the FDA they were developing the film as a means of guarding against pediatric exposure to protect against diversion and supervise dosing decisions." True statement out of the government's brief.

They asked the FDA if they agreed with proposed statement. They asked them if they agreed. Out of the government's brief.

"When he saw the response, Baxter told executives that they would need to collect data on this as a post-marketing exercise before we could make a specific

claim." Your Honor, that's out of the government's brief. That's out of the government's brief.

"When Baxter spoke with -- government's language, "When Baxter spoke to doctors, he gave unbiased, complete information about pediatric exposure and the film." That's out of the government's brief.

"Baxter approved Indivior's hiring of professionals to do a study that would provide the data they would need to support the claims." That's out of the government's brief. This is not a criminal.

"And delegated project management to one of the medical affair managers." True statement out of the government's brief.

"Baxter told the company president that the results could be significant and the company had a moral obligation to act if there was a public health concern." Out of the government's brief.

"Baxter submitted a sworn petition conveying the pediatric data and position regarding safety of the film and asking that they consider whether generics should have some of the same qualities."

Your Honor, it's really -- I mean, the litany of situations, the litany of situations that are presented here where the client did the right thing, that the client did the right thing, is just, you know, Your Honor, it's just beyond

the pale. It's just truly beyond the pale.

Your Honor, I ask Your Honor to sentence Dr. Baxter on the offense to which he pled guilty. And to the extent, Your Honor, that we are looking at these contested issues, I would say, Your Honor, and I read Your Honor's transcript, you know, about Thaxter. You heard the argument and Your Honor respectfully said, "I don't need to decide these things." But, Your Honor, to the extent they're informing the Court's decision, and to the extent they're informing the Court's decision about general deterrence and specific deterrence, Your Honor, I would just ask you, please, please, to the extent that these are contested facts, that the Court recognize and know that these are facts which are at issue.

Finally, Your Honor, just with respect to the minimization that Mr. Mayer made about Dr. Baxter's general good character. These people wrote these letters because they're true. They wrote these letters about Dr. Baxter and his commitment to opioid safety because they're true. This is not, Your Honor, one of those situations that Your Honor has seen too many times which from the moment that the government -- someone finds they're under investigation, they learn to start doing charitable works, or they start learning to do other things. This is a situation where the man's life's work is what ultimately defines his character. This is not some contrived Eleventh Hour, you know, what could we put

in front of the court? This is the man's life's work.

Your Honor, knowing -- we've mentioned in our brief, unlike someone else sentenced in this case, my client doesn't have $18 million in the bank. The presentence report writer in this case knows that Dr. Baxter has a million two. He has lost his life's work. He has lost his job. He is cobbling it together. The collateral consequences for this man, Your Honor, are not inconsequential when Your Honor is contemplating what the penalty is. There is a good chance, Your Honor, that we're going to be spending the first part of next year arguing about whether or not he should be excluded. And I have to sit -- and that's part of the reason, Your Honor, we are vigorously fighting about these factual representations, because this is the record ultimately that someone is going to be looking at downstream.

Your Honor, we're, in essence, fighting exclusion so he can continue his life's work. But if he can't, Your Honor, he's done. He's done. At 58 years old, he can't practice in his chosen profession. He doesn't hold a U.S. medical license, Your Honor. He's licensed in the UK. But that's at risk. That's at risk. Your Honor, the most recent correspondence that Dr. Baxter has gotten from the regulatory authority -- the licensing authority in the UK: Let us know how this sentencing turns out.

There are serious collateral consequences,

Your Honor, that are implicated here. Very, very serious collateral consequences. I mean, the guy has lost his ability to operate in his chosen profession. He has -- he's trying to make it as a consultant. And, quite frankly, Your Honor, you know, the government which ramped up their press release, the following day, you know, my client loses one of his customers. You know, it's -- there's a lot here, Your Honor, that leaves a very, very, very bitter taste in one's mouth.

Lastly, Your Honor, just on his health issues. I know, Your Honor, because I read certain of Your Honor's other opinions, is sensitive to the situation with respect to COVID. We know it's not made up. We know people are dying. I'm not going to cite all the statistics. Dr. Baxter has conditions that would seriously put him at health risk were Your Honor to incarcerate him. I believe, Your Honor, there is nothing in this world that would justify a day of incarceration. At most, this is a probationary offense. But to the extent, Your Honor, that the Court is thinking, you know, via punishment here, Your Honor, this man has exactly the kind of health issues that put him at risk in the event that he winds up going into a federal correctional institution.

Your Honor has the information. You know, to the extent that you need any further documentation about that, I'd certainly be more than happy to provide it.

But, Your Honor, I thank you for giving me the

opportunity to speak on Dr. Baxter's behalf. If you have any questions for me, I'm more than happy to answer. I know Dr. Baxter has a few things he'd like to say to the Court.

THE COURT: All right. Thank you, Counsel.

If there's nothing further from counsel, I'll ask Dr. Baxter, Dr. Baxter, is there anything that you would like to say to me before I pronounce sentence in your case?

THE DEFENDANT: Yes. Thank you, Your Honor.

Thank you, Your Honor. Your Honor, it saddens and pains me to be before you awaiting sentence in this case. As you've read, I've devoted the vast majority of my professional life to addressing opioid addiction. And with Indivior, my focus was on making medical treatments of opioid addiction more readily available and accessible while ensuring patient safety. I completely concur with the lawyers for the government that we should do all we can to ensure that treatment is available, is patient-focused, and is delivered in a safe manner.

It honestly breaks my heart that I stand here as an officer of the company responsible for a subordinate having provided misleading labeling to a representative of MassHealth. I deeply regret that this happened but want to make clear that had I known about it, it would have been addressed immediately. And I fully accept responsibility, Your Honor.

Throughout my time at the company I was a vocal advocate for the proposition that any claim made must be accurate. Whilst I was not in a position to supervise sales, on the occasions when I was alerted to potentially troubling conduct on the sales side, I elevated them to members of our management with the relevant responsibility. I believe I did what you would have wanted me to do, Your Honor.

As a result of my failing to address something about which I knew nothing, I'm not only at risk of going to jail but of losing my livelihood. Since separating from the company in 2016, I've worked, as you heard, to establish a consulting business which I'm now at risk of losing. My license to practice medicine is also at risk.

Your Honor, I hope that you will allow me to serve whatever sentence you believe appropriate outside of jail. I'm dealing with some health issues, as is my wife, and it would present genuine hardship on me and my family if I were to go to jail.

Finally, I would like to thank my family and friends for taking time away from their own families and professions and writing to this court on my behalf. I'd also like to thank you, Your Honor, for taking the time to review and consider those letters as well as all of the other materials before you. Thank you.

THE COURT: Thank you, Dr. Baxter.

Well, the following are the reasons for the imposition of sentence in this case. Counsel, of course, is well aware of the factors that I'm required to consider. In imposing a sentence, I have to consider the nature and circumstances of the offense as well as the history and characteristics of the defendant. I have to consider the seriousness of the offense, the need to promote respect for the law, and to provide just punishment. I have to consider the need to afford adequate deterrence to criminal conduct. I'm required to impose a sentence that is sufficient, but not greater than necessary, to comply with these purposes.

Of course, I've considered the arguments of counsel as well as the information provided -- the information in the presentence investigation report as well as that provided by counsel, and the argument of counsel. Needless to say, there is considerable dispute as to the factors that I'm required to consider in terms of their relevancy in this case. But I believe that I have a sufficient understanding that allows me to determine an appropriate sentence.

The government seeks a term of imprisonment. And the government in this case, as well as in others, of course, in so-called white collar crimes seeks a term of imprisonment because they believe that that affords the most appropriate deterrence to others; the so-called general deterrence. The government I don't believe thinks that particularly in

relation to the particular offense of which Dr. Baxter has pled guilty that Dr. Baxter will commit future crimes. But the government is naturally concerned about others in his position and similar positions.

And it's no secret that society and the government, the federal government in particular, is particularly concerned about the pharmaceutical industry as well as other industries that affect the health and safety of the public. And, unfortunately, we've had a series, not only in the pharmaceutical industry but in other industries, that have directly affected the health and safety of our fellow citizens where those who are engaged in sales overstate the safety of the product to those who are involved in the distribution of a particular product. And nowhere is that more dangerous than in a case of medicines.

And I applaud the government for its vigor in this undertaking. And I think the United States Attorney's Office in this district has certainly taken a lead in those prosecutions, for which they're to be commended.

But, of course, every defendant is different. And as counsel has pointed out, there are two sides to every story. I understand that it's not necessarily true the allegations that are made by the government in every case.

The fact is that the defendant has pled guilty in this case, as pointed out, to the responsible official

misdemeanor case and not to a felony. I certainly take that into account. And the parties have entered into a stipulated range, even though the government does ask for a sentence of incarceration, as I've mentioned.

Now, in the stipulation, the government also agreed that if there is still a health concern related to COVID-19 disease the United States does not oppose the Court considering that fact in determining the appropriate sentence. And I do consider that fact.

It was presented by the defense counsel without contradiction that -- from Dr. Baxter's physician that he does suffer from many medical conditions, some of which are established to make it a risk of a more serious outcome if he were to contract the COVID-19 disease, in particular, his diabetes for which he takes oral medication and injectable medication and a special diet.

He also has a heart condition, which is not explained in the doctor's letter but which I did a little research on. He has a disease which enlarges the heart muscle which, in most cases, does not result in death, although it can result in symptoms and in rare cases may have a serious outcome but if treated properly does not terminate one's life prematurely. And, of course, we hope that's true in Dr. Baxter's situation.

So, while that heart disease may sound ominous, it

may not be in his case. As I said, I did a little research on that. But he has hypertension, high blood pressure, but it is true and presumably controlled with medication, as many of us have I might add.

The government suggests that I might delay his reporting for a six-month prison term until the present vaccine has been administered widely so that it is -- we have a so-called condition of herd immunity. But we don't know when that's going to be. And there's -- I don't know of any proposal that -- and I wish this was established -- that inmates of federal institutions would have a high priority, but I'm not sure that's going to be. We don't know when that's going to take place. We're a long way from establishing the level of immunity from the vaccines. I mean, it just -- the first injections have just been given, I guess yesterday, to the public, and I'm not sure that that's appropriate to do that.

While I think there are grounds, as the government indicates, for incarceration on a general deterrence basis, I believe in Dr. Baxter's case that's overcome by the present situation and his medical conditions. I don't believe it's appropriate, for him, to impose a prison sentence. And, accordingly, I am going to place him on probation in accord with the stipulation of the parties. And I am going to add some conditions to that probation which I'll go over now.

Accordingly, for the reasons I've stated, it is the judgment of the Court that the defendant is hereby placed on probation for a term of one year. While on probation, he must comply with the following mandatory conditions. These are conditions that are set forth by law that he has to comply with.

He must not commit another federal, state or local crime.

He must not unlawfully possess a controlled substance.

The otherwise mandatory drug testing condition is suspended based on my determination that he poses a low risk of substance abuse.

He must cooperate in the collection of DNA as directed by the probation officer.

He must comply with the standard conditions of supervision that have been adopted by the Court, as well as the following special conditions:

He must pay any monetary penalty that is imposed.

He must reside in a residence free of firearms, ammunition, destructive devices, and dangerous weapons.

He must submit his person, property, house, residence, vehicle, papers, computers, and other electronic communication or data storage devices or office, to a search conducted by a United States Probation Officer. Failure to

submit to a search may be grounds for revocation. He must warn any other occupants that the premises may be subject to searches pursuant to this condition. An officer may conduct a search pursuant to this condition only when reasonable suspicion exists that the defendant has violated a condition of his supervision and that the areas to be searched contain evidence of this violation.

In other words, this doesn't mean that the probation officer can just come in and search his house. But it's a provision that if there's a suspicion that he is violating his condition of probation in some way and that there's reasonable suspicion of that, then the probation officer can conduct a search. And that's a condition that helps make sure that he doesn't violate the conditions of his supervision.

He must submit to home detention for a period of six months. Now, that's a long period of home detention, but I think it's appropriate under the circumstances of this case.

Now, what that means is he must remain in his residence, except for: Employment, if he has to leave to engage in any of the aspects of his employment; for religious services; for medical care or treatment; for required attendance in court, if necessary; or for any administrative proceedings in relation to his -- in relation to his licensure or other matters relating to his occupation; or to visit his attorney's office in relation to any legal matters.

Otherwise, he needs the permission of his probation officer to leave his residence. So, otherwise, he has to remain in his residence.

And he must -- the probation office will contact him to apply some sort of location monitoring on him so that they can make sure that he does not violate this home detention.

In addition, he must provide 100 hours of community service during his year of probation. And he can leave his residence, by the way, to provide that 100 hours of community service. And that can be -- it must be approved in advance by his probation officer, but it can be something that helps the community. He might very well want to do something that would help in his indicated area of drug addiction. But, in any event, I'm not requiring that, but something that would help the community. And, again, it has to be approved in advance by the probation office.

He also must pay to the United States a special assessment of $25 and a fine in the amount of $100,000. And it's my understanding that that amount has been paid.

Madam Clerk, is that correct? Do you know?

THE CLERK: Yes, Your Honor, that's been paid in full.

THE COURT: Thank you.

I advise the defendant that he has waived his right to appeal in accord with the terms of his plea agreement. And

if he does undertake to appeal despite his waiver, he may lose the benefits of his plea agreement. If a right of appeal does exist, a person who is unable to pay the cost may apply for leave to appeal without prepayment of such cost. Any notice of appeal must be filed within 14 days of the entry of judgment or within 14 days of a notice of appeal by the government. If requested, the clerk will prepare and file a notice of appeal on behalf of the defendant.

Are there any further matters that the Court must resolve in this case?

MR. RAMSEYER: Your Honor, Randy Ramseyer for the government. One matter. These documents were filed under seal because the Court hadn't ruled on the other two cases.

THE COURT: Yes, sir.

MR. RAMSEYER: We would ask that these documents be unsealed as well as in the other cases.

THE COURT: Yes. Well, I've been waiting for all the cases before I made a decision in that regard. And I will proceed to do that, to make such a decision.

MR. RAMSEYER: Thank you, Your Honor.

MR. CACCIA: Your Honor, one question. Sorry. One question with respect to Dr. Baxter's release conditions. Your Honor, his current employment periodically requires travel from his home to New Jersey. I would just ask the Court to perhaps include that in his release conditions and

subject to notification to probation and approval by probation that that work travel be permitted.

THE COURT: Yes, sir. Well, I haven't limited his travel specifically in terms of his condition, but he does -- as a standard condition of probation, it is necessary for him to keep the probation office advised of his whereabouts. So he would need to advise them when he's -- when he plans to travel.

MR. CACCIA: I understand, Your Honor.

THE COURT: And the probation officer will meet with him and go over those matters with him in due course.

MR. CACCIA: Thank you, Your Honor.

THE COURT: He will be -- since he lives in Richmond, I assume he will continue to live in Richmond, he will be supervised by the probation office in the Eastern District of Virginia in the Richmond office, and so they will handle that.

All right. Anything further then?

THE PROBATION OFFICER: Your Honor, the probation officer would ask that any costs associated with his location monitoring be paid by the defendant.

THE COURT: Yes, ma'am. I will ask the clerk to put that in the judgment.

THE PROBATION OFFICER: Thank you.

THE COURT: All right. If there's nothing further

then, we will adjourn court. Thank you, Counsel.

(Proceedings concluded at 12:05 p.m.)

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REPORTER'S CERTIFICATE

I, DONNA J. PRATHER, do hereby certify that the above and foregoing, consisting of the preceding 55 pages, constitutes a true and accurate transcript of my stenographic notes and is a full, true and complete transcript of the proceedings to the best of my ability.

Dated this 4th day of January, 2021.

Donna J. Prather

DONNA J. PRATHER, RPR, CRR, CBC, CCP
Federal Official Court Reporter